

1. Invertebrates		
Pink Mucket	<i>Lampsilis abrupta</i>	E
Louisiana Pearlshell	<i>Margaritifera hembeli</i>	T
Fat Pocketbook	<i>Potamilus capax</i>	E
Inflated Heelsplitter	<i>Potamilus inflatus</i>	T
Rabbitsfoot	<i>Quadrula cylindrica</i>	T
2. Fish		
Gulf Sturgeon	<i>Acipenser oxyrinchus desotoi</i>	T
Pallid Sturgeon	<i>Scaphirhynchus albus</i>	E
Smalltooth Sawfish	<i>Pristis pectinata</i>	E
3. Amphibians		
Dusky Gopher Frog	<i>Lithobates sevosus</i>	E
4. Reptiles (including eggs)		
Loggerhead Sea Turtle	<i>Caretta caretta</i>	T
Green Sea Turtle	<i>Chelonia mydas</i>	T
Hawksbill Sea Turtle	<i>Eretmochelys imbricata</i>	E
Kemp's Ridley Sea Turtle	<i>Lepidochelys kempii</i>	E
Leatherback Sea Turtle	<i>Dermochelys coriacea</i>	E
Ringed Map Turtle	<i>Graptemys oculifera</i>	T
Gopher Tortoise	<i>Gopherus polyphemus</i>	T
Black Pinesnake	<i>Pituophis melanoleucus lodingi</i>	T
Louisiana Pinesnake	<i>Pituophis ruthveni</i>	T
5. Birds (including eggs)		
Whooping Crane	<i>Grus americana</i>	E
Piping Plover	<i>Charadrius melodus</i>	T
Red Knot	<i>Calidris canutus rufa</i>	T
Interior Least Tern	<i>Sterna antillarum athalassos</i>	E
Red-cockaded Woodpecker	<i>Picoides borealis</i>	E
6. Mammals		
West Indian Manatee	<i>Trichechus manatus</i>	T
Northern Long-eared Bat	<i>Myotis septentrionalis</i>	T
Sperm Whale	<i>Physeter macrocephalus</i>	E
Florida Panther	<i>Felis concolor coryi</i>	E
7. Plants		
American Chaffseed	<i>Schwalbea americana</i>	E
Earth-fruit	<i>Geocarpon minimum</i>	T
Louisiana Quillwort	<i>Isoetes louisianensis</i>	E
Pondberry	<i>Lindera melissifolia</i>	E
E = Endangered; T = Threatened		

AUTHORITY NOTE: Promulgated in accordance with R.S. 56:1904.

HISTORICAL NOTE: Promulgated by the Department of Wildlife and Fisheries, Office of Wildlife, LR 15:1099 (December 1989), amended LR 18:877 (August 1992), LR 37:2438 (August 2011), LR 44:798 (April 2018), LR 46:193 (February 2020).

Jack Montoucet
Secretary

2002#021

RULE

Workforce Commission Office of Workers' Compensation Administration

Pain Medical Treatment Guidelines (LAC 40:I.Chapter 21)

The Louisiana Workforce Commission has amended certain portions of the Medical Guidelines contained in the *Louisiana Administrative Code*, Title 40, Labor and Employment, Part 1, Workers' Compensation Administration, Subpart 2, Medical Guidelines, Chapter 21, regarding chronic pain guidelines. This Rule is promulgated by the authority vested in the director of the Office of Workers' Compensation found in R.S. 23:1291 and R.S. 23:1310.1(C). This Rule is hereby adopted on the day of promulgation.

Title 40

LABOR AND EMPLOYMENT

Part I. Workers' Compensation Administration

Subpart 2. Medical Guidelines

Chapter 21. Pain Medical Treatment Guidelines

Subchapter A. Chronic Pain Disorder Medical

Treatment Guidelines

Editor's Note: Form LWC-WC 1009, Disputed Claim for Medical Treatment has been moved to §2328 of this Part.

§2101. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation (OWCA) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana Workers' Compensation Act as injured workers with chronic pain. Although the primary purpose of this document is advisory and educational, the guidelines are enforceable under the Louisiana Workers' Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical care, services, and treatment that varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers' Compensation Administration, LR 37:1681 (June 2011), amended LR 46:194 (February 2020).

§2103. General Guideline Principles

A. The principles summarized in this Section are key to the intended implementation of all Office of Workers' Compensation medical treatment guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Act.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth education is currently a component of treatment regimens which employing functional, restorative, preventive and rehabilitative programs. No treatment plan is complete

without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention. Facilitation through language interpretation, when necessary, is a priority and part of the medical care treatment protocol.

3. **Informed Decision Making.** Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit when a chronic pain condition allows functional improvement. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan when a chronic pain condition allows attainment of functional goals. Injured workers may not reach functional goals to return to work and therefore they will require a significantly different plan. Nurse case managers, physical therapists, and other members of the health care team play an integral role in informed decision-making and achievement of functional goals. Patient education and informed decision-making should facilitate self-management of symptoms and prevention of further injury.

4. **Treatment Parameter Duration.** Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient adherence, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with R.S. 23:1203.1.

5. **Active Interventions.** Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains when chronic pain conditions allow attainment of functional goals because some chronic pain patients require active interventions as well maintenance procedures and medications.

6. **Active Therapeutic Exercise Program.** Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

7. **Positive Patient Response.** Positive results are defined primarily as functional gains that can be objectively measured.

a. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, ability to function at work, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Not all chronic pain patients will reach any functional goals and may only improve ADL's and or pain complaints due to severity of the injury. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

8. **Re-Evaluation of Treatment Every Three to Four Weeks.** If a given treatment or modality is not producing positive results within three to four weeks or within the time to produce effect in the non-chronic pain guidelines, the physical therapist must consult with the treating physician for consideration for a referral to a pain specialist or surgeon or other appropriate specialist for other treatment options. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

9. **Surgical Interventions.** Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

10. **Pharmacy-Louisiana Law and Regulation.** All prescribing will be done in accordance with the laws of the state of Louisiana as they pertain respectively to each individual licensee, including, but not limited to: Louisiana State Board of Medical Examiners regulations governing medications used in the treatment of non-cancer-related chronic or intractable pain; Louisiana Board of Pharmacy Prescription Monitoring Program; Louisiana Department of Health and Hospitals licensing and certification standards for pain management clinics; other laws and regulations affecting the prescribing and dispensing of medications in the state of Louisiana.

11. **Six Month-Time Frame.** Injuries resulting in temporary total disability require maintenance treatment and may not attain return to work in six months.

12. **Return to Work.** Return-to-work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. An injured worker's return-to-work status shall not be the sole cause to deny reasonable and medically necessary treatment under these guidelines. Two good practices are: early contact with injured workers and provide modified work positions for short-term injuries. The practitioner may provide specific physical limitations and the patient should never be released to non-specific and vague descriptions such as "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, from including, but not limited to, occupational health nurse, physical therapist, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist, chiropractor or another professional. American Medical Association clarifies "disability" as "activity limitations and/or participation restrictions in an individual with a health condition, disorder or disease" versus

“impairment” as “a significant deviation, loss, or loss of use of any body structure or body function in an individual with a health condition, disorder or disease”.

13. Delayed Recovery. Within the discretion of the treating physician, strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after initiation of treatment of an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment requires clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

14. Guideline Recommendations and Inclusion of Medical Evidence. All recommendations are based on available evidence and/or consensus judgment. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. Per R.S. 1203.1, when interpreting medical evidence statements in the guideline, the following apply to the strength of recommendation.

Strong	Level 1 Evidence	We Recommend
Moderate	Level 2 and Level 3 Evidence	We Suggest
Weak	Level 4 Evidence	Treatment is an Option
Inconclusive	Evidence is Either Insufficient or Conflicting	

a. ...

15. Treatment of Pre-Existing Conditions The conditions that preexisted the work injury/disease will need to be managed under two circumstances: (a) A pre-existing condition exacerbated by a work injury/disease should be treated until the patient has returned to their objectively verified prior level of functioning or Maximum Medical Improvement (MMI); and (b) A pre-existing condition not directly caused by a work injury/disease but which may prevent recovery from that injury should be treated until its objectively verified negative impact has been controlled. The focus of treatment should remain on the work injury/disease.

B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1682 (June 2011), amended by the Louisiana Workforce Commission, Office of Workers Compensation, LR 40:1155 (June 2014), amended LR 46:194 (February 2020).

§2104. Overview of Chronic Pain Management

A. It is estimated by the Institute of Medicine that approximately 100 million adults suffer from chronic pain in the United States. The World Health Organization’s survey found that 37 percent of adults in 10 developed countries have chronic pain conditions. This overview covers the biopsychosocial nature of chronic pain and a comprehensive plan of care including: functional assessment and goal setting, psychological assessment, medication management, sleep considerations, and active therapy assisted by

international pain management procedures with continued therapy afterwards as well as indicated surgery.

B. Chronic pain may develop from persistent acute pain due to neuroplastic changes occurring in the central nervous system. All chronic pain appears to involve a central sensitization which changes the perception of pain. Thus, treatment patterns are aimed at a number of mechanisms contributing to chronic pain.

C. Chronic pain is recognized as a biopsychosocial disease process. Each treatment plan should be individualized with a patient-centered approach addressing the many available treatment combinations. Therefore, all areas of the chronic pain guideline should be considered when developing a treatment plan. This includes: the mandatory psychological evaluation; an active therapy plan; medications specific to the pain process for that patient; continuing functional assessment; complementary medication alternatives, when appropriate; and continued return to work/regular daily activity.

D. Once a patient has been identified as a chronic pain patient, usually three months after an injury when pain persists or when pain persists beyond a reasonable post-operative period, the physician should perform a complete re-evaluation or may refer the patient to a pain specialist or surgeon for consultation. This will assist both the patient and the provider in developing an appropriate treatment plan. Although it is unusual to identify an unknown pathology at this point in the treatment, it is recommended that the provider acknowledge the full complement of patient symptoms and concerns. Repeating or ordering new imaging may be necessary.

E. It is essential that the patient and provider understand the type of pain the patient is experiencing and how the pain affects day-to-day activities. Identifying the presence of neuropathic pain, as well as any sources of nociceptive pain, will assist the patient and provider when choosing medication and other forms of treatment recommended in the guideline.

F. During the chronic pain assessment, it is suggested that all physicians review with the patient their usual activities over several different typical 24-hour periods. This will assist both parties in understanding what functions are not able to be performed by the patient, how significantly sleep is impacted, and whether pain is affecting social and family relationships. This information is also essential for establishing agreed upon functional goals.

G. All chronic pain patients should have psychological evaluations. Patients may merely need assistance with coping mechanisms, and/or anxiety or depression may be caused or exacerbated by chronic pain. Treatment in this area is essential for the chronic pain patient. Cognitive behavioral sessions are frequently effective for these conditions.

H. Review of the current prescribed and over-the-counter medications is an important part of this initial chronic pain evaluation. If the patient has been chronically on opioids, a pain specialist referral should be considered to identify the necessity of the opioids and the proper dose. It is also reasonable to taper opioids in order to determine the patient’s baseline and how other medications are actually affecting the pain.

1. The following is a general summary of the required elements. A number of other guidelines, including the Centers for Disease Control and Prevention (CDC) for Primary Care Practitioners and Board of Medical Examiners, have confirmed these steps.

a. An opioid trial shall be performed before chronic opioids are determined to be useful for patients. About 50 percent of patients will not be able to tolerate the side effects and/or not show a sufficient increase in function with opioid use. Patients should be aware that this is a trial and like any other medication trial, it will not be continued unless there is sufficient benefit. The average benefit is about a 30 percent decrease in pain. Thus, all other required treatment must be continued during the time period of the chronic opioid trial.

b. Long acting opioids should never be used for acute pain, post-operative pain, or before an opioid trial has been completed. There is no evidence they are more beneficial than short acting opioids, and the trial should begin with short acting opioids.

c. A risk assessment tool, such as the Opioid Risk Tool (ORT) or Screener and Opioid Assessment for Patients with Pain (SOAPP) should be completed to assure the provider that there are no prior elements suggesting substance abuse or, when such elements are present, the physician may choose to refer to a provider with more expertise in substance abuse.

d. Urine drug testing should be done prior to initiating controlled substance.

e. Check the Prescription Monitoring Program (PMP). Follow Louisiana Revised Statutes 40:973, 40:978 and 40:978.3.

f. The psychological evaluation should have been completed and hopefully treatment as appropriate is being continued.

g. A functional history should be taken and functional goals should be set. This needs to be followed throughout all chronic pain treatment to determine if the patient is increasing or decreasing in function.

h. A provider physician agreement must be completed. This is extremely helpful as it reviews for the patient the expectations regarding his/her behavior as well as the expectations regarding when a physician would choose to taper or remove the patient from opioids and what other treatment is expected to continue during an opioid trial.

2. If the opioid trial is successful, the physician should continue to monitor with random drug testing and PMP checks. "Random drug testing" should be four times a year or possibly more with documented suspicion of abuse or diversion. Quantitative testing is appropriate in cases of inconsistent findings, suspicions, or for particular medications that patient is utilizing that is not in the qualitative testing. In addition, the Current Opioid Misuse Measure (COMM) is an example of a tool that can be used for patients on opioids to screen for possible abuse. It should be noted that current estimates suggest approximately 14 to 19 percent of chronic opioid users may become addicted to opioids.

I. The patient will need to be monitored for side effects. Constipation is anticipated. There may also be problems with sexual dysfunction. Opioids may increase or cause sleep apnea problems, and this should be monitored. At all visits, the functional status of the patient should be recorded.

This can be accomplished with reliable, patient-reported functional status tools. Function is preferably validated by physical exam or by other objective measures from the provider.

J. Lack of sleep is a significant problem for patients with uncontrolled chronic pain. Taking a good history in this area and promoting an appropriate sleep regime is essential for patients, if they are to establish a productive life-style.

K. Active therapy is one of the most important components. Regular exercise is shown to decrease depression as well as decrease chronic pain. Helping the patient choose appropriate physical activities and cognitive activities will be important for recovery. Physician directed exercise, home stretching exercise, does not have to be formal course of physical therapy (as long as the patient has previously undergone a formal course of physical therapy).

L. Although treating chronic pain patients is challenging due to the many disciplines and treatment patterns available, the rewards are great when a patient with chronic pain is able to resume work and engage in satisfying life activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 46:196 (February 2020).

§2105. Introduction to Chronic Pain

A. - B. ...

C. Pain can generally be classified as:

1. ...

2. neuropathic including pain originating from brain, peripheral nerves or both; and

3. psychogenic which originates in mood, characterological, social, or psychophysiological processes.

D. - E. ...

F. *Chronic pain* is defined as "pain that persists for at least 30 days beyond the usual course of an acute disease or a reasonable time for an injury to heal or that is associated with a chronic pathological process that causes continuous pain (e.g., Complex Regional Pain Syndrome)." The very definition of chronic pain describes a delay or outright failure to relieve pain associated with some specific illness or accident. Delayed recovery should prompt a clinical review of the case and a psychological evaluation by the health care provider. Referral to a specialist with experience in pain management is recommended.

G. The term "chronic pain syndrome" has been incorrectly used and defined in a variety of ways that generally indicate a belief on the part of the health care provider that the patient's pain is inappropriate or out of proportion to existing problems or illness. Use of the term "chronic pain syndrome" should be discontinued because the term ceases to have meaning due to the many different physical and psychosocial issues associated with it. The IASP offers taxonomy of pain, which underscores the wide variety of pathological conditions associated with chronic pain. This classification system may not address the psychological and psychosocial issues that occur in the perception of pain, suffering, and disability and may require referral to psychiatric or psychological clinicians. Practitioners should use the nationally accepted terminology indicated in the most current ICD system. Chronic pain can be diagnosed as F45.42 "Pain disorder with related psychological factors" when the associated body part code is

also provided. Alternately, chronic pain can also be diagnosed as F54 "Psychological factors affecting physical conditions," and this code should also be accompanied by the associated body part. G89.4 "chronic pain associated with significant psychosocial dysfunction" may also be utilized.

H. Injured patients generally initiate treatment with complaints of pain, which is generally attributable to a specific injurious event, but occasionally to an ostensible injury. Thus, the physician should not automatically assume that complaints of acute pain are directly attributable to pathophysiology at the tissue level. Pain is known to be associated with sensory, affective, cognitive, social, and other processes. The pain sensory system itself is organized into two parts, often called first and second pain. A-Delta nerve fibers conduct first pain via the neospinothalamic tract to the somatosensory cortex and provide information about pain location and quality. In contrast, unmyelinated C fibers conduct second pain via the paleospinothalamic tract and provide information about pain intensity. Second pain is more closely associated with emotion and memory neural systems than it is with sensory systems.

I. As a patient's condition transitions through the acute, subacute, and chronic phases, the central nervous system (CNS) is reorganized. The temporal summation of second pain produces a sensitization or "windup" of the spinal cord, and the connections between the brain regions involved in pain perception, emotion, arousal, and judgment are changed by persistent pain. These changes cause the CNS's "pain neuromatrix" to become sensitized to pain. This CNS reorganization is also associated with changes in the volume of brain areas, decreased grey matter in the prefrontal cortex, and the brain appearing to age more rapidly. As pain continues over time, the CNS remodels itself so that pain becomes less closely associated with sensation, and more closely associated with arousal, emotion, memory, and beliefs. Because of these CNS processes, all clinicians should be aware that as the patient enters the subacute phase, it becomes increasingly important to consider the psychosocial context of the disorder being treated, including the patient's social circumstances, arousal level, emotional state, and beliefs about the disorder. However, behavioral complications and physiological changes associated with chronicity and central sensitization may also be present in the acute phase, and within hours of the initial injury. It is the intent of many of the treatments in this guideline to assist in remodeling these CNS changes.

J. Chronic pain is a phenomenon not specifically relegated to anatomical or physiologic parameters. The prevailing biomedical model (which focuses on identified disease pathology as the sole cause of pain) cannot capture all of the important variables in pain behavior. While diagnostic labels may pinpoint contributory physical and/or psychological factors and lead to specific treatment interventions that are helpful, a large number of patients defy precise taxonomic classification. Furthermore, such diagnostic labeling often overlooks important social contributions to the chronic pain experience. Failure to address these operational parameters of the chronic pain experience may lead to incomplete or faulty treatment plans. The concept of a "pain disorder" is perhaps the most useful

term, in that it captures the multi-factorial nature of the chronic pain experience.

K. It is recognized that some health care practitioners, by virtue of their experience, additional training, and/or accreditation by pain specialty organizations, have much greater expertise in the area of chronic pain evaluation and treatment than others. Referrals for the treatment of chronic pain should be to such recognized specialists. Chronic pain treatment plans should be monitored and coordinated by physicians with expertise in pain management including specialty training, and/or certification.

L. Most acute and some chronic pain problems are adequately addressed in other OWCA medical treatment guidelines, and are generally not within the scope of this guideline. However, because chronic pain is more often than not multi-factorial, involving more than one pathophysiologic or mental disorder, some overlap with other guidelines is inevitable. This guideline is meant to apply to any patient who fits the operational definition of chronic pain discussed at the beginning of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1683 (June 2011), amended LR 46:197 (February 2020).

§2107. Definitions

A. - E. ...

F. Central Sensitization. The experience of pain evoked by the excitation of non-nociceptive neurons or of nerve fibers that normally relay non-painful sensations to the spinal cord. This results when non-nociceptive afferent neurons act on a sensitized central nervous system (CNS). Experimental data suggest that pathways normally carrying pain signals themselves become overstimulated and/or fail to respond to inhibitory influences causing increased pain. An example is 'wind-up' which occurs when cells in the dorsal horn of the spinal cord increase their rate of action potential discharge in response to repeated stimulation by nociceptors.

G. - H. ...

I. Hyperesthesia (positive sensory phenomenon). Includes allodynia, hyperalgesia, and hyperpathia. Elicited by light touch, pin prick, cold, warm, vibration, joint position sensation or two-point discrimination, which is perceived as increased or more.

J. Hyperpathia. A condition of altered perception such that stimuli which would normally be innocuous, if repeated or prolonged, result in severe explosive persistent pain.

K. ...

L. Hypoesthesia/Hypesthesia (negative sensory phenomena). diminished sensitivity to stimulation.

M. Malingering. Intentional feigning of illness or disability in order to achieve external incentives such as recreational drugs or money.

N. - S. ...

T. Neuropathy. A disturbance of function or pathological change in a nerve: in one nerve (mononeuropathy); in several nerves (mononeuropathy multiplex); or diffuse and bilateral (polyneuropathy). Neuropathy should be associated with objective findings such as consistent sensory abnormalities, consistent motor findings (e.g., weakness, atrophy, fasciculation's, muscle cramping), and/or

neuropathic abnormalities on EMG/nerve conduction testing.

U. - V. ...

W. Pain Threshold. The smallest stimulus perceived by a subject as painful during laboratory testing. The term also loosely applies to the biological variation among human beings in sensing and coping with pain.

X. ...

Y. Peripheral Neuropathic Pain. Pain initiated or caused by a primary lesion or dysfunction in the peripheral nervous system.

Z. Somatic Dysfunction: impaired or altered function of related components of the somatic (body framework) system which includes skeletal, arthrodial, and myofascial structures.

AA. ...

BB. Sympathetically Maintained Pain (smp). A pain that is maintained by sympathetic efferent pathways and is eliminated by blockade of these pathways. It is intensified by circulating catecholamines.

CC. Tender Points. Tenderness on palpation at a tendon insertion, muscle belly or over bone. Palpation should be done with the thumb or forefinger, applying pressure approximately equal to a force of 4 kilograms (blanching of the entire nail bed).

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1684 (June 2011), amended LR 46:198 (February 2020).

§2109. Initial Evaluation and Diagnostic Procedures

A. ...

1. History and Physical Examination (Hx and PE). These are generally accepted, well-established, and widely used procedures that establish the foundation/basis for and dictate subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. The medical records should reasonably document the following.

a. Medical history—as in other fields of medicine, a thorough patient history is an important part of the evaluation of chronic pain. In taking such a history, factors influencing a patient's current status can be made clear and taken into account when planning diagnostic evaluation and treatment. It may be necessary to acquire previous medical records. One efficient manner in which to obtain historical information and patient reported functional status is by using a questionnaire. The questionnaire may be sent to the patient prior to the initial visit or administered at the time of the office visit. History should ascertain the following elements:

i. - vii. ...

viii. belief system—Patients should be asked about their value systems, including spiritual and cultural beliefs, in order to determine how these may influence the patient's and family's response to illness and treatment recommendations.

ix. functional assessment—Functional ability should be assessed and documented at the beginning of treatment. Periodic assessment should be recorded

throughout the course of care to follow the trajectory of recovery. Functional measures are likely to be more reliable over time than pain measures.

(a). Patient-reported outcomes, whether of pain or function, are susceptible to a phenomenon called response shift. This refers to changes in self-evaluation, which may accompany changes in health status. Patient self-reports may not coincide with objective measures of outcome, due to reconceptualization of the impact of pain on daily function and internal recalibration of pain scales. Response shift may obscure treatment effects in clinical trials and clinical practice, and it may lead to apparent discrepancies in patient-reported outcomes following treatment interventions. While methods of measuring and accounting for response shift are not yet fully developed, understanding that the phenomenon exists can help clinicians understand what is happening when some measures of patient progress appear inconsistent with other measures of progress.

x. activities of daily living (ADLs)—Pain has a multidimensional effect on the patient that is reflected in changes in usual daily vocational, social, recreational, and sexual activities;

xi. past and present psychological problems;

xii. history of abuse—physical, emotional, sexual;

xiii. history of disability in the family;

xiv. sleep disturbances: poor sleep has been shown to increase patient's self-perceived pain scores. Pre-injury and post-injury sleep should be recorded.

xv. causality—How did this injury occur? Was the problem initiated by a work-related injury or exposure? Patient's perception of causality (e.g., was it their fault or the fault of another).

b. - b.i. ...

ii. pain diagram drawings to document the distribution of pain.

iii. Visual Analog Scale (VAS)—Current pain, highest pain level, and usual pain level may be recorded. Include a discussion of the range of pain during the day and how activities, use of modalities, and other actions affect the intensity of pain.

iv. duration—including intermittent pain, activity related pain;

v. place of onset—circumstances during which the pain began (e.g., an accident, an illness, a stressful incident, or spontaneous onset);

vi. pain characteristics—such as burning, shooting, stabbing, and aching. Time of pain occurrence, as well as intensity, quality, and radiation, give clues to the diagnosis and potential treatment. Quality of pain can be helpful in identifying neuropathic pain which is normally present most of the day, at night, and is often described as burning;

vii. list of activities which aggravate or exacerbate, ameliorate, decrease, or have no effect on the level of pain;

viii. associated symptoms—Does the patient have numbness or paresthesia, dysesthesia, weakness, bowel or bladder dysfunction, altered temperature, increased sweating, cyanosis or edema? Is there local tenderness, allodynia, hyperesthesia, or hyperalgesia? Does the patient have constitutional symptoms such as fevers, chills, night sweats, unexplained weight loss, or pain that awakes them from a deep sleep at night?

c. Medical management history:

i. prior treatment—chronological review of medical records including previous medical evaluations and response to treatment interventions. In other words, what has been tried and which treatments have helped?;

ii. ...

iii. medications—history of and current use of medications, including opioids, over the counter medications and herbal/dietary supplements, to determine drug usage (or abuse) interactions and efficacy of treatment. Drug allergies and other side effects experienced with previous or current medication therapy and adherence to currently prescribed medications should be documented. Ideally, this includes dosing schedules as reported by the patient or patient representative. Information should be checked against the Louisiana Prescription Monitoring Program (PMP), offered by the Louisiana Pharmacy Board;

iv. ...

v. psychosocial functioning—determine if the following are present: current symptoms of depression or anxiety; evidence of stressors in the workplace or at home, and past history of psychological problems. Other confounding psychosocial issues may be present, including the presence of psychiatric disease. Due to the high incidence of co-morbid problems in populations that develop chronic pain, it is recommended that patients diagnosed with Chronic Pain be referred for a full psychosocial evaluation;

vi. - vii. ...

viii. family history pertaining to similar disorders.

d. Substance use/abuse:

i. ...

ii. smoking history and use of nicotine replacements;

iii. history of current and prior prescription and recreational drug use and abuse;

iv. the use of caffeine or caffeine-containing beverages;

v. substance abuse information may be only fully obtainable from multiple sources over time. Patient self-reports may be unreliable. Patient self-reports should always be checked against medical records.

e. Other factors affecting treatment outcome:

i. - ii. ...

iii. Other scales may be used to identify cases which are likely to require more complex care. Examples include:

(a). fear avoidance beliefs questionnaire;

(b). tampa scale of kinesiophobia;

(c). pain catastrophizing scale.

f. Physical examination:

i. neurologic evaluation—includes cranial nerves survey, muscle tone and strength, atrophy, detailed sensory examination (see ii-below), motor evaluation (station, gait, coordination), reflexes (normal tendon reflexes and presence or absence of abnormal reflexes such as frontal lobe release signs or upper motor neuron signs), cerebellar testing, signs suggestive of a sensory ataxia (positive Romberg, impaired proprioception, etc.), and provocative neurological maneuvers.

ii. sensory evaluation—A detailed sensory examination is crucial in evaluating a patient with chronic pain complaints. Quantitative sensory testing, such as

Semmes-Weinstein, may be useful tools in determining sensory abnormalities. Ideally, the examination should determine if the following sensory signs are present and consistent on repeated examination:

(a). - (i). ...

iii. musculoskeletal evaluation—range of motion, segmental mobility, musculoskeletal provocative maneuvers, palpation, observation, and functional activities. All joints, muscles, ligaments, and tendons should be examined for asymmetry, swelling, laxity, and tenderness. A portion of the musculoskeletal evaluation is the myofascial examination. The myofascial examination includes palpating soft tissues for evidence of tightness and trigger points.

iv. evaluation of non-physiologic findings:

(a). Waddell's Signs cannot be used to predict or diagnose malingering. It is not an appropriate test for assessing non-physiologic causes of low back pain. The sole purpose of the Waddell's signs is to identify low back pain patients who may need further psychosocial assessment prior to surgery. Refer to Personality/Psychological/Psychosocial Evaluation.

(b). ...

(c). Inconsistencies between formal exam and observed abilities of range-of-motion, motor strength, gait and cognitive/emotional state should be noted in the assessment.

2. Personality /Psychosocial/ Psychiatric/
Psychological Evaluation

a. These are generally accepted and well-established and widely used diagnostic procedures not only with selected use in acute pain problems, but have also with more widespread use in subacute and chronic pain populations.

i. Diagnostic evaluations should distinguish between conditions that are pre-existing, aggravated by the current injury, or work related.

b. Psychosocial evaluations should determine if further psychosocial or behavioral interventions are indicated for patients diagnosed with chronic pain. The interpretations of the evaluation should provide clinicians with a better understanding of the patient in his or her social environment, thus allowing for more effective rehabilitation. Psychosocial assessment requires consideration of variations in pain experience and expression resulting from affective, cognitive, motivational and coping processes, and other influences such as gender, age, race, ethnicity, national origin, religion, sexual orientation, disability, language, or socioeconomic status.

c. While there is some agreement about which psychological factors need to be assessed in patients with chronic pain, a comprehensive psychological evaluation should attempt to identify both primary psychiatric risk factors or "red flags" (e.g., psychosis, active suicidality) as well as secondary risk factors or "yellow flags" (e.g., moderate depression, job dissatisfaction). Significant personality disorders must be taken into account when considering a patient for spinal cord stimulation and other major procedures.

d. Psychometric testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. There is good evidence that psychometric testing can have significant ability to predict

medical treatment outcome. For example, one study found that psychometric testing exceeded the ability of discography to predict disability in patients with low back pain. Pre-procedure psychiatric/psychological evaluation must be done prior to diagnostic confirmatory testing for a number of procedures. Examples include discography for fusion, spinal cord stimulation, or intrathecal drug delivery systems, and a psychologist employed by the physician planning to perform the procedure should not do them and they should not be done by a psychologist employed by the physician planning to perform the procedure.

e. In many instances, psychological testing has validity comparable to that of commonly used medical tests; for example, the correlation between high trait anger and blood pressure is equal to the correlation between reduced blood flow and the failure of a synthetic hemodialysis graft. Thus, psychometric testing may be of comparable validity to medical tests and may provide unique and useful diagnostic information.

f. All patients who are diagnosed as having chronic pain should be referred for a psychosocial evaluation, as well as concomitant interdisciplinary rehabilitation treatment. This referral should be performed in a way so as to not imply that the patient's claims are invalid or that the patient is malingering or mentally ill. Even in cases where no diagnosable mental condition is present, these evaluations can identify social, cultural, coping, and other variables that may be influencing the patient's recovery process and may be amenable to various treatments including behavioral therapy. As pain is understood to be a biopsychosocial phenomenon, these evaluations should be regarded as an integral part of the assessment of chronic pain conditions.

i. Qualifications

(a). A psychologist with a PhD, PsyD, or EdD credentials or a physician with Psychiatric MD/DO credentials may perform the initial comprehensive evaluations. It is preferable that these professionals have experience in diagnosing and treating chronic pain disorders and/or working with patients with physical impairments.

(b). Psychometric tests should be administered by psychologists with a PhD, PsyD, or EdD or health professionals working under the supervision of a doctorate level psychologist. Physicians with appropriate training may also administer such testing, but interpretation of the tests should be done by properly credentialed mental health professionals.

ii. Clinical Evaluation. Special note to health care providers: most providers are required to adhere to the federal regulations under the Health Insurance Portability and Accountability Act (HIPAA). Unlike general health insurers, workers' compensation insurers are not required to adhere to HIPAA standards. Thus, providers should assume that sensitive information included in a report sent to the insurer could be forwarded to the employer. It is recommended that the health care provider either obtain a full release from the patient regarding information that may go to the employer or not include sensitive health information not directly related to the work related conditions in reports sent to the insurer.

(a). All chronic pain patients should have a clinical evaluation that addresses the following areas

recalling that not all details should be included in the report sent to the insurer due to the HIPAA issue noted above:

(i). history of injury—The history of the injury should be reported in the patient's words or using similar terminology. Caution must be exercised when using translators.

[a]. - [e]. ...

[f]. adherence with treatment;

[g]. coping strategies used, including perceived locus of control, catastrophizing, and risk aversion;

[h]. - [i]. ...

(ii). health history

[a]. - [b]. ...

[c]. psychiatric history: to include past diagnoses, counseling, medications, and response to treatment;

[d]. history of substance related and addictive disorders to include: alcohol, opioids, medications (sedative, hypnotic, and anxiolytic), stimulants, prescriptions drug abuse, nicotine use and other substances of abuse/dependence;

[e]. ...

[f]. past, recent, and concurrent stressors.

[g]. ...

(iii). psychosocial history

[a]. childhood history, including abuse/neglect;

[b]. - [d]. ...

[e]. legal history, including but not limited to substance use related, domestic violence, criminal and civil litigation;

[f]. employment history;

[g]. military duty: Because post-traumatic stress disorder (PTSD) might be an unacceptable condition for many military personnel to acknowledge, it may be prudent to screen initially for signs of depression or anxiety—both of which may be present in PTSD;

[h]. signs of pre-injury psychological dysfunction;

[i]. ...

[j]. current living situation including roommates, family, intimate partners, and financial support;

[k]. prior level of function including self-care, community, recreational, and employment activities.

(iv). ...

(v). assessment of any danger posed to self or others.

(vi). - (vii). ...

(viii). causality—to address medically probable cause and effect, and to distinguish pre-existing psychological symptoms, traits, and vulnerabilities from current symptoms.

(ix). ...

(x). mental status exam including orientation, cognition, activity, speech, thinking, affect, mood, and perception. May include screening tests such as the mini mental status exam or frontal assessment battery if appropriate.

iii. Tests of Psychological Functioning. Psychometric Testing is a valuable component of a consultation to assist the physician in making a more

effective treatment plan. Psychometric testing is useful in the assessment of mental conditions, pain conditions, cognitive functioning, treatment planning, vocational planning, and evaluation of treatment effectiveness. While there is no general agreement as to which psychometric tests should be specifically recommended for psychological evaluations of chronic pain conditions, standardized tests are preferred over those which are not for assessing diagnosis. Generally, it is helpful if tests consider the following issues: validity, physical symptoms, affective disorders, character disorders and traits, and psychosocial history. Character strengths that support the healing/rehabilitative process should also be evaluated and considered with any dysfunctional behavior patterns or pathology to more accurately assess the patient's prognosis and likely response to a proposed intervention. In contrast, non-standardized tests can be useful for "ipsative" outcome assessment, in which a test is administered more than once and a patient's current and past reports are compared. It is appropriate for the mental health provider to use their discretion and administer selective psychometric tests within their expertise and within standards of care in the community. Use of screening psychometrics by non-mental health providers is encouraged, but mental health provider consultation should always be utilized for chronic pain patients in which invasive palliative pain procedures or chronic opiate treatment is being contemplated. Some of these tests are available in Spanish and other languages, and many are written at a sixth grade reading level. Examples of frequently used psychometric tests performed include, but not limited to, the following.

(a). Comprehensive Inventories for Medical Patients

(i). Battery for Health Improvement, 2nd Edition (BHI-2);

(ii). Millon Behavioral Medical Diagnostic (MBMD);

(b). Comprehensive Psychological Inventories.

(i). Millon Clinical Multiaxial Inventory;

(ii). Minnesota Multiphasic Personality Inventory, 2nd Edition (MMPI-2).

(iii). Personality Assessment Inventory (PAI).

(c). Brief Multidimensional Screens for Medical Patients. Treating providers, to assess a variety of psychological and medical conditions, including depression, pain, disability and others, may use brief instruments. These instruments may also be employed as repeated measures to track progress in treatment, or as one test in a more comprehensive evaluation. Brief instruments are valuable in that the test may be administered in the office setting and hand scored by the physician. Results of these tests should help providers distinguish which patients should be referred for a specific type of comprehensive evaluation.

(i). Brief Battery for Health Improvement, 2nd Edition (BBHI-2);

(ii). Pain Patient Profile (P-3);

(iii). SF-36®;

(iv). Sickness Impact Profile (SIP);

(v). McGill Pain Questionnaire (MPQ);

(vi). McGill Pain Questionnaire—Short Form (MPQ-SF);

(vii). Oswestry Disability Questionnaire.;

(viii). Visual Analog Scales (VAS).;

(ix). Numerical Rating Scale (NRS);

(x). Chronic Pain Grade Scale (CPGS);

(xi). Pain Catastrophizing Scale (PCS).

(d). Brief Multidimensional Screens for Psychiatric Patients. These tests are designed for detecting various psychiatric syndromes, but in general are more prone to false positive findings when administered to medical patients.

(i). Brief Symptom Inventory (BSI);

(ii). Brief Symptom Inventory—18 (BSI-18);

(iii). Symptom Check List -90 Revised (SCL 90 R).

(e). Brief Specialized Psychiatric Screening Measures:

(i). Beck Depression Inventory (BDI);

(ii). Center of Epidemiologic Studies—Depression Questionnaire (CES-D);

NOTE: Designed for assessment of psychiatric patients, not pain patients, which can bias results, and this should be a consideration when using.

(iii). Brief Patient Health Questionnaire from PRIME - MD. (The PHQ-9 may also be used as a depression screen.);

(iv). Zung Depression Questionnaire;

NOTE: The Zung Depression Scale must be distinguished from the Modified Zung Depression scale used by the DRAM (a QPOP measure). The Zung Depression Scale has different items and a different scoring system than the Modified Zung Depression scale, making the cutoff scores markedly different. The cutoff scores for one measure cannot be used for the other.

(v). General Anxiety Disorder 7-item scale (GAD-7).

3. Diagnostic Studies. Imaging of the spine and/or extremities is a generally accepted, well-established, and widely used diagnostic procedure when specific indications, based on history and physical examination, are present. Practitioners should be aware of the radiation doses associated with various procedures and provide appropriate warnings to patients. Unnecessary CT scans or X-rays increase the lifetime risk of cancer death. Physicians should refer to individual OWCA guidelines for specific information about specific testing procedures. Tests should be performed to rule in or out specific diagnoses especially cases that are difficult to diagnose or fail to progress.

a. Radiographic Imaging, MRI, CT, bone scan, radiography, and other special imaging studies may provide useful information for many musculoskeletal disorders causing chronic pain. It is probably most helpful in ruling out rare, significant diagnoses that may present with pain, such as metastatic cancer. Most imaging is likely to demonstrate aging changes which are usually not pathologic. However, it is good to remember every medical condition can be exacerbated. Refer to specific OWCA Medical Treatment Guidelines for details. Before the test is performed, patients should be informed of the purpose of the exam (e.g., to rule out unsuspected cancer) and the likelihood of finding non-pathologic changes that are part of the normal aging process.

b. Electrodiagnostic studies may be useful in the evaluation of patients with suspected myopathic or neuropathic disease and may include Nerve Conduction

Studies (NCS), Standard Needle Electromyography, or Somatosensory Evoked Potential (SSEP). The evaluation of electrical studies is complex and should be performed by specialists who are well trained in the use of this diagnostic procedure.

c. Special testing procedures may be considered when attempting to confirm the current diagnosis or reveal alternative diagnosis. Additional special tests may be performed at the discretion of the physician.

d. Testing for Complex Regional Pain Syndrome (CRPS-I) or Sympathetically Maintained Pain (SMP) is described in the OWCA's Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.

4. Laboratory testing is a generally accepted, well-established and widely used procedure.

a. Patients should be carefully screened at the initial exam for signs or symptoms of diabetes, hypothyroidism, arthritis, and related inflammatory diseases. For patients at risk for sleep apnea, testing may be appropriate depending on medication use and issues with insomnia. The presence of concurrent disease does not refute work-relatedness of any specific case. This frequently requires laboratory testing. When a patient's history and physical examination suggest infection, metabolic or endocrinologic disorders, tumorous conditions, systemic musculoskeletal disorders (e.g., rheumatoid arthritis or ankylosing spondylitis), or problems potentially related to medication (e.g., renal disease and non-steroidal anti-inflammatory medications), then laboratory tests, including, but not limited to the following can provide useful diagnostic information:

i. thyroid stimulating hormone (TSH) for hypothyroidism;

ii. diabetic screening: recommended for men and women with a BMI over 30, patients with a family history of diabetes, those from high risk ethnic groups, and patients with a previous history of impaired glucose tolerance. There is some evidence that diabetic patients with upper extremity disorders have sub-optimal control of their diabetes;

iii. serum protein electrophoresis;

iv. sedimentation rate and C-reactive protein (CRP) are nonspecific but elevated in infection, neoplastic conditions, and rheumatoid arthritis. Other screening tests to rule out inflammatory or autoimmune disease may be added when appropriate;

v. serum calcium, phosphorus, uric acid, alkaline, and acid phosphatase for metabolic, endocrine and neoplastic conditions;

vi. complete blood count (CBC), liver, and kidney function profiles for metabolic or endocrine disorders or for adverse effects of various medications;

vii. bacteriological (microorganism) work-up for wound, blood, and tissue;

viii. vitamin B12 levels may be appropriate for some patients.

b. The OWCA recommends that the workers' compensation carrier cover initial lab diagnostic procedures to ensure that an accurate diagnosis and treatment plan is established. When an authorized treating provider has justification for the test, insurers should cover the costs. Laboratory testing may be required periodically to monitor patients on chronic medications.

5. Injections-Diagnostic

a. Spinal Diagnostic Injections. Diagnostic spinal injections are commonly used in chronic pain patients and they usually have been performed previously in the acute or subacute stage. They may rarely be necessary for aggravations of low back pain. Refer to the OWCA Low Back Pain Medical Treatment Guideline for indications.

b. Diagnostic Peripheral nerve blocks such as Genicular Nerves, 3rd Occipital, nerves, Greater and Lesser Occipital nerves, intercostal nerves, Ilioinguinal nerves, iliohypogastric nerves, lateral femoral cutaneous nerves, medial branch facet nerves (cervical, thoracic and lumbar), sacral lateral branches of Sacroiliac joints, Selective nerve root blocks and transforaminal epidural injections and other pure sensory nerves suspected of causing pain. Also include diagnostic facet joint injection as a diagnostic block.

c. Medial Branch Facet Blocks (Cervical, Thoracic and Lumbar) and Sacral Lateral Branch Blocks. If provide 80 percent or more pain reduction as measured by a numerical pain index scale within one hour of the medial branch blocks up to three levels per side, then rhizotomy of the medial branch nerves, up to four nerves per side, may be done without confirmation block. If the initial set of medial branch blocks provides less than 80 percent but at least 50 percent pain reduction as measured by a numerical pain index scale or documented functional improvement, the medial branch block should be repeated for confirmation before a rhizotomy is performed. If 50 percent or greater pain reduction is achieved as measured by the NPIS with two sets of medial branch blocks for facet joint pain, then rhizotomy may be performed.

d. In general, relief should last for at least the duration of the local anesthetic used and should significantly result in functional improvement and relief of pain. Refer to Injections- Spinal Therapeutic for information on other specific therapeutic injections.

6. Special tests are generally well-accepted tests and are performed as part of a skilled assessment of the patient's capacity to return to work, his/her strength capacities, and/or physical work demand classifications and tolerance. The procedures in this Subsection are listed in alphabetical order.

a. Computer-enhanced evaluations. These may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range of motion (ROM), endurance, or strength. Values obtained can include degrees of motion, torque forces, pressures, or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation. These evaluations should not be used alone to determine return to work restrictions.

i. Frequency. One time for evaluation, one for mid-treatment assessment, and one at final evaluation.

b. Functional Capacity Evaluation (FCE): This is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return-to-work. FCEs should not be used as the sole criteria to diagnose malingering. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion (ROM), coordination and strength, worker habits, employability as well as psychosocial aspects of competitive employment may be evaluated. Reliability of patient reports and overall effort during testing is also reported.

Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; non-material and material handling activities. Standardized national guidelines (such as National Institute for Occupational Safety and Health (NIOSH)) should be used as the basis for FCE recommendations.

i. Frequency: Once when the patient is unable to return to the pre-injury position and further information is desired to determine permanent work restrictions. Prior authorization is required for repeat FCEs.

ii. Most studies of FCEs were performed on chronic low back cases. There is some evidence that an FCE fails to predict which injured workers with chronic low back pain will have sustained return to work. Another cohort study concluded that there was a significant relation between FCE information and return to work, but the predictive efficiency was poor. There is some evidence that time off work and gender are important predictors for return to work, and floor-to-waist lifting may also help predict return to work; however, the strength of that relationship has not been determined.

iii. A full review of the literature reveals no evidence to support the use of FCEs to prevent future injuries. There is some evidence in chronic low back pain patients that FCE task performance is weakly related to time on disability and time for claim closure, and even claimants who fail on numerous physical performance FCE tasks may be able to return to work. These same issues may exist for lower extremity issues.

iv. Depth and breadth of FCE should be assessed on a case-by-case basis and should be determined by tester and/or referring medical professional. In many cases, a work tolerance screening or return to work performance will identify the ability to perform the necessary job tasks. There is some evidence that a short form FCE reduced to a few tests produces a similar predictive quality compared to the longer two-day version of the FCE regarding length of disability and recurrence of a claim after return to work.

v. When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the physical demands and the duties of the job that the worker is attempting to perform. A jobsite evaluation is usually necessary. A job description should be reviewed by the provider and FCE evaluator prior to this evaluation. FCEs cannot be used in isolation to determine work restrictions. It is expected that the FCE may differ from both self-report of abilities and pure clinical exam findings in chronic pain patients. The length of a return to work evaluation should be based on the judgment of the referring physician and the provider performing the evaluation. Since return to work is a complicated multidimensional issue, multiple factors beyond functional ability and work demands should be considered and measured when attempting determination of readiness or fitness to return to work. FCEs should not be used as the sole criteria to diagnose malingering.

c. Job site evaluation is a comprehensive analysis of the physical, mental, and sensory components of a specific job. The goal of the Job Site evaluation is to identify any job

modification needed to ensure the safety of the employee upon return to work. These components may include, but are not limited to: postural tolerance (static and dynamic); aerobic requirements; range of motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; environmental requirements of a job; repetitiveness; essential functions of a job; and ergonomic set up. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

i. ...

ii. Jobsite evaluation and alteration should include input from a health care professional with experience in ergonomics or a certified ergonomist, the employee, and the employer. The employee must be observed performing all job functions in order for the jobsite evaluation to be a valid representation of a typical workday. If the employee is unable to perform the job function for observation, a co-worker in an identical job position may be observed instead. Periodic follow-up is recommended to assess the effectiveness of the intervention and need for additional ergonomic changes.

iii. A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work.

iv. Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include but are not limited to the following:

(a). to determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;

(b). to make recommendations for and to assess the potential for ergonomic changes;

(c). to provide a detailed description of the physical and cognitive job requirements;

(d). to assist patients in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner;

(e). to give detailed work/activity restrictions.

d. Vocational Assessment. Once an authorized practitioner has reasonably determined and objectively documented that a patient will not be able to return to his/her former employment and can reasonably prognosticate final restrictions, implementation of a timely vocational assessment can be performed. The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of Maximum Medical Improvement (MMI) should not be delayed solely due to lack of attainment of a vocational assessment.

i. ...

e. Work tolerance screening (Fitness for Duty) is a determination of an individual's tolerance for performing a specific job based on a job activity or task. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the

patient's return-to-work potential. May be used when a full FCE is not indicated. In order for a work tolerance to be performed in place of a FCE, an updated job description must be provided to the tester.

i. Frequency. One time for initial screen. May monitor improvements in strength every three to four weeks up to a total of six visits.

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§2111. Therapeutic Procedures—Non-Operative

A. Non-operative therapeutic rehabilitation is applied to patients with chronic and complex problems of de-conditioning and functional disability. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity and complexity of the problem, and anticipated therapeutic effect. Treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

B. All treatment plans begin with shared decision making with the patient. Before initiation of any therapeutic procedure, an authorized treating physician, employer, and insurer should consider these important issues in the care of the injured worker:

1. Patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to Return-to-Work in this Section for detailed information.

2. Reassessment of the patient's status in terms of functional improvement should be documented after each treatment. If patients are not responding within the recommended time periods, alternative treatment interventions, further diagnostic studies or specialist and/or surgeon consultations should be pursued. Continued treatment should be monitored using objective measures such as:

- a. ...
- b. fewer restrictions at work or performing activities of daily living (ADL);
- c. decrease in usage of medications related to the work injury; and
- d. measurable functional gains, such as increased range of motion, documented increase in strength, increased ability to stand, sit or lift, or patient completed functional evaluations;

3. - 4. ...

C. The following procedures are listed in alphabetical order.

1. Acupuncture

a. Overview. When acupuncture has been studied in randomized clinical trials, it is often compared with sham acupuncture and/or no acupuncture (usual care). The differences between true acupuncture and usual care have been moderate but clinically important. These differences can be partitioned into two components: non-specific effects and specific effects. Non-specific effects include patient beliefs and expectations, attention from the acupuncturist, administration of acupuncture in a relaxing setting, and other components of what is often called the placebo effect. Specific effects refer to any additional effects which occur in the same setting of expectations and attention, but they are

attributable to the penetration of the skin in the specific, classic acupuncture points on the surface of the body by the needles themselves.

i. A sham procedure is intended as a non-therapeutic procedure that appears similar to the patient as the purported therapeutic procedure being tested. In most controlled studies, sham and classic acupuncture have produced similar effects. However, the sham controlled studies have shown consistent advantages of both true and sham acupuncture over no acupuncture when the studies have included a third comparison group that was randomized to usual medical care. Having this third comparison group has been advantageous in the interpretation of the non-specific effects of acupuncture since the third comparison group controls for some influences on study outcome. These influences include: more frequent contact with providers; the natural history of the condition; regression to the mean; the effect of being observed in a clinical trial; and for biased reporting of outcomes if the follow-up observations are done consistently in all three treatment groups. Controlling for these factors enables researchers to more closely estimate the contextual and personal interactive effects of acupuncture as it is generally practiced.

ii. There is some evidence that in the setting of chronic joint pain arising from aromatase inhibitor treatment of non-metastatic breast cancer, the symptomatic relief from acupuncture is strongly influenced by the expectations with which patients approach treatment, and a patient who expects significant benefits from acupuncture is more likely to derive benefits from sham acupuncture than a patient with low expectations is to derive benefits from real acupuncture. On average, real and sham acupuncture do not lead to significantly different symptom responses, but different treatment expectations do lead to different symptom responses.

iii. Clinical trials of acupuncture typically enroll participants who are interested in acupuncture and who may respond to some of the non-specific aspects of the intervention more than patients who have no interest in or desire for acupuncture. The non-specific effects of acupuncture may not be produced in patients who have no wish to be referred for it.

iv. There is a high quality study which does not support good evidence that true acupuncture is meaningfully superior to sham acupuncture with blunt needles in relieving the bothersomeness of nonspecific low back pain. The overall evidence from similar high quality studies does not support evidence of a treatment difference between true and sham acupuncture. In these studies, 5 to 15 treatments were provided. Comparisons of acupuncture and sham acupuncture have been inconsistent, and the advantage of true over sham acupuncture has been small in relation to the advantage of sham over no acupuncture.

v. Acupuncture is recommended for subacute or chronic pain patients who are trying to increase function and/or decrease medication usage and have an expressed interest in this modality. It is also recommended for subacute or acute pain for patients who cannot tolerate NSAIDs or other medications.

vi. Acupuncture is not the same procedure as dry needling for coding purposes; however, some acupuncturists may use acupuncture treatment for myofascial trigger points.

Dry needling is performed specifically on myofascial trigger points. Refer to Trigger Point Injections, and Dry Needling Treatment.

vii. Acupuncture should generally be used in conjunction with manipulative and physical therapy/rehabilitation.

viii. Credentialed practitioners with experience in evaluation and treatment of chronic pain patients must perform evaluations prior to acupuncture treatments. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. It may be used when pain medication is reduced or not tolerated; as an adjunct to physical rehabilitation and surgical intervention; and/or as part of multidisciplinary treatment to hasten the return of functional activity. Acupuncture must be performed by practitioners with the appropriate credentials in accordance with state and other applicable regulations. Therefore, if not otherwise within their professional scope of practice and licensure, those performing acupuncture must have the appropriate credentials, such as L.A.c. R.A.c, or Dipl. Ac.

ix. There is good evidence that the small therapeutic effects of needle acupuncture, active laser acupuncture, and sham acupuncture for reducing pain or improving function among patients older than 50 years with moderate to severe chronic knee pain from symptoms of osteoarthritis are due to non-specific effects similar to placebo.

x. The Agency for Healthcare Research and Quality (AHRQ) supports acupuncture as effective for chronic low back pain. There is good evidence that acupuncture is effective in the treatment of low back pain in patients with positive expectations of acupuncture. There is good evidence that acupuncture, true or sham, is superior to usual care for the reduction of disability and pain in patients with chronic nonspecific low back pain, but true and sham acupuncture are likely to be equally effective. There is some evidence that acupuncture is better than no acupuncture for axial chronic low back pain. In summary, there is strong evidence that true or sham acupuncture may be useful for chronic low back pain in patients with high expectations, and it should be used accordingly.

xi. Indications. All patients being considered for acupuncture treatment should have subacute or chronic pain (lasting approximately three to four weeks depending on the condition) and meet the following criteria:

(a). they should have participated in an initial active therapy program; and

(b). they should show a preference for this type of care or previously have benefited from acupuncture; and

(c). they must continue to be actively engaged in physical rehabilitation therapy and return to work.

xii. It is less likely to be successful in patients who are more focused on pain than return to function. Time to produce effect should clearly be adhered to.

b. Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a

period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range-of-motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

c. Acupuncture with electrical stimulation: is the use of electrical current (micro- amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

d. Other acupuncture modalities may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, and soft tissue manipulation/massage. Refer to Therapy- Active (Therapeutic Exercise) and Therapy-Passive sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

e. Total time frames for acupuncture and acupuncture with electrical stimulation are not meant to be applied to acupuncture and acupuncture with electrical stimulation separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

i. time to produce effect: three to six treatments;

ii. frequency: one to three times per week;

iii. optimum duration: one to two months;

iv. maximum duration: 14 treatments within six months.

f. Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

2. Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Stress-related psycho-physiological reactions may arise as a reaction to organic pain and in some cases may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely with coaching by a biofeedback specialist. There is good evidence that biofeedback or relaxation therapy is equal in effect to cognitive behavioral therapy for chronic low back pain. There is good evidence that cognitive behavioral therapy, but not behavioral therapy (e.g., biofeedback), shows weak to small effects in reducing pain and small effects on

improving disability, mood, and catastrophizing in patients with chronic pain.

a. Indications for biofeedback include cases of musculoskeletal injury in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of pain, anxiety, panic, anger or emotional distress, opioid withdrawal, insomnia/ sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized for relaxation training. Mental health professionals may also utilize it as a component of psychotherapy, where biofeedback and other behavioral techniques are integrated with psychotherapeutic interventions. Biofeedback is often used in conjunction with physical therapy or medical treatment.

b. - c. ...

d. Psychologists or psychiatrists, who provide psycho-physiological therapy which integrates biofeedback with psychotherapy, should be either Biofeedback Certification Institute of America (BCIA) certified or practicing within the scope of their training. All non-licensed health care providers of Biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by the authorized treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by licensed health care providers, who follow a set treatment and educational protocol. Such treatment may utilize standardized material, relaxation tapes, or smart phone apps.

- i. time to produce effect: three to four sessions;
- ii. frequency: one to two times per week;
- iii. optimum duration: five to six sessions;
- iv. maximum duration: 10 to 12 sessions.

Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate functional gains.

3. Complementary Medicine

a. Overview. Complementary Medicine, termed Complementary Alternative Medicine (CAM) in some systems, is a term used to describe a broad range of treatment modalities, a number of which are generally accepted and supported by some scientific literature and others which still remain outside the generally accepted practice of conventional Western Medicine. In many of these approaches, there is attention given to the relationship between physical, emotional, and spiritual well-being. While CAM may be performed by a myriad of both licensed and non-licensed health practitioners with training in one or more forms of therapy, credentialed practitioners should be used when available or applicable.

b. Although CAM practices are diverse and too numerous to list, they can be generally classified into five domains.

i. Alternative Medical Systems. These are defined as medical practices that have developed their own systems of theory, diagnosis, and treatment and have evolved independent of and usually prior to conventional Western Medicine. Some examples are Traditional Chinese Medicine, Ayurvedic Medicine, Homeopathy, and Naturopathy.¹

ii. Mind-Body Interventions. These include practices such as hypnosis, meditation, bioenergetics, and prayer. Reflexology does not appear to relieve low back pain.

iii. Biological-Based Practices. These include herbal and dietary therapy as well as the use of nutritional supplements. To avoid potential drug interactions, supplements should be used in consultation with an authorized treating physician.

iv. Body-Based Therapy. This category includes Rolting bodywork. For information on yoga, please refer to Therapeutic Exercise.

v. Energy-Based Practices. Energy-based practices include a wide range of modalities that support physical as well as spiritual and/or emotional healing. Some of the more well-known energy practices include Qi Gong, Tai Chi, Healing Touch, and Reiki. Practices such as Qi Gong and Tai Chi are taught to the patient and are based on exercises the patient can practice independently at home. Other energy-based practices such as Healing Touch and Reiki that involve a practitioner/patient relationship may provide some pain relief. Tai Chi may improve range-of-motion in those with rheumatoid arthritis. There is some evidence that a 10-week tai chi program was effective for improving pain symptoms and disability compared with usual care controls for those who have chronic low back pain symptoms. There is insufficient evidence that the results from Qi Gong are equivalent to exercise therapy.

c. Methods used to evaluate chronic pain patients for participation in CAM will differ with various approaches and with the training and experience of individual practitioners. A patient may be referred for CAM therapy when the patient's cultural background, religious beliefs, or personal concepts of health suggest that an unconventional medical approach might assist in the patient's recovery or when the physician's experience and clinical judgment support a CAM approach. The patient must demonstrate a high degree of motivation to return to work and improve his or her functional activity level while participating in therapy. Other more traditional conservative treatments should generally be attempted before referral to CAM. Treatment with CAM requires prior authorization.

d. All CAM treatments require prior authorization and must include agreed upon number of visits for time to produce functional effects.

e. Time Frames for Complementary Medicine:

i. time to produce effect—Functional treatment goals and number of treatments for time to produce effect should be set with the practitioner and the patient before the beginning of treatment.

ii. frequency—per CAM therapy selected.

iii. optimum duration—should be based upon the physician's clinical judgment and demonstration by the patient of positive symptomatic and functional gains. Practitioner provided CAM therapy is not recommended on a maintenance basis.

4. Direct Cortical Stimulation. There are several types of cortical stimulation to relieve pain. All of these are undergoing further investigation and are considered experimental at this time. The limited studies available do not allow translation to the workers' compensation chronic pain population. An invasive option is implantation in the

epidural motor cortex. Given the invasive nature and lack of evidence applying to the working population, direct cortical stimulation is not recommended.

5. Disturbances of Sleep

a. Overview. Disturbances of sleep are common in chronic pain. An essential element of chronic pain treatment is restoration of normal sleep cycles. Although primary insomnia may accompany pain as an independent co-morbid condition, it more commonly occurs secondary to the pain condition itself. Exacerbations of pain often are accompanied by exacerbations of insomnia; the reverse can also occur. Sleep laboratory studies have shown disturbances of sleep architecture in pain patients. Loss of deep slow-wave sleep and increase in light sleep occur and sleep efficiency, the proportion of time in bed spent asleep, is decreased. These changes are associated with patient reports of non-restorative sleep. Sleep apnea may also occur as a primary diagnosis or be caused or exacerbated by opioid and hypnotic use. This should be investigated diagnostically. (Refer to Medications and Medical Management, Opioids).

i. A recent systematic review explored the relationship between sleep and pain. It noted that studies of healthy individuals and those in pain from medical conditions both showed decreased pain thresholds after sleep deprivation. In this report some studies focusing on sleep continuity disruption showed a disruption of the natural pain inhibitory function. Sleep continuity disruption may be one of the most common sleep problems associated with pain. Thus, clinicians should strongly focus on assuring functional sleep for patients.

ii. Many chronic pain patients develop behavioral habits that exacerbate and maintain sleep disturbances. Excessive time in bed, irregular sleep routine, napping, low activity, and worrying in bed are all maladaptive responses that can arise in the absence of any psychopathology. Relaxation training such as progressive relaxation, biofeedback, mindfulness meditation, or imagery training, and other forms of cognitive therapy can reduce dysfunctional beliefs and attitudes about sleep.

iii. There is some evidence that behavioral modification, such as patient education and group or individual counseling with cognitive behavioral therapy, can be effective in reversing the effects of insomnia. Cognitive and behavioral interventions should be undertaken before prescribing medication solely for insomnia. Behavioral modifications are easily implemented and can include:

(a). maintaining a regular sleep schedule, retiring and rising at approximately the same time on weekdays and weekends, regardless of the number of hours slept;

(b). limiting naps to 30 minutes twice per day or less;

(c). avoiding caffeinated beverages after lunchtime;

(d). making the bedroom quiet and comfortable, eliminating disruptive lights, sounds, television sets, pets, and keeping a bedroom temperature of about 65°F;

(e). avoiding alcohol or nicotine within two hours of bedtime;

(f). avoiding large meals within two hours of bedtime;

(g). avoiding exposure to TV screens or computers within two hours of bedtime.

(h). exercising vigorously during the day, but not within two hours of bedtime, since this may raise core temperature and activate the nervous system;

(i). associating the bed with sleep and sexual activity only, using other parts of the home for television, reading and talking on the telephone;

(j). leaving the bedroom when unable to sleep for more than 20 minutes, and returning to the bedroom when ready to sleep again;

(k). reducing time in bed to estimated typical sleeping time;

(l). engaging in relaxing activities until drowsy.

b. Behavioral modifications should be trialed before the use of hypnotics. Reinforcing these behaviors may also decrease hypnotic use and overall medication costs. Some patients may use other medications to assist in sleep, such as: trazadone, amitriptyline, doxepin, or low doses of melatonin. There is some evidence that group cognitive behavioral therapy reduces the severity and daytime consequences of insomnia for at least six months. There is some evidence that Ramelteon, while producing a small amount of reduction in sleep latency, does not appreciably increase total sleep time or daytime function. There is some evidence that a dietary supplement containing melatonin, magnesium, and zinc, conveyed in pear pulp, taken one hour before bedtime, results in significantly better quality of sleep and quality of life than a placebo treatment in long-term care facility residents aged 70 and older with primary insomnia.

c. Many medications used in chronic pain can affect the sleep cycle. There is some evidence that the following medications exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.

d. Insomnia requires difficulty initiating or maintaining sleep, waking up early, or insufficient restorative sleep despite adequate opportunity for sleep, as well as, daytime symptoms of sleep deprivation. In general, recommendations for treatment of insomnia include Cognitive Behavioral Therapy.

6. Education/Informed/Shared decision making of the patient and family, as well as the employer, insurer, policy makers, and the community should be the primary emphasis to prevent disability. Unfortunately, practitioners often think of education and informed decision making last, after medications, manual therapy, and surgery.

a. Informed decision making is the hallmark of a successful treatment plan. In most cases, the continuum of treatment from the least invasive to the most invasive (e.g., surgery) should be discussed. The intention is to find the treatment along this continuum which most completely addresses the condition. Patients should identify their personal values and functional goals of treatment at the first visit. It is recommended that specific individual goals are articulated at the beginning of treatment as this is likely to lead to increased patient satisfaction above that achieved from improvement in pain or other physical function. Progress toward the individual functional goals identified should be addressed at follow-up visits and throughout

treatment by other members of the health care team as well as an authorized physician.

b. Documentation of the informed decision process should occur whenever diagnostic tests or referrals from an authorized treating physician are contemplated. The informed decision making process asks the patients to set their personal functional goals of treatment and describe their current health status and any concerns they have regarding adhering to the diagnostic or treatment plan proposed. The provider should clearly describe the following¹ as appropriate to the patient:

i. the expected functional outcomes from the proposed treatment or the expected results and plan of action if diagnostic tests are involved;

ii. expected course of illness/injury without the proposed intervention;

iii. any side effects and risks to the patient;

iv. required post-treatment rehabilitation time and impact on work, if any;

v. alternative therapies or diagnostic testing.

c. Before diagnostic tests or referrals for invasive treatment take place, the patient should be able to clearly articulate the goals of the intervention, the general side effects and risks associated with it and his/her decision regarding compliance with the suggested plan. There is some evidence that information provided only by video is not sufficient education.

d. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with providing reassuring information to the patient and informed decision making. More in-depth education currently exists within a treatment regimen employing functional restoration, prevention, and cognitive behavioral techniques. Patient education and informed decision making should facilitate self-management of symptoms and prevention.

e. Time Frames for Education/Informed Decision Making

i. Time to produce effect—varies with individual patient.

ii. Frequency—should occur at every visit.

7. Injections—Spinal Therapeutic

a. General Description. The following injections are considered to be reasonable treatment for patients with chronic pain exacerbations when therapy is continuing and specific indications are met. Refer to the OWCA's appropriate Medical Treatment Guideline for indications. Monitored Anesthesia Care is acceptable for diagnostic and therapeutic procedures. For post-MMI care, refer to Injection Therapy Maintenance Management, in this guideline.

b. Steroid Associated Issues

i. The majority of diabetic patients will experience an increase in glucose following steroid injections. Average increases in one study were 125 mg/dL and returned to normal in 48 hours, whereas in other studies, the increased glucose levels remained elevated up to seven days, especially after multiple injections. All diabetic patients should be told to follow their glucose levels carefully over the seven days after a steroid injection. For patients who have not been diagnosed with diabetes, one can

expect some increase in glucose due to insulin depression for a few days after a steroid injection. Clinicians may consider diabetic screening tests for those who appear to be at risk for type 2 diabetes.

ii. Intra-articular or epidural injections cause rapid drops in plasma cortisol levels which usually resolve in one to four weeks. There is some evidence that an intra-articular injection of 80 mg of methylprednisolone acetate into the knee has about a 25 percent probability of suppressing the adrenal gland response to exogenous adrenocorticotrophic hormone (ACTH) for four or more weeks after injection, but complete recovery of the adrenal response is seen by week eight after injection. This adrenal suppression could require treatment if surgery or other physiologically stressful events occur.

iii. There is good evidence that there are no significant differences between epidural injections with corticosteroid plus local anesthetic versus local anesthetic alone; however, there are measureable differences with respect to morning cortisol levels at three and six weeks after the injection, suggesting that the corticosteroid injection is capable of inducing suppression of the hypothalamic-pituitary-adrenal axis.

iv. Case reports of Cushing's syndrome, hypopituitarism, and growth hormone deficiency have been reported uncommonly and have been tied to systemic absorption of intra-articular and epidural steroid injections. Cushing's syndrome has also been reported from serial occipital nerve injections and paraspinal injections.

v. Morning cortisol measurements may be ordered prior to repeating steroid injections or prior to the initial steroid injection when the patient has received multiple previous steroid injections.

vi. The effect of steroid injections on bone mineral density (BMD) and any contribution to osteoporotic fractures is less clear. Patients on long-term steroids are clearly more likely to suffer from fractures than those who do not take steroids. However, the contribution from steroid injections to this phenomenon does not appear to be large. A well-controlled, large retrospective cohort study found that individuals with the same risk factors for osteoporotic fractures were 20 percent more likely to suffer a lumbar fracture if they had an epidural steroid injection. The risk increased with multiple injections. Other studies have shown inconsistent findings regarding BMD changes. Thus, the risk of epidural injections must be carefully discussed with the patient, particularly for patients over 60, and repeat injections should generally be avoided unless the functional goals to be reached outweigh the risk for future fracture. Patients with existing osteoporosis or other risk factors for osteoporosis should rarely receive epidural steroid injections.

c. Time Frames for Intra-Articular and Epidural Injections

i. Maximum Duration. Given this information regarding increase in blood glucose levels, effects on the endocrine system, and possible osteoporotic influence, it is suggested that the total dose of corticosteroid for intra-articular and epidural injections be limited to a total of 320 mg per 80 kg patient or 3-4 mg/kg per person per year [all joints or injections combined]

d. Epidural steroid injections (ESI) may include caudal, transforaminal, or interlaminar injections (cervical, thoracic or lumbar).

i. Epidural injections may be used for radicular pain or radiculopathy. If an injection provides at least 50 percent relief, a repeat of the same pain relieving injection may be given at least two weeks apart with fluoroscopic guidance. No more than two levels may be injected in one session. If there is not a minimum of 50 percent pain reduction as measured by a numerical pain index scale or documented functional improvement, similar injections should not be repeated, although the practitioner may want to consider a different approach or different level depending on the pathology. Maximum of two series of three effective pain relieving injections may be done in one year based upon the patient's response to pain and function.

ii. Spinal Stenosis Patients. Refer to the OWCA's Low Back Pain Medical Treatment Guideline for patients with radicular findings and claudication for indications.

iii. For chronic radiculopathy, injections may be repeated. Patients should be reassessed after each injection session for a 50 percent improvement in pain (as measured by accepted pain scales) and/or evidence of functional improvement. A positive result could include a return toward baseline function, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation.

e. Intradiscal Steroid Injections. There is some evidence that intradiscal steroid injection is unlikely to relieve pain or provide functional benefit in patients with non-radicular back pain; therefore, they are not recommended.

i. Intradiscal injections of other substances such as bone marrow, stem cells, are not recommended at this time due to lack of evidence and possible complications.

f. Transforaminal Injection with Etanercept. Transforaminal injection with a tumor necrosis factor alpha inhibitor is thought to decrease the inflammatory agents which may be associated with the pathophysiology of lumbar radicular pain from a herniated disc.

i. It is not recommended due to the results of a study which showed no advantage over steroids or saline injections.

g. Zygapophyseal (Facet) Injection

i. Description—an accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid with very limited uses. Up to three joints, either unilaterally or bilaterally. Injections may be repeated only when a functional documented response lasts for three months. A positive result would include a return to baseline function as established at MMI, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met and verified by the designated primary physician. May be repeated up to three times a year. There is no justification for a combined facet and medial branch block.

h. Sacroiliac Joint Injection

i. Description—A generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance. May include the use of corticosteroids. Sacroiliac joint injections may be

considered either unilaterally or bilaterally. The injection may only be repeated with 50 percent improvement in Visual Analog Scale with documented functional improvement. Should the designated primary physician consider Sacroiliac Joint (lateral Branch Neurotomy), the diagnostic S1-S3 lateral branch blocks would need to be documented with 80 percent to 100 percent improvement in symptoms for the duration of the local anesthetic. Should the diagnostic lateral branch nerve blocks only result in 50 percent to 80 percent improvement in symptoms then the confirmatory nerve blocks are recommended. In the event that the diagnostic lateral nerve blocks result in less than 50 percent improvement, then the lateral branch neurotomy is not recommended.

ii. Time Frames for Sacro-Iliac Joint Injections

(a). Maintenance Duration. Four Sacroiliac joint injections and/ or three lateral branch levels four times per year either unilaterally or bilaterally. Injections may be repeated only when a functional documented response lasts for three months. After three Sacroiliac joint injections or three sessions of three lateral branch blocks within one 12-month period, RF Ablation of lateral branches should be considered.

8. Injections—Other (Including Radio Frequency): The following are in alphabetical order.

a. Botulinum Toxin Injection

i. Description—Used to temporarily weaken or paralyze muscles. May reduce muscle pain in conditions associated with spasticity, or dystonia. Neutralizing antibodies develop in at least four percent of patients treated with botulinum toxin type A, rendering it ineffective. Several antigenic types of botulinum toxin have been described. Botulinum toxin type B, first approved by the Food and Drug Administration (FDA) in 2001, is similar pharmacologically to botulinum toxin type A. It appears to be effective in patients who have become resistant to the type A toxin. The immune responses to botulinum toxins type A and B are not cross-reactive, allowing type B toxin to be used when type A action is blocked by antibody. Experimental work with healthy human volunteers suggests that muscle paralysis from type B toxin is not as complete or as long lasting as that resulting from type A. The duration of treatment effect of botulinum toxin type B for cervical dystonia has been estimated to be 12 to 16 weeks. EMG needle guidance may permit more precise delivery of botulinum toxin to the target area.

(a). There is strong evidence that botulinum toxin A has objective and asymptomatic benefits over placebo for cervical dystonia. There is good evidence that a single injection of botulinum toxin type B is more effective than placebo in alleviating the severity and pain of idiopathic cervical dystonia. The duration of effect of botulinum toxin type B is not certain but appears to be approximately 12 to 18 weeks.

(b). There is a lack of adequate evidence supporting the use of these injections to lumbar musculature for the relief of isolated low back pain. There is insufficient evidence to support its use for longer-term pain relief of other myofascial trigger points and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated

injections of trigger points in the upper trapezii. Therefore, it is not recommended for use for low back pain or other myofascial trigger points.

(c). They may be used for chronic piriformis syndrome. There is some evidence to support injections for electromyographically proven piriformis syndrome. Prior to consideration of botulinum toxin injection for piriformis syndrome, patients should have had marked (80 percent or better) but temporary improvement, verified with demonstrated improvement in functional activities, from three separate trigger point injections. To be a candidate for botulinum toxin injection for piriformis syndrome, patients should have had symptoms return to baseline or near baseline despite an appropriate stretching program after trigger point injections. Botulinum toxin injections of the piriformis muscle should be performed by a physician experienced in this procedure and utilize either ultrasound, fluoroscopy, or EMG needle guidance. Botulinum toxin should be followed by limb strengthening and reactivation.

ii. Indications—for conditions which produce dystonia or piriformis syndrome. It is important to note that dystonia, torticollis, and spasticity are centrally mediated processes that are distinct from spasm, tightness, or myofascial pain. True dystonia is uncommon and consists of a severe involuntary contraction which results in abnormal postures or movements. Cervical dystonia or torticollis is the most common dystonia seen in the work related population. There should be evidence of limited range of motion prior to the injection.

(a). There is insufficient evidence to support its use in myofascial trigger points for longer-term pain relief, and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore, it is not recommended for use for other myofascial trigger points.

iii. Complications—There is good evidence that cervical botulinum toxin A injections cause transient dysphagia and neck weakness. Allergic reaction to medications, dry mouth, and vocal hoarseness may also occur. Dry mouth and dysphagia occur 15 percent of the time after one injection. Rare systemic effects include flu-like syndrome, weakening of distant muscle. There is an increased risk of systemic effects in patients with motor neuropathy or disorders of the neuromuscular junction.

iv. Time Frames for Botulinum Toxin Injections

(a). Time to produce effect: 24 to 72 hours post injection with peak effect by four to six weeks.

(b). Frequency. No less than three months between re-administration. Patients should be reassessed after each injection session for approximately an 80 percent improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for three months. A positive result would include a return to baseline function, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation.

(c). Optimum duration: three to four months.

(d). Maximum duration. Currently unknown. Repeat injections should be based upon functional improvement and therefore used sparingly in order to avoid

development of antibodies that might render future injections ineffective. In most cases, not more than four injections are appropriate due accompanying muscle atrophy.

b. Medial Branch Facet Blocks (Cervical, Thoracic and Lumbar). If provide 80 percent or more pain reduction as measured by a numerical pain index scale within one hour of the medial branch blocks up to three levels per side, then rhizotomy of the medial branch nerves, up to four nerves per side, may be done without confirmation block. If the initial set of medial branch blocks provides less than 80 percent but at least 50 percent pain reduction as measured by a numerical pain index scale or documented functional improvement, the medial branch block should be repeated for confirmation before a rhizotomy is performed. If 50 percent or greater pain reduction is achieved with two sets of medial branch blocks for facet joint pain, then rhizotomy may be performed.

c. Peripheral Nerve Blocks. Used to diagnose and treat pain causers such as Genicular Nerves, 3rd Occipital nerves, Greater and Lesser Occipital nerves, intercostal nerves, ilioinguinal nerves, iliohypogastric nerves, lateral femoral cutaneous nerves, medial branch facet nerves (cervical, thoracic and lumbar), sacral lateral branches of Sacroiliac joints, Selective nerve root blocks and other pure sensory nerves suspected of causing pain. A positive diagnostic nerve block that provides at least 50 percent pain reduction and with possible functional improvement is confirmation that Radiofrequency Ablation of said nerve is indicated. This treatment usually provides relief for 6 to 18 months. Maintenance retreatment with RF is indicated after six months if the same pain returns.

d. Prolotherapy. Also known as sclerotherapy, prolotherapy consists of a series of injections of hypertonic dextrose, with or without glycerine and phenol, into the ligamentous structures of the low back. Its proponents claim that the inflammatory response to the injections will recruit cytokine growth factors involved in the proliferation of connective tissue, stabilizing the ligaments of the low back when these structures have been damaged by mechanical insults.

i. There is good evidence that prolotherapy alone is not an effective treatment for chronic low back pain. There is some evidence that prolotherapy of the sacroiliac (SI) joint is longer lasting, up to 15 months, than intra-articular steroid injections. The study was relatively small and long-term blinding was unclear; however, all injections were done under fluoroscopic guidance. Indications included an 80 percent reduction in pain from an SI joint injection with local anesthetic, as well as physical findings of SI joint dysfunction. Lasting functional improvement has not been shown and approximately three injections were required. The injections are invasive, and may be painful to the patient. The use of prolotherapy for low back pain is generally not recommended, as the majority of patients with SI joint dysfunction will do well with a combination of active therapy and manipulation and not require prolotherapy. However, it may be used in select patients. Prolotherapy is not recommended for other non-specific back pain.

ii. Indications: insufficient functional progress after six months of an appropriate program that includes a

combination of active therapy, manual therapy and psychological evaluation and treatment. There should be documented relief from previously painful maneuvers (e.g., Patrick's or Faber's test, Gaenslen, distraction or gapping, and compression test). A positive result from SI joint diagnostic block including improvement in at least three previously identified physical functions. Standards of evaluation should follow those noted in the diagnostic section. Refer to §2109.A.5, Injections-Diagnostic.

iii. At the minimum, manual therapy, performed on a weekly basis per guideline limits by a professional specializing in manual therapy (such as a doctor of osteopathy, physical therapist, or chiropractor) would address any musculoskeletal imbalance causing sacroiliac joint pain such as lumbosacral or sacroiliac dysfunction, pelvic imbalance, or sacral base unleveling. This thorough evaluation would include identification and treatment to resolution of all causal conditions such as iliopsoas, piriformis, gluteal or hamstring tonal imbalance, leg length inequality, loss of motion of the sacrum, lumbar spine or pelvic bones, and ligamentous, visceral or fascial restrictions.

iv. An active therapy program would consist of a functionally appropriate rehabilitation program which is advanced in a customized fashion as appropriate commensurate with the patient's level of strength and core spinal stability. Such a program would include stretching and strengthening to address areas of muscular imbalance as noted above and neuromuscular re-education to address maintenance of neutral spine via core stabilization with concomitant inhibition of lumbar paravertebral muscles. Patients who demonstrate a directional preference are usually not candidates for this procedure and should receive a trial of directional preference therapy.

v. Informed decision making must be documented including a discussion of possible complications and the likelihood of success. It is suggested that a non-injection specialist determine whether all reasonable treatment has been attempted and to verify the physical findings evaluate the individual. Procedures should not be performed in patients who are unwilling to engage in the active therapy and manual therapy necessary to recover.

e. Radio Frequency Ablation—Dorsal Nerve Root Ganglion. Due to the combination of possible adverse side effects, time limited effectiveness, and mixed study results, this treatment is not recommended.

f. Radio Frequency Ablation—Genicular Nerves and other peripheral sensory nerves: genicular nerves are peripheral sensory nerves on the surface of the knee. After total knee arthroplasty, it is believed that peripheral neuromas or injury occurs in the genicular nerves causing disabling pain. Diagnostic genicular nerve blocks diagnose this problem and must provide at least 50 percent reduction of pain and demonstrated objective functional improvement to warrant Radiofrequency ablation of genicular nerves. This RF Ablation treatment usually provides 6 to 18 months or more of relief. Radiofrequency Ablation of other peripheral sensory nerves listed in Subparagraph 8.c of this Subsection must also follow diagnostic nerve blocks which provide at least 50 percent reduction of pain and possible functional improvement of said nerve.

g. Radio Frequency (RF) Denervation—Medial Branch Neurotomy/Facet Denervation

i. Description. A procedure designed to denervate the facet joint (Cervical, Thoracic and Lumbar) by ablating the corresponding sensory medial branches. Percutaneous radiofrequency is the method generally used. Pulsed radiofrequency at 42 degrees C should not be used as it may result in incomplete denervation. Cooled radiofrequency is generally not recommended due to current lack of evidence.

(a). If the medial branch blocks provide 80 percent or more pain reduction as measured by a numerical pain index scale within one hour of the medial branch blocks, then rhizotomy of the medial branch nerves, up to four nerves per side, may be done. If the first medial branch block provides less than 80 percent but at least 50 percent pain reduction as measured by a numerical pain index scale or documented functional improvement, the medial branch block should be repeated before a rhizotomy is performed. If 50 percent or greater pain reduction is achieved with two sets of medial branch blocks for facet joint pain, then rhizotomy may be performed.

(b). Generally, RF pain relief lasts at least six months and repeat radiofrequency neurotomy can be successful and last longer. RF neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Permanent images should be recorded to verify placement of the needles.

ii. Needle Placement. Multi-planar fluoroscopic imaging is required for all injections.

iii. Indications—those patients with proven, significant, facetogenic pain. This procedure is not recommended for patients with multiple pain generators, except in those cases where the facet pain is deemed to be greater than 50 percent of the total pain in the given area. Treatment is limited to no more than 3 facet joint levels or four medial branch nerves unilateral or bilateral at any one-treatment session. After RF ablation is completed additional levels adjacent to the original levels may require additional medial branch blocks to identify if there are additional levels requiring RF ablation. The same rules apply to the additional levels, as if the first levels did not exist.

iv. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions that may have been previously ordered prior to the facet treatment (Refer to Therapy-Active).

v. Complications: bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

vi. Post-Procedure Therapy—Active Therapy: implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term, home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of 4 to 10 visits post-procedure. Patients who are unwilling to engage in this therapy should not receive this procedure.

vii. Requirements for repeat radiofrequency medial branch neurotomy or other peripheral nerve ablation: In some cases, pain may recur. Successful RF neurotomy usually provides from 6 to 18 months or more of relief.

(a). Before a repeat RF neurotomy is done, a confirmatory medial branch injection or diagnostic nerve block should only be performed if the patient's pain pattern presents differently than the initial evaluation. In occasional patients, additional levels of medial branch blocks and RF neurotomy may be necessary. The same indications and limitations apply.

h. Radio Frequency Denervation—Sacro-Iliac (SI) Joint: This procedure requires neurotomy of multiple nerves, such as L5 dorsal ramus, and/or lateral branches of S1-S3 under C-arm fluoroscopy.

i. Needle Placement: Multi-planar fluoroscopic imaging is required for all steroid injections. Permanent images are suggested to verify needle placement.

ii. Indications: The following three requirements must be fulfilled.

(a). The patient has physical exam findings of at least three positive physical exam maneuvers (e.g., Patrick's sign, Faber's test, Gaenslen distraction or gapping, or compression test). Insufficient functional progress during or after six months of an appropriate program that includes a combination of active therapy, manual therapy, and psychological evaluation and treatment;

(b). At the minimum, manual therapy, performed on a weekly basis per guideline limits by a professional specializing in manual therapy (such as a doctor of osteopathy, physical therapist, or chiropractor) would address any musculoskeletal imbalance causing sacroiliac joint pain such as lumbosacral or sacroiliac dysfunction, pelvic imbalance, or sacral base unleveling¹. This thorough evaluation would include identification and treatment to resolution of all causal conditions such as iliopsoas, piriformis, gluteal or hamstring tonal imbalance, leg length inequality, loss of motion of the sacrum, lumbar spine or pelvic bones, and ligamentous, visceral or fascial restrictions; and

(c). An active therapy program would consist of a functionally appropriate rehabilitation program which is advanced in a customized fashion as appropriate commensurate with the patient's level of strength and stability. Such a program would include stretching and strengthening to address areas of muscular imbalance as noted above and neuromuscular re-education to address maintenance of neutral spine via core stabilization with concomitant inhibition of lumbar paravertebral muscles. Patients who demonstrate a directional preference are usually not candidates for this procedure and should receive a trial of directional preference therapy. Patients with confounding findings suggesting zygapophyseal joint or intervertebral disc pain generators should be excluded.

(i). Two fluoroscopically guided blocks of the Sacroiliac joint or appropriate three lateral branches with anesthetics and/or steroid, with relief of pain for the appropriate time periods, and functional improvement must be documented. If the above block provides less than 80 percent but at least 50 percent pain reduction as measured by a numerical pain index scale or documented functional improvement, the sacral peripheral nerve injection or SI joint

block should be repeated before a rhizotomy is done. If 50 percent or greater pain reduction is achieved with two sets of blocks (as outlined above) for the SI joint, then rhizotomy may be performed. Pain relief from RF Ablation must last a minimum of six months in order to repeat the RF treatment. There is no need to repeat the SI joint Injection or lateral branch injection after the first RF treatment if the pain that returns is the same as the original pain that required the first RF. It is well known that 67 percent of those with lumbar facet pain also suffer with Sacroiliac joint pain and do also require treatment with SI joint blocks and or SI Joint or Sacral nerve RF Ablation to reach Maximal Medical Improvement. (Implanted Stimulators or Pumps do not usually treat SI joint or facet pain.)

iii. Complications: damage to sacral nerve roots—issues with bladder dysfunction etc. Bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

iv. Post-Procedure Therapy—Active Therapy: implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of 4 to 10 visits post-procedure. Patients who are unwilling to engage in this therapy should not receive this procedure.

v. Requirements for Repeat Radiofrequency SI Joint Neurotomy. In some cases, pain may recur. Successful RF neurotomy usually provides from 6 to 18 months of relief. Repeat neurotomy should only be performed if the initial procedure resulted in improved function for six months. There is no need for repeat Sacroiliac joint or lateral branch injection before RF.

i. Transdiscal Biacuplasty

i. Description: cooled radiofrequency procedure intended to coagulate fissures in the disc and surrounding nerves which could be pain generators.

ii. It is not recommended due to lack of published data demonstrating effectiveness.

j. Trigger Point Injections

i. Description. Trigger point injections are generally accepted treatments. Trigger point treatments can consist of the injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers. These muscle fibers produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection can be enhanced if treatments are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response of injections. Needling must be performed by practitioners with the

appropriate credentials in accordance with state and other applicable regulations.

(a). Conscious sedation for patients receiving trigger point injections may be considered. However, the patient must be alert to help identify the site of the injection.

ii. Indications: Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as active therapy programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program, as tolerated, while undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems. Any abnormalities need to be ruled out prior to injection.

iii. Trigger point injections are indicated in patients with consistently observed, well-circumscribed trigger points. This demonstrates a local twitch response, characteristic radiation of pain pattern, and local autonomic reaction such as persistent hyperemia following palpation. Generally, trigger point injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a six-week time frame. However, trigger point injections may be occasionally effective when utilized in the patient with immediate, acute onset of pain or in a post-operative patient with persistent muscle spasm or myofascial pain.

iv. Complications: Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, penetration of viscera, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

v. Time Frames for Trigger Point Injections

(a). time to produce effect—local anesthetic 30 minutes; 24 to 48 hours for no anesthesia.

(b). frequency—No more than four injection sites per session per week for acute exacerbations only, to avoid significant post-injection soreness.

(c). optimum/maximum duration—four sessions per year. Injections may only be repeated when the above functional and time goals are met.

9. Interdisciplinary rehabilitation programs are the gold standard of treatment for individuals with chronic pain who have not responded to less intensive modes of treatment, except for those determined to be temporarily totally disabled. There is good evidence that interdisciplinary programs that include screening for psychological issues, identification of fear-avoidance beliefs and treatment barriers, and establishment of individual functional and work goals will improve function and decrease disability. There is good evidence that multidisciplinary rehabilitation (physical therapy and either psychological, social, or occupational therapy) shows small effects in reducing pain and improving disability compared to usual care and that multidisciplinary biopsychosocial rehabilitation is more effective than physical treatment for disability improvement after 12

months of treatment in patients with chronic low back pain. Patients with a significant psychosocial impact are most likely to benefit.

a. The International Classification of Functioning, Disability and Health (ICF) model should be considered in patient program planning. The following factors should be addressed: body function and structures, activity expectations, participation barriers, and environmental and personal factors. In general, interdisciplinary programs deal with evaluate and treat multiple and sometimes irreversible conditions, including but not limited to: painful musculoskeletal, neurological, and other chronic painful disorders and psychological issues, drug dependence, abuse, or addiction; high levels of stress and anxiety, failed surgery and pre-existing or latent psychopathology. The number of professions involved on the team in a chronic pain program may vary due to the complexity of the needs of the person served. The OWCA recommends consideration of referral to an interdisciplinary program within six months post-injury in patients with delayed recovery unless surgical interventions or other medical and/or psychological treatment complications intervene.

b. Chronic pain patients need to be treated as outpatients within a continuum of treatment intensity. Outpatient chronic pain programs are available with services provided by a coordinated interdisciplinary team within the same facility (formal) or as coordinated among practices by an authorized treating physician (informal). Formal programs are able to provide coordinated, high intensity level of services and are recommended for most chronic pain patients who have received multiple therapies during acute management.

c. Patients with addiction problems, high-dose opioid use, or abuse of other drugs may require inpatient and/or outpatient chemical dependency treatment programs before or in conjunction with other interdisciplinary rehabilitation. Guidelines from the American Society of Addiction Medicine are available and may be consulted relating to the intensity of services required for different classes of patients in order to achieve successful treatment.

d. Informal interdisciplinary pain programs may be considered for patients who are currently employed, those who cannot attend all-day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, physician, and insurer should agree on treatment approach, methods, and goals. Generally, the type of outpatient program needed will depend on the degree of impact the pain has had on the patient's medical, physical, psychological, social, and/or vocational functioning.

e. Inpatient pain rehabilitation programs are rarely needed but may be necessary for patients with any of the following conditions: High risk for medical instability; Moderate to severe impairment of physical/functional status; Moderate to severe pain behaviors; Moderate impairment of cognitive and/or emotional status; Dependence on medications from which he or she needs to be withdrawn; and the need for 24-hour supervised nursing and for those temporarily totally disabled. Whether formal or informal, should be comprised of the following dimensions.

i. Communication. To ensure positive functional outcomes, communication between the patient, insurer and

all professionals involved must be coordinated and consistent. Any exchange of information must be provided to all parties, including the patient. Care decisions would be communicated to all parties and should include the family and/or support system.

ii. Documentation. Thorough documentation by all professionals involved and/or discussions with the patient. It should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification. It is advisable to have the patient undergo objective functional measures.

iii. Treatment Modalities. Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active and self-monitored passive treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of Active and Passive Therapies, refer to Therapy - Active, and Therapy - Passive. All treatment timeframes may be extended based upon the patient's positive functional improvement.

iv. Therapeutic Exercise Programs. There is good evidence that exercise alone or as part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen. A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an on-going exercise regime.

v. Return-to-Work. An authorized treating physician should continually evaluate the patient for their potential to return to work. For patients currently employed, efforts should be aimed at keeping them employed. Formal rehabilitation programs should provide assistance in creating work profiles. For more specific information regarding return-to-work, refer to the Return-to-work section in this guideline.

vi. - vii. ...

viii. Risk Assessments. The following should be incorporated into the overall assessment process, individual program planning, and discharge planning: aberrant medication related behavior, addiction, suicide, and other maladaptive behavior.

ix. Family/Support System Services as Appropriate. The following should be considered in the initial assessment and program planning for the individual: ability and willingness to participate in the plan, coping, expectations, educational needs, insight, interpersonal dynamics, learning style, problem solving, responsibilities, and cultural and financial factors. Support would include counseling, education, assistive technology, and ongoing communication.

x. Discharge Planning. Follow-up visits will be necessary to assure adherence to treatment plan. Programs

should have community and/or patient support networks available to patients on discharge.

f. Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning and psychological involvement. Programs should have sufficient personnel to work with the individual in the following areas: behavioral, functional, medical, cognitive, communication, pain management, physical, psychological, social, spiritual, recreation and leisure, and vocational. Services should address impairments, activity limitations, participation restrictions, environmental needs, and personal preferences of the worker. The following programs are listed in order of decreasing intensity:

i. Formal Interdisciplinary Rehabilitation programs

(a). Interdisciplinary Pain Rehabilitation. An interdisciplinary pain rehabilitation program provides outcome-focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons with pain and encourage their appropriate use of health care system and services. The program can benefit persons who have limitations that interfere with their physical, psychological, social, and/or vocational functioning. The program shares information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

(i). The interdisciplinary team maintains consistent integration and communication to ensure that all interdisciplinary team members are aware of the plan of care for the patient, are exchanging information, and implement the plan of care. The team members make interdisciplinary team decisions with the patient and then ensure that decisions are communicated to the entire care team.

(ii). Teams that assist in the accomplishment of functional, physical, psychological, social, and vocational goals must include: a medical director, pain team physician(s) who should preferably be board certified in an appropriate specialty, and a pain team psychologist. The medical director of the pain program and each pain team physician should be board certified in pain management or be board certified in his/her specialty area and have completed a one-year fellowship in interdisciplinary pain medicine or palliative care recognized by a national board, or two years of experience in an interdisciplinary pain rehabilitation program, or if less than two years of experience, participate in a mentorship program with an experienced pain team physician. The pain team psychologist should have one year's full-time experience in an interdisciplinary pain program, or if less than two years of experience, participate in a mentorship program with an experienced pain team psychologist. Other disciplines on the team may include, but are not limited to, biofeedback therapist, occupational therapist, physical therapist, registered nurse (RN), case manager, exercise physiologist, psychiatrist, and/or nutritionist. A recent French interdisciplinary functional spine restoration program demonstrated increased return to work at 12 months.

[a]. time to produce effect: three to four weeks;

[b]. frequency: Full time programs: no less than five hours/day, five days/week; part-time programs—four hours per day, two to three days per week.

[c]. optimum duration: 3 to 12 weeks at least two to three times a week. Follow-up visits weekly or every other week during the first one to two months after the initial program is completed.;

[d]. maximum duration: four months for full-time programs and up to six months for part-time programs. Periodic review and monitoring thereafter for one year, and additional follow-up based on the documented maintenance of functional gains.

(b). Occupational Rehabilitation: This is a formal interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day in which a patient completes work simulation tasks until the patient can tolerate a full work day. A full work day is case specific and is defined by the previous employment of the patient. Safe workplace practices and education of the employer and family and/or social support system regarding the person's status should be included. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return to work.

(i). The following are best practice recommendations for an occupational rehabilitation program:

[a]. work assessments including a work-site evaluation when possible (Refer to Return-To-Work);

[b]. practice of component tasks with modifications as needed;

[c]. development of strength and endurance for work tasks;

[d]. education on safe work practices;

[e]. education of the employer regarding functional implications of the worker when possible;

[f]. involvement of family members and/or support system for the worker;

[g]. promotion of responsibility and self-management;

[h]. assessment of the worker in relationship to productivity, safety, and worker behaviors;

[i]. identification of transferable skills of the worker;

[j]. development of behaviors to improve the ability of the worker to return to work or benefit from other rehabilitation; and

[k]. discharge includes functional/work status, functional abilities as related to available jobs in the community, and a progressive plan for return to work if needed.

(ii). There is some evidence that an integrated care program, consisting of workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reported reduction of pain. The occupational medicine rehabilitation interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation, team physicians having experience in occupational rehabilitation,

an occupational therapist, and a physical therapist. As appropriate, the team may also include any of the following: a chiropractor, an RN, a case manager, a psychologist, a vocational specialist, or a certified biofeedback therapist.

(iii). Time Frames for Occupational Rehabilitation:

[a]. time to produce effect: two weeks;

[b]. frequency: two to five visits per week; up to eight hours per day;

[c]. optimum duration: two to four weeks;

[d]. maximum duration: six weeks.

Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains.

(c). Opioid/Chemical Treatment Programs: Refer to the OWCA's Chronic Pain Disorder Medical Treatment Guideline. Recent programs which incorporate both weaning from opioids and interdisciplinary therapy appear to demonstrate positive long-term results.

ii. Informal Rehabilitation Program: A coordinated Interdisciplinary Pain Rehabilitation Program is one in which the authorized treating physician coordinates all aspects of care. This type of program is similar to the formal programs in that it is goal-oriented and provides interdisciplinary rehabilitation services to manage the needs of the patient in the following areas: functional; medical; physical; psychological; social; and vocational.

(a). This program is different from a formal program in that it involves lower frequency and intensity of services/treatment. Informal rehabilitation is geared toward those patients who do not need the intensity of service offered in a formal program or who cannot attend an all-day program due to employment, daycare, language or other barriers.

(b). Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The OWCA recommends the authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop the plan of care. Communication among care providers regarding clear objective goals and progress toward the goals is essential. Employers should be involved in return to work and work restrictions, and the family and/or social support system should be included in the treatment plan. Professionals from other disciplines likely to be involved include: a biofeedback therapist, an occupational therapist, a physical therapist, an RN, a psychologist, a case manager, an exercise physiologist, a psychiatrist, and/or a nutritionist.

(c). Time Frames for Informal Interdisciplinary Rehabilitation Program:

(i). time to produce effect: three to four weeks ;

(ii). frequency: full-time programs—no less than five hours per day, five days per week; part-time programs—four hours per day for two to three days per week;

(iii). optimum duration: 3 to 12 weeks at least two to three times a week. Follow-up visits weekly or every other week during the first one to two months after the initial program is completed;

(iv). maximum duration: four months for full-time programs and up to six months for part-time

programs. Periodic review and monitoring thereafter for one year, and additional follow-up based upon the documented maintenance of functional gains.

10. Medications and Medical Management. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. The medication history may consist of evaluating patient refill records through pharmacies and the Prescription Monitoring Program (PMP) to determine if the patient is receiving their prescribed regimen. Appropriate application of pharmacological agents depends on the patient's age, past history (including history of substance abuse), drug allergies and the nature of all medical problems. It is incumbent upon the healthcare provider to thoroughly understand pharmacological principles when dealing with the different drug families, their respective side effects, drug interactions and primary reason for each medication's usage. Healthcare providers should be aware that Interventional procedures can reduce or stop the need for medications while also improving functional capabilities. Patients should be aware that medications alone are unlikely to provide complete pain relief. In addition to pain relief, a primary goal of drug treatment is to improve the patient's function as measured behaviorally. Besides taking medications, continuing participation in exercise programs and using self-management techniques such as biofeedback, cognitive behavioral therapy, and other individualized physical and psychological practices are required elements for successful chronic pain management. Management must begin with establishing goals and expectations, including shared decision making about risks and benefits of medications.

a. Medication reconciliation is the process of comparing the medications that the patient is currently taking with those for which the patient has orders. This needs to include drug name, dosage, frequency, and route. The reconciliation can assist in avoiding medications errors such as omissions, duplications, dosing errors, or drug interactions. The results can also be used to assist discussion with the patient regarding prescribing or changing medications and the likelihood of side effects, drug interactions, and achieving expected goals. At a minimum, medication reconciliation should be performed for all patients upon the initial visit and whenever refilling or prescribing new medications.

b. Control of chronic non-malignant pain is expected to frequently involve the use of medication. Strategies for pharmacological control of pain cannot be precisely specified in advance. Rather, drug treatment requires close monitoring of the patient's response to therapy, flexibility on the part of the prescriber and a willingness to change treatment when circumstances change. Many of the drugs discussed in the medication section were licensed for indications other than analgesia, but are effective in the control of many types of chronic pain.

c. It is generally wise to begin management with lower cost non-opioid medications whose efficacy equals higher cost medications and medications with a greater safety profile. At practitioner's discretion, decisions to progress to more expensive, non-generic, and/or riskier products are made based on the drug profile, patient feedback, and improvement in function. The provider must

carefully balance the untoward side effects of the different drugs with therapeutic benefits, as well as monitor for any drug interactions.

d. All medications should be given an appropriate trial in order to test for therapeutic effect. The length of an appropriate trial varies widely depending on the individual drug. Certain medications may take several months to determine the efficacy, while others require only a few doses. It is recommended that patients with chronic nonmalignant pain be maintained on drugs that have the least serious side effects. For example, patients need to be tried or continued on acetaminophen and/or antidepressant medications whenever feasible as part of their overall treatment for chronic pain. Patients with renal or hepatic disease may need increased dosing intervals with chronic acetaminophen use. Chronic use of NSAIDs is a concern due to increased risk of cardiovascular events and GI bleeding.

e. The use of sedatives and hypnotics is not generally recommended for chronic pain patients. It is strongly recommended that such pharmacological management be monitored or managed by an experienced pain medicine physician, medical psychologist or psychiatrist. Multimodal therapy is the preferred mode of treatment for chronic pain patients whether or not these drugs were used acutely or sub-acutely.

f. Pharmaceutical neuropathic pain studies are limited. Diabetic peripheral neuropathy (DPN) and post-herpetic neuralgia (PHN) are the two most frequently studied noncancerous neuropathic pain conditions in randomized clinical trials of drug treatment. Some studies enroll only DPN or PHN patients, while other studies may enroll both kinds of patients. There appear to be consistent differences between DPN and PHN with respect to placebo responses, with DPN showing greater placebo response than PHN. Thus, there is an increased likelihood of a "positive" trial result for clinical trials of drug treatment for PHN than for DPN.

g. Although many studies focus on mean change in pain, this may not be the most reliable result. It does not necessarily allow for subgroups that may have improved significantly. Furthermore, the DPN and PHN studies do not represent the type of neurologic pain usually seen in workers' compensation.

h. For these reasons, few pharmaceutical agents listed in this Guideline are supported by high levels of evidence, but the paucity of evidence statements should not be construed as meaning that medication is not to be encouraged in managing chronic pain patients.

i. It is advisable to begin with the lowest effective dose proven to be useful for neuropathic pain in the literature. If the patient is tolerating the medication and clinical benefit is appreciated, maximize the dose for that medication or add another second line medication with another mechanism of action. If a medication is not effective, taper off the medication and start another agent. Maintain goal dosing for up to eight weeks before determining its effectiveness. Many patients will utilize several medications from different classes to achieve maximum benefit.

j. The preceding principles do not apply to chronic headache or trigeminal neuralgia patients. These patients

should be referred to a physician specializing in the diagnosis and treatment of headache and facial pain.

k. For the clinician to interpret the following material, it should be noted that: drug profiles listed are not complete; dosing of drugs will depend upon the specific drug, especially for off-label use; and not all drugs within each class are listed, and other drugs within the class may be appropriate for individual cases. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar medications or when there is a concern for drug interactions.

l. The following drug classes are listed in alphabetical order, not in order of suggested use, which is outlined above for neuropathic pain.

i. Alpha-Acting Agents: Noradrenergic pain-modulating systems are present in the central nervous system, and the Alpha-2 adrenergic receptor may be involved in the functioning of these pathways. Alpha-2 agonists may act by stimulating receptors in the substantia gelatinosa of the dorsal horn of the spinal cord, inhibiting the transmission of nociceptive signals. Spasticity may be reduced by presynaptic inhibition of motor neurons. Given limited experience with their use, they cannot be considered first-line analgesics or second-line analgesics for neurogenic pain, but a trial of their use may be warranted in many cases of refractory pain.

(a). Clonidine (Catapres, Kapvay, Nexiclon)

(i). Description—Central Alpha 2 agonist.

(ii). Indications—Sympathetically mediated pain, treatment of withdrawal from opioids.

[a]. As of the time of this guideline writing, formulations of clonidine have been FDA approved for hypertension.

(iii). Major Contraindications—Severe coronary insufficiency, renal impairment.

(iv). Dosing and Time to Therapeutic Effect—Increase dosage weekly to therapeutic effect.

(v). Major Side Effects—Sedation, orthostatic hypotension, sexual dysfunction, thrombocytopenia, weight gain, agitation, rebound hypertension with cessation.

(vi). Drug Interactions—Beta adrenergics, tricyclic antidepressants.

(vii). Laboratory Monitoring—Renal function, blood pressure.

ii. Anticonvulsants: Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, they appear to act as channel blocking agents. A large variety of sodium channels are present in nervous tissue, and some of these are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Gabapentin and pregabalin, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. All patients on these medications should be monitored for suicidal ideation. Many of these medications are not recommended for women of child bearing age due to possible teratogenic effects.

(a). Gabapentin and pregabalin are commonly prescribed for neuropathic pain. There is an association between older anticonvulsants including gabapentin and non-traumatic fractures for patients older than 50; this should be taken into account when prescribing these medications.

(b). Gabapentin and pregabalin have indirect (not GABA A or GABA B receptor mediated) GABA-mimetic qualities rather than receptor mediated actions. This can potentially result in euphoria, relaxation, and sedation. It is likely that they also affect the dopaminergic “reward” system related to addictive disorders. Misuse of these medications usually involves doses 3 to 20 times that of the usual therapeutic dose. The medication is commonly used with alcohol or other drugs of abuse. Providers should be aware of the possibility and preferably screen patients for abuse before prescribing these medications. Withdrawal symptoms, such as insomnia, nausea, headache, or diarrhea, are likely when high doses of pregabalin have been used. Tolerance can also develop.

(c). Gabapentin (Fanatrex, Gabarone, Gralise, Horizant, Neurontin)

(i). Description—Structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors. Gabapentin affects the alpha-2-delta-1 ligand of voltage gated calcium channels, thus inhibiting neurotransmitter containing intra-cellular vesicles from fusing with the pre-synaptic membranes and reducing primary afferent neuronal release of neurotransmitters (glutamate, CGRP, and substance P). It may also modulate transient receptor potential channels, NMDA receptors, protein kinase C and inflammatory cytokines, as well as possibly stimulating descending norepinephrine mediated pain inhibition.

(ii). Indications. As of the time of this guideline writing, formulations of gabapentin have been FDA approved for post-herpetic neuralgia and partial onset seizures.

[a]. There is strong evidence that gabapentin is more effective than placebo in the relief of painful diabetic neuropathy and post-herpetic neuralgia.

[b]. There is some evidence that gabapentin may benefit some patients with post-traumatic neuropathic pain. There is good evidence that gabapentin is not superior to amitriptyline. There is some evidence that nortriptyline (Aventyl, Pamelor) and gabapentin are equally effective for pain relief of postherpetic neuralgia. There is some evidence that the combination of gabapentin and morphine may allow lower doses with greater analgesic effect than the drugs given separately. There is strong evidence that gabapentin is more effective than placebo for neuropathic pain, even though it provides complete pain relief to a minority of patients. There is some evidence that a combination of gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug.

(iii). Relative Contraindications—Renal insufficiency. Dosage may be adjusted to accommodate renal dysfunction.

(iv). Dosing and Time to Therapeutic Effect—Dosage should be initiated at a low dose in order to avoid somnolence and may require four to eight weeks for

titration. Dosage should be adjusted individually. It is taken three to four times per day, and the target dose is 1800 mg.

(v). Major Side Effects—Confusion, sedation, dizziness, peripheral edema. Patients should also be monitored for suicidal ideation and drug abuse.

(vi). Drug Interactions—antacids.

(vii). Laboratory Monitoring—Renal function.

(b). Pregabalin (Lyrica)

(i). Description: structural derivative of the inhibitory neuro transmitter gamma aminobutyric acid which inhibits calcium influx at the alpha-2-subunit of voltage-gated calcium channels of neurons. By inhibiting calcium influx, there is inhibition of release for excitatory neurotransmitters.

(ii). Indications. As of the time of this guideline writing, pregabalin is FDA approved for the treatment of neuropathic pain, post-herpetic neuralgia, fibromyalgia, diabetic peripheral neuropathy, and partial-onset seizure in adults with epilepsy.

[a]. There is an adequate meta-analysis supporting strong evidence that in the setting of painful diabetic neuropathy, pregabalin as a stand-alone treatment is more effective than placebo in producing a 50 percent pain reduction, but this goal is realized in only 36 percent of patients treated with pregabalin compared with 24 percent of patients treated with placebo. There is an absence of published evidence regarding its effectiveness in improving physical function in this condition. There is also some evidence that pregabalin may be effective in treating neuropathic pain due to spinal cord injury. Unfortunately, most of the studies reviewed used pain as the primary outcome. Only one study considered function and found no improvement.

[b]. When pregabalin is compared with other first line medications for the treatment of neuropathic pain and diabetic peripheral neuropathy, such as amitriptyline and duloxetine, there is good evidence that it is not superior to these medications. Additionally, amitriptyline was found more effective compared to pregabalin for reducing pain scores and disability. Side effects were similar for the two medications. Therefore, amitriptyline is recommended for patients without contraindications, followed by duloxetine or pregabalin. This is based on improved effectiveness in treating neuropathic pain and a favorable side effect profile compared to pregabalin. Pregabalin may be added to amitriptyline therapy.

[c]. Pregabalin seems to be not effective and/or not well tolerated in a large percentage of patients. This is evident in several of the studies using run-in phases, enrichment, and partial enrichment techniques to strengthen the results. This analysis technique excludes placebo responders, non-responders, and adverse events prior to the treatment part of the study. This was done in the large meta-analysis, and one study had 60 percent of participants excluded in the run-in phase.

[d]. Duloxetine, pregabalin, and amitriptyline are approximately of equal benefit with respect to pain relief in the setting of diabetic peripheral neuropathy. There is some evidence that they exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with

duloxetine or amitriptyline. However, amitriptyline and pregabalin are likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.

(iii). Relative Contraindications. Avoid use with hypersensitivity to pregabalin or other similar class of drugs, avoid abrupt withdrawal, avoid use with a CNS depressant or alcohol, and exercise caution when using:

[a]. in the elderly,

[b]. with renal impairment,

[c]. with CHF class III/IV,

[d]. with a history of angioedema,

[e]. with depression.

(iv). Dosing and Time to Therapeutic Effect. Pregabalin comes in dosages ranging from 25 mg to 300 mg in 25 mg and 50 mg increments. For neuropathic pain, start at 75 mg twice daily for one week and then increase to 150 mg twice daily for two to three weeks if needed, with a possible final increase to 300 mg twice daily with a max dose of 600 mg/day. The full benefit may be achieved as quickly as 1 week, but it may take six to eight weeks. To discontinue, taper the dose down for at least one week.

(v). Major Side Effects: dizziness (less than 45 percent), somnolence (less than 36 percent), peripheral edema (less than 16 percent), weight gain (less than 16 percent), xerostomia (less than 15 percent), headache (less than 14 percent), fatigue (less than 11 percent), tremor (less than 11 percent), blurred vision/diplopia (less than 12 percent), constipation (less than 10 percent), confusion (less than seven percent), euphoria (less than seven percent), impaired coordination (less than six percent), thrombocytopenia (less than one percent). Patients should be monitored for hypersensitivity reactions, angioedema, suicidality, withdrawal symptoms, and seizures during abrupt discontinuation.

(vi). In regards to euphoria, pregabalin has higher rates compared to gabapentin in patients with history of substance misuse. Thus, prescribers should be aware that there is a potential for misuse.

(vii). Drug Interactions. Avoid use with antiepileptic agents and any CNS depression medications. Specifically avoid use with carbinoxamine, doxylamine, and ginkgo. Monitor closely when pregabalin is use with opioids.

(viii). Laboratory Monitoring: creatinine at baseline.

(c.) Other Anticonvulsants with Limited Third Line Use. It is recommended that a physician experienced in pain management be involved in the care when these medications are used.

(i). Topiramate (Topamax, Topiragen): sulfamate substitute monosacchride. FDA approved for epilepsy or prophylaxis for migraines. Topiramate is without evidence of efficacy in diabetic neuropathic pain, the only neuropathic condition in which it has been adequately tested. The data we have includes the likelihood of major bias due to last observation carried forward imputation, where adverse event withdrawals are much higher with active treatment than placebo control. Despite the strong potential for bias, no difference in efficacy between topiramate and placebo was apparent. There is good evidence that

topiramate demonstrates minimal effect on chronic lumbar radiculopathy or other neuropathic pain. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

(ii). Lamotrigine (Lamictal): This anti-convulsant drug is not FDA approved for use with neuropathic pain. Due to reported deaths from toxic epidermal necrolysis and Stevens Johnson syndrome, increased suicide risk, and incidents of aseptic meningitis, it is used with caution for patients with seizure or mood disorders. There is insufficient evidence that lamotrigine is effective in treating neuropathic pain and fibromyalgia at doses of about 200 to 400 mg daily. Given the availability of more effective treatments including antiepileptics and antidepressant medicines, lamotrigine does not have a significant place in therapy based on the available evidence. The adverse effect profile of lamotrigine is also of concern. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

(iii). Zonisamide: There is insufficient evidence that zonisamide provides pain relief in any neuropathic pain condition. There are a number of drug interactions and other issues with its use. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

(iv). Carbamazepine (Tegretol) Has important effects as an inducer of hepatic enzymes and may influence the metabolism of other drugs enough to present problems in patients taking interacting drugs. Dose escalation must be done carefully, since there is good evidence that rapid dose titration produces side-effects greater than the analgesic benefits. Carbamazepine is likely effective in some people with chronic neuropathic pain but with caveats. No trial was longer than four weeks, had good reporting quality, nor used outcomes equivalent to substantial clinical benefit. In these circumstances, caution is needed in interpretation, and meaningful comparison with other interventions is not possible. Carbamazepine is generally not recommended; however, it may be used as a third or fourth line medication. It may be useful for trigeminal neuralgia.

(v). Valproic Acid: There is insufficient evidence to support the use of valproic acid or sodium valproate as a first-line treatment for neuropathic pain. It should be avoided in women of child bearing age. There is more robust evidence of greater efficacy for other medications. However, some guidelines continue to recommend it. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

(vi). Levetiracetam: There is no evidence that levetiracetam is effective in reducing neuropathic pain. It is associated with an increase in participants who experienced adverse events and who withdrew due to adverse events. Therefore, this is not recommended.

(vii). Lacosamide: Has limited efficacy in the treatment of peripheral diabetic neuropathy. Higher doses did not give consistently better efficacy but were associated with significantly more adverse event withdrawals. Where adverse event withdrawals are high with active treatment compared with placebo and when last observation carried forward imputation is used, as in some of these studies, significant overestimation of treatment efficacy can result. It

is likely, therefore, that lacosamide is without any useful benefit in treating neuropathic pain; any positive interpretation of the evidence should be made with caution if at all. Therefore, this is not recommended.

iii. ...

(a). Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression. First line drugs for neuropathic pain are the tricyclics with the newer formulations having better side effect profiles. SNRIs are considered second line drugs due to their costs and the number needed to treat for a response. Duloxetine may be considered for first line use in a patient who is a candidate for pharmacologic treatment of both chronic pain and depression. SSRIs are used generally for depression rather than neuropathic pain and should not be combined with moderate to high-dose tricyclics.

(b). All patients being considered for antidepressant therapy should be evaluated and continually monitored for suicidal ideation and mood swings.

(i). Tricyclics and Older Agents (e.g., amitriptyline, nortriptyline, doxepin [Silenor, Sinequan, Adapin], desipramine [Norpramin, Pertofrane], imipramine [Tofranil], trazodone [Desyrel, Oleptro])

[a]. Description. Serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing CNS serotonergic tone can help decrease pain perception in non-antidepressant dosages. TCAs decrease reabsorption of both serotonin and norepinephrine. They also impact Na channels. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain. However, higher doses may produce more cholinergic side effects than newer tricyclics such as nortriptyline and desipramine. Doxepin and trimipramine also have sedative effects.

[i]. There is some evidence that in the setting of chronic low back pain with or without radiculopathy, amitriptyline is more effective than pregabalin at reducing pain and disability after 14 weeks of treatment. There is some evidence that in the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline. There is insufficient low quality evidence supporting the use of desipramine to treat neuropathic pain. Effective medicines with much greater supportive evidence are available. There may be a role for desipramine in patients who have not obtained pain relief from other treatments. There is no good evidence of a lack of effect; therefore, amitriptyline should continue to be used as part of the treatment of neuropathic pain. Only a minority of people will achieve satisfactory pain relief. Limited information suggests that failure with one antidepressant does not mean failure with all. There is insufficient evidence to support the use of nortriptyline as a

first line treatment. However, nortriptyline has a lower incidence of anticholinergic side effects than amitriptyline. It may be considered for patients who are intolerant to the anticholinergic effects of amitriptyline. Effective medicines with greater supportive evidence are available, such as duloxetine and pregabalin.

[ii]. There is some evidence that a combination of some gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug, without increasing side effects of either drug.

[b]. Indications. Some formulations are FDA approved for depression and anxiety. For the purposes of this guideline, they are recommended for neuropathic pain and insomnia. They are not recommended as a first line drug treatment for depression.

[c]. Major Contraindications—Cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, high suicide risk, uncontrolled hypertension and orthostatic hypotension. A screening cardiogram may be done for those 40 years of age or older, especially if higher doses are used. Caution should be utilized in prescribing TCAs. They are not recommended for use in elderly patients 65 years of age or older, particularly if they are at fall risk.

[d]. Dosing and Time to Therapeutic Effect—Varies by specific tricyclic. Low dosages, less than 100 mg, are commonly used for chronic pain and/or insomnia. Lower doses decrease side effects and cardiovascular risks.

[e]. Major Side Effects. Side effects vary according to the medication used; however, the side effect profile for all of these medications is generally higher in all areas except GI distress, which is more common among the SSRIs and SNRIs. Anticholinergic side effects including, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, urinary retention, and weight gain. Dry mouth leads to dental and periodontal conditions (e.g., increased cavities). Patients should also be monitored for suicidal ideation and drug abuse. Anticholinergic side effects are more common with tertiary amines (amitriptyline, imipramine, doxepin) than with secondary amines (nortriptyline and desipramine).

[f]. Drug Interactions—Tramadol (may cause seizures, both also increase serotonin/norepinephrine, so serotonin syndrome is a concern), clonidine, cimetidine (Tagemet), sympathomimetics, valproic acid (Depakene, Depakote, Epilim, Stavzor), warfarin (Coumadin, Jantoven, Marfarin), carbamazepine, bupropion (Aplezin, Budeprion, Buproban, Forfivo, Wellbutrin, Zyban), anticholinergics, quinolones.

[g]. Recommended Laboratory Monitoring—renal and hepatic function. EKG for those on high dosages or with cardiac risk.

(ii). Selective serotonin reuptake inhibitors (SSRIs) (e.g., citalopram (Celexa), fluoxetine (Prozac, Rapiflux, Sarafem, Selfemra), paroxetine (Paxil, Pexeva), sertraline (Zoloft)) are not recommended for neuropathic pain. They may be used for depression.

(iii). Selective Serotonin Nor-epinephrine Reuptakes Inhibitor (SSNRI)/Serotonin Nor-epinephrine Reuptake Inhibitors (SNRI).

[a]. Description—Venlafaxine (Effexor), desvenlafaxine (Pristiq), duloxetine, and milnacipran (Savella).

[i]. There is strong evidence that duloxetine monotherapy is more effective than placebo in relieving the pain of diabetic peripheral neuropathy; however, monotherapy leads to a 50 percent pain reduction in only half of patients who receive a therapeutic dose.

[ii]. AHRQ supports the use of duloxetine for chronic low back pain.

[iii] There is good evidence that in patients with painful diabetic neuropathy who have not had good responses to monotherapy with 60 mg of duloxetine or 300 mg of pregabalin, a clinically important benefit can be achieved by either of two strategies: doubling the dose of either drug, or combining both drugs at the same dose. It is likely that the strategy of combining the two drugs at doses of 60 and 300 mg respectively is more beneficial overall.

[iv]. There was no evidence to support the use of milnacipran to treat neuropathic pain conditions, although it is used for fibromyalgia. It is not generally recommended but may be used if patients cannot tolerate other medications.

[v]. There is insufficient evidence to support the use of venlafaxine in neuropathic pain. However, it may be useful for some patients who fail initial recommended treatments. Venlafaxine is generally reasonably well tolerated, but it can precipitate fatigue, somnolence, nausea, and dizziness in a minority of people. The sustained release formulations are generally more tolerable as inter-dose withdrawal symptoms can be avoided. They should be trialed if the patient cannot tolerate the immediate release formulation.

[b]. Indications. At the time of writing this guideline, duloxetine has been FDA approved for treatment of diabetic neuropathic pain and chronic musculoskeletal pain. Therefore, best evidence supports the use of duloxetine alone or with pregabalin.

[c]. Relative Contraindications—Seizures, eating disorders.

[d]. Major Side Effects—Depends on the drug, but commonly includes dry mouth, nausea, fatigue, constipation, and abnormal bleeding. Serotonin syndrome is also a risk. Gastrointestinal (GI) distress, drowsiness, sexual dysfunction less than other classes. Hypertension and glaucoma with venlafaxine. Cardiac issues with venlafaxine and withdrawal symptoms unless tapered. Studies show increased suicidal ideation and attempts in adolescents and young adults. Patients should also be monitored for suicidal ideation and drug abuse.

[e]. Drug Interactions—drug specific.

[f]. Laboratory Monitoring—Renal and hepatic monitoring, venlafaxine may cause cholesterol or triglyceride increases.

(iv). Atypical Antidepressants/Other Agents—may be used for depression; however, are not appropriate for neuropathic pain.

iv. Cannabinoid Products. At the time of writing, marijuana use is illegal under federal law and cannot be recommended for use in this guideline.

v. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). NSAIDs are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs. The response of the individual injured worker to a specific

medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case, with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The FDA advises that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Administration of proton pump inhibitors, Histamine 2 Blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration in patients at higher risk for this adverse event (e.g., age > 60, concurrent antiplatelet or corticosteroid therapy). They do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and they should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as abnormal liver function. Patients with renal or hepatic disease may need increased dosing intervals with chronic use. Chronic use of NSAIDs is generally not recommended due to increased risk of cardiovascular events and GI bleeding.

(a). Topical NSAIDs may be more appropriate for some patients as there is some evidence that topical NSAIDs are associated with fewer systemic adverse events than oral NSAIDs.

(b). NSAIDs may be associated with non-unions. Thus, their use with fractures is questionable.

(c). Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent on the patient's age and general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC) and liver and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

(d). There is no evidence to support or refute the use of oral NSAIDs to treat neuropathic pain conditions.

(e). AHRQ supports the use of NSAIDs for chronic low back pain.

(i). Non-Selective Non-Steroidal Anti-Inflammatory Drugs: Includes NSAIDs and acetylsalicylic acid. Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms, in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious GI toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

[a]. Time Frames for Non-Selective Non-Steroidal Anti-Inflammatory Drugs:

[i]. optimum duration: one week;

[ii]. maximum continuous duration (not interment): one year. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

(ii). Selective Cyclo-oxygenase-2 (COX-2) Inhibitors: COX-2 inhibitors differ from the traditional NSAIDs in adverse side effect profiles. The major advantages of selective COX-2 inhibitors over traditional

NSAIDs are that they have less GI toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency; thus, renal function may need monitoring.

[a]. There is good evidence that celecoxib (Celebrex) in a dose of 200 mg per day, administered over a long period, does not have a worse cardiovascular risk profile than naproxen at a dose of up to 1000 mg per day or ibuprofen at a dose of up to 2400 mg per day. There is good evidence that celecoxib has a more favorable safety profile than ibuprofen or naproxen with respect to serious GI adverse events, and it has a more favorable safety profile than ibuprofen with respect to renal adverse events. There is an absence of evidence concerning the relative safety of celecoxib at doses greater than 200 mg per day.

[b]. COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short-term. COX-2 inhibitors are indicated in select patients who do not tolerate traditional NSAIDs. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65 years of age, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

[c]. Time Frames for Selective Cyclo-oxygenase-2 (COX-2) Inhibitors:

[i]. optimum duration: 7 to 10 days;

[ii]. maximum duration: chronic use is appropriate in individual cases. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

vi. Opioids: Opioids are the most powerful analgesics. Their use in acute pain and moderate-to-severe cancer pain is well accepted. Their use in chronic nonmalignant pain, however, is fraught with controversy and lack of scientific research. Deaths in the United States from opioids have escalated in the last 15 years. The CDC states the following in their 2016 Primary Care guideline for prescribing opioids: Opioid pain medication use presents serious risk, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States. In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly. Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths. The Drug Abuse Warning Network estimated that less than 420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available. Opioid poisoning has also been identified in work-related populations.

(a). Effectiveness and Side Effects: Opioids include some of the oldest and most effective drugs used in the control of severe pain. The discovery of opioid receptors and their endogenous peptide ligands has led to an understanding of effects at the binding sites of these naturally occurring substances. Most of their analgesic effects have been attributed to their modification of activity in pain pathways within the central nervous system; however, it has become evident that they also are active in

the peripheral nervous system. Activation of receptors on the peripheral terminals of primary afferent nerves can mediate anti-nociceptive effects, including inhibition of neuronal excitability and release of inflammatory peptides. Some of their undesirable effects on inhibiting gastrointestinal motility are peripherally mediated by receptors in the bowel wall.

(i). Most studies show that only around 50 percent of patients tolerate opioid side effects and receive an acceptable level of pain relief. Depending on the diagnosis and other agents available for treatment, the incremental benefit can be small.

(ii). There is strong evidence that in the setting of chronic nonspecific low back pain, the short and intermediate term reduction in pain intensity of opioids, compared with placebo, falls short of a clinically important level of effectiveness. There is an absence of evidence that opioids have any beneficial effects on function or reduction of disability in the setting of chronic nonspecific low back pain. AHRQ found that opioids are effective for treating chronic low back pain. However, the report noted no evidence regarding the long-term effectiveness or safety for chronic opioids.

(iii). There is good evidence that opioids are more efficient than placebo in reducing neuropathic pain by clinically significant amounts. There is a lack of evidence that opioids improve function and quality of life more effectively than placebo. There is good evidence that opioids produce significantly more adverse effects than placebo such as constipation, drowsiness, dizziness, nausea, and vomiting. There is a lack of evidence that they are superior to gabapentin or nortriptyline for neuropathic pain reduction.

(iv). Patients should have a thorough understanding of the need to pursue many other pain management techniques in addition to medication use in order to function with chronic pain. They should also be thoroughly aware of the side effects and how to manage them. There is strong evidence that adverse events such as constipation, dizziness, and drowsiness are more frequent with opioids than with placebo. Common side effects are drowsiness, constipation, nausea, and possible testosterone decrease with longer term use.

(v). There is some evidence that in the setting of chronic low back pain with disc pathology, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief in spite of higher opioid dosage than when these symptoms are absent. A study comparing Arkansas Medicaid and a national commercial insurance population found that the top five percent of opioid users accounted for 48 to 70 percent of total opioid use. Utilization was increased among those with mental health and substance use disorders and those with multiple pain conditions. Psychological issues should always be screened for and treated in chronic pain patients. Therefore, for the majority of chronic pain patients, chronic opioids are unlikely to provide meaningful increase in function in daily activities. However, a subpopulation of patients may benefit from chronic opioids when properly prescribed and all requirements from medical management are followed.

(b). **Hyperalgesia:** Administration of opioid analgesics leads not only to analgesia, but may also lead to a paradoxical sensitization to noxious stimuli. Opioid induced hyperalgesia has been demonstrated in animals and humans using electrical or mechanical pain stimuli. This increased sensitivity to mildly painful stimuli does not occur in all patients and appears to be less likely in those with cancer, clear inflammatory pathology, or clear neuropathic pain. When hyperalgesia is suspected, opioid tapering is appropriate.

(c). **Opioid Induced Constipation (OIC):** Some level of constipation is likely ubiquitous among chronic opioid users. An observational study of chronic opioid users who also used some type of laxative at least four times per week noted that approximately 50 percent of the patients were dissatisfied and they continue to report stool symptoms. 71 percent used a combination of natural and dietary treatment, 64.3 percent used over-the-counter laxatives, and 30 percent used prescription laxatives. Other studies report similar percentages. There are insufficient quality studies to recommend one specific type of laxative over others.

(i). The easiest method for identifying constipation, which is also recommended by a consensus, multidisciplinary group, is the Bowel Function Index. It assesses the patient's impression over the last seven days for ease of defecation, feeling of incomplete bowel evacuation, and personal judgment re-constipation.

(ii). Stepwise treatment for OIC is recommended, and all patients on chronic opioids should receive information on treatment for constipation. Dietary changes increasing soluble fibers are less likely to decrease OIC and may cause further problems if GI motility is decreased. Stool softeners may be tried, but stimulant and osmotic laxatives are likely to be more successful. Osmotic laxatives include lactulose and polyethylene glycol. Stimulants include bisacodyl, sennosides, and sodium picosulfate, although there may be some concern regarding use of stimulants on a regular basis.

(iii). Opioid rotation or change in opioids may be helpful for some patients. It is possible that sustained release opioid products cause more constipation than short acting agents due to their prolonged effect on the bowel opioid receptors. Tapentadol is a μ -opioid agonist and norepinephrine reuptake inhibitor. It is expected to cause less bowel impairment than oxycodone or other traditional opioids. Tapentadol may be the preferred opioid choice for patients with OIC.

(iv). Other prescription medications may be used if constipation cannot adequately be controlled with the previous measures. Naloxegol is a pegylated naloxone molecule that does not pass the blood brain barrier and thus can be given with opioid therapy. There is good evidence that it can alleviate OIC and that 12.5 mg starting dose has an acceptable side effect profile.

(v). Methylnaltrexone does not cross the blood brain barrier and can be given subcutaneously or orally. It is specifically recommended for opioid induced constipation for patients with chronic non-cancer pain.

(vi). Misoprostol is a synthetic prostaglandin E1 agonist and has the side effect of diarrhea in some patients. It also has been tried for opioid induced constipation, although it is not FDA approved for this use.

(vii). Naldemedine is an opioid antagonist indicated for the treatment of opioid induced constipation in adult patients with chronic pain.

(viii). Lubiprostone is a prostaglandin E1 approved for use in opioid constipation.

(ix). Most patients will require some therapeutic control for their constipation. The stepwise treatment discussed should be followed initially. If that has failed and the patient continues to have recurrent problems with experiencing severe straining, hard or lumpy stool with incomplete evacuation, or infrequent stools for 25 percent of the time despite the more conservative measures, it may be appropriate to use a pharmaceutical agent.

(d). Physiologic Responses to Opioids: Physiologic responses to opioids are influenced by variations in genes which code for opiate receptors, cytochrome P450 enzymes, and catecholamine metabolism. Interactions between these gene products significantly affect opiate absorption, distribution, and excretion. Hydromorphone, oxymorphone, and morphine are metabolized through the glucuronide system. Other opioids generally use the cytochrome P450 system. Allelic variants in the mu opiate receptor may cause increased analgesic responsiveness to lower drug doses in some patients. The genetic type can predict either lower or higher needs for opioids. For example, at least 10 percent of Caucasians lack the CYP450 2D6 enzyme that converts codeine to morphine. In some cases, genetic testing for cytochrome P450 type may be helpful. When switching patients from codeine to other medications, assume the patient has little or no tolerance to opioids. Many gene-drug associations are poorly understood and of uncertain clinical significance. The treating physician needs to be aware of the fact that the patient's genetic makeup may influence both the therapeutic response to drugs and the occurrence of adverse effects. A Comprehensive genetic testing panel may be ordered by treating physician for these multiple P450 genes once in a lifetime and utilized whenever there is a question of metabolism or unusual response of any drugs used to treat pain conditions, because multiple drugs and associated genes can cause problems with opioid metabolism.

(e). Adverse Events: Physicians should be aware that deaths from unintentional drug overdoses exceed the number of deaths from motor vehicle accidents in the US. Most of these deaths are due to the use of opioids, usually in combination with other respiratory depressants such as alcohol or benzodiazepines. The risk for out of hospital deaths not involving suicide was also high. The prevalence of drug abuse in the population of patients undergoing pain management varies according to region and other issues. One study indicated that one-fourth of patients being monitored for chronic opioid use have abused drugs occasionally, and one-half of those have frequent episodes of drug abuse. 80 percent of patients admitted to a large addiction program reported that their first use of opioids was from prescribed medication.

(i). There is good evidence that in generally healthy patients with chronic musculoskeletal pain,

treatment with long-acting opioids, compared to treatments with anticonvulsants or antidepressants, is associated with an increased risk of death of approximately 69 percent, most of which arises from non-overdose causes, principally cardiovascular in nature. The excess cardiovascular mortality principally occurs in the first 180 days from starting opioid treatment.

(ii). There is some evidence that compared to an opioid dose under 20 MED per day, a dose of 20-50 mg nearly doubles the risk of death, a dose of 50 to 100 mg may increase the risk more than fourfold, and a dose greater than 100 mg per day may increase the risk as much as sevenfold. However, the absolute risk of fatal overdose in chronic pain patients is fairly low and may be as low as 0.04 percent. There is good evidence that prescription opioids in excess of 200 MED average daily doses are associated with a near tripling of the risk of opioid-related death, compared to average daily doses of 20 MED. Average daily doses of 100-200 mg and doses of 50-99 mg per day may be associated with a doubling of mortality risk, but these risk estimates need to be replicated with larger studies.

(iii). Doses of opioids in excess of 120 MED have been observed to be associated with increased duration of disability, even when adjusted for injury severity in injured workers with acute low back pain. Higher doses are more likely to be associated with hypo-gonadism, and the patient should be informed of this risk. Higher doses of opioids also appear to contribute to the euphoric effect. The CDC recommends Primary Care Practitioners limiting to 90 MED per day to avoid increasing risk of overdose or referral to a pain specialist.

(iv). In summary, there is strong evidence that any dose above 50 MED per day is associated with a higher risk of death and 100 mg or greater appears to significantly increase the risk. Interventional techniques such as Spinal Cord Stimulation or Intrathecal Catheters and Programmable pumps should be considered in order to stop oral opioids usage.

(v). Workers who eventually are diagnosed with opioid abuse after an injury are also more likely to have higher claims cost. A retrospective observational cohort study of workers' compensation and short-term disability cases found that those with at least one diagnosis of opioid abuse cost significantly more in days lost from work for both groups and in overall healthcare costs for the short-term disability groups. About 0.5 percent of eligible workers were diagnosed with opioid abuse.

(f). Dependence versus Addiction: The central nervous system actions of these drugs account for much of their analgesic effect and for many of their other actions, such as respiratory depression, drowsiness, mental clouding, reward effects, and habit formation. With respect to the latter, it is crucial to distinguish between two distinct phenomena: dependence and addiction.

(i). Dependence is a physiological tolerance and refers to a set of disturbances in body homeostasis that leads to withdrawal symptoms, which can be produced with abrupt discontinuation, rapid reduction, decreasing blood levels, and/or by administration of an antagonist.

(ii). Addiction is a primary, chronic, neurobiological disease, with genetic, psychological, and

environmental factors influencing its development and manifestations. It is a behavioral pattern of drug craving and seeking which leads to a preoccupation with drug procurement and an aberrant pattern of use. The drug use is frequently associated with negative consequences.

(iii). Dependence is a physiological phenomenon, which is expected with the continued administration of opioids, and need not deter physicians from their appropriate use. Before increasing the opioid dose, the physician should review other possible causes for the decline in analgesic effect. Increasing the dose may not result in improved function or decreased pain. Remember that it is recommended for total morphine milligram equivalents (MME) per day to remain at 50 or below. Consideration should be given to possible new psychological stressors or an increase in the activity of the nociceptive pathways. Other possibilities include new pathology, low testosterone level that impedes delivery of opioids to the central nervous system, drug diversion, hyperalgesia, or abusive use of the medication.

(g). Choice of Opioids: No long-term studies establish the efficacy of opioids over one year of use or superior performance by one type. There is no evidence that one long-acting opioid is more effective than another, or more effective than other types of medications, in improving function or pain. There is some evidence that long-acting oxycodone (Dazidox, Endocodone, ETH-oxycodone, Oxycontin, Oxyfast, OxyIR, Percolone, Roxicodone) and oxymorphone have equal analgesic effects and side effects, although the milligram dose of oxymorphone (Opana) is one-half that of oxycodone. There is no evidence that long-acting opioids are superior to short-acting opioids for improving function or pain or causing less addiction. A number of studies have been done assessing relief of pain in cancer patients. A recent systematic review concludes that oxycodone does not result in better pain relief than other strong opioids including morphine and oxymorphone. It also found no difference between controlled release and immediate release oxycodone. There is some evidence that extended release hydrocodone has a small and clinically unimportant advantage over placebo for relief of chronic low back pain among patients who are able to tolerate the drug and that 40 percent of patients who begin taking the drug do not attain a dose which provides pain relief without unacceptable adverse effects. Hydrocodone ER does not appear to improve function in comparison with placebo. A Cochrane review of oxycodone in cancer pain also found no evidence in favor of the longer acting opioid. There does not appear to be any significant difference in efficacy between once daily hydromorphone and sustained release oxycodone. Nausea and constipation are common for both medications between 26 to 32 percent. November 21, 2017, the FDA Commissioner, Scott Gottlieb, M.D., issued a Statement to promote development of generic versions of opioids formulated to deter abuse. One year earlier the FDA issued a statement encouraging development of Abuse Deterrent Formulations for opioids as a meaningful health benefit designed to reduce opioid abuse in the U.S. and to potentially and eventually remove conventional non deterrent opioids from the market if found to be unsafe.

(i). There is some evidence that in the setting of neuropathic pain, a combination of morphine plus

nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline.

(ii). Long-acting opioids should not be used for the treatment of acute, sub-acute, or post-operative pain, as this is likely to lead to drug dependence and difficulty tapering the medication. Additionally, there is a potential for respiratory depression to occur. The FDA requires that manufacturers develop Risk Evaluation and Mitigation Strategies (REMS) for most opioids. Physicians should carefully review the plans or educational materials provided under this program. Clinical considerations should determine the need for long-acting opioids given their lack of evidence noted above.

(iii). Addiction and abuse potentials of commonly prescribed opioid drugs may be estimated in a variety of ways, and their relative ranking may depend on the measure which is used. One systematic study of prescribed opioids estimated rates of drug misuse were estimated at 21 to 29 percent and addiction at 8 to 12 percent. There is good evidence that in the setting of new onset chronic non-cancer pain, there is a clinically important relationship between opioid prescription and subsequent opioid use disorder. Compared to no opioid use, short-term opioid use approximately triples the risk of opioid use disorder in the next 18 months. Use of opioids for over 90 days is associated with very pronounced increased risks of the subsequent development of an opioid use disorder, which may be as much as one hundredfold when doses greater than 120 MED are taken for more than 90 days. The absolute risk of these disorders is very uncertain but is likely to be greater than 6.1 percent for long duration treatment with a high opioid dose. Pain physicians should be consulted when the MED reaches 100 to develop an updated treatment plan.

(iv). Hydrocodone is the most commonly prescribed opioid in the general population and is one of the most commonly abused opioids in the population. However, the abuse rate per 1000 prescriptions is lower than the corresponding rates for extended release oxycodone, hydromorphone (Dilaudid, Palladone), and methadone. Extended release oxycodone appears to be the most commonly abused opioid, both in the general population and in the abuse rate per 1000 prescriptions. Tramadol, by contrast, appears to have a lower abuse rate than for other opioids.

(v). Types of opioids are listed below:

[a]. Buprenorphine: (various formulations) is prescribed as an intravenous injection, transdermal patch, buccal film, or sublingual tablet due to lack of bioavailability of oral agents. Depending upon the formulation, buprenorphine may be indicated for the treatment of pain or for the treatment of opioid dependence (addiction).

[i]. Buprenorphine for Opioid Dependence (addiction): FDA has approved a number of buccal films including those with naloxone and a sublingual tablet to treat opioid dependence (addiction).

[ii]. Buprenorphine for Pain: The FDA has approved specific forms of an intravenous and subcutaneous injectable, transdermal patch, and a buprenorphine buccal film to treat pain. However, by law,

the transdermal patch and the injectable forms cannot be used to treat opioid dependence (addiction), even by DATA-2000 waived physicians authorized to prescribe buprenorphine for addiction. Transdermal forms may cause significant skin reaction. Buprenorphine is not recommended for most chronic pain patients due to methods of administration, reports of euphoria in some patients, and lack of proof for improved efficacy in comparison with other opioids. 1

[iii]. There is insufficient evidence to support or refute the suggestion that buprenorphine has any efficacy in any neuropathic pain condition.

[iv]. There is good evidence transdermal buprenorphine is not inferior to oral tramadol in the treatment of moderate to severe musculoskeletal pain arising from conditions like osteoarthritis and low back pain. The population of patients for whom it is more appropriate than tramadol is not established but would need to be determined on an individual patient basis if there are clear reasons not to use oral tramadol.

[v]. In a well done study, 63 percent of those on buccal buprenorphine achieved a 30 percent or more decrease in pain at 12 weeks compared to a 47 percent placebo response. Approximately 40 percent of the initial groups eligible for the study dropped out during the initial phase when all patients received the drug to test for incompatibility.

[vi]. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. There is strong evidence that buprenorphine is superior to placebo with respect to retention in treatment, and good evidence that buprenorphine is superior to placebo with respect to positive urine testing for opiates.

[vii]. There is an adequate meta-analysis supporting good evidence that transdermal fentanyl and transdermal buprenorphine are similar with respect to analgesia and sleep quality, and they are similar with respect to some common adverse effects such as constipation and discontinuation due to lack of effect. However, buprenorphine probably causes significantly less nausea than fentanyl, and it probably carries a lower risk of treatment discontinuation due to adverse events. It is also likely that both transdermal medications cause less constipation than oral morphine.

[viii]. Overall, due to cost and lack of superiority, buprenorphine is not a front line opioid choice. However, it may be used in those with a history of addiction or at high risk for addiction who otherwise qualify for chronic opioid use. It is also appropriate to consider buprenorphine products for tapering strategies and those on high dose morphine of 90 MED or more.

[b]. Codeine with Acetaminophen: Some patients cannot genetically metabolize codeine and therefore have no response. Codeine is not generally used on a daily basis for chronic pain. Acetaminophen dose per day should be limited to 2 grams.

[c]. Fentanyl (Actiq, Duragesic, Fentora, Sublimazem, Subsys): is not recommended for use with musculoskeletal chronic pain patients. It has been associated

with a number of deaths and has high addiction potential. Fentanyl should never be used transbuccally in this population. If Fentanyl it is being considered for a very specific patient population, it requires support from a pain specialist. Subsys is only indicated for Cancer Pain.

[d]. Meperidine (Demerol): is not recommended for chronic pain. It and its active metabolite, normeperidine, present a serious risk of seizure and hallucinations. It is not a preferred medication for acute pain as its analgesic effect is similar to codeine.

[e]. Methadone: requires special precautions given its unpredictably long half-life and non-linear conversion from other opioids such as morphine. It may also cause cardiac arrhythmias due to QT prolongation and has been linked with a greater number of deaths due to its prolonged half-life. No conclusions can be made regarding differences in efficacy or safety between methadone and placebo, other opioids, or other treatments. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. Methadone should only be prescribed by those with experience in managing this medication. Conversion from another opioid to methadone (or the other way around) can be very challenging, and dosing titration must be done very slowly (no more than every seven days). Unlike many other opioids, it should not be used on an "as needed" basis, as decreased respiratory drive may occur before the full analgesic effect of methadone is appreciated. If methadone is being considered, genetic screening is appropriate. CYP2B6 polymorphism appears to metabolize methadone more slowly than the usual population and may cause more frequent deaths.

[f]. Morphine: may be used in the non-cancer pain population. A study in chronic low back pain suggested that individuals with a greater amount of endogenous opioids will have a lower pain relief response to morphine.

[g]. Oxycodone and Hydromorphone: There is no evidence that oxycodone (as oxycodone CR) is of value in treating people with painful diabetic neuropathy, postherpetic neuralgia, or other neuropathic conditions. There was insufficient evidence to support or refute the suggestion that hydromorphone has any efficacy in any neuropathic pain condition. Oxycodone was not associated with greater pain relief in cancer patients when compared to morphine or oxymorphone.

[h]. Propoxyphene (Darvon, Davon-N, PP-Cap): has been withdrawn from the market due to cardiac effects including arrhythmias.

[i]. Tapentadol (Nucynta): is a mu opioid agonist which also inhibits serotonin and norepinephrine reuptake activity. It is currently available in an intermediate release formulation and may be available as extended release if FDA approved. Due to its dual activity, it can cause seizures or serotonin syndrome, particularly when taken with other SSRIs, SNRIs, tricyclics, or MAO inhibitors. It has not been tested in patients with severe renal or hepatic damage. It has similar opioid abuse issues as other opioid medication; however, it is promoted as having fewer GI side effects, such

as constipation. There is good evidence that extended release tapentadol is more effective than placebo and comparable to oxycodone. In that study, the percent of patients who achieved 50 percent or greater pain relief was: placebo, 18.9 percent, tapentadol, 27.0 percent, and oxycodone, 23.3 percent. There is some evidence that tapentadol can reduce pain to a moderate degree in diabetic neuropathy, average difference 1.4/10 pain scale, with tolerable adverse effects. However, a high quality systematic review found inadequate evidence to support tapentadol to treat chronic pain. Tapentadol is not recommended as a first line opioid for chronic, subacute, or acute pain due to the cost and lack of superiority over other analgesics. There is some evidence that tapentadol causes less constipation than oxycodone. Therefore, it may be appropriate for patients who cannot tolerate other opioids due to GI side effects.

[j]. Tramadol (Rybix, Ryzolt, Ultram):

[i]. Description: an opioid partial agonist that does not cause GI ulceration or exacerbate hypertension or congestive heart failure. It also inhibits the reuptake of norepinephrine and serotonin which may contribute to its pain relief mechanism. There are side effects similar to opioid side effects and may limit its use. They include nausea, sedation, and dry mouth. 1

[ii]. Indications: mild to moderate pain relief. As of the time of this guideline writing, formulations of tramadol have been FDA approved for management of moderate to moderately severe pain in adults. This drug has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Unlike other pure opioids agonists, there is a ceiling dose to tramadol due to its serotonin activity (usually 300-400 mg per day). There is some evidence that it alleviates neuropathic pain following spinal cord injury. There is inadequate evidence that extended-release tramadol/acetaminophen in a fixed-dose combination of 75mg/650 mg is more effective than placebo in relieving chronic low back pain; it is not more effective in improving function compared to placebo. There is some evidence that tramadol yields a short-term analgesic response of little clinical importance relative to placebo in post-herpetic neuralgia which has been symptomatic for approximately six months. However, given the effectiveness of other drug classes for neuropathic pain, tramadol should not be considered a first line medication. It may be useful for patients who cannot tolerate tricyclic antidepressants or other medications.

[iii]. Contraindications: use cautiously in patients who have a history of seizures, who are taking medication that may lower the seizure threshold, or taking medications that impact serotonin reuptake and could increase the risk for serotonin syndrome, such as monoamine oxidase inhibitors (MAO) inhibitors, SSRIs, TCAs, and alcohol. Use with caution in patients taking other potential QT prolonging agents. Not recommended in those with prior opioid addiction. Has been associated with deaths in those with an emotional disturbance or concurrent use of alcohol or other opioids. Significant renal and hepatic dysfunction requires dosage adjustment.

[iv]. Side Effects: may cause impaired alertness or nausea. This medication has physically addictive

properties, and withdrawal may follow abrupt discontinuation.

[v]. Drug Interactions: opioids, sedating medications, any drug that affects serotonin and/or norepinephrine (e.g., SNRIs, SSRIs, MAOs, and TCAs).

[vi]. Laboratory Monitoring: renal and hepatic function.

(vi). Health care professionals and their patients must be particularly conscientious regarding the potential dangers of combining over-the-counter acetaminophen with prescription medications that also contain acetaminophen. Opioid and acetaminophen combination medication are limited due to the acetaminophen component. Total acetaminophen dose per day should not exceed 4 grams per any 24-hour period and is preferably limited to 2 grams per day to avoid possible liver damage.

(vii). Indications: The use of opioids is well accepted in treating cancer pain, where nociceptive mechanisms are generally present due to ongoing tissue destruction, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In chronic non-malignant pain, by contrast, tissue destruction has generally ceased, meaning that central and neuropathic mechanisms frequently overshadow nociceptive processes. Expected survival in chronic pain is relatively long, and return to a high-level of function is a major goal of treatment. Therefore, approaches to pain developed in the context of malignant pain may not be transferable to chronic non-malignant pain. Opioids are generally not the best choice of medication for controlling neuropathic pain. Tricyclics, SNRIs, and anticonvulsants should be tried before considering opioids for neuropathic pain.

[a]. In most cases, analgesic treatment should begin with acetaminophen, aspirin, NSAIDs, and possibly Baclofen or Tizanidine. While maximum efficacy is modest, they may reduce pain sufficiently to permit adequate function. When these drugs do not satisfactorily reduce pain, medications specific to the diagnosis should be used (e.g., neuropathic pain medications as outlined in Medications and Medical Management).

[b]. There is good evidence from a prospective cohort study that in the setting of common low back injuries, when baseline pain and injury severity are taken into account, a prescription for more than seven days of opioids in the first six weeks is associated with an approximate doubling of disability one year after the injury. Therefore, prescribing after two weeks in a non-surgical case requires a risk assessment. If prescribing beyond four weeks, a full opioid trial is suggested including toxicology screen. Best practice suggests that whenever there is use of opioids for more than seven days, providers should follow all recommendations for screening and follow-ups of chronic pain use.

[c]. Consultation or referral to a pain specialist behavioral therapist should be considered when the pain persists but the underlying tissue pathology is minimal or absent and correlation between the original injury and the severity of impairment is not clear. Consider consultation if suffering and pain behaviors are present and the patient manifests risk behaviors described below, or when standard

treatment measures have not been successful or are not indicated.

[d]. A psychological consultation including psychological testing (with validity measures) is indicated for all chronic pain patients as these patients are at high risk for unnecessary procedures and treatment and prolonged recovery.

[e]. Many behaviors have been found related to prescription-drug abuse patients. None of these are predictive alone, and some can be seen in patients whose pain is not under reasonable control; however, the behaviors should be considered warning signs for higher risk of abuse or addiction by physicians prescribing chronic opioids. Refer to Subsection, High Risk Behavior, below.

(ix). Recommendations for Opioid Use: When considering opioid use for moderate to moderately severe chronic pain, a trial of opioids must be accomplished as described below and the patient must have failed other chronic pain management regimes. Physicians should complete the education recommended by the FDA, risk evaluation and mitigation strategies (REMS) provided by drug manufacturing companies.

[a]. General Indications—There must be a clear understanding that opioids are to be used for a limited term in the first instance (see trial indications below). The patient should have a thorough understanding of all of the expectations for opioid use. The level of pain relief is expected to be relatively small, two to three points on a VAS pain scale, although in some individual patients it may be higher. For patients with a high response to opioid use, care should be taken to assure that there is no abuse or diversion occurring. The physician and patient must agree upon defined functional goals as well as pain goals. If functional goals are not being met, the opioid trial should be reassessed. The full spectrum of side effects should be reviewed. The shared decision making agreement signed by the patient must clarify under what term the opioids will be tapered. Refer to Subsection on the shared decision making agreement, below.

[b]. Therapeutic Trial Indications—A therapeutic trial of opioids should not be employed unless the patient has begun multi-disciplinary pain management. The trial shall last one month. If there is no functional effect, the drug should be tapered. Chronic use of opioids should not be prescribed until the following have been met:

[i]. The failure of pain management alternatives, including active therapies, cognitive behavioral therapy, pain self-management techniques, and other appropriate medical techniques.

[ii]. Physical and psychological and/or psychiatric assessment including a full evaluation for alcohol or drug addiction, dependence or abuse, performed by two specialists including the authorized treating physician and a physician or psychologist specialist with expertise in chronic pain. The patient should be stratified as to low, medium, or high risk for abuse based on behaviors and prior history of abuse. High risk patients are those with active substance abuse of any type or a history of opioid abuse. These patients should generally not be placed on chronic opioids. If it is deemed appropriate to do so, physician addiction specialists should be monitoring the care. Moderate risk factors include a history of non-opioid

substance abuse disorder, prior trauma particularly sexual abuse, tobacco use, widespread pain, poor pain coping, depression, and dysfunctional cognitions about pain and analgesic medications (see below). Pre-existing respiratory or memory problems should also be considered. Patients with a past history of substance abuse or other psychosocial risk factors should be co-managed with a physician addiction specialist.

[iii]. Risk Factors to Consider: history of severe post-operative pain, opioid analgesic tolerance (daily use for months), current mixed opioid agonist/antagonist treatment (e.g., buprenorphine, naltrexone), chronic pain (either related or unrelated to the surgical site), psychological comorbidities (e.g., depression, anxiety, catastrophizing), history of substance use disorder, history of “all over body pain”, history of significant opioid sensitivities (e.g., nausea, sedation), and history of intrathecal pump use or nerve stimulator implanted for pain control.

[iv]. Employment requirements are outlined. The patient’s employment requirements should also be discussed as well as the need to drive. It is generally not recommended to allow workers in safety sensitive positions to take opioids. Opioid naïve patients or those changing doses are likely to have decreased driving ability. Some patients on chronic opioids may have nominal interference with driving ability; however, effects are specific to individuals. Providers may choose to order certified driver rehabilitation assessment.

[v]. Urine drug screening for substances of abuse and substances currently prescribed. Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. It is appropriate to screen for alcohol and marijuana use and have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. Alcohol use in combination with opioids is likely to contribute to death.

[vi]. Review of the Prescription Monitoring Program. Louisiana Revised Statutes 40:978 and 40:1001-1014. Informed, written, witnessed consent by the patient including the aspects noted above. Patients should also be counseled on safe storage and disposal of opioids.

[vii]. The trial, with a short-acting agent, should document sustained improvement of pain control, at least a 30 percent reduction, and of functional status, including return-to-work, and/or increase in activities of daily living. It is necessary to establish goals which are specific, measurable, achievable, and relevant prior to opioid trial or adjustment to measure changes in activity/function. Measurement of functional goals may include patient completed validated functional tools. Frequent follow-up at least every two to four weeks may be necessary to titrate dosage and assess clinical efficacy.

[c]. On-Going, Long-Term Management after a successful trial should include:

[i]. prescriptions from a single practitioner;

[ii]. ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects; full review at least every three months;

[iii]. ongoing effort to gain improvement of social and physical function as a result of pain relief;

[iv]. review of the Prescription Monitoring Program (PMP);

[v]. shared decision making agreement detailing the following:

{a}. side effects anticipated from the medication;

{b}. requirement to continue active therapy;

{c}. need to achieve functional goals including return to work for most cases;

{d}. reasons for termination of opioid management, referral to addiction treatment, or for tapering opioids (tapering is usually for use longer than 30 days). Examples to be included in the contract include, but are not limited to:

{i}. diversion of medication;

{ii}. lack of functional effect at higher doses;

{iii}. non-compliance with other drug use;

{iv}. drug screening showing use of drugs outside of the prescribed treatment or evidence of non-compliant use of prescribed medication;

{v}. requests for prescriptions outside of the defined time frames;

{vi}. lack of adherence identified by pill count, excessive sedation, or lack of functional gains;

{vii}. excessive dose escalation with no decrease in use of short-term medications;

{viii}. apparent hyperalgesia;

{ix}. shows signs of substance use disorder (including but not limited to work or family problems related to opioid use, difficulty controlling use, craving);

{x}. experiences overdose or other serious adverse event;

{xi}. shows warning signs for overdose risk such as confusion, sedation, or slurred speech.

{e}. patient agreements should be written at a sixth grade reading level to accommodate the majority of patients.

{f}. use of random drug screening, initially, four times a year or possibly more with documented suspicion of abuse or diversion or for stabilization or maintenance phase of treatment. In addition to those four or more random urine drug screens, quantitative testing is appropriate in cases of inconsistent findings, suspicions, or for particular medications that patient is utilizing that is not in the qualitative testing;

{i}. drugs or drug classes for which screening is performed should only reflect those likely to be present based on the patient's medical history or current clinical presentation, illicit substances, the practitioner's suspicion, and without duplication;

{ii}. qualitative urine drug testing (UDT) (i.e., immunoassay to evaluate, indicates the drug is present) that is utilized for pain management or substance abuse monitoring, may be considered medically necessary for: baseline screening/Induction phase before initiating

treatment or at time treatment is initiated, stabilization phase of treatment with targeted weekly qualitative screening for a maximum of four weeks. (This type of monitoring is done to identify those patients who are expected to be on a stable dose of opioid medication within a four-week timeframe.) Maintenance phase of treatment with targeted qualitative screening once every one to three months. Subsequent monitoring phase of treatment at a frequency appropriate for the risk level of the individual patient. (This type of monitoring is done to identify those patients who are noncompliant or abusing prescription drugs or illicit drugs.) Note: In general, qualitative urine drug testing should not require more than four tests in a 12-month period. Additional testing, as listed above, would require clinical justification of medical necessity;

{iii}. quantitative UDT (i.e., gas chromatography and or mass spectrometry [GCMS] as confirmatory, indicates the amount of drug is present) that is utilized for pain management or substance abuse monitoring, may be considered medically necessary under the following circumstances: When immunoassays for the relevant drug(s) are not commercially available, or in specific situations when qualitative urine drug levels are required for clinical decision making. The following qualitative urine drug screen results must be present and documented: positive for a prescription drug that is not prescribed to the patient; or negative for a prescription drug that is prescribed to the patient; or Positive for an illicit drug;

{iv}. quantitative testing is not appropriate for every specimen and should not be done routinely. This type of test should be performed in a setting of unexpected results and not on all specimens. The rationale for each quantitative test must be supported by the ordering clinician's documentation. The record must show that an inconsistent positive finding was noted on the qualitative testing or that there was not an available qualitative test to evaluate the presence of semisynthetic or synthetic opioid, illicit drugs or other medications used for pain management in a patient. Simultaneous blood and urine drug screening or testing is not appropriate and should not be done;

{v}. urine testing, when included as one part of a structured program for pain management, has been observed to reduce abuse behaviors in patients with a history of drug misuse. Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. Clinicians should determine before drug screening how they will use knowledge of marijuana use. It is appropriate to screen for alcohol and marijuana use and have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. Alcohol use in combination with opioids is likely to contribute to death. From a safety standpoint, it is more important to screen for alcohol use than marijuana use as alcohol is more likely to contribute to unintended overdose;

{vi}. physicians should recognize that occasionally patients may use non-prescribed substances because they have not obtained sufficient relief on the prescribed regime;

[vi]. chronic use limited to two oral opioids;

[vii]. transdermal medication use, other than buprenorphine, is generally not recommended;

[viii]. use of acetaminophen-containing medications in patients with liver disease should be limited; including over-the-counter medications. Acetaminophen dose should not exceed 4 grams per day for short-term use or 2 to 3 grams/day for long-term use in healthy patients. A safer chronic dose may be 1800 mg/day;

[ix]. continuing review of overall therapy plan with regard to non-opioid means of pain control and functional status;

[x]. tapering of opioids may be necessary for many reasons including the development of hyperalgesia, decreased effects from an opioid, lack of compliance with the opioid contract, or intolerance of side effects. Some patients appear to experience allodynia or hyperalgesia on chronic opioids. This premise is supported by a study of normal volunteers who received opioid infusions and demonstrated an increase in secondary hyperalgesia. Options for treating hyperalgesia include withdrawing the patient from opioids and reassessing their condition. In some cases, the patient will improve when off of the opioid. In other cases, another opioid may be substituted;

{a}. tapering may also be appropriate by patient choice, to accommodate “fit-for-duty” demands, prior to major surgery to assist with post-operative pain control, to alleviate the effects of chronic use including hypogonadism, medication side effects, or in the instance of a breach of drug agreement, overdose, other drug use aberrancies, or lack of functional benefit. It is also appropriate for any of the tapering criteria listed in Section E above;

{b}. generally, tapering can be accomplished by decreasing the dose 10 percent per week. This will generally take 6 to 12 weeks and may need to be done one drug class at a time. Behavioral support is required during this service. Tapering may occur prior to MMI or in some cases during maintenance treatment.

[xi]. medication assisted treatment with buprenorphine or methadone may be considered for opioid abuse disorder, in addition to behavioral therapy. Refer to Opioid Addiction Treatment;

[xii]. inpatient treatment may be required for addiction or opioid tapering in complex cases. Refer to Interdisciplinary Rehabilitation Programs for detailed information on inpatient criteria;

[d]. Relative Contraindications. Extreme caution should be used in prescribing controlled substances for workers with one or more “relative contraindications”: Consultation with a pain or addiction specialist may be useful in these cases.

[i]. history of alcohol or other substance abuse, or a history of chronic, benzodiazepine use;

[ii]. sleep apnea: If patient has symptoms of sleep apnea, diagnostic tests should be pursued prior to chronic opioid use;

[iii]. off work for more than six months with minimal improvement in function from other active therapy;

[iv]. severe personality disorder or other known severe psychiatric disease per psychiatrist or psychologist;

[v]. monitoring of behavior for signs of possible substance abuse indicating an increased risk for addiction and possible need for consultation with an addiction specialist.

[e]. High Risk Behavior. The following are high risk warning signs for possible drug abuse or addiction. Patients with these findings may need a consultation by a physician experienced in pain management and/or addiction. Behaviors in the first list are warning signs, not automatic grounds for dismissal, and should be followed up by a reevaluation with the provider.

[i]. Repeated behaviors in the first list may be more indicative of addiction and behaviors in the second list should be followed by a substance abuse evaluation:

{a}. First List: less suggestive for addiction but are increased in depressed patients—Frequent requests for early refills; claiming lost or stolen prescriptions; Opioid(s) used more frequently, or at higher doses than prescribed; Using opioids to treat non-pain symptoms; Borrowing or hoarding opioids; Using alcohol or tobacco to relieve pain; Requesting more or specific opioids; Recurring emergency room visits for pain; Concerns expressed by family member(s); Unexpected drug test results; Inconsistencies in the patient’s history.

{b}. Second List: more suggestive of addiction and are more prevalent in patients with substance use disorder—Buying opioids on the street; stealing or selling drugs; Multiple prescribers (“doctor shopping”); Trading sex for opioids; Using illicit drugs; Positive urine drug tests for illicit drugs; Forging prescriptions; Aggressive demands for opioids; Injecting oral/topical opioids; Signs of intoxication (ETOH odor, sedation, slurred speech, motor instability, etc.).

[ii]. Both daily and monthly users of nicotine were at least three times more likely to report non-medical use of opioid in the prior year. At least one study has demonstrated a prevalence of smokers and former smokers among those using opioids and at higher doses compared to the general population. It also appeared that smokers and former smokers used opioids more frequently and in higher doses than never smokers. Thus, tobacco use history may be a helpful prognosticator.

[iii]. In one study, four specific behaviors appeared to identify patients at risk for current substance abuse: increasing doses on their own, feeling intoxicated, early refills, and oversedating oneself. A positive test for cocaine also appeared to be related.

[iv]. One study found that half of patients receiving 90 days of continuous opioids remained on opioids several years later and that factors associated with continual use included daily opioid greater than 120 MED prior opioid exposure, and likely opioid misuse.

[v]. One study suggested that those scoring at higher risk on the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), also had greater reductions in sensory low back pain and a greater desire to take morphine. It is unclear how this should be viewed in practice.

[f]. Dosing and Time to Therapeutic Effect—oral route is the preferred route of analgesic administration because it is the most convenient and cost-effective method of administration. Transbuccal administration should be avoided other than for buprenorphine. A daily dosage above 50 MED may be appropriate for certain patients. However, when the patient's dosage exceeds 50 MED per day and/or the patient is sedentary with minimal function, consideration should be given to lowering the dosage. Some patients may require dosages above 90 MED per day. However, if the patient reaches a dosage above 90 MED per day, it is appropriate to taper or refer to a pain or addiction specialist. The provider should also adhere to all requirements in this guideline and closely monitor the patient as this is considered a high risk dosage. In some cases, buprenorphine may be a preferred medication for pain control in those patients. Consultation may be necessary.

[g]. Major Side Effects—there is great individual variation in susceptibility to opioid-induced side effects and clinicians should monitor for these potential side effects. Common initial side effects include nausea, vomiting, drowsiness, unsteadiness, and confusion. Occasional side effects include dry mouth, sweating, pruritus, hallucinations, and myoclonus. Rare side effects include respiratory depression and psychological dependence. Constipation and nausea/vomiting are common problems associated with long-term opioid administration and should be anticipated, treated prophylactically, and monitored constantly. Stool softeners, laxatives, and increased dietary fluid may be prescribed. Refer to Opioid Induced Constipation. Chronic sustained release opioid use is associated with decreased testosterone in males and females and estradiol in pre-menopausal females. Patients should be asked about changes in libido, sexual function, and fatigue. Appropriate lab testing and replacement treatment should be completed.

[h]. Naloxone or oral and injection Naltrexone: may be prescribed when any risk factors are present. The correct use of Naloxone and Naltrexone should be discussed with the patient and family.

[i]. Benzodiazepines: should not be prescribed when opioids are used.

[j]. Sedation: driving and other tasks—Although some studies have shown that patients on chronic opioids do not function worse than patients not on medication, caution should be exerted, and patients should be counseled never to mix opioids with the use of alcohol or other sedating medication. When medication is increased or trials are begun, patients should not drive for at least five days. Chronic untreated pain, sedatives especially when mixed with opiates or alcohol, and disordered sleep can also impair driving abilities.

[k]. Drug Interactions—Patients receiving opioid agonists should not be given a mixed agonist-antagonist such as pentazocine [Talacen, Talwin] or butorphanol [Stadol] because doing so may precipitate a withdrawal syndrome and increase pain.

[l]. All sedating medication, especially benzodiazepines, should be avoided or limited to very low doses. Over-the-counter medications such as antihistamines, diphenhydramine, and prescription medications such as

hydroxyzine (Anx, Atarax, Atazine, Hypam, Rezine, Vistaril) should be avoided except when being used to manage withdrawal during tapering of opioids. Alcohol should not be used.

[m]. Recommended Laboratory Monitoring – Primary laboratory monitoring is recommended for acetaminophen/aspirin/NSAIDs combinations (renal and liver function, blood dyscrasias) although combination opioids are not recommended for long-term use. Morphine and other medication may require renal testing and other screening. A comprehensive genetic testing panel may be ordered by treating physician for these multiple P450 genes once in a lifetime and utilized whenever there is a question of metabolism or unusual response of any drugs used to treat pain conditions, because multiple drugs and associated genes can cause problems with opioid metabolism.

[n]. Sleep Apnea Testing: Both obstructive and central sleep apnea are likely to be exaggerated by opioid use or may occur secondary to higher dose chronic opioid use and combination medication use, especially benzodiazepines and sedative hypnotics. Patients should be questioned about sleep disturbance and family members or sleeping partners questioned about loud snoring or gasping during sleep. If present, qualified sleep studies and sleep medicine consultation should be obtained. Portable sleep monitoring units are generally not acceptable for diagnosing primary central sleep apnea. Type 3 portable units with two airflow samples and an O2 saturation device may be useful for monitoring respiratory depression secondary to opioids, although there are no studies on this topic.

[o]. Regular consultation of the Prescription Monitoring Program (PMP): Physicians should review their patients on the system whenever drug screens are done. This information should be used in combination with the drug screening results, functional status of the patient, and other laboratory findings to review the need for treatment and level of treatment appropriate for the patient.

[p]. Addiction: If addiction occurs, patients will require treatment. Refer to Opioid Addiction Treatment. After detoxification, they may need long-term treatment with naltrexone (Depade, ReVia, Vivitrol), an antagonist which can be administered in a long-acting form or buprenorphine which requires specific education per the Drug Enforcement Agency (DEA).

[q]. Potentiating Agents –There is some evidence that dextromethorphan does not potentiate the effect of morphine opioids and therefore is not recommended to be used with opioids.

vii. Post-Operative Pain Management: Proper post-operative pain management may avoid overuse and misuse of opioids. A recent practice guideline strongly recommends a multi-modal approach to post-operative pain. Suggestions include use of TENS, cognitive behavioral therapy, use of oral medication over parenteral medication and patient controlled analgesia when parenteral medication is used, use of NSAIDs (for appropriate procedures) or acetaminophen, gabapentin or pregabalin may also be used, and peripheral regional anesthesia when appropriate. Ketamine is also suggested for major surgeries, patients with high opioid tolerance or those who have difficulty tolerating opioids. However, ketamine does have side effects such as hallucination and nightmares. It is not recommended as a

first line medication for most patients. A Comprehensive genetic testing panel may be ordered by treating physician for these multiple P450 genes once in a lifetime and utilized whenever there is a question of metabolism or unusual response of any drugs used to treat pain conditions, because multiple drugs and associated genes can cause problems with opioid metabolism.

(a). Pre-operative psychological preparation or neuroscience education may improve post-operative pain management. Pre-operative cognitive-behavioral therapy or other psychological intervention likely improves in-hospital mobilization and analgesic use for lumbar spinal fusion patients and for other surgical patients. One randomized study compared patients who received one session of pre-operative pain neuroscience education from physical therapist prior to lumbar discectomy and those who did not. There was no change in the primary outcomes from surgery. However, significant changes occurred in secondary outcomes which included preparation for surgery, surgery meeting their expectations, and a 45 percent decrease in health expenditure for the follow up year. Thus, pre-operative pain neuroscience education may prove a useful addition for any patient prior to surgical decisions. Refer to Therapy-Active, for a description of Pain Neuroscience Education. Optimal surgical outcomes are more likely when the patient commits to a post-operative active therapy program.

(b). Generally, post-operative pain management is under the supervision of the surgeon and hospitalist with the goal of returning to the pre-operative level of pharmaceutical management. For a specific procedure's post-operative management, refer to the related medical treatment guideline.

(c). Surgical procedures may be necessary for patients already taking chronic opioids, and they may encounter difficulty with pain control post-operatively. These patients will usually require higher doses of opioids during their post-operative phase and may benefit the most from multimodal therapy and/or ketamine as described in Topical Drug Delivery. It is strongly advised that physicians consult a pain specialist or addiction specialist when caring for post-operative patients with a history of substance abuse or previous addiction. Refer to Post-Operative Pain Management.

viii. Skeletal Muscle Relaxants are most useful for acute musculoskeletal injury or exacerbation of injury. Chronic use of benzodiazepines or any muscle relaxant is not recommended due to their habit-forming potential, seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on chronic opioids due to respiratory depression.

(a). Baclofen (intrathecal or oral)

(i). Description—may be effective due to stimulation of Gamma Aminobutyric Acid (GABA) receptors.

(ii). Indications—Pain from muscle rigidity. As of the time of this guideline writing, formulations of baclofen injection have been FDA approved for the management of severe spasticity of a spinal cord or cerebral origin.

(iii). Side Effects—Exacerbation of psychotic disorders, may precipitate seizures in epileptics, dry mouth, and sexual dysfunction.

(iv). Recommended Laboratory Monitoring—Renal and hepatic function.

(v). Caution: Abrupt discontinuation of baclofen can precipitate a withdrawal syndrome and has been seen with both low and high doses. The most common side effects of baclofen withdrawal include pruritis, tremor, and mood disturbance. In extreme circumstances, seizures, muscle rigidity (resembling neuroleptic malignant syndrome), and even death can occur.

(b). Cyclobenzaprine (Amrix, Fexmid, Flexeril)

(i). Description: structurally related to tricyclics.

(ii). Indications—acute exacerbated chronic pain associated with muscle spasm. As of the time of this guideline writing, formulations of this drug are FDA approved as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. It should only be used for short periods (less than two weeks) because of lack of evidence for effectiveness with prolonged use.

(iii). Major Contraindications: cardiac dysrhythmias.

(iv). Dosing and Time to Therapeutic Effect: variable, onset of action is one hour.

(v). Major Side Effects: sedation, anticholinergic, blurred vision. Patients should also be monitored for suicidal ideation and drug abuse.

(vi). Drug Interactions : contraindicated for use with MAO inhibitors; interacts with tramadol, duloxetine, escitalopram, and fluoxetine. Likely interactions with other SSRIs and SNRIs. Drug interactions are similar to those for tricyclics. Refer also to information on tricyclics in Medications and Medical Management.

(vii). Recommended Laboratory Monitoring: hepatic and renal function.

(c). Carisoprodol (Soma, Soproval, Vanadom): This medication should not be used in chronic pain patients due to its addictive nature secondary to the active metabolite meprobamate.

(d). Metaxalone (Skelaxin)

(i). Description: central acting muscle relaxant.

(ii). Indications: acute exacerbated chronic pain associated with muscle spasm. As of the time of this guideline writing, formulations of this drug are FDA approved as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. It should only be used for short periods (less than two weeks) because of lack of evidence for effectiveness with prolonged use.

(iii). Major Contraindications: significantly impaired renal or hepatic disease, pregnancy, and disposition to drug induced hemolytic anemia.

(iv). Dosing and Time to Therapeutic Effect: 800 mg, three to four times per day, onset of action one hour.

(v). Major Side Effects: sedation, hematologic abnormalities.

(vi). Drug Interactions: other sedating drugs (e.g., opioids, benzodiazepines).

(vii). Recommended Laboratory Monitoring: hepatic function, CBC.

(e). Methocarbamol

(i). Description: central action muscle relaxant.

(ii). Indications: muscle spasm.

(iii). Major Contraindications: hypersensitivity, possible renal compromise.

(iv). Dosing and Time to Therapeutic Effect: 1500 mg. four times per day. Longer dosing 4000 to 4500 mg per day.

(v). Major Side Effects: decreased cognition, light headedness, GI effects among other.

(vii). Drug Interactions: alcohol and other CNS depressants.

(f). Tizanidine (Zanaflex)

(i). Description: alpha 2 adrenergic agonist.

(ii). Indications: true centrally mediated spasticity, musculoskeletal disorders. As of the time of this guideline writing, formulations of tizanidine have been FDA approved for the management of spasticity in spinal cord injury and multiple sclerosis.

(iii). Major Contraindications: concurrent use with ciprofloxacin (Cipro, Proquin) or fluvoxamine (Luvox); or hepatic disease.

(iv). Dosing and Time to Therapeutic Effect: 4 mg/day orally and gradually increase in 2 to 4 mg increments on an individual basis over two to four weeks; maintenance, 8 mg orally every six to eight hours (max dose 36 mg/day).

(v). Major Side Effects: hypotension, sedation, hepatotoxicity, hallucinations and psychosis, dry mouth.

(vi). Drug Interactions: Alcohol can increase sedation, and concurrent use with ciprofloxacin or fluvoxamine is contraindicated. Several other medications increase tizanidine plasma concentrations (e.g., oral contraceptives, verapamil, and cimetidine). Use with caution with other alpha agonists and other antihypertensives as they may increase the risk of hypotension.

(vii). Laboratory Monitoring: hepatic function, blood pressure.

ix. Smoking Cessation Medications and Treatment: Tobacco dependence is chronic and may require repeated attempts to quit. All smoking cessation programs should be accompanied by behavioral support which may include practical counseling sessions and social support, which usually includes telephone follow-up. A variety of medications have been used including Bupropion SR, nicotine patches, gum, inhaler, lozenges or nasal spray, and varenicline. When nicotine supplements are used, cotinine testing will be positive. Urine anabasine or exhaled carbon monoxide 5 ppm or less may be used to check tobacco abstinence.

(a). There is some evidence that among adults motivated to quit smoking, 12 weeks of open-label treatment including counseling and one of the following: nicotine patch, varenicline, or combination nicotine replacement therapy (nicotine patch and nicotine lozenge) are equally

effective in assisting motivated smokers to quit smoking over a period of one year.

(b). There is some evidence that among adults motivated to quit smoking, abrupt smoking cessation is the more effective method that leads to lasting abstinence over a period of four weeks to six months compared to gradual cessation, even for smokers who initially prefer to quit by gradual reduction.

x. Topical Drug Delivery

(a). Description: topical creams and patches may be an alternative treatment of localized musculoskeletal and neuropathic disorders and can be especially helpful in avoiding opioid use.

(b). Indications: neuropathic pain for many agents; episodic use of NSAIDs and salicylates for joint pain or musculoskeletal disorders. All topical agents should be used with strict instructions for application as well as maximum number of applications per day to obtain the desired benefit and avoid potential toxicity.

(c). Dosing and Time to Therapeutic Effect: all topical agents should be prescribed with clear instructions for application and maximum number of applications per day to obtain the desired benefit and avoid potential toxicity. For most patients, the effects of long-term use are unknown. Thus, episodic use may be preferred for some agents.

(d). Side Effects: localized skin reactions may occur, depending on the medication agent used.

(e). Topical Agents

(i). Capsaicin: As of the time of this guideline writing, formulations of capsaicin have been FDA approved for management of pain associated with post-herpetic neuralgia. Capsaicin offers a safe and effective alternative to systemic NSAID therapy. Although it is quite safe, the local stinging or burning sensation that typically dissipates with regular use, usually after the first 7 to 10 days of treatment, limits effective use of capsaicin. Patients should be advised to apply the cream on the affected area with a plastic glove or cotton applicator and to avoid inadvertent contact with eyes and mucous membranes.

[a]. There is good evidence that low dose capsaicin (0.075 percent) applied four times per day will decrease pain up to 50 percent. There is strong evidence that a single application of eight percent capsaicin is more effective than a control preparation of 0.04 percent capsaicin for up to 12 weeks. However, there may be a need for frequent application, and it is not known whether subsequent applications of capsaicin are likely to be as effective as the first application. There is some evidence that in patients who are being treated with capsaicin 8 percent patches, two methods of pre-treatment are equally effective in controlling application pain and in enabling patients to tolerate the patch: topical four percent lidocaine cream applied to the area for one hour before placement of the capsaicin patch and 50 mg oral tramadol taken 30 minutes before patch placement.

(ii). Clonidine: There is good evidence that topical clonidine gel 0.1 percent is likely to alleviate pain from diabetic peripheral neuropathy in patients who display a nociceptive response to the application of 0.1 percent capsaicin applied to the pretibial area. It is likely that patients who do not display a pain response to pretibial capsaicin are not likely to have a clinically meaningful

analgesic response to clonidine gel. It is unknown if this screening test applies to other types of neuropathic pain. Clonidine gel may be used for neuropathic pain.

[a]. Lofexidine (Lucemyra) is now available and indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt discontinuation in adults. This is necessary to block or reduce life threatening side effects of opioid withdrawal. This drug will be beneficial in drug treatment centers and for physicians finding necessity to abruptly stop opioid medication.

(iii). Ketamine and Tricyclics: Topical medications, such as the combination of ketamine and amitriptyline, have been proposed as an alternative treatment for neuropathic disorders including CRPS. A study using a 10 percent concentration showed no signs of systemic absorption. This low-quality study demonstrated decreased allodynia at 30 minutes for some CRPS patients. However, as of the time of this guideline writing, neither tricyclic nor ketamine topicals are FDA approved for topical use in neuropathic pain. Furthermore, there is good evidence that neither two percent topical amitriptyline nor 1 percent topical ketamine reduces neuropathic pain syndromes. Despite the lack of evidence, it is physiologically possible that topical tricyclics and a higher dose of ketamine could have some effect on neuropathic pain. Other less expensive topicals and compounds, including over-the-counter, should be trialed before more expensive compounds are ordered. The use of topical tricyclics and/or ketamine should be limited to patients with neuritic and/or sympathetically mediated pain with documented supporting objective findings such as allodynia and/or hyperalgesia. Continued use of these agents beyond the initial prescription requires documentation of effectiveness, including functional improvement, and/or decreased use of other medications, particularly decreased use of opioids or other habituating medications.

(iv). Lidocaine: As of the time of this guideline writing, formulations of lidocaine (patch form) have been FDA approved for pain associated with post-herpetic neuralgia. Evidence is mixed for long-term use of lidocaine topically. Physicians should always take into account the blood level that may be achieved with topical use as toxic levels have been reported and there is variability and systemic absorption among individuals. There is good evidence that lidocaine five percent plasters, applied for up to 12 hours to the lower extremities of patients with post-herpetic neuralgia and diabetic painful neuropathy, is non-inferior to pregabalin for the same indications. The topical lidocaine is associated with significantly fewer drug-related adverse events over four weeks of observation. There is some evidence that a five percent lidocaine patch may be used as a secondary option for patients with focal neuropathic pain. A 30 to 50 percent pain reduction may be achieved in those who tolerate the patch. Up to three patches may be used simultaneously for 12 hours per day. It should be applied only to intact skin. Metered dose eight percent pump sprays have also been used and usually require a three times per day reapplication. There is some evidence that the eight percent sprays are effective for short-term, two-week use. However, the effects of long-term use are unknown.

(v). Topical Salicylates and Nonsalicylates: have been shown to be effective in relieving pain in acute

musculoskeletal conditions and single joint osteoarthritis. Topical salicylate and nonsalicylates achieve tissue levels that are potentially therapeutic, at least with regard to COX inhibition.

[a]. There is insufficient evidence to support the use of topical rubefacients containing salicylates for acute injuries or chronic conditions. They seem to be relatively well tolerated in the short-term, based on limited data. The amount and quality of the available data mean that uncertainty remains about the effects of salicylate-containing rubefacients.

[b]. There is good evidence that diclofenac gel (Voltaren, Solaraze) reduces pain and improves function in mild-to-moderate hand osteoarthritis. There is good evidence that topical diclofenac and ketoprofen are more effective than placebo preparations for purposes of relieving pain attributable to knee osteoarthritis. There is good evidence that topical NSAIDs probably reduce the risk of GI adverse effects by approximately one-third compared to oral NSAIDs. Topical diclofenac does not appear to affect the anti-platelet properties of aspirin unlike the oral version. The topical solution of two percent sodium diclofenac applied thrice a day is equal to 1.5 percent four times per day.

[c]. Diclofenac gel has been FDA approved for acute pain due to minor strains, pains, and contusions and for relief of pain due to osteoarthritis of the joints amenable to topical treatment, such as those of the knees, shoulders, and hands. It is likely that other NSAIDs would also be effective topically. Thus, topical NSAIDs are permitted when patients show functional improvement.

[d]. Other than local skin reactions, the side effects of therapy are minimal, although not non-existent. The usual contraindications to use of these compounds needs to be considered. Local skin reactions are rare and systemic effects are even less common. Their use in patients receiving warfarin therapy may result in alterations in bleeding time. Overall, the low level of systemic absorption can be advantageous. This allows the topical use of these medications when systemic administration is relatively contraindicated, such as is the case in patients with hypertension, cardiac failure, or renal insufficiency. Both topical salicylates and NSAIDs are appropriate for many chronic pain patients. However, in order to receive refills, patients should demonstrate increased function, decreased pain, or decreased need for oral medications.

(vi). Other Compounded Topical Agents: At the time of writing this guideline, no studies identified evidence for the effectiveness of compounded topical agents other than those recommended above. Therefore, other compounded topical agents are not generally recommended. In rare cases, they may be appropriate for patients who prefer a topical medication to chronic opioids or who have allergies or side effects from other more commonly used oral agents.

(vii). Prior authorization is required for all agents that have not been recommended above.

xi. Other Agents

(a). Glucosamine: There is good evidence that glucosamine does not improve pain related disability in those with chronic low back pain and degenerative changes on radiologic studies; therefore, it is not recommended for chronic lower spinal or non-joint pain. For chronic pain

related to joint osteoarthritis, see specific extremity guidelines. Glucosamine should not be combined with chondroitin as it is ineffective.

(b). Oral Herbals: There is insufficient evidence due to low quality studies that an oral herbal medication, Compound Qishe Tablet, reduced pain more than placebo. There is also insufficient evidence that Jingfukang and a topical herbal medicine, Compound Extractum Nucis Vomicae, reduced pain more than Diclofenac Diethylamine Emulgel. Further research is very likely to change both the effect size and our confidence in the results. Currently, no oral herbals are recommended.

(c). Vitamin D: A large beneficial effect of vitamin D across different chronic painful conditions is unlikely. Therefore, it is not recommended.

(d). Alpha-Lipoic Acid: An adequate meta-analysis shows that there is some evidence that alpha-lipoic acid at a dose of 600 mg per day may reduce the symptoms of painful diabetic neuropathy in the short term of three to five weeks. The effect of the intravenous route appears to be greater than that of the oral route, but the oral route may have a clinically relevant effect. Doses of 1200 or 1800 mg have not been shown to have additional therapeutic benefit. This medication may be used for neuropathic pain.

11. Non-Invasive Brain Stimulation: This has been proposed as a treatment for chronic pain. Varieties include repetitive transcranial magnetic stimulation (rTMS), cranial electrotherapy stimulation (CES), and transcranial direct current stimulation (tDCS).

a. Single doses of high-frequency rTMS of the motor cortex may have small short-term effects on chronic pain. It is likely that multiple sources of bias may exaggerate this observed effect. The effects do not meet the predetermined threshold of minimal clinical significance and multiple-dose studies do not consistently demonstrate effectiveness. The available evidence suggests that low-frequency rTMS, rTMS applied to the pre-frontal cortex, CES, and tDCS are not effective in the treatment of chronic pain.

b. Therefore, these devices are not recommended due to lack of evidence and safety concerns.

12. Opioid Addiction Treatment: The DSM-V renames opioid addiction as substance use disorder (SUD) and classifies opioid use disorder according to categories defined as mild (two to three features of stated criteria), moderate (four to five features of stated criteria), or severe (six to seven features of stated criteria).

a. Definitions

i. Opioid physical dependence: opioid withdrawal symptoms (withdrawals) which occur as a result of abrupt discontinuation of an opioid in an individual who became habituated to the medication or through administration of an antagonist. Opioid physical dependency is not in and of itself consistent with the diagnosis of addiction/substance use disorder.

ii. Tolerance: a physiologic state caused by the regular use of an opioid in which increasing doses are needed to maintain the same affect. In patients with "analgesic tolerance," increased doses of the opioid may be needed to maintain pain relief.

iii. Opioid misuse: the utilization of opioid medications outside of the prescribing instructions for which

it was originally prescribed. Misuse may be as innocuous as taking slightly more or less medications than prescribed to crushing or snorting an opioid.

iv. Opioid abuse: the use of any substance for a non-therapeutic purpose or the use of a medication for purposes other than those for which the agent is prescribed. Abuse includes intentional use for altering a state of consciousness. Abuse frequently affects the individual's ability to fulfill normal societal roles, resulting in difficulty with employment, or legal, or interpersonal problems.

v. Pseudo-addiction: addiction-like behaviors consistent with overutilization of medications outside of the prescribing provider's instructions and recommendations for the express purpose of improved pain management. This occurs when a patient believes there is insufficient pain relief. Once pain is adequately managed with a higher dose of medications than initially prescribed or with improved therapy, the behaviors consistent with addiction are discontinued.

vi. Addiction: a primary chronic neurobiological disease influenced by genetic, psychosocial, and/or environmental factors. It is characterized by impaired control over drug use, compulsive drug use, and continued drug use despite harm and because of craving.

b. Substance use disorder/addiction in the workers' compensation system can be encountered in three ways. First, the individual has an active substance use disorder at the time of injury. The party responsible for treatment of the substance use disorder may be outside of the workers' compensation system. However, if there is no other paying party and the treatment is necessary in order to recover from the current workers' compensation injury, treatment may be covered by the workers' compensation payor. The second possibility is that a patient with a substance use disorder, who is currently in recovery at the time of the workers' compensation injury, relapses as a result of the medications which are prescribed by the treating provider. This patient may become re-addicted and will manifest substance use disorder characteristics and symptoms consistent with the diagnosis. The third possibility is an individual with no history of substance use disorder who is injured as a result of an occupational accident. This particular individual becomes "addicted" to the medications as a result of the medications being prescribed. This is most likely to occur with the use of opioids but could possibly occur with use of other medications such as benzodiazepines or specific muscle relaxants such as carisoprodol.

c. If the treating provider is suspicious of a patient exhibiting opioid misuse, abuse, or addiction, the patient should preferably be evaluated by a specialist in the field of addiction medicine. It would be the responsibility of the specialist to identify medication misuse, abuse, addiction, or pseudo-addiction and to determine what additional treatment, if any, needs to be implemented.

d. During the initial injury evaluation, an authorized treating provider should obtain an addiction history as part of a complete history and physical. If it is determined at the time of the initial evaluation by the treating provider that there is the pre-existing condition of active SUD or history of opioid addiction/SUD, then it is prudent to consider an evaluation with an addiction medicine physician prior to issuing opioid treatments if possible. The addiction

medication specialist will be able to counsel the patient accordingly, determine medication needs, and determine the appropriate follow-up to hopefully avoid aggravation or relapse of substance abuse disorders which will complicate the recovery process. Many patients exhibit opioid misuse, opioid abuse, and pseudo-addictive behaviors. These issues can be managed once the problem is identified and a discussion is carried out with the patient regarding these abnormal behaviors.

e. Once the diagnosis of SUD is confirmed, an addiction medicine trained physician familiar with addiction treatment should assist in co-managing the patient's care and the problematic drug prescriptions. This co-management technique is critical for the injured worker with a SUD diagnosis during the initial injury phase, recovery, and stabilization phase until he/she has reached MMI. If it is determined during the active treatment and recovery phase that there is no longer a need for opioids, then the addiction medicine trained physician will be in charge of the transition from use of opioids to safe taper/discontinuation of the opioids while monitoring for relapse of addiction.

f. Co-management is equally important for managing the chronic pain patient that has a concomitant opioid addiction/SUD with a legitimate need for analgesic medications. The addiction medicine trained physician in all likelihood will monitor the patient more closely including judicious prescribing, PMP reviews, urine drug testing, drug counts, and clarifying functional improvement as a result of the medications prescribed and frequent follow-ups which may initially seem excessive.

g. All abstinence addiction treatment begins with a discontinuation of the addicting substance; this is referred to as the detox phase of the treatment and can be performed in a number of ways. However, detoxification alone is not considered adequate addiction treatment. Detoxification is simply a method of discontinuing the medications in an effort to stabilize the patient prior to more extensive treatment.

h. Phase 1

i. The methods of detoxification can include: abrupt discontinuation—not recommended due to high rate of relapse due to craving and withdrawal symptoms; slow but progressive taper—10 percent of total dosage per week as an outpatient treatment; conversion to a different medication opioid (buprenorphine/naloxone) to enable a more stable and comfortable taper occasionally done as an outpatient but commonly done as part of a more comprehensive treatment program, and; rapid detox under anesthesia—not recommended due to relatively high incidence of complications and high expense. The methodology chosen for phase 1 detoxification is left up to the specialist and is simply the initial phase of stabilization prior to considering the need for a phase 2 of addiction treatment program.

i. Phase 2

i. Once a patient is safely through the detoxification phase and the condition is stabilized regardless of the method chosen, then successful addiction treatment begins generally utilizing a number of techniques to prevent the return to active substance use and addiction. This phase of treatment generally involves teaching the patient to develop control over the compulsions,

psychosocial factors, and associated mental health issues which are critical to maintain abstinence. This phase of treatment is generally managed in a 30 – 90 day non-hospital residential treatment program. The treatment prescribed in a residential treatment program generally includes individual and group therapy with certified addiction counselors and psychologists. Phase 2 of treatment may or may not be combined with opioid substitution therapy with medications such as buprenorphine/naloxone (partial agonist of the opioid receptor), methadone, or naltrexone. Injectable depot naltrexone may be used.

ii. Buprenorphine/naloxone therapy utilizes a sublingual partial opioid receptor agonist which binds to the opioid receptor, reducing craving and resulting in analgesia when necessary. Due to its high affinity to the opioid receptor, it blocks the effect of non-approved additional opioid use. The buprenorphine is administered either sublingually or, when FDA approved, as a subcutaneous implant. Naloxone was added to the sublingual drug formulation to discourage using this medication intravenously. With intravenous administration of buprenorphine/naloxone, the naloxone becomes absorbed neutralizing the effects of opioids. Buprenorphine/naloxone can be an excellent option in patients requiring analgesic medications with a prior history of opioid addiction because buprenorphine results in less sedation and euphoria than the other standard schedule II opioid medications. Prescribing Suboxone film (buprenorphine/naloxone) for addiction purposes can only be done by a physician and requires special training and certification. Once special training is completed, an application is filed with the DEA to obtain a special DEA license referred to as an X-DEA number. This X-DEA number needs to accompany all prescription for Suboxone when delivered to the pharmacy and identifies the prescription is being issued specifically for the treatment of addiction/SUD.

iii. Methadone may be an option if the patient is admitted to a federally licensed methadone treatment facility where a daily dose of medication is administered and the patient continues to utilize therapeutic treatments/cognitive behavioral therapies as noted above. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. The methodology and rationale for methadone treatment is to saturate the opioid receptors with methadone (a slow onset and prolonged duration opioid), reducing the opioid craving. The majority of the opioid receptors are bound by the methadone leaving very few unbound opioid receptors available in the event additional opioids are utilized in an attempt to achieve the euphoric effect. When the patient is stabilized on a methadone dose determined by the federally licensed methadone clinic and their associated physicians, the patient's drug-seeking, craving, legal issues, and attempts to utilize non-approved medications is reduced. Patients will frequently return to more productive lives free of the compulsions, cravings, and legal issues and are usually able to maintain jobs and improve family dynamics.

iv. Other medications which may be useful and can be utilized during the phase 2 and 3 treatment include

opioid receptor antagonists such as naltrexone (ReVia, Vivitrol) which produces no euphoria. The purpose of naltrexone therapy is to add an additional layer of protection and treatment for the patients by allowing them to receive a daily oral dose of naltrexone (ReVia) or a monthly injection of naltrexone (Vivitrol). Administration of naltrexone will bind with very high affinity to the opioid receptor resulting in the opioid receptors being non-responsive to other opioid utilization thereby preventing any euphoric response or reinforcement with unsanctioned opioid use. This treatment method can be problematic in an individual receiving intramuscular naltrexone therapy especially if that individual requires surgery and post-operative pain management because the analgesics needed for post-operative pain management will be significantly less effective because of the prolonged opioid antagonist properties of the naltrexone.

j. In Summary

i. Medication assisted treatment for patients addicted to opioids is the treatment recommended by most experts. A Canadian evidence-based guideline recommends long-term treatment with buprenorphine/naloxone, or methadone for some patients, based on the high relapse rate without medication assistance. The likelihood of relapse in the workers' compensation population for individuals who have become addicted through prescription drug use is unknown. Buprenorphine implants are likely equally effective as sublingual buprenorphine for preventing illicit opioid use. Implants are significantly costlier. Naltrexone treatment, an opioid agonist, has also been used to maintain abstinence. It can be provided in monthly injections or orally three times per week. Choice of these medications should be made by the addiction specialist.

k. Phase 3

i. Aftercare begins after discharge from the non-hospital residential treatment program and is designed for long-term management of addiction. This phase is potentially the time when relapse is most likely to occur if the patient has not developed significant skills necessary to deal with the compulsions, cravings, and associated psychosocial factors contributing to SUD. Long-term strategies include: intense outpatient programs (IOP); group therapy/meetings such as Narcotics Anonymous, and; residential communities (RC) which are groups of patients living together in a community for up to six months for the express purpose of maintaining abstinence from their drug of choice but at the same time transitioning and learning how to live in the general community. Residential communities are extremely useful to give patients an opportunity to be reintroduced to employment and psychosocial interactions with family and friends while maintaining contact with the community supporting their addiction recovery. In addition, phase 3 medication treatment may include utilization of opioid substitution therapy (buprenorphine/naloxone) or opioid receptor antagonist therapy as noted above.

ii. It must be noted that relapse is common despite the utilization of intense cognitive behavioral therapy, addiction treatment strategies, and long-term phase 3 treatment and medication. Risk monitoring should be continued, including checking for behavioral aberrancies, checking the PMP, and drug testing. Additional treatment or readmission for repeat treatment is not uncommon.

13. Opioid/Chemical Treatment Program Requirements

a. Chemical dependency for workers' compensation issues will usually be related to opioids, anxiolytics, or hypnotics as prescribed for the original workers' compensation injury. Chemical dependency should be treated with specific programs providing medical and psychological assessment, treatment planning, and individual as well as group counseling and education. Established functional goals which are measurable, achievable, and time specific are required.

b. Inpatient or outpatient programs may be used, depending upon the level of intensity of services required. Formal inpatient treatment programs are appropriate for patients who have more intense (e.g., use extraordinarily excessive doses of prescription drugs to which they have developed tolerance) or multiple drug abuse issues (e.g., benzodiazepines and/or alcohol) and those with complex medical conditions or psychiatric issues related to drug misuse. A medical physician with appropriate training and preferably board certified in addiction medicine should provide the initial evaluation and oversee the program. Full primary assessment should include behavioral health assessment; medical history; physical examination; mental status; current level of functioning; employment history; legal history; history of abuse, violence, and risk taking behavior; education level; use of alcohol, tobacco and other drugs; and social support system. The initial medical exam should include appropriate laboratory testing such as liver function, screening for sexual diseases, etc.

c. Addiction specialists, alcohol and drug counselors, psychologists, psychiatrists, and other trained health care providers as needed, are involved in the program. Peer and group support is an integral part of the program and families are encouraged to attend. Peer support specialists should receive competency-based training. A designated individual is assigned to each worker to assist in coordinating care. There should be good communication between the program and other external services, external health care providers, Al-Anon, Alcoholics Anonymous (AA), and pain medicine providers. Drug screening should be performed as appropriate for the individual, at least weekly during the initial detoxification and intensive treatment phases. Quarterly random drug screens per year should be completed for those that are being prescribed opioid medications and drug diversion control methods should be in place.

d. Clear withdrawal procedures are delineated for voluntary, against medical advice, and involuntary withdrawal. Withdrawal programs must have a clear treatment plan and include description of symptoms of medical and emotional distress, significant signs of opioid withdrawal, and actions taken. All programs should have clear direction on how to deal with violence in order to assure safety for all participants. Transition and discharge should be carefully planned with full communication to outside resources. Duration of inpatient programs are usually four weeks while outpatient programs may take 12 weeks.

e. Drug detoxification may be performed on an outpatient or inpatient basis. Detoxification is unlikely to succeed in isolation when not followed by prolonged chemical dependency treatment. Isolated detoxification is usually doomed to failure with very high recidivism rates.

f. Both ultra-rapid and rapid-detoxification are not recommended due to possible respiratory depression and death and the lack of evidence for long range treatment success. Refer to Opioid Addiction Treatment, for more specific details on treatment plans.

g. Tapering opioids on an outpatient basis requires a highly motivated patient and diligent treatment team and may be accomplished by decreasing the current dose 10 percent per day or per week. Tapering programs under the supervision of physicians with pain expertise may proceed more aggressively. Tapering should be accompanied by addiction counseling. Failing a trial of tapering, a patient should be sent to a formal addiction program. When the dose has reached one-third of the original dose, the taper should proceed at half or less of the initial rate. Doses should be held or possibly increased if severe withdrawal symptoms, pain, or reduced treatment failure otherwise occurs. This method is tedious, time consuming, and more likely to fail than more rapid and formalized treatment programs.

h. Time Frames for Opioid/Chemical Treatment Programs

i. time to produce effect: three to four weeks
ii. frequency: Full time programs - no less than five hours/day, five days/week; part time programs - four hours/day for two to three days per week.

iii. optimum duration: 2 to 12 weeks at least two to three times a week. With follow-up visits weekly or every other week during the first one to two months after the initial program is completed.

iv. maximum duration: four months for full time programs and up to six months for part-time programs. Periodic review and monitoring thereafter for one year, additional follow-up based upon the documented maintenance of functional gains.

14. Orthotics/prosthetics/equipment

a. Devices and adaptive equipment may be necessary in order to reduce impairment and disability, to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Indications would be to provide relief of the industrial injury, prevent further injury and control neurological and orthopedic injuries for reduced stress during functional activities. In addition, they may be used to modify tasks through instruction in the use of a device or physical modification of a device. Equipment needs may need to be reassessed periodically. Refer to Return-to-work for more detailed information.

b. - c. ...

d. For chronic pain disorders, equipment such as foot orthoses may be helpful. The injured worker should be educated as to the potential harm from using a lumbar support for a period of time greater than which is prescribed. Harmful effects include de-conditioning of the trunk musculature, skin irritation, and general discomfort. Use of cervical collars is not recommended for chronic cervical myofascial pain. Special cervical orthosis and/or equipment may have a role in the rehabilitation of a cervical injury such as those injuries to a cervical nerve root resulting in upper extremity weakness or a spinal cord injury with some degree of paraparesis or tetraparesis or post spinal fusion surgery. Use of such devices would be in a structured rehabilitation setting as part of a comprehensive rehabilitation program.

e. - f. ...

15. Personality/psychological/psychiatric/psychosocial intervention

a. Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use in acute pain problems, and more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic pain and should be implemented as soon as the problem is identified.

b. Studies have noted that there is not a direct connection between impairment and disability nor is there a direct connection between lumbar imaging and pain. It appears that the lack of connections is likely accounted for by differences among individuals in level of depression, coping strategies, or other psychological distress.

c. There is some evidence that in the setting of chronic low back pain when disc pathology is present, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief in spite of higher opioid dosage than when these symptoms are absent. Therefore, psychological issues should always be screened for and treated in chronic pain patients.

d. Psychological treatments for pain can be conceptualized as having a neuropsychological basis. These treatments for pain have been shown to decrease physiological reactivity to stress, alter patterns of brain activation as demonstrated by functional MRI (fMRI), alter the volume of grey matter and other structures in the brain, and alter blood flow patterns in the brain. The most researched psychological treatment is Cognitive Behavioral Therapy (CBT) which is summarized in this Section.

e. The screening or diagnostic workup should have clarified and distinguished between pre-existing, aggravated, and/or purely causative psychological conditions. Therapeutic and diagnostic modalities include, but are not limited to, individual counseling, and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or a structured pain management program.

f. A psychologist with a PhD, PsyD, EdD credentials, or a psychiatric MD/DO may perform psychosocial treatments. The following professionals may also perform treatment in consultation with a psychologist with a PhD, PsyD, EdD, or Psychiatric MD/DO: other licensed mental health providers, licensed health care providers with training in CBT, or providers certified as CBT therapists with experience in treating chronic pain disorders in injured workers.

g. If a diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) or most current ICD has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication to treat a diagnosed condition may be ordered by an authorized treating physician or by the consulting psychiatrist. Visits for management of psychiatric medications are medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending on the patient and medications selected.

h. Psychosocial interventions include psychotherapeutic treatments for behavioral health conditions, as well as behavioral medicine treatments. These interventions may similarly be beneficial for patients without psychiatric conditions but who may need to make major life changes in order to cope with pain or adjust to disability. Examples of these treatments include cognitive behavioral therapy (CBT), relaxation training, mindfulness training, and sleep hygiene psychoeducation.

i. CBT refers to a group of psychological therapies that are sometimes referred to by more specific names such as rational emotive behavior therapy, rational behavior therapy, rational living therapy, cognitive therapy, and dialectic behavior therapy. Variations of CBT methods can be used to treat a variety of conditions, including chronic pain, depression, anxiety, phobias, and post-traumatic stress disorder (PTSD). For patients with multiple diagnoses, more than one type of CBT might be needed. The CBT used in research studies is often "manualized CBT," meaning that the treatment follows a specific protocol in a manual. In clinical settings, CBT may involve the use of standardized materials, but it is also commonly adapted by a psychologist or psychiatrist to the patient's unique circumstances. If the CBT is being performed by a non-mental health professional, a manual approach would be strongly recommended.

j. CBT must be distinguished from neuropsychological therapies used to teach compensatory strategies to brain injured patients, which are also called "cognitive therapy." Many other clinical providers also provide a spectrum of cognitive interventions including: motivational interviewing, pain neuroscience education, and other interventions aimed at patient education and change in behavior. Refer to Therapy-Active, for details.

k. It should be noted that most clinical trials on CBT exclude subjects who have significant psychiatric diagnoses. Consequently, the selection of patients for CBT should include the following considerations. CBT is instructive and structured, using an educational model with homework to teach inductive rational thinking. Because of this educational model, a certain level of cognitive ability and literacy is assumed for most CBT protocols. Patients who lack the cognitive and educational abilities required by a CBT protocol are unlikely to be successful. Further, given the highly structured nature of CBT, it is more effective when a patient's circumstances are relatively stable. For example, if a patient is about to be evicted, is actively suicidal, or is coming to sessions intoxicated, these matters will generally preempt CBT treatment for pain and require other types of psychotherapeutic response. Conversely, literate patients whose circumstances are relatively stable, but who catastrophize or cope poorly with pain or disability, are often good candidates for CBT for pain. Similarly, literate patients whose circumstances are relatively stable, but who exhibit unfounded medical phobias, are often good candidates for CBT for anxiety.

l. CBT is often combined with active therapy in an interdisciplinary program, whether formal or informal. It must be coordinated with a psychologist or psychiatrist. CBT can be done in a small group or individually, and the usual number of treatments varies between 8 and 16 sessions.

m. Before CBT or other psychological treatments are performed, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a psychologist with a PhD, PsyD, or EdD or a psychiatric MD/DO.

n. Psychological disorders associated with distress and dysfunction are common in chronic pain. One study demonstrated that the majority of patients who had failed other therapy and participated in an active therapy program also suffered from major depression. However, in a program that included CBT and other psychological counseling, the success rate for return to work was similar for those with and without an ICD diagnosis. This study further strengthens the argument for having some psychological intervention included in all chronic pain treatment plans.

o. Hypnosis

i. The term hypnosis can encompass a number of therapy types including relaxation, imagery, focused attention, interpersonal processing, and suggestion. Hypnosis has been used in depression and for distress related to medical procedures.

ii. A number of studies support the use of hypnosis for chronic pain management. At least one pilot study suggested that hypnotic cognitive therapy assists recovery in chronic pain. Other imaging studies support the concept that hypnosis can actively affect cortical areas associated with pain. Thus, this therapy may be used at the discretion of the psychologist. A more recent meta-analysis was completed which purported to show evidence for hypnosis. However, the heterogeneity of the studies included prevents this study from meeting our standards for evidence.

iii. For all psychological/psychiatric interventions, an assessment and treatment plan must be provided to the treating physician prior to initiating treatment. The treatment plan must include specific, measurable, achievable, and realistic behavioral goals, with specific interventions and time frames to achieve those goals. The report should also address pertinent issues such as pre-existing, exacerbated or aggravated, and/or causative issues, as well as a realistic functional prognosis.

p. Time Frames for Cognitive Behavioral Therapy (CBT) or Similar Treatment

i. time to produce effect: 12-16 hours of treatment (one hour individual sessions or alternately one to two hour group sessions).

ii. frequency: one to two times weekly for the first two weeks, decreasing to one time per week thereafter.

iii. maximum duration: 24 one hour sessions.

NOTE: Before CBT or other psychological/psychiatric interventions are done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a psychologist with a PhD, PsyD, or EdD, or a Psychiatric MD/DO.

q. Time Frames for Other Psychological/Psychiatric Interventions

i. time to produce effect: six to eight weeks.

ii. frequency: one to two times weekly for the first two to four weeks (excluding hospitalization, if required), decreasing to one time per week for the second month. Thereafter, two to four times monthly with the exception of exacerbations, which may require increased frequency of visits. Not to include visits for medication management.

iii. optimum duration: two to six months.

iv. maximum duration: commonly six months for most cases. Extensions under conditions as noted below. (Not to include visits for medication management). For select patients (e.g., ongoing medical procedures or complications, medication dependence, diagnostic uncertainty, delays in care due to patient or systemic variables), less intensive but longer supervised psychological/psychiatric treatment may be required. If counseling beyond six months is indicated, the nature of the psychosocial risks being managed or functional progress must be documented. Progress notes for each appointment should include goal setting, with specific, measurable, achievable, and realistic goals, and a timetable with an expected end point. In complex cases, goal setting may include maintaining psychological equilibrium while undergoing invasive procedures.

16. Restriction of Activities

a. Continuation of normal daily activities is the recommendation for most patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

b. Some level of immobility may occasionally be appropriate which could include splinting/casting or as part of a structured schedule that includes energy conservation or intentional rest breaks between activities. While these interventions may have been ordered in the acute phase, the provider should be aware of their impact on the patient's ability to adequately comply with and successfully complete rehabilitation. Activity should be increased based on the improvement of core strengthening.

c. Patients should be educated regarding the detrimental effects of immobility versus the efficacious use of limited rest periods. Adequate rest allows the patient to comply with active treatment and benefit from the rehabilitation program. In addition, complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation and promotes disability. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers.

17. Return-to-Work

a. Return to work and/or work-related activities whenever possible is one of the major components in treatment and rehabilitation. Return-to-work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee, and be updated at each additional visit. A return-to-work format should be part of a company's health plan, knowing that return-to-work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society.

b. A prolonged time off work is likely to lead to chronic disability. In complex cases, experienced nurse case managers may be required to assist in return-to-work. Other services, including psychological evaluation and/or treatment, jobsite analysis, and vocational assistance may be employed.

c. Two counseling sessions with an occupational physician, and work site visit if necessary, may be helpful for workers who are concerned about returning to work.

d. At least one study suggests that health status is worse for those patients who do not return to work than those who do. Self-employment and injury severity predict return to work. Difficulty with pain control, ADLs, and anxiety and depression were common among patients who did not return to work.

e. The following should be considered when attempting to return an injured worker with chronic pain to work.

i. Job History Interview: An authorized treating physician should perform a job history interview at the time of the initial evaluation and before any plan of treatment is established. Documentation should include the workers' job demands, stressors, duties of current job, and duties of job at the time of the initial injury. In addition, cognitive and social issues should be identified and treatment of these issues should be incorporated into the plan of care.

ii. Coordination of Care: Management of the case is a significant part of return-to-work and may be the responsibility of an authorized treating physician, occupational health nurse, risk manager, or others. Case management is a method of communication between the primary provider, referral providers including occupational and physical therapists, insurer, employer, and employee. Because case management may be coordinated by a variety of professionals, the case manager should be identified in the medical record.

iii. Communication is essential between the patient, authorized treating physician, employer, and insurer. Employers should be contacted to verify employment status, job duties and demands, and policies regarding injured workers. In addition, availability of temporary and permanent restrictions, for what duration, as well as other placement options should be discussed and documented. All communications in the absence of the patient are required to be documented and made available to the patient.

iv. Establishment of Return-To-Work Status: Return-to-work for persons with chronic pain should be thought of as therapeutic, assuming that work is not likely to aggravate the basic problem or increase the discomfort. In some cases of chronic pain, the worker may not be currently working or even employed. The goal of return-to-work would be to return the worker to any level of employment with the current employer or to return them to any type of new employment. Temporary restrictions may be needed while recommended ergonomic or adaptive equipment is obtained; employers should obtain recommended equipment in a timely manner.

v. Establishment of Activity Level Restrictions: A formal job description for the injured worker is necessary to identify physical demands at work and assist in the creation of modified duty. A Job Site Evaluation may be utilized to identify tasks such as pushing, pulling, lifting, reaching, grasping, pinching, sitting, standing, posture, and ambulatory distance and terrain. If applicable, a job site evaluation may also be utilized to assess temperature, air flow, noise and the number of hours that may be worked per day in a specific environment. Also refer to Section, Jobsite

Evaluation and Alterations. Due to the lack of predictability regarding exacerbation of symptoms affecting function, an extended, occupationally focused functional capacity evaluation may be necessary to determine the patient's tolerance for job type tasks over a continued period of time. Job requirements should be reviewed for the entire eight hours or more of the working day. When prescribing the FCE, the physician must assess the probability of return to work against the potential for exacerbation of the work related condition. Work restriction assigned by the authorized treating physician may be temporary or permanent. The case manager should continue to seek out modified work until restrictions become less cumbersome or as the worker's condition improves or deteriorates. Ergonomic changes recommended by the worksite evaluation should be put in place.

(a). Between one and three days after the evaluation, there should be a follow-up evaluation by the treating therapist and/or an authorized treating physician to assess the patient's status. Patients should be encouraged to report their status post FCE.

vi. Rehabilitation and Return-to-work: As part of rehabilitation, every attempt should be made to simulate work activities so that an authorized treating physician may promote adequate job performance. The use of ergonomic or adaptive equipment, therapeutic breaks, and interventional modalities at work may be necessary to maintain employment.

vii. Vocational Assistance: Formal vocational rehabilitation is a generally accepted intervention and can assist disabled persons to return to viable employment. Assisting patients to identify vocational goals will facilitate medical recovery and aid in the maintenance of MMI by 1) increasing motivation towards treatment and 2) alleviating the patient's emotional distress. Physically limited patients will benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment utilizing the information from occupational and physical therapy assessments may be performed. This vocational assessment may identify rehabilitation program goals, as well as optimize both patient motivation and utilization of rehabilitation resources. This may be extremely helpful in decreasing the patient's fear regarding an inability to earn a living, which can add to his/her anxiety and depression.

(a). Recommendations to Employers and Employees of Small Businesses: Employees of small businesses who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses hire other workers and if the injured employee returns to the job, the supervisor/owner may have an extra employee. Case managers may assist with resolution of these problems, and with finding modified job tasks, or jobs with reduced hours, etc., depending upon company philosophy and employee needs.

(b). Recommendations to Employers and Employees of Mid-Sized and Large Businesses: Employers are encouraged by the OWCA to identify modified work within the company that may be available to injured workers

with chronic pain who are returning to work with temporary or permanent restrictions. To assist with temporary or permanent placement of the injured worker, it is suggested that a program be implemented that allows the case manager to access descriptions of all jobs within the organization.

18. Therapy—active

a. The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. All active therapy plans should be made directly with patients in the interest of achieving long-term individualized goals.

b. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instruction(s). Active therapy is intended to promote independence and self-reliance in managing the physical pain as well as to improve the functional status in regard to the specific diagnosis, general conditioning and well-being. At times, a provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient. Therapy in this Section should not be merely a repeat of previous therapy but should focus specifically on the individual goals and abilities of the patient with chronic pain.

c. The goal of active therapy is to teach the patient exercises that they can perform regularly on their own. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

d. On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care, need for post-operative therapy, and co-morbidities may also extend durations of care. Interventional injections require postoperative active therapy coupled with home exercise to improve function, with a reset of the recommended number of sessions, regardless of the number of therapy visits previously conducted. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" has been completed, then alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

e. Pain Neuroscience Education (PNE): an educational strategy used by physical therapists and other practitioners that focuses on teaching people in pain more about the neurobiological and neurophysiological processes involved in their pain experience, versus a focus on anatomical and pathoanatomical education. PNE helps patients develop an understanding of various pain processes including central sensitization, peripheral sensitization,

inhibition, facilitation, the brain's processing of threat appraisal, and various biological systems involved in a pain experience. This reconceptualization of pain via PNE is then combined with various behavioral strategies including aerobic exercise, pacing, graded exposure, graded activity, and goal setting. PNE is likely to positively influence pain ratings, disability, fear-avoidance behaviors, pain catastrophization, and limitations in movement, pain knowledge, and healthcare utilization. PNE is recommended with active therapy for chronic pain patients.

f. The following active therapies are listed in alphabetical order:

i. ...

(a). ...

(b). frequency: one to five times per week

(c). - (d). ...

ii. Aquatic Therapy: is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, range-of-motion, flexibility, body mechanics, and pain management. Aquatic Therapy is the implementation of active therapeutic procedures (individual or group) in a swimming or therapeutic pool heated to 88 to 92 degrees. The water provides a buoyancy force that lessens the amount of force of gravity applied to the body, and the pool should be large enough to allow full extremity range of motion and full erect posture. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. Aquatic vests, belts and other devices can be used to provide stability, balance, buoyancy, and resistance. In addition, the compression of the water against the affected extremity and ability to move easier with decreased gravity allow for resulting muscular compression against vessels improving lymphatic drainage resulting in decreased edema. Aquatic Therapy may also provide an additional stimulus to assist with desensitization.

(a). There is good evidence that aquatic exercise and land-based exercise show comparable outcomes for function and mobility among people with symptomatic osteoarthritis of the knee or hip.

(b). Indications: The therapy may be indicated for individuals who:

(i). cannot tolerate active land-based or full-weight bearing therapeutic procedures;

(ii). require increased support in the presence of proprioceptive deficit;

(iii). are at risk of compression fracture due to decreased bone density;

(iv). have symptoms that are exacerbated in a dry environment;

(v). have a higher probability of meeting active therapeutic goals than in a dry environment.

(c). Time Frames for Aquatic Therapy

(i). time to produce effect: four to five treatments

(ii). frequency: three to five times per week

(iii). optimum duration: four to six weeks

(iv). maximum duration: six weeks

(d). After the supervised aquatics program has been established, either a self-directed aquatic program or a

transition to a self-directed dry environment exercise program is recommended.

iii. Functional activities are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, and sensory motor integration.

(a). ...

(b). frequency: one to five times per week

(c). ...

(d). maximum duration: eight weeks

iv. Functional electrical stimulation is an accepted treatment in which the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. Indications include muscle atrophy, weakness, and sluggish muscle contraction secondary to pain, injury, neuromuscular dysfunction, peripheral nerve lesion, or radicular symptoms. This modality may be prescribed for use at home when patients have demonstrated knowledge of how to self-administer and are in an independent exercise program.

(a). - (d). ...

v. Neuromuscular re-education is a generally accepted treatment. It is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength, movement patterns, neuromuscular response, proprioception, kinesthetic sense, coordination, education of movement, balance and posture.

(a). There is some evidence that there is a modest benefit from adding a back school to other treatments such as NSAIDs, massage, transcutaneous electrical nerve stimulation (TENS), and other physical therapy modalities. However, a recent adequate quality systematic review found no evidence for the effectiveness of back schools for treating chronic low back pain.

(b). Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent control.

(c). Time Frames for Neuromuscular Re-education

(i). time to produce effect: two to six treatments

(ii). frequency: one to three times per week

(iii). optimum duration: four to eight weeks

(iv). maximum duration: eight weeks

vi. Spinal stabilization is a generally well-accepted treatment. The goal of this therapeutic program is to strengthen the spine in its neutral and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the ability to move and function normally through postures and activities without creating undue vertebral stress.

(a). Time Frames for Spinal Stabilization

(i). time to produce effect: four to eight treatments.

(ii). frequency: one to three times per week.

(iii). optimum duration: four to eight weeks.

(iv). maximum duration: eight weeks.

vii. Therapeutic Exercise with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. May also include alternative/complementary exercise movement therapy (with oversight of a physician or physical therapist).

(a). Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, improved proprioception, and coordination, and increased range of motion are used to promote normal movement patterns.

(b). Yoga may be an option for motivated patients with appropriate diagnoses.

(c). Therapeutic exercise programs should be tissue specific to the injury and address general functional deficits as identified in the diagnosis and clinical assessment. Patients should be instructed in and receive a home exercise program that is progressed as their functional status improves. Upon discharge, the patient would be independent in the performance of the home exercise program and would have been educated in the importance of continuing such a program. Educational goals would be to maintain or further improve function and to minimize the risk for aggravation of symptoms in the future.

(d). Available evidence supporting therapy mainly exists in the chronic low back literature.

(e). Time Frames for Therapeutic Exercise

(i). time to produce effect: two to six treatments

(ii). frequency: two to five times per week

(iii). optimum duration: four to eight weeks and concurrent with an active daily home exercise program.

(iv). maximum duration: 8 to 12 weeks of therapist oversight. Home exercise should continue indefinitely. Additional sessions may be warranted during periods of exacerbation of symptoms.

(f). Time Frames for Yoga

(i). time to produce effect: eight sessions

(ii). maximum duration: 48 sessions are the maximum expected duration

viii.. Work Conditioning: These programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program includes, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, postural control, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full- or optimal- function and return to work. The service may include the time-limited use of modalities, both active and passive, in conjunction with therapeutic exercise, functional activities, general conditioning body mechanics and lifting techniques re-training. These programs are usually initiated once re-conditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified- or full-duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(a). length of visit: two to four hours per day

(b). - (d). ...

ix. ...

(a). - (b). ...

(c). optimum duration: two to four weeks

(d). maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

19. Therapy—Passive

a. Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies such as postural stabilization and exercise programs to help control swelling, pain and inflammation during the active rehabilitation process. They may be used intermittently as a licensed practitioner deems appropriate, or regularly if there are episodes of acute pain superimposed upon a chronic pain problem.

b. On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and comorbidities may extend durations of care. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after six to eight visits no treatment effect is observed, alternative treatment interventions, further diagnostic studies or further consultations should be pursued.

c. The following passive therapies are listed in alphabetical order.

i. Electrical Stimulation (Unattended): low frequency transcutaneous muscle stimulator—Electrical stimulation, once applied, requires minimal on-site supervision by the licensed practitioner. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A home unit may be purchased or rented if treatment is effective and frequent use is recommended.

(a). - (b). ...

(c). optimum maximum duration: four treatments for clinic use.

ii. Iontophoresis: is an accepted treatment which consists of the transfer of medication into superficial tissue, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (lidocaine), inflammation (hydrocortisone, salicylate, dexamethasone sodium phosphate), edema (mecholy, hyaluronidase, salicylate), ischemia (magnesium, mecholy, iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars and keloids (chlorine, iodine, acetate).

(a). time to produce effect: two to four treatments

(b). frequency: three times per week with at least 48 hours between treatments

(c). - (d). ...

iii. Low Level Laser: Not recommended as there is no proven benefit for this intervention due to lack of studies of sufficient quality. There is not enough research at this time to support this modality in the treatment of chronic pain. Results of low level laser have been mixed and often of poor quality.

iv. Manual treatment including manipulation is defined as osteopathic manipulative treatment, chiropractic manipulative treatment, manual therapy, manipulation, or mobilization. Manual treatments may be applied by osteopathic physicians (DOs), chiropractors (DCs), physical therapists (PTs), occupational therapists (OTs), or medical doctors (MDs). Some popular and useful techniques include but are not limited to: high velocity, low amplitude (HVLA); muscle energy (ME) or hold-relax; strain-counterstrain (SCS); a balanced ligamentous tension (BLT); and myofascial release (MFR). Under these different types of manipulation, many subsets of different techniques that can be described as a) direct—a forceful engagement of a restrictive/pathologic barrier, b) indirect—a gentle/non-forceful disengagement of a restrictive/pathologic barrier, c) the patient actively assists in the treatment, and d) the patient relaxing, allowing the practitioner to move and balance the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body, including muscles, tendons, ligaments, joints, fascia, and viscera. This may consist of a variety of techniques. Pre-treatment assessment should be performed as part of each manual treatment visit to ensure that the correct diagnosis and correct treatment is employed.

(a). The decision to refer a patient for spinal manipulation rather than for other treatments should be made on the basis of patient preference and relative safety, not on an expectation of a greater treatment effect. It may be the first line of treatment, in combination with active therapy for some patients, and should strongly be considered for patients with positive provocative testing for SI joint dysfunction or facet dysfunction who are not recovering in the first few weeks.

(b). Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, local primary bone tumor with questionable osseous integrity, Paget's disease, active inflammatory arthritis, aortic aneurysm, and signs of progressive neurologic deficits.

(c). AHRQ supports use of spinal manipulation for chronic low back pain. In addition, based on multiple studies with some and good levels of evidence, there is good evidence supporting the use of manual therapy for treating chronic low back pain and chronic neck pain. There is also good evidence that supervised exercise therapy with added manual mobilization shows moderate, clinically important reductions in pain compared to non-exercise controls in people with osteoarthritis of the knee. There is not sufficient evidence to reliably determine whether manual muscle energy technique (MET) is likely to be effective in practice.

(d). Time Frames for Manual Treatment Including Manipulation

(i). time to produce effect: six to nine treatments.

(ii). frequency: one to three times per week for the first two weeks as indicated by the severity of the condition. Treatment may continue at one treatment per week for the next six weeks.

(iii). optimum duration: four to six weeks.

(iv). maximum duration: eight weeks. At week eight, patients should be re-evaluated. Care beyond eight weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at one treatment every other week until the patient has reached MMI and maintenance treatments, using the accompanying post MMI guideline, have been determined. Refer to Maintenance Management section. Extended durations of care beyond what is considered "maximum" may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities.

v. Manipulation Under General Anesthesia (MUA) refers to manual manipulation of the lumbar spine in combination with the use of a general anesthetic or conscious sedation. It is intended to improve the success of manipulation when pain, muscle spasm, guarding, and fibrosis appear to be limiting its application in patients otherwise suitable for their use.

(a). There have been no high quality studies to justify its benefits given the risks of general anesthetic and conscious sedation. It is not recommended.

vi. Manipulation Under Joint Anesthesia (MUJA) refers to manipulation of the lumbar spine in combination with a fluoroscopically guided injection of anesthetic with or without corticosteroid agents into the facet joint at the level being manipulated.

(a). There are no controlled clinical trials to support its use. It is not recommended.

vii. Massage—Manual or Mechanical. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by or with the practitioners' hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range-of-motion, or to increase muscle relaxation and flexibility prior to exercise.

(a). - (d). ...

viii. Mobilization (Soft Tissue) is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release, and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. Soft tissue mobilization can also use various instruments to assist the practitioner. These are typically labeled "instrument assisted soft-tissue techniques". These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

(a). - (d). ...

ix. Percutaneous Electrical Nerve Stimulation (PENS): Needles are used to deliver low-voltage electrical current under the skin. Theoretically this therapy prevents pain signals traveling through small nerve fibers from reaching the brain, similar to the theory of TENS.

(a). There is good evidence that PENS produces improvement of pain and function compared to placebo; however, there is no evidence that the effect is prolonged after the initial three week treatment episode. There are no well-done studies that show PENS performs better than TENS for chronic pain patients. PENS is more invasive, requires a trained health care provider and has no clear long-term effect; therefore it is not generally recommended.

(b). Time Frames for Percutaneous Electrical Nerve Stimulation (PENS)

(i). time to produce effect: one to four treatments.

(ii). frequency: two to three times per week.

(iii). optimum duration: nine sessions.

(iv). maximum duration: 12 sessions per year.

x. Superficial Heat and Cold Therapy (Including Infrared Therapy) is a generally accepted treatment. Superficial heat and cold are thermal agents applied in various manners that lowers or raises the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. Includes application of heat just above the surface of the skin at acupuncture points. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm and promote stretching/flexibility. Cold and heat packs can be used at home as an extension of therapy in the clinic setting.

(a). - (d). ...

xi. Traction—Manual is an accepted treatment and an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation.

(a). - (b). ...

(c). optimum and maximum duration: one month

xii. Traction—Mechanical is indicated for decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Traction modalities are contraindicated in patients with tumor, infections, fracture, or fracture dislocation. Non-oscillating inversion traction methods are contraindicated in patients with glaucoma or hypertension.

(a). There is some evidence that mechanical traction, using specific, instrumented axial distraction technique, is not more effective than active graded therapy without mechanical traction. Therefore, mechanical traction is not recommended for chronic axial spine pain.

(b). Time Frames for Mechanical Traction

(i). time to produce effect: one to three sessions up to 30 minutes. If response is negative after three treatments, discontinue this modality.

(ii). frequency: two to three times per week

(iii). optimum/maximum duration: one month

xiii. Transcutaneous Electrical Nerve Stimulation (TENS) should include least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation.

(a). One double-blinded, placebo-controlled study, found that low frequency TENS induces analgesia which is detected on functional MRI with change in brain activity in multiple regions. There was no functional follow-up. High-frequency TENS may be more effective than low frequency for patients on opioids.

(b). Time Frames for Transcutaneous Electrical Nerve Stimulation (TENS)

(i). time to produce effect: Immediate

(ii). frequency: variable

(iii). optimum duration: three sessions. If beneficial, provide with home unit.

(iv). Maximum duration: three sessions. Purchase if effective.

xiv. Dry Needling (DN). Description: DN is a skilled intervention performed by physical therapists (PTs) and Chiropractors (DCs) that utilizes a solid filament needle to penetrate the skin and underlying tissues to treat relevant muscular, neural, and other connective tissues for the evaluation and management of neuromusculoskeletal conditions, pain, movement impairments, and disability. The technique can be done with or without electrical stimulation. It has been used for tendinopathies, headaches and occipital neuralgia, plantar fasciitis, shoulder pain, lateral epicondylalgia, spinal pain, hip and knee pain. The goal of dry needling is to improve overall function and disability by decreasing pain and improving range-of-motion, strength, and/or muscle firing patterns. It is a technique that is utilized in conjunction with other physical therapy treatments including therapeutic exercise, manual therapy, stretching, neuromuscular re-education, postural education, and pain neuroscience education.

(a). Indications: Dry needling is indicated when myofascial trigger points are identified in muscles in conjunction with decreased range-of-motion, decreased strength, altered muscle firing patterns, and/or pain which negatively affect a patient's overall function.

(b). Complications: Potential but rare complications of dry needling include infection and pneumothorax. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

(c). There is some evidence that the inclusion of two sessions of trigger point dry needling into a twice daily five-week exercise program was significantly more effective in improving shoulder pain-related disability than an exercise program alone at 3, 6, and 12 month follow-ups in people with chronic subacromial pain syndrome. Both interventions were equally effective in reducing pain over 12 months.

(d). There is some evidence that four sessions of trigger point deep dry needling with passive stretching over

two weeks was significantly more effective in reducing neck pain and improving neck disability than passive stretching alone in the short-term and at six-month follow-up in people with chronic nonspecific neck pain.

(e). Based on a number of meta-analysis and systematic reviews, studies have shown some advantage for dry needling. However, there are also a number of studies with negative results. Because of the low quality of studies and heterogeneity, no form of evidence can be drawn from these reviews, which include a number of anatomic sites.

(f). Time Frames for Dry Needling (DN)

(i). time to produce effect: three to six treatments

(ii). frequency: one to three times per week

(iii). optimum duration: one to two months

(iv). maximum duration: 14 treatments within 6 months

xv. Ultrasound (Including Phonophoresis) is an accepted treatment which uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation and muscle facilitation. Phonophoresis is the transfer of medication through the use of sonic generators to the target tissue to control inflammation and pain.

(a). Phonophoresis is the transfer of medication to the target tissue to control inflammation and pain through the use of sonic generators. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

(b). There is no high quality evidence to support the use of ultrasound for improving pain or quality of life in patients with non-specific chronic low back pain.

(c). Time Frames for Ultrasound (Including Phonophoresis)

(i). time to produce effect: one to four treatments

(ii). frequency: one to two treatments per week

(iii). optimum duration: four to six treatments

(iv). Maximum duration: eight treatments

xvi. Vertebral Axial Decompression (VAX-D)/DRX, 9000: Motorized traction devices which purport to produce non-surgical disc decompression by creating negative intradiscal pressure in the disc space include devices with the trade names of VAX-D and DRX 9000.

(a). There are no good studies to support their use. They are not recommended.

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§2113. Therapeutic Procedures—Operative

A. When considering operative intervention in chronic pain management, the treating physician must carefully

consider the inherent risk and benefit of the procedure. All operative intervention should be based on a positive correlation with clinical findings, the clinical course, and diagnostic tests. A comprehensive assessment of these factors should have led to a specific diagnosis with positive identification of the pathologic condition. Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.

1. Surgical procedures are seldom meant to be curative and should be employed in conjunction with other treatment modalities for maximum functional benefit. Functional benefit should be objectively measured and includes the following:

a. return-to-work or maintaining work status;

b. fewer restrictions at work or performing activities of daily living (ADLs);

c. decrease in usage of medications prescribed for the work-related injury;

d. measurable functional gains, such as increased range-of-motion or documented increase in strength;

2. Education of the patient should include the proposed goals of the surgery, expected gains, risks or complications, and alternative treatment.

3. Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician. If a treating physician recommends a specific smoking cessation program peri-operatively, this should be covered by the insurer. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels. The surgeon will make the final determination as to whether smoking cessation is required prior to surgery. Similarly, patients with uncontrolled diabetes are at increased risk of post-operative infection and poor wound healing. It is recommended that routine lab work prior to any surgical intervention include a hemoglobin A1c. If it is higher than the recommended range, the surgery should be postponed until optimization of blood sugars has been achieved.

4. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities, and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

5. Monitored anesthesia care is acceptable for diagnostic and therapeutic procedures.

6. Neurostimulation

a. Description—Spinal cord stimulation (SCS) is the delivery of low-voltage electrical stimulation to the spinal cord or peripheral nerves to inhibit or block the sensation of pain. The system uses implanted electrical leads and a battery powered implanted pulse generator (IPG).

b. There is some evidence that SCS is superior to reoperation in the setting of persistent radicular pain after lumbosacral spine surgery, and there is some evidence that SCS is superior to conventional medical management in the same setting. Success was defined as achieving 50 percent or

more pain relief. However, the study could not demonstrate increased return to work. Some functional gains have been demonstrated. These findings may persist at three years of follow-up in patients who had an excellent initial response and who are highly motivated.

c. There is some evidence that a higher-frequency, 500Hz to 10 KHz spinal cord stimulator is more effective than a traditional low frequency 50 Hz stimulator in reducing both back pain and leg pain in patients who have had a successful trial of an external stimulator. Two-thirds of the patients had radiculopathy and one-half had predominant back pain. The higher frequency device appears to lead to greater patient satisfaction than the low frequency device, which is likely to be related to the fact that the higher frequency device does not produce paresthesias in order to produce a pain response. In contrast to the low frequency stimulator, which requires recharging about twice per month, the higher frequency stimulator is recommended for every one to three days recharging for 0.5 to 3 hours. A United Kingdom study of cost effectiveness for high frequency spinal cord stimulators found high cost effectiveness compared to traditional non-rechargeable or rechargeable stimulators, re-operation, or medical management.

d. Some evidence shows that SCS is superior to re-operation and conventional medical management for severely disabled patients who have failed conventional treatment and have Complex Regional Pain Syndrome (CRPS I) or failed back surgery with persistent radicular neuropathic pain.

e. A recent randomized trial found that patients with spinal cord stimulators for CRPS preferred different types and levels of stimulation for pain relief. No difference was found between 40,500Hz, 1200 Hz, and 10KHz levels or burst stimulation.

f. SCS can be used for patients who have CRPS II. Spinal cord stimulation for spinal axial pain has traditionally not been very successful. Recent technological advances such as higher frequency and burst stimulation have demonstrated better results for axial spine pain. These technologically superior spinal cord stimulators are recommended for axial spine pain.

g. SCS may be most effective in patients with CRPS I or II who have not achieved relief with oral medications, rehabilitation therapy, or therapeutic nerve blocks, and in whom the pain has persisted for longer than six months.

h. It is particularly important that patients meet all of the indications before a permanent neurostimulator is placed because several studies have shown that workers' compensation patients are less likely to gain significant relief than other patients. As of the time of this guideline writing, spinal cord stimulation devices have been FDA approved as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral and bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, leg pain and arm pain.

i. Particular technical expertise is required to perform this procedure and is available in some neurosurgical, rehabilitation, and anesthesiology training programs and fellowships. Physicians performing this procedure must be trained in neurostimulation implantation

and participate in ongoing training workshops on this subject, such as those sponsored by the American Society of Interventional Pain Practitioners (ASIPP), North American Neuromodulation Society (NANS), or as sponsored by implant manufacturers. Permanent electrical lead and IPG placement should be performed by surgeons (orthopedic or neurosurgery) with fellowship training in spine based surgical interventions or other physicians who have completed an Accreditation Council for Graduate Medical Education (ACGME) accredited pain medicine fellowship or training and have completed the required number of supervised implantations during fellowship or training.

j. Complications—Serious, less common complications include spinal cord compression, paraplegia, epidural hematoma, epidural hemorrhage, undesirable change in stimulation, seroma, CSF leakage, infection, erosion, allergic response. Other complications consist of dural puncture, hardware malfunction or equipment migration, pain at implantation site, loss of pain relief, chest wall stimulation, and other surgical risks. In recent studies, device complication rates have been reported to be 25 percent at six months, 32 percent at 12 months, and 45 percent at 24 months. The most frequent complications are reported to be electrode migration (14 percent) and loss of paresthesia (12 percent), up to 24 percent required additional surgery. In a recent review of spinal stimulation, 34.6 percent of all patients reported a complication, most of them being technical equipment-related issues or undesirable stimulation.

k. Surgical Indications—Patients with established CRPS I or II, or radicular or trunk pain, or a failed spinal surgery with persistent functionally limiting radicular pain greater than axial pain, who have failed conservative therapy including active and/or passive therapy, pre-stimulator trial psychiatric evaluation and treatment, medication management, or therapeutic injections. Traditional SCS is not recommended for patients with the major limiting factor of persistent axial spine pain. Higher frequency stimulators may be used for patients with predominantly axial back pain or trunk pain. Traditional or other SCS may be indicated in a subset of patients who have a clear neuropathic radicular pain (radiculitis) with or without previous surgery. The extremity pain should account for at least 50 percent or greater of the overall back and leg pain experienced by the patient. Prior authorization is required. Habituation to opioid analgesics in the absence of a history of addictive behavior does not preclude the use of SCS. Patients with severe psychiatric disorders, issues of secondary gain, and one or more primary risk factors are not candidates for the procedure. The prognosis worsens as the number of secondary risk factors increases. Approximately, one third to one half of patients who qualify for SCS can expect a substantial long-lasting pain relief; however, it may not influence allodynia and hypesthesia. Patients' expectations need to be realistic, and therefore, patients should understand that the SCS intervention is not a cure for their pain but rather a masking of their symptomatology which might regress over time. There appears to be a likely benefit of up to three years, although some practitioners have seen benefits persist for longer periods.

i. Prior to surgical intervention, the patient and treating physician should identify functional operative goals

and the likelihood of achieving improved ability to perform activities of daily living or work, as well as possible complications. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

ii. Informed decision making should be documented for all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. Since many patients with the most common conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

iii. Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician. If a treating physician recommends a specific smoking cessation program perioperative, this should be covered by the insurer. Typically the patient should show some progress toward cessation at about six weeks. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels. The surgeon will make the final determination as to whether smoking cessation is required prior to surgery. Patients with demonstrated success may continue the program up to three months or longer if needed based on the operative procedure. Smoking cessation should continue throughout the post-operative period. Refer to Smoking Cessation Medications and Treatment for further details.

iv. Patients must meet the following criteria in order to be considered candidates for neurostimulation:

(a). Traditional or other SCS may be indicated in a subset of patients who have a clear neuropathic or radicular pain (radiculitis) or trunk pain; are not candidates for surgical intervention on the spine; have burning pain in a distribution amenable to stimulation coverage and have pain at night not relieved by position. The extremity pain should account for at least 50 percent or greater of the overall arm or leg and back pain experienced by the patient. Higher frequency stimulators may be used for patients with predominantly axial back pain.

(b). Prior to the stimulator trial, a comprehensive psychiatric or psychological evaluation, and a chronic pain evaluation. Refer to Personality/Psychological Evaluation for Pain Management, for more information. This evaluation should include a standardized detailed personality inventory with validity scales (e.g., MMPI-2, MMPI-2-RF, or PAI); pain inventory with validity measures (e.g., BHI 2, MBMD); clinical interview and complete review of the medical records. The psychologist or psychiatrist performing these evaluations should not be an employee of the physician performing the implantation. This evaluation must be completed, with favorable findings, before the screening trial is scheduled. Before proceeding to a spinal stimulator trial, the evaluation should find the following:

(i). no indication of falsifying information;
(ii). no indication of invalid results on testing; and

(iii). no primary psychiatric risk factors or “red flags” (e.g., psychosis, active suicidality, severe depression, or addiction). (Note that tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation); and

(iv). a level of secondary risk actors or “yellow flags” (e.g., moderate depression, job dissatisfaction, dysfunctional pain conditions) judged to be below the threshold for compromising the patient’s ability to benefit from neurostimulation;

(v). the patient is cognitively capable of understanding and operating the neurostimulation control device; and

(vi). the patient is cognitively capable of understanding and appreciating the risks and benefits of the procedure; and

(vii). the patient is familiar with the implications of having an implant, can accept the complications, potential disfigurement, and effort it takes to maintain the device; and

(viii). the patient is cognitively capable of understanding the course of injury both with and without neurostimulation; and

(ix). the patient has demonstrated a history of motivation in and adherence to prescribed treatments; and

(x). the patient understands the work related restrictions that may occur with placement of the stimulator. All reasonable surgical and non-surgical treatment has been exhausted; and

(xi). the topography of pain and its underlying pathophysiology are amenable to stimulation coverage (the entire painful area has been covered); and

(xii). a successful neurostimulation screening test of at least three to seven days for a percutaneous trial or 7 to 10 days for an open surgically implanted trial lead.

(c). For a spinal cord neurostimulation screening test, a temporary lead is either implanted surgically with an incision or percutaneously attached to the skin and attached to an external source to validate therapy effectiveness. A screening test is considered successful if the patient meets both of the following criteria: (a) experiences a 50 percent decrease radicular or CRPS in pain, which may be confirmed by visual analogue scale (VAS) or Numerical Rating Scale (NRS), and (b) demonstrates objective functional gains or decreased utilization of pain medications.

(i). Objective, measurable, functional gains must be evaluated by the primary treating physician prior to and before discontinuation of the trial. If the trial is with a surgically implanted lead below the skin, then the trial is from 7 to 10 days. If the trial is percutaneous, then the trial is three to seven days. Functional gains may include: standing, walking, positional tolerance, upper extremity activities, increased social participation, or decreased medication use.

1. Contraindications

i. unsuccessful SCS test—inability to obtain objective, documented, functional improvement or reduction of pain;

ii. those with cardiac pacemakers should be evaluated on an individual basis as some may qualify for surgery;

iii. patients who are unable to properly operate the system;

iv. patients who are anti-coagulated and cannot be without anticoagulation for a few days (e.g., patients with artificial heart valves);

v. patients with frequent severe infections;

vi. patients for whom a future MRI is planned unless the manufacturer has approval for the body part that will be the subject of the MRI.

m. **Operative Treatment—Implantation** of stimulating lead or leads connected by extensions to either an implanted neurostimulator or an implanted receiver powered by an external transmitter. The procedure may be performed either as an open or a percutaneous procedure, depending on the presence of epidural fibrosis and the anatomical placement required for optimal efficacy. During the final procedure for non-high frequency devices or for those without surgically implanted trial leads, the patient must be awakened to establish full coverage from the placement of the lead. One of the most common failures is misplaced leads. Functional improvement is anticipated for up to three years or longer when objective functional improvement has been observed during the time of neurostimulation screening exam.

n. **Post-Operative Considerations**

i. MRI may be contraindicated depending on the model and implant location.

ii. Work restrictions postplacement include no driving when active paresthesias are present. This does not apply to higher frequency stimulators as no paresthesia is present. Thus, use of potentially dangerous or heavy equipment while the lower frequency simulator is active is prohibited. The physician may also limit heavy physical labor to prevent lead dislodgement.

o. **Post-Operative Therapy—Active and/or passive therapy** should be employed to improve function. Implantable stimulators will require frequent monitoring such as adjustment of the unit and replacement of implanted batteries. Estimated battery life of SCS implantable devices is usually 5 to 10 years depending on the manufacturer.

7. **Dorsal Root Ganglion Stimulator** (See Neurostimulation)

8. **Peripheral Nerve Stimulation**—There are no randomized controlled studies for this treatment. This modality should only be employed with a clear nerve injury or when the majority of pain is clearly in a nerve distribution in patients who have completed six months of other appropriate therapy including the same pre-trial psychosocial evaluation and treatment as are recommended for spinal cord stimulation. A screening trial should take place over three to seven days and is considered successful if the patient meets both of the following criteria: (a) experiences a 50 percent decrease in pain, which may be confirmed by Visual Analogue Scale (VAS) or Numerical Rating Scale (NRS) and (b) demonstrates objective functional gains or decreased utilization of pain medications. Objective, measurable, functional gains must be evaluated by an independent occupational therapist and/or physical therapist and the primary treating physician prior to and before discontinuation of the trial. The primary treating doctor is not the doctor who placed the nerve stimulator. It

may be used for proven occipital, ulnar, median, and other isolated nerve injuries.

9. **Intrathecal drug delivery**—Recommended in patients in whom other conservative measures have failed or in those requiring high dose oral opiates or experiencing side effects to control pain or in cases of spasticity or uncontrolled muscle spasms. Oral pain medication would not be appropriate for chronic pain in conjunction with an Intrathecal pain pump, except for up to the initial ten days after implant for purpose of postop incisional pain or weaning and stopping oral opiates. Treatment for concomitant acute pain separate from chronic pain can combine oral opiates and pump medication at reduced doses orally. Pumps require refilling every one to six months for the life of the patient. More than one medication may be needed in the pump. Once implanted the managing physician must arrange for continuity of care for refills and or pump adjustments. Oral opiates should be stopped 7-10 days after implantation or pump and Intrathecal catheter and pump should be titrated to control chronic pain. A PTM (Patient therapy manager) may be used for breakthrough pain. Acute pain may be treated concomitantly with short courses or oral opiates. Intrathecal pumps may be considered when dystonia and spasticity are dominant features or when pain is not able to be managed using any other non-operative treatment or in cases inadequate opiate management by other routes. Specific brands of infusion systems have been FDA approved for the following: chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of baclofen for the management of severe spasticity. Other medications commonly used and acceptable in the pump as defined in the The Polyanalgesic Consensus Conference (PACC) Recommendations on Intrathecal Drug Infusion Systems Best Practices and Guidelines 2017 Tim Deer et al “Neuromodulation: Technology at the Neural Interface”.

a. Due to lack of proven efficacy and safety, the following medications are not recommended: magnesium, benzodiazepines, neostigmine, tramadol, and ketamine.

b. **Description**—This mode of therapy delivers small doses of medications directly into the cerebrospinal fluid.

c. **Complications**—Intrathecal delivery is associated with significant complications, such as infection, catheter disconnects, CSF leak, arachnoiditis, pump failure, nerve injury, and paralysis.

i. Typical adverse events reported with opioids (i.e., respiratory depression, tolerance, and dependence) or spinal catheter-tip granulomas that might arise during intrathecal morphine or hydromorphone treatment have not currently been recorded for ziconotide. The most common presentation of an intraspinal mass is a sudden increase in dosage required for pain relief, with new neurologic defects secondary to a mass effect. Technical errors can lead to drug overdose which can be life-threatening. Withdrawal or death can occur if pump refill is denied or prevented.

ii. Surveys have shown technical problems requiring surgical correction in 18 percent to 40 percent of patients. CSF leakage may occur with multiple dural

punctures since the needle is larger than the spinal catheter. Follow PACC guidelines on efficacy. The function of the pump depends on its electronic power source, which may be disrupted by the magnet of an MRI; therefore, after the patient has an MRI, the pump should be checked immediately after the MRI to ensure that it does not need to be restarted. The delivery rate can be affected by atmospheric pressure and body temperature. Some pumps are recommended to be emptied before the MRI and refilled immediately after the MRI.

d. Indications—Clinical studies are conflicting, regarding long-term, effective pain relief in patients with non-malignant pain. This treatment must be have preauthorization and the recommendation of at least one physician experienced in chronic pain management. The procedure should be performed by physicians with documented experience.

i. Prior to surgical intervention, the patient and treating physician should identify the possible functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work, as well as possible complications. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

ii. Informed decision-making should be documented for all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. Since many patients with the most common conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

e. This small eligible sub-group of patients must meet all of the following indications:

i. ...

ii. All reasonable surgical and non-surgical treatment has been exhausted including failure of conservative therapy including active and/or passive therapy, medication management, or therapeutic injections; and

iii. Pre-trial psychiatric or psychological evaluation has been performed (same as for SCS); and

iv. There is no evidence of current addictive behavior. (Tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation.); and

v. It is recommended that patients be tapered off of opioids before the trial or keep on same dose and wean and stop within two weeks post implant or wean and stop two to three weeks before trial per PACC Guidelines for Trialng; and

vi. A successful trial of continuous infusion by a percutaneous spinal infusion pump for a minimum of 24 hours or by bolus infusion. A screening test is considered successful if the patient (a) experiences a 50 percent decrease in pain, which may be confirmed by VAS, and (b) demonstrates objective functional gains or decreased utilization of other pain medications.

f. Contraindications—Infection, body size insufficient to support the size and weight of the implanted

device. Patients with other implanted programmable devices should be given these pumps with caution since interference between devices may cause unintended changes in infusion rates.

10. Neuroablation with Rhizotomy as the Exception

a. Neuroablation or neuro-destructive procedures are not commonly used in the management of non-malignant pain. These techniques require specific expertise to perform, have erratic results, and high rates of complication. Therefore, the OWCA does not recommend the use of neuroablative procedures, except medial branch nerve rhizotomy, for injured workers with chronic pain.

11. Dorsal Nerve Root Resection: This procedure is not recommended. There exists the possibility of complications including unintended extensive nerve damage causing significant motor or sensibility changes from larger than anticipated lesioning of the ganglia at the dorsal ganglia level. For radio-frequency ablation refer to Radio Frequency Ablation - Dorsal Nerve Root Ganglion.

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HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1711 (June 2011), amended LR 46:246 (February 2020).

§2115. Maintenance Management

A. ...

B. Maintenance care in CRPS and CPD requires a close working relationship between the carrier, the providers, and the patient. Providers and patients have an obligation to design a cost-effective, medically appropriate program that is predictable and allows the carrier to set aside appropriate reserves. Carriers and adjusters have an obligation to assure that medical providers can design medically appropriate programs. Designating a primary physician for maintenance management is strongly recommended.

C. Maintenance care will be based on principles of patient self-management. When developing a maintenance plan of care, the patient, physician and insurer should attempt to meet the following goals:

1. maximal independence will be achieved through the use of home exercise programs or exercise programs requiring special facilities (e.g., pool, health club) and educational programs;

2. modalities will emphasize self-management and self-applied treatment;

3. management of pain or injury exacerbations will emphasize initiation of active therapy techniques and may occasionally require anesthetic injection blocks;

4. dependence on treatment provided by practitioners other than an authorized treating physician will be minimized;

5. reassessment of the patient's function must occur regularly to maintain daily living activities and work function;

6. patients will understand that failure to comply with the elements of the self-management program or therapeutic plan of care may affect consideration of other interventions.

D. It is recommended that valid functional tests are used with treatments to track efficacy. The following are specific maintenance interventions and parameters.

1. Home Exercise Programs and Exercise Equipment. Most patients have the ability to participate in a home

exercise program after completion of a supervised exercise rehabilitation program. Programs should incorporate an exercise prescription including the continuation of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Many patients will benefit from several booster sessions per year, which may include motivational interviewing and graded activity.

a. Some patients may benefit from the purchase or rental of equipment to maintain a home exercise program. Determination for the need of home equipment should be based on medical necessity to maintain MMI, compliance with an independent exercise program, and reasonable cost. Before the purchase or long-term rental of equipment, the patient should be able to demonstrate the proper use and effectiveness of the equipment. Effectiveness of equipment should be evaluated on its ability to improve or maintain functional areas related to activities of daily living or work activity. Prior to purchasing the equipment a physical therapist who has treated the patient may visit a facility with the patient to assure proper use of the equipment. Occasionally, compliance evaluations may be made through a four-week membership at a facility offering similar equipment. Home exercise programs are most effective when done three to five times a week.

2. Exercise Programs Requiring Special Facilities. Some patients may have higher compliance with an independent exercise program at a health club versus participation in a home program. All exercise programs completed through a health club facility should focus on the same parameters of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Selection of health club facilities should be limited to those able to track attendance and utilization, and provide records available for physician and insurer review. Prior to purchasing a membership, a physical therapist who has treated the patient may visit a facility with the patient to assure proper use of the equipment.

a. ...

b. maximum maintenance duration: three months. Continuation beyond three months should be based on functional benefit and patient compliance. Health club membership should not extend beyond three months if attendance drops below two times per week on a regular basis.

3. Patient Education Management. Educational classes, sessions, or programs may be necessary to reinforce self-management techniques. This may be performed as formal or informal programs, either group or individual.

a. ...

4. Psychological Management. An ideal maintenance program will emphasize management options implemented in the following order: individual self-management (pain control, relaxation and stress management, etc.); group counseling; individual counseling by a psychologist or psychiatrist; and in-patient treatment. Exacerbation of the injury may require psychological treatment to restore the patient to baseline. In those cases, use treatments and timeframe parameters listed in the Biofeedback and Psychological Evaluation or Intervention sections.

a. Maintenance duration: 6 to 10 visits during the first year and four to six visits per year thereafter. In cases of

significant exacerbation or complexity, refer to Section G.15, on psychological treatment.

5. Non-opioid medication management: In some cases, self-management of pain and injury exacerbations can be handled with medications, such as those listed in the Medication section. Physicians must follow patients who are on any chronic medication or prescription regimen for efficacy and side effects. Laboratory or other testing may be appropriate to monitor medication effects on organ function.

a. ...

6. Opioid Medication Management. In very selective cases, scheduled opioids or an implanted programmable pump with different medications including opioids may prove to be the most cost effective means of insuring the highest function and quality of life; however, inappropriate selection of these patients may result in a high degree of iatrogenic illness including addiction and drug overdose. A patient should have met the criteria in the opioids section of these guidelines before beginning maintenance opioids. Laboratory or other testing may be appropriate to monitor medication effects on organ function. The following management is suggested for maintenance opioids:

a. The medications should be clearly linked to improvement of function, not just pain control. All follow-up visits should document the patient's ability to perform routine functions satisfactorily. Examples include the abilities to: perform: work tasks, drive safely, pay bills or perform basic math operations, remain alert and upright for 10 hours per day, or participate in normal family and social activities. If the patient is not maintaining reasonable levels of activity the patient should usually be tapered from the opioid and tried on a different long-acting opioid.

b. A low risk opioid medication regimen is defined, as less than 50 MED per day. This may minimally increase or decrease over time. Dosages will need to be adjusted based on side effects of the medication and objective function of the patient. A patient may frequently be maintained on non- opioid medications to control side effects, treat mood disorders, or control neuropathic pain; however, only one long-acting opioid and one short-acting opioid for rescue use should be prescribed. Buccally absorbed opioids other than buprenorphine are not appropriate for these non-malignant pain patients. Transdermal opioid medications are not recommended, other than buprenorphine.

c. All patients on chronic opioid medication dosages need to sign an appropriate opioid contract with their physician for prescribing the opioids.

d. The patient must understand that continuation of the medication is contingent on their cooperation with the maintenance program. Use of non-prescribed drugs may result in tapering of the medication. The clinician should order random drug testing at least annually and when deemed appropriate to monitor medication compliance.

e. Patients on chronic opioid medication dosages must receive them through one prescribing physician.

i. Maintenance duration: 12 visits within a 12-month period to review the opioid plan. Laboratory and other monitoring as appropriate.

7. Therapy Management. Some treatment may be helpful on a continued basis during maintenance care if the therapy maintains objective function and decreases

medication use. With good management, exacerbations should be uncommon; not exceeding two times per year and using minimal or no treatment modality beyond self-management. On occasion, exacerbated conditions may warrant durations of treatment beyond those listed below. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after six to eight visits no treatment effect is observed, alternative treatment interventions should be pursued.

a. Maintenance duration: Active Therapy, Acupuncture, or Manipulation: 10 visits [for each treatment] during the first year and then decreased to five visits per year thereafter.

8. Injection Therapy

a. Trigger Point Injections and Dry Needling. These injections or dry needling may occasionally be necessary to maintain function in those with myofascial problems.

i. Maintenance duration for trigger point injections: not more than four injections per session not to exceed four sessions per 12-month period.

ii. Maintenance duration for dry needling: no more than one to three times per week not to exceed 14 treatments within six months.

b. Epidural and Selective Nerve Root Injections. Patients who have experienced functional benefits from these injections in the past may require injection for exacerbations of the condition. Recall that the total steroid injections at all sites, including extremities, should be limited to 3-4 mg/kg per rolling 12 months to avoid side effects from steroids.

i. Maintenance duration: two to four injections per 12-month period. For chronic radiculopathy or post herpetic neuralgia or intercostal neuralgia, injections may be repeated only when a functional documented response produces a positive result. A positive result could include positive pain response, a return to baseline function as established at MMI, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met and verified by the designated primary physician.

c. Time Frames for Zygapophyseal (Facet) Injections

i. Maintenance duration: four injections per year and limited to three joint levels either unilaterally or bilaterally as in Facet Joint and Medial Branch Facet Joint. Injections may be repeated (instead of proceeding with RF) only when a functional documented response lasts for three months. A positive result would include a return to baseline function as established at MMI, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met and verified by the designated primary physician.

d. Time Frames for Radiofrequency Medial Branch Neurotomy/ Facet Rhizotomy and Sacroiliac joint (lateral Branch Neurotomy and other peripheral nerves listed in these rules.

i. Maintenance duration: two times per year not exceeding three levels. The patient must meet the criteria as described in Radio Frequency Denervation. The initial indications including repeat blocks and limitations apply. The long-term effects of repeat rhizotomies, especially on younger patients are unknown. In addition, the patient should always reconsider all of the possible permanent complications before consenting to a repeat procedure. There are no studies addressing the total number of RF neurotomies that should be done for a patient. Patient should receive at least six months with improvement of 50 percent or more in order to qualify for repeat procedures.

ii. optimum/maximum maintenance Duration: twice a year after the initial rhizotomy.

9. Purchase or Rental of Durable Medical Equipment (DME). It is recognized that some patients may require ongoing use of self-directed modalities for the purpose of maintaining function and/or analgesic effect. Purchase or rental of modality based equipment should be done only if the assessment by the physician and/or physical/occupational therapist has determined the effectiveness, compliance, and improved or maintained function by its application. It is generally felt that large expense purchases such as spas, whirlpools, and special mattresses are not necessary to maintain function.

10. Implanted Programmable Pumps or Implanted Spinal Cord Stimulators. Facet pain, Sacroiliac joint pain, Genicular nerve pain, peripheral nerve pain and occasional acute exacerbation of radicular pain is common in patients with these implanted devices. It is necessary to continue to treat previously treated Genicular nerve pain, facet pain, sacroiliac joint pain, peripheral nerve pain and occasional radicular pain with injections, and maintenance RF Ablation and occasional Epidural injections as listed elsewhere in these rules. The presence of these implanted devices does not preclude diagnosis and treatment of these conditions as well as maintenance of these conditions both before and after implantation of these devices. Also these implanted devices require regular maintenance, adjustments; pump refills every one to six months, stimulator adjustments and management for the life of these devices.

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HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1713 (June 2011), amended LR 46:250 (February 2020).

Subchapter B. Complex Regional Pain Syndrome

Editor's Note: Form LWC-WC 1009, Disputed Claim for Medical Treatment has been moved to §2328 of this Part.

§2117. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation (OWCA) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana's Workers' Compensation Act as injured workers with cervical spine injuries. Although the primary purpose of this document is advisory and educational, these guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers'

Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical Care, services, and treatment that varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1716 (June 2011), amended LR 46:252 (February 2020).

§2119. General Guideline Principles

A. The principles summarized in this Section are key to the intended implementation of all Office of Workers' Compensation medical treatment guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Worker's Compensation Act.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of workers' compensation injuries. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth education is currently a component of treatment regimens which employ functional, restorative, preventive and rehabilitative programs. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention. Facilitation through language interpretation, when necessary, is a priority and part of the medical care treatment protocol.

3. Treatment parameter duration time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient adherence, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with R.S. 23:1203.1.

4. - 5. ...

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured.

a. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, ability to function at work, cognition, psychological behavior, and

efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-Evaluation of Treatment Every Three to Four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, or within the time to produce effect in the non-chronic pain guidelines, the patient should be re-evaluated by the treating physician that referred him to PT and consideration should be given for a referral to a pain specialist or surgeon or other appropriate specialist for other treatment options. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. ...

10. Six Month-Time Frame. Injuries resulting in temporary total disability require maintenance treatment and may not attain return to work in six months.

11. Return To Work. Return to work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. An injured worker's return-to-work status shall not be the sole cause to deny reasonable and medically necessary treatment under these guidelines. Two good practices are: early contact with injured workers and provide modified work positions for short-term injuries. The practitioner may provide specific physical limitations and the patient should never be released to non-specific and vague descriptions such as "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, from including, but not limited to, occupational health nurse, physical therapist, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist, chiropractor or another professional. American Medical Association clarifies "disability" as "activity limitations and/or participation restrictions in an individual with a health condition, disorder or disease" versus "impairment" as "a significant deviation, loss, or loss of use of any body structure or body function in an individual with a health condition, disorder or disease".

12. Delayed Recovery. Within the discretion of the treating physician, strongly consider a psychological

evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after initiation of treatment of an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment requires clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

13. Recommendations and Inclusion of Medical Evidence. All recommendations are based on available evidence and/or consensus judgment. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. When interpreting medical evidence statements in the guideline, the following apply to the strength of recommendation.

Strong	Level 1 Evidence	We Recommend
Moderate	Level 2 and Level 3 Evidence	We Suggest
Weak	Level 4 Evidence	Treatment is an Option
Inconclusive	Evidence is Either Insufficient or Conflicting	

a. ...

14. Treatment of Pre-Existing Conditions The conditions that preexisted the work injury/disease will need to be managed under two circumstances: (a) A pre-existing condition exacerbated by a work injury/disease should be treated until the patient has returned to their objectively verified prior level of functioning or Maximum Medical Improvement (MMI); and (b) A pre-existing condition not directly caused by a work injury/disease but which may prevent recovery from that injury should be treated until its objectively verified negative impact has been controlled. The focus of treatment should remain on the work injury/disease.

B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1716 (June 2011), amended by the Louisiana Workforce Commission, Office of Workers Compensation, LR 40:1157 (June 2014), amended LR 46:253 (February 2020).

§2125. Initial Evaluation

A. - A.1.e.v. ...

vi. Pre-existing Conditions. Treatment of these conditions is appropriate when the preexisting condition is aggravated by work related injury.

f. - f.vi. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1718 (June 2011), amended LR 46:254 (February 2020).

§2127. Diagnostic Procedures

A. - A.2.b. ...

B. Injections—diagnostic sympathetic

1. - 2. ...

a. Since fluoroscopic and/or CT guidance during procedures is recommended to document technique and needle placement, an experienced physician should perform the procedure. The practitioner should have experience in ongoing injection training workshops provided by organizations such as the American Society of Interventional Pain Physicians (ASIPP) or Spine Intervention Society (SIS) and be knowledgeable in radiation safety. In addition, practitioners should obtain fluoroscopy training and radiation safety credentialing from their Departments of Radiology, as applicable.

3. - 5.a. ...

i. Stellate Ganglion Block. For diagnosis and treatment of sympathetic pain involving the face, head, neck, and upper extremities secondary to CRPS-I and II. This block is commonly used for differential diagnosis and is the preferred treatment of CRPS-I pain involving the upper extremity. Kuntz Fiber Blockade (T1-T3 sympathetic chain) on the affected side is necessary for upper extremity pain not responsive to stellate ganglion blockade.

5.a.i.(a). - 5.a.iii. ...

iv. Thoracic Sympathetic Block. Useful for abdominal or pelvic visceral pain secondary to CRPS I and II. Use the same guidance as for lumbar sympathetic Block.

C. Thermography (infrared stress thermography)

1 - 4.b. ...

c. Digital infrared temperature monitoring should be used before and after sympathetic block where indicated to evaluate response to sympatholytic intervention.

D. - D.3.c. ...

E. Other Diagnostic Tests Not Specific for CRPS. The following tests and procedures are not used to establish the diagnosis of CRPS but may provide additional information. The following are listed in alphabetical order.

1. - 4. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1719 (June 2011), amended LR 46:254 (February 2020).

§2131. Therapeutic Procedures—Non-Operative

A. - C.4.a.iv.(b). ...

b. Sympathetic Injections

i. Description. Sympathetic injections are generally accepted, well-established procedures. They include stellate ganglion blocks, Kuntz Fiber blocks, thoracic sympathetic blocks, lumbar sympathetic, and intravenous regional (Bier) blocks. Regional blocks frequently use bretylium with additional agents (narcotics and or anti-inflammatory drugs). There is some evidence that bretylium reduces pain intensity. It is recommended that all patients receiving therapeutic blocks participate in PT and/or OT immediately after each block as well as in an appropriate exercise program that may include a functionally directed rehabilitation program.

ii. ...

iii. Special Considerations. Except for Bier blocks, fluoroscopic and/or CT guidance during procedures is recommended to document technique and needle placement; an experienced physician should perform the procedure. The practitioner should participate in ongoing injection training workshops provided by organizations such as the American

Society of Interventional Pain Physicians (ASIPP) and the Spinal Intervention Society (SIS) and be knowledgeable in radiation safety. In addition, practitioners should obtain fluoroscopy training and radiation safety credentialing from their Departments of Radiology, as applicable.

iv. - vi.(a). ...

(b). Frequency: Variable, depending upon duration of pain relief and functional gains. During the first two weeks of treatment, blocks may be provided every three to five days, based on patient response. After the first two weeks, blocks may be given weekly with tapering for a maximum of seven injections over six weeks. If pain relief and functional gains plateau before seven injections in six weeks, a trial of spinal cord or DRG spinal stimulation should be considered. Refer to chronic pain guidelines for treatment parameters.

(c). - (g). ...

vii. Radiofrequency Sympathectomy in CRPS

(a). Thoracic, Lumbar and Sacral sympathetic ganglia, including Kuntz Fibers, Splanchnic Ganglia, sacral and L5 sympathetic ganglia, can be treated with RF ablation after successful diagnostic blocks with at least 50 percent relief of pain and improved function. This procedure can be repeated no more than every 6 months.

5. - 5.b....

c. Inpatient pain rehabilitation programs are rarely needed but may be necessary for patients with any of the following conditions: High risk for medical instability; Moderate to severe impairment of physical/functional status; Moderate to severe pain behaviors; Moderate impairment of cognitive and/or emotional status; Dependence on medications from which he or she needs to be withdrawn; and the need for 24-hour supervised nursing.

d. Interdisciplinary pain programs, whether formal or informal, should be comprised of the following dimensions:

i. Communication. To ensure positive functional outcomes, communication between the patient, insurer and all professionals involved must be coordinated and consistent. Any exchange of information must be provided to all professionals, including the patient. Care decisions would be communicated to all.

ii. Documentation. Through documentation by all professionals involved and/or discussions with the patient, it should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification.

iii. Treatment Modalities. Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of Active and Passive Therapies, refer to those Subparagraphs of this guideline. All treatment timeframes may be extended based upon the patient's positive functional improvement.

iv. Therapeutic Exercise Programs. There is strong evidence that these programs, including aerobic conditioning and strengthening, are superior to treatment programs that do not include exercise. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen. A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an on-going exercise regime.

v. Return-to-Work. The authorized treating physician should continually evaluate the patient for their potential to return to work. When return-to-work is an option, it may be appropriate to implement a Work Hardening Program (as described in this Section). For patients currently employed, efforts should be aimed at keeping them employed. For more specific information regarding return-to-work, refer to the Return-to-work section in this guideline.

vi. Patient Education. Patients with pain need to re-establish a healthy balance in lifestyle. All providers should educate patients on how to overcome barriers to resuming daily activity, including pain management, decreased energy levels, financial constraints, decreased physical ability, and change in family dynamics.

vii. Psychosocial Evaluation and Treatment. Psychosocial evaluation should be initiated, if not previously done. Providers of care should have a thorough understanding of the patient's personality profile; especially if dependency issues are involved. Psychosocial treatment may enhance the patient's ability to participate in pain treatment rehabilitation, manage stress, and increase their problem-solving and self-management skills.

viii. Vocational Assistance. Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to Return-to-work section for detailed information.

e. Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning and psychological involvement. The following programs are listed in order of decreasing intensity.

i. Formal Rehabilitation Programs

(a). Interdisciplinary Pain Rehabilitation. An Interdisciplinary Pain Rehabilitation Program provides outcomes-focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons with pain and encourage their appropriate use of health care system and services. The program can benefit persons who have limitations that interfere with their physical, psychological, social, and/or vocational functioning. The program shares information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

(b). The interdisciplinary team maintains consistent integration and communication to ensure that all interdisciplinary team members are aware of the plan of care for the patient, are exchanging information, and implement the plan of care. The team members make interdisciplinary

team decisions with the patient and then ensure that decisions are communicated to the entire care team.

(c). The medical director of the pain program should be board certified in his or her specialty area, have at least two years full-time experience in an interdisciplinary pain rehabilitation program, and ideally be board certified in pain management. Individuals who assist in the accomplishment of functional, physical, psychological, social and vocational goal must include, at the least, a medical director, pain physician(s), psychologist, Biofeedback Therapist, Occupational Therapist, Physical Therapist, and Registered Nurse. Other disciplines on the team may include, but are not limited to, case manager, exercise physiologist, psychiatrist, and/or nutritionist.

(i). time to produce effect: three to four weeks;

(ii). frequency: No less than five hours/day, five days/week;

(iii). optimum duration: three to four weeks five times a week, followed by six to nine weeks of follow-up one to three times a week;

(iv). maximum duration: four months, including follow-up. Periodic review and monitoring thereafter on an as needed basis, is founded upon the documented maintenance of functional gains.

(d). Work hardening is an interdisciplinary program addressing a patient's employability and return-to-work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. A full workday is case specific and is defined by the previous employment of the patient. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

(e). The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation, team physicians having experience in occupational rehabilitation, occupational therapy, physical therapy, case manager, and psychologist. As appropriate, the team may also include: chiropractor, RN, or vocational specialist.

(i). time to produce effect: two weeks;

(ii). frequency: two to five visits per week, up to eight hours/day;

(iii). optimum duration: two to four weeks;

(iv). maximum duration: six weeks.

Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Informal Rehabilitation Program. A coordinated interdisciplinary pain rehabilitation program is one in which the authorized treating physician coordinates all aspects of care. This type of program is similar to the formal programs in that it is goal oriented and provides interdisciplinary rehabilitation services to manage the needs of the patient in the following areas: functional, medical, physical, psychological, social, and vocational.

(a). This program is different from a formal program in that it involves lesser frequency and intensity of services/treatment. Informal rehabilitation is geared toward those patients who do not need the intensity of service

offered in a formal program or who cannot attend an all-day program due to employment, daycare, language or other barriers.

(b). Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The OWCA recommends the authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop the plan of care.

(i). time to produce effect: three to eight weeks;

(ii). frequency: two to six hours per day, two to five days each week;

(iii). optimum duration: 6 to 12 weeks, including follow-up;

(iv). maximum duration: four months, including follow-up. Periodic review and monitoring thereafter on an as needed basis, is founded upon the documented maintenance of functional gains.

6. - 6.a. ...

b. All medications should be given an appropriate trial in order to test for therapeutic effect. Trials of medication requiring specific therapeutic drug levels may take several months to achieve, depending upon the half-life of the drug. It is recommended that patients with CRPS be maintained on drugs that have the least serious side effects. For example, patients need to be tried or continued on acetaminophen and or antidepressant medications whenever feasible as part of their overall treatment for chronic pain. It is recommended that use of opioid analgesic and sedative hypnotic medications in chronic pain patients be used in a very limited manner, with total elimination desirable whenever clinically feasible. See Chronic Pain Medication Section for further guidance.

c. For the clinician to interpret the following material, it should be noted that: drug profiles listed are not complete; dosing of drugs will depend upon the specific drug, especially for off-label use; and not all drugs within each class are listed, and other drugs within the class may be appropriate for individual cases. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar medications or when there is a concern regarding drug interactions.

d. ...

i. Anticonvulsants. Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, they appear to act as channel blocking agents. A large variety of sodium channels are present in nervous tissue, and some of these are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Gabapentin and pregabalin, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. All patients on these medications should be monitored for suicidal ideation. Many of these medications are not recommended for women of child-bearing age due to possible teratogenic effects.

(a). Gabapentin and pregabalin are commonly prescribed for neuropathic pain. There is an association between older anticonvulsants including gabapentin and non-traumatic fractures for patients older than 50; this

should be taken into account when prescribing these medications.

(b). Gabapentin and pregabalin have indirect (not GABA A or GABA B receptor mediated) GABA-mimetic qualities rather than receptor mediated actions. This can potentially result in euphoria, relaxation, and sedation. It is likely that they also affect the dopaminergic “reward” system related to addictive disorders. Misuse of these medications usually involves doses 3 to 20 times that of the usual therapeutic dose. The medication is commonly used with alcohol or other drugs of abuse. Providers should be aware of the possibility and preferably screen patients for abuse before prescribing these medications. Withdrawal symptoms, such as insomnia, nausea, headache, or diarrhea, are likely when high doses of pregabalin have been used. Tolerance can also develop.

(c). Gabapentin (Fanatrex, Gabarone, Gralise, Horizant, Neurontin)

(i). Description—Structurally related to gamma aminobutyric acid (GABA) but does not interact with GABA receptors. Gabapentin affects the alpha-2-delta-1 ligand of voltage gated calcium channels, thus inhibiting neurotransmitter containing intra-cellular vesicles from fusing with the pre-synaptic membranes and reducing primary afferent neuronal release of neurotransmitters (glutamate, CGRP, and substance P). It may also modulate transient receptor potential channels, NMDA receptors, protein kinase C and inflammatory cytokines, as well as possibly stimulating descending norepinephrine mediated pain inhibition.

(ii). Indications—As of the time of this guideline writing, formulations of gabapentin have been FDA approved for post-herpetic neuralgia and partial onset seizures.

[a]. There is strong evidence that gabapentin is more effective than placebo in the relief of painful diabetic neuropathy and post-herpetic neuralgia.

[b]. There is some evidence that gabapentin may benefit some patients with post-traumatic neuropathic pain. There is good evidence that gabapentin is not superior to amitriptyline. There is some evidence that nortriptyline (Aventyl, Pamelor) and gabapentin are equally effective for pain relief of postherpetic neuralgia. There is some evidence that the combination of gabapentin and morphine may allow lower doses with greater analgesic effect than the drugs given separately. There is strong evidence that gabapentin is more effective than placebo for neuropathic pain, even though it provides complete pain relief to a minority of patients. There is some evidence that a combination of gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug.

(iii). Relative Contraindications—Renal insufficiency. Dosage may be adjusted to accommodate renal dysfunction.

(iv). Dosing and Time to Therapeutic Effect—Dosage should be initiated at a low dose in order to avoid somnolence and may require four to eight weeks for titration. Dosage should be adjusted individually. It is taken three to four times per day, and the target dose is 1800 mg.

(v). Major Side Effects—Confusion, sedation, dizziness, peripheral edema. Patients should also be monitored for suicidal ideation and drug abuse.

(vi). Drug Interactions—antacids.

(vii). Laboratory Monitoring—Renal function.

ii. ...

(a). Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression. First line drugs for neuropathic pain are the tricyclics with the newer formulations having better side effect profiles. SNRIs are considered second line drugs due to their costs and the number needed to treat for a response. Duloxetine may be considered for first line use in a patient who is a candidate for pharmacologic treatment of both chronic pain and depression. SSRIs are used generally for depression rather than neuropathic pain and should not be combined with moderate to high-dose tricyclics.

(b). All patients being considered for antidepressant therapy should be evaluated and continually monitored for suicidal ideation and mood swings.

(i). Tricyclics and Older Agents (e.g., amitriptyline, nortriptyline, doxepin [Silenor, Sinequan, Adapin], desipramine [Norpramin, Pertofrane], imipramine [Tofranil], trazodone [Desyrel, Oleptro])

[a]. Description—Serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing CNS serotonergic tone can help decrease pain perception in non-antidepressant dosages. TCAs decrease reabsorption of both serotonin and norepinephrine. They also impact Na channels. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain. However, higher doses may produce more cholinergic side effects than newer tricyclics such as nortriptyline and desipramine. Doxepin and trimipramine also have sedative effects.

[i]. There is some evidence that a combination of some gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug, without increasing side effects of either drug.

[b]. Indications—Some formulations are FDA approved for depression and anxiety. For the purposes of this guideline, they are recommended for neuropathic pain and insomnia. They are not recommended as a first line drug treatment for depression.

[c]. Major Contraindications—Cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, high suicide risk, uncontrolled hypertension and orthostatic hypotension. A screening cardiogram may be done for those 40 years of age or older, especially if higher doses are used. Caution should be utilized in prescribing TCAs. They are not recommended for use in elderly patients 65 years of age or older, particularly if they are at fall risk.

[d]. Dosing and Time to Therapeutic Effect—Varies by specific tricyclic. Low dosages, less than 100 mg, are commonly used for chronic pain and/or insomnia. Lower doses decrease side effects and cardiovascular risks.

[e]. Major Side Effects—Side effects vary according to the medication used; however, the side effect profile for all of these medications is generally higher in all areas except GI distress, which is more common among the SSRIs and SNRIs. Anticholinergic side effects including, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, urinary retention, and weight gain. Dry mouth leads to dental and periodontal conditions (e.g., increased cavities). Patients should also be monitored for suicidal ideation and drug abuse. Anticholinergic side effects are more common with tertiary amines (amitriptyline, imipramine, doxepin) than with secondary amines (nortriptyline and desipramine).

[f]. Drug Interactions—Tramadol (may cause seizures, both also increase serotonin/norepinephrine, so serotonin syndrome is a concern), clonidine, cimetidine (Tagamet), sympathomimetics, valproic acid (Depakene, Depakote, Epilim, Stavzor), warfarin (Coumadin, Jantoven, Marfarin), carbamazepine, bupropion (Aplezin, Budeprion, Buproban, Forfivo, Wellbutrin, Zyban), anticholinergics, quinolones.

[g]. Recommended Laboratory Monitoring—Renal and hepatic function. Electrocardiogram (EKG) for those on high dosages or with cardiac risk.

iv. Opioids are the most powerful analgesics. Their use in acute pain and moderate-to-severe cancer pain is well accepted. Their use in chronic nonmalignant pain, however, is fraught with controversy and lack of scientific research. Deaths in the United States from opioids have escalated in the last 15 years. The CDC states the following in their 2016 Primary Care guideline for prescribing opioids: Opioid pain medication use presents serious risk, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States. In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly. Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths. The Drug Abuse Warning Network estimated that less than 420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available. Opioid poisoning has also been identified in work-related populations.

(a). Effectiveness and Side Effects: Opioids include some of the oldest and most effective drugs used in the control of severe pain. The discovery of opioid receptors and their endogenous peptide ligands has led to an understanding of effects at the binding sites of these naturally occurring substances. Most of their analgesic effects have been attributed to their modification of activity in pain pathways within the central nervous system; however, it has become evident that they also are active in the peripheral nervous system. Activation of receptors on the peripheral terminals of primary afferent nerves can mediate anti-nociceptive effects, including inhibition of neuronal excitability and release of inflammatory peptides. Some of their undesirable effects on inhibiting gastrointestinal motility are peripherally mediated by receptors in the bowel wall.

(i). Most studies show that only around 50 percent of patients tolerate opioid side effects and receive an acceptable level of pain relief. Depending on the diagnosis and other agents available for treatment, the incremental benefit can be small.

(ii). There is good evidence that opioids are more efficient than placebo in reducing neuropathic pain by clinically significant amounts. There is a lack of evidence that opioids improve function and quality of life more effectively than placebo. There is good evidence that opioids produce significantly more adverse effects than placebo such as constipation, drowsiness, dizziness, nausea, and vomiting. There is a lack of evidence that they are superior to gabapentin or nortriptyline for neuropathic pain reduction.

(iii). Patients should have a thorough understanding of the need to pursue many other pain management techniques in addition to medication use in order to function with chronic pain. They should also be thoroughly aware of the side effects and how to manage them. There is strong evidence that adverse events such as constipation, dizziness, and drowsiness are more frequent with opioids than with placebo. Common side effects are drowsiness, constipation, nausea, and possible testosterone decrease with longer term use.

(b). Hyperalgesia: Administration of opioid analgesics leads not only to analgesia, but may also lead to a paradoxical sensitization to noxious stimuli. Opioid induced hyperalgesia has been demonstrated in animals and humans using electrical or mechanical pain stimuli. This increased sensitivity to mildly painful stimuli does not occur in all patients and appears to be less likely in those with cancer, clear inflammatory pathology, or clear neuropathic pain. When hyperalgesia is suspected, opioid tapering is appropriate.

(c). Opioid Induced Constipation (OIC): Some level of constipation is likely ubiquitous among chronic opioid users. An observational study of chronic opioid users who also used some type of laxative at least four times per week noted that approximately 50 percent of the patients were dissatisfied and they continue to report stool symptoms. 71 percent used a combination of natural and dietary treatment, 64.3 percent used over-the-counter laxatives, and 30 percent used prescription laxatives. Other studies report similar percentages. There are insufficient quality studies to recommend one specific type of laxative over others.

(i). The easiest method for identifying constipation, which is also recommended by a consensus, multidisciplinary group, is the Bowel Function Index. It assesses the patient's impression over the last seven days for ease of defecation, feeling of incomplete bowel evacuation, and personal judgment re-constipation.

(ii). Stepwise treatment for OIC is recommended, and all patients on chronic opioids should receive information on treatment for constipation. Dietary changes increasing soluble fibers are less likely to decrease OIC and may cause further problems if GI motility is decreased. Stool softeners may be tried, but stimulant and osmotic laxatives are likely to be more successful. Osmotic laxatives include lactulose and polyethylene glycol. Stimulants include bisacodyl, sennosides, and sodium

picosulfate, although there may be some concern regarding use of stimulants on a regular basis.

(iii). Opioid rotation or change in opioids may be helpful for some patients. It is possible that sustained release opioid products cause more constipation than short acting agents due to their prolonged effect on the bowel opioid receptors. Tapentadol is a u-opioid agonist and norepinephrine reuptake inhibitor. It is expected to cause less bowel impairment than oxycodone or other traditional opioids. Tapentadol may be the preferred opioid choice for patients with OIC.

(iv). Other prescription medications may be used if constipation cannot adequately be controlled with the previous measures. Naloxegol is a pegylated naloxone molecule that does not pass the blood brain barrier and thus can be given with opioid therapy. There is good evidence that it can alleviate OIC and that 12.5 mg starting dose has an acceptable side effect profile.

(v). Methylnaltrexone does not cross the blood brain barrier and can be given subcutaneously or orally. It is specifically recommended for opioid induced constipation for patients with chronic non-cancer pain.

(vi). Misoprostol is a synthetic prostaglandin E1 agonist and has the side effect of diarrhea in some patients. It also has been tried for opioid induced constipation, although it is not FDA approved for this use.

(vii). Naldemedine is an opioid antagonist indicated for the treatment of opioid-induced constipation in adult patients with chronic pain.

(viii). Lubiprostone is a prostaglandin E1 approved for use in opioid constipation.

(ix). Most patients will require some therapeutic control for their constipation. The stepwise treatment discussed should be followed initially. If that has failed and the patient continues to have recurrent problems with experiencing severe straining, hard or lumpy stool with incomplete evacuation, or infrequent stools for 25 percent of the time despite the more conservative measures, it may be appropriate to use a pharmaceutical agent.

(d). Physiologic Responses to Opioids. Physiologic responses to opioids are influenced by variations in genes which code for opiate receptors, cytochrome P450 enzymes, and catecholamine metabolism. Interactions between these gene products significantly affect opiate absorption, distribution, and excretion. Hydromorphone, oxycodone, and morphine are metabolized through the glucuronide system. Other opioids generally use the cytochrome P450 system. Allelic variants in the mu opiate receptor may cause increased analgesic responsiveness to lower drug doses in some patients. The genetic type can predict either lower or higher needs for opioids. For example, at least 10 percent of Caucasians lack the CYP450 2D6 enzyme that converts codeine to morphine. In some cases, genetic testing for cytochrome P450 type may be helpful. When switching patients from codeine to other medications, assume the patient has little or no tolerance to opioids. Many gene-drug associations are poorly understood and of uncertain clinical significance. The treating physician needs to be aware of the fact that the patient's genetic makeup may influence both the therapeutic response to drugs and the occurrence of adverse effects. A Comprehensive genetic testing panel may be ordered by

treating physician for these multiple P450 genes once in a lifetime and utilized whenever there is a question of metabolism or unusual response of any drugs used to treat pain conditions, because multiple drugs and associated genes can cause problems with opioid metabolism

(e). Adverse Events. Physicians should be aware that deaths from unintentional drug overdoses exceed the number of deaths from motor vehicle accidents in the US. Most of these deaths are due to the use of opioids, usually in combination with other respiratory depressants such as alcohol or benzodiazepines. The risk for out of hospital deaths not involving suicide was also high. The prevalence of drug abuse in the population of patients undergoing pain management varies according to region and other issues. One study indicated that one-fourth of patients being monitored for chronic opioid use have abused drugs occasionally, and one-half of those have frequent episodes of drug abuse. 80 percent of patients admitted to a large addiction program reported that their first use of opioids was from prescribed medication.

(i). There is good evidence that in generally healthy patients with chronic musculoskeletal pain, treatment with long-acting opioids, compared to treatments with anticonvulsants or antidepressants, is associated with an increased risk of death of approximately 69 percent, most of which arises from non-overdose causes, principally cardiovascular in nature. The excess cardiovascular mortality principally occurs in the first 180 days from starting opioid treatment.

(ii). There is some evidence that compared to an opioid dose under 20 MED per day, a dose of 20-50 mg nearly doubles the risk of death, a dose of 50 to 100 mg may increase the risk more than fourfold, and a dose greater than 100 mg per day may increase the risk as much as sevenfold. However, the absolute risk of fatal overdose in chronic pain patients is fairly low and may be as low as 0.04 percent. There is good evidence that prescription opioids in excess of 200 MED average daily doses are associated with a near tripling of the risk of opioid-related death, compared to average daily doses of 20 MED. Average daily doses of 100-200 mg and doses of 50-99 mg per day may be associated with a doubling of mortality risk, but these risk estimates need to be replicated with larger studies.

(iii). Doses of opioids in excess of 120 MED have been observed to be associated with increased duration of disability. Higher doses are more likely to be associated with hypo-gonadism, and the patient should be informed of this risk. Higher doses of opioids also appear to contribute to the euphoric effect. The CDC recommends Primary Care Practitioners limiting to 90 MED per day to avoid increasing risk of overdose or referral to a pain specialist.

(iv). In summary, there is strong evidence that any dose above 50 MED per day is associated with a higher risk of death and 100 mg or greater appears to significantly increase the risk. Interventional techniques such as spinal cord stimulation or intrathecal catheters and programmable pumps should be considered in order to stop oral opioids usage.

(v). Workers who eventually are diagnosed with opioid abuse after an injury are also more likely to have higher claims cost. A retrospective observational cohort

study of workers' compensation and short-term disability cases found that those with at least one diagnosis of opioid abuse cost significantly more in days lost from work for both groups and in overall healthcare costs for the short-term disability groups. About 0.5 percent of eligible workers were diagnosed with opioid abuse.

(f). Dependence versus Addiction. The central nervous system actions of these drugs account for much of their analgesic effect and for many of their other actions, such as respiratory depression, drowsiness, mental clouding, reward effects, and habit formation. With respect to the latter, it is crucial to distinguish between two distinct phenomena: dependence and addiction.

(i). Dependence is a physiological tolerance and refers to a set of disturbances in body homeostasis that leads to withdrawal symptoms, which can be produced with abrupt discontinuation, rapid reduction, decreasing blood levels, and/or by administration of an antagonist.

(ii). Addiction is a primary, chronic, neurobiological disease, with genetic, psychological, and environmental factors influencing its development and manifestations. It is a behavioral pattern of drug craving and seeking which leads to a preoccupation with drug procurement and an aberrant pattern of use. The drug use is frequently associated with negative consequences.

(iii). Dependence is a physiological phenomenon, which is expected with the continued administration of opioids, and need not deter physicians from their appropriate use. Before increasing the opioid dose, the physician should review other possible causes for the decline in analgesic effect. Increasing the dose may not result in improved function or decreased pain. Remember that it is recommended for total morphine milligram equivalents (MME) per day to remain at 50 or below. Consideration should be given to possible new psychological stressors or an increase in the activity of the nociceptive pathways. Other possibilities include new pathology, low testosterone level that impedes delivery of opioids to the central nervous system, drug diversion, hyperalgesia, or abusive use of the medication.

(g). Choice of Opioids. No long-term studies establish the efficacy of opioids over one year of use or superior performance by one type. There is no evidence that one long-acting opioid is more effective than another, or more effective than other types of medications, in improving function or pain. There is some evidence that long-acting oxycodone (Dazidox, Endocodone, ETH-oxycodone, Oxycontin, Oxyfast, OxyIR, Percolone, Roxicodone) and oxymorphone have equal analgesic effects and side effects, although the milligram dose of oxymorphone (Opana) is one-half that of oxycodone. There is no evidence that long-acting opioids are superior to short-acting opioids for improving function or pain or causing less addiction. A number of studies have been done assessing relief of pain in cancer patients. A recent systematic review concludes that oxycodone does not result in better pain relief than other strong opioids including morphine and oxymorphone. It also found no difference between controlled release and immediate release oxycodone. There is some evidence that extended release hydrocodone has a small and clinically unimportant advantage over placebo for relief of chronic low

back pain among patients who are able to tolerate the drug and that 40 percent of patients who begin taking the drug do not attain a dose which provides pain relief without unacceptable adverse effects. Hydrocodone ER does not appear to improve function in comparison with placebo. A Cochrane review of oxycodone in cancer pain also found no evidence in favor of the longer acting opioid. There does not appear to be any significant difference in efficacy between once daily hydromorphone and sustained release oxycodone. Nausea and constipation are common for both medications between 26 to 32 percent. November 21, 2017, the FDA Commissioner, Scott Gottlieb, M.D., issued a Statement to promote development of generic versions of opioids formulated to deter abuse. One year earlier the FDA issued a statement encouraging development of Abuse Deterrent Formulations for opioids as a meaningful health benefit designed to reduce opioid abuse in the U.S. and to potentially and eventually remove conventional non deterrent opioids from the market if found to be unsafe.

(i). There is some evidence that in the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline.

(ii). Long-acting opioids should not be used for the treatment of acute, sub-acute, or post-operative pain, as this is likely to lead to drug dependence and difficulty tapering the medication. Additionally, there is a potential for respiratory depression to occur. The FDA requires that manufacturers develop Risk Evaluation and Mitigation Strategies (REMS) for most opioids. Physicians should carefully review the plans or educational materials provided under this program. Clinical considerations should determine the need for long-acting opioids given their lack of evidence noted above.

(iii). Addiction and abuse potentials of commonly prescribed opioid drugs may be estimated in a variety of ways, and their relative ranking may depend on the measure which is used. One systematic study of prescribed opioids estimated rates of drug misuse were estimated at 21 to 29 percent and addiction at 8 to 12 percent. There is good evidence that in the setting of new onset chronic non-cancer pain, there is a clinically important relationship between opioid prescription and subsequent opioid use disorder. Compared to no opioid use, short-term opioid use approximately triples the risk of opioid use disorder in the next 18 months. Use of opioids for over 90 days is associated with very pronounced increased risks of the subsequent development of an opioid use disorder, which may be as much as one hundredfold when doses greater than 120 MED are taken for more than 90 days. The absolute risk of these disorders is very uncertain but is likely to be greater than 6.1 percent for long duration treatment with a high opioid dose. Pain physicians should be consulted when the MED reaches 100 to develop an updated treatment plan

(iv). Hydrocodone is the most commonly prescribed opioid in the general population and is one of the most commonly abused opioids in the population. However, the abuse rate per 1000 prescriptions is lower than the corresponding rates for extended release oxycodone, hydromorphone (Dilaudid, Palladone), and methadone.

Extended release oxycodone appears to be the most commonly abused opioid, both in the general population and in the abuse rate per 1000 prescriptions. Tramadol, by contrast, appears to have a lower abuse rate than for other opioids.

(v). Types of opioids are listed below.

[a]. Buprenorphine: (various formulations) is prescribed as an intravenous injection, transdermal patch, buccal film, or sublingual tablet due to lack of bioavailability of oral agents. Depending upon the formulation, buprenorphine may be indicated for the treatment of pain or for the treatment of opioid dependence (addiction).

[i]. Buprenorphine for Opioid Dependence (addiction). FDA has approved a number of buccal films including those with naloxone and a sublingual tablet to treat opioid dependence (addiction).

[ii]. Buprenorphine for Pain: The FDA has approved specific forms of an intravenous and subcutaneous injectable, transdermal patch, and a buprenorphine buccal film to treat pain. However, by law, the transdermal patch and the injectable forms cannot be used to treat opioid dependence (addiction), even by DATA-2000 waived physicians authorized to prescribe buprenorphine for addiction. Transdermal forms may cause significant skin reaction. Buprenorphine is not recommended for most chronic pain patients due to methods of administration, reports of euphoria in some patients, and lack of proof for improved efficacy in comparison with other opioids.

[iii]. There is insufficient evidence to support or refute the suggestion that buprenorphine has any efficacy in any neuropathic pain condition.

[iv]. There is good evidence transdermal buprenorphine is not inferior to oral tramadol in the treatment of moderate to severe musculoskeletal pain arising from conditions like osteoarthritis and low back pain. The population of patients for whom it is more appropriate than tramadol is not established but would need to be determined on an individual patient basis if there are clear reasons not to use oral tramadol. In a well-done study, 63 percent of those on buccal buprenorphine achieved a 30 percent or more decrease in pain at 12 weeks compared to a 47 percent placebo response. Approximately 40 percent of the initial groups eligible for the study dropped out during the initial phase when all patients received the drug to test for incompatibility.

[v]. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. There is strong evidence that buprenorphine is superior to placebo with respect to retention in treatment, and good evidence that buprenorphine is superior to placebo with respect to positive urine testing for opiates.

[vi]. There is an adequate meta-analysis supporting good evidence that transdermal fentanyl and transdermal buprenorphine are similar with respect to analgesia and sleep quality, and they are similar with respect

to some common adverse effects such as constipation and discontinuation due to lack of effect. However, buprenorphine probably causes significantly less nausea than fentanyl, and it probably carries a lower risk of treatment discontinuation due to adverse events. It is also likely that both transdermal medications cause less constipation than oral morphine.

[vii]. Overall, due to cost and lack of superiority, buprenorphine is not a front line opioid choice. However, it may be used in those with a history of addiction or at high risk for addiction who otherwise qualify for chronic opioid use. It is also appropriate to consider buprenorphine products for tapering strategies and those on high dose morphine of 90 MED or more.

[b]. Codeine with Acetaminophen: Some patients cannot genetically metabolize codeine and therefore have no response. Codeine is not generally used on a daily basis for chronic pain. Acetaminophen dose per day should be limited to 2 grams.

[c]. Fentanyl (Actiq, Duragesic, Fentora, Sublimazem, Subsys) is not recommended for use with musculoskeletal chronic pain patients. It has been associated with a number of deaths and has high addiction potential. Fentanyl should never be used transbuccally in this population. If Fentanyl it is being considered for a very specific patient population, it requires support from a pain specialist. Subsys is only indicated for cancer pain.

[d]. Meperidine (Demerol) is not recommended for chronic pain. It and its active metabolite, normeperidine, present a serious risk of seizure and hallucinations. It is not a preferred medication for acute pain as its analgesic effect is similar to codeine.

[e]. Methadone requires special precautions given its unpredictably long half-life and non-linear conversion from other opioids such as morphine. It may also cause cardiac arrhythmias due to QT prolongation and has been linked with a greater number of deaths due to its prolonged half-life. No conclusions can be made regarding differences in efficacy or safety between methadone and placebo, other opioids, or other treatments. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. Methadone should only be prescribed by those with experience in managing this medication. Conversion from another opioid to methadone (or the other way around) can be very challenging, and dosing titration must be done very slowly (no more than every seven days). Unlike many other opioids, it should not be used on an "as needed" basis, as decreased respiratory drive may occur before the full analgesic effect of methadone is appreciated. If methadone is being considered, genetic screening is appropriate. CYP2B6 polymorphism appears to metabolize methadone more slowly than the usual population and may cause more frequent deaths.

[f]. Morphine may be used in the non-cancer pain population. A study in chronic low back pain suggested that individuals with a greater amount of endogenous opioids will have a lower pain relief response to morphine.

[g]. Oxycodone and Hydromorphone: There is no evidence that oxycodone (as oxycodone CR) is of value in treating people with painful diabetic neuropathy, postherpetic neuralgia, or other neuropathic conditions. There was insufficient evidence to support or refute the suggestion that hydromorphone has any efficacy in any neuropathic pain condition. Oxycodone was not associated with greater pain relief in cancer patients when compared to morphine or oxymorphone.

[h]. Propoxyphene (Darvon, Davon-N, PP-Cap) has been withdrawn from the market due to cardiac effects including arrhythmias.

[i]. Tapentadol (Nucynta) is a mu opioid agonist which also inhibits serotonin and norepinephrine reuptake activity. It is currently available in an intermediate release formulation and may be available as extended release if FDA approved. Due to its dual activity, it can cause seizures or serotonin syndrome, particularly when taken with other SSRIs, SNRIs, tricyclics, or MAO inhibitors. It has not been tested in patients with severe renal or hepatic damage. It has similar opioid abuse issues as other opioid medication; however, it is promoted as having fewer GI side effects, such as constipation. There is good evidence that extended release tapentadol is more effective than placebo and comparable to oxycodone. In that study, the percent of patients who achieved 50 percent or greater pain relief was: placebo, 18.9 percent, tapentadol, 27.0 percent, and oxycodone, 23.3 percent. There is some evidence that tapentadol can reduce pain to a moderate degree in diabetic neuropathy, average difference 1.4/10 pain scale, with tolerable adverse effects. However, a high quality systematic review found inadequate evidence to support tapentadol to treat chronic pain. Tapentadol is not recommended as a first line opioid for chronic, subacute, or acute pain due to the cost and lack of superiority over other analgesics. There is some evidence that tapentadol causes less constipation than oxycodone. Therefore, it may be appropriate for patients who cannot tolerate other opioids due to GI side effects.

[j]. Tramadol (Rybix, Ryzolt, Ultram)

[i]. Description: an opioid partial agonist that does not cause GI ulceration or exacerbate hypertension or congestive heart failure. It also inhibits the reuptake of norepinephrine and serotonin which may contribute to its pain relief mechanism. There are side effects similar to opioid side effects and may limit its use. They include nausea, sedation, and dry mouth.

[ii]. Indications: mild to moderate pain relief. As of the time of this guideline writing, formulations of tramadol have been FDA approved for management of moderate to moderately severe pain in adults. This drug has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Unlike other pure opioids agonists, there is a ceiling dose to tramadol due to its serotonin activity (usually 300-400 mg per day). There is some evidence that it alleviates neuropathic pain following spinal cord injury. There is inadequate evidence that extended-release tramadol/acetaminophen in a fixed-dose combination of 75 mg/650 mg is more effective than placebo in relieving chronic low back pain; it is not more effective in improving function compared to placebo. There is some evidence that tramadol yields a short-term analgesic

response of little clinical importance relative to placebo in post-herpetic neuralgia which has been symptomatic for approximately six months. However, given the effectiveness of other drug classes for neuropathic pain, tramadol should not be considered a first line medication. It may be useful for patients who cannot tolerate tricyclic antidepressants or other medications.

[iii]. Contraindications: use cautiously in patients who have a history of seizures, who are taking medication that may lower the seizure threshold, or taking medications that impact serotonin reuptake and could increase the risk for serotonin syndrome, such as monoamine oxidase inhibitors (MAO) inhibitors, SSRIs, TCAs, and alcohol. Use with caution in patients taking other potential QT prolonging agents. Not recommended in those with prior opioid addiction. Has been associated with deaths in those with an emotional disturbance or concurrent use of alcohol or other opioids. Significant renal and hepatic dysfunction requires dosage adjustment.

[iv]. Side effects: may cause impaired alertness or nausea. This medication has physically addictive properties, and withdrawal may follow abrupt discontinuation.

[v]. Drug interactions: opioids, sedating medications, any drug that affects serotonin and/or norepinephrine (e.g., SNRIs, SSRIs, MAOs, and TCAs).

[vi]. Laboratory Monitoring: renal and hepatic function.

(vi). Health care professionals and their patients must be particularly conscientious regarding the potential dangers of combining over-the-counter acetaminophen with prescription medications that also contain acetaminophen. Opioid and acetaminophen combination medication are limited due to the acetaminophen component. Total acetaminophen dose per day should not exceed 4 grams per any 24-hour period and is preferably limited to 2 grams per day to avoid possible liver damage.

(vii). Indications. The use of opioids is well accepted in treating cancer pain, where nociceptive mechanisms are generally present due to ongoing tissue destruction, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In chronic non-malignant pain, by contrast, tissue destruction has generally ceased, meaning that central and neuropathic mechanisms frequently overshadow nociceptive processes. Expected survival in chronic pain is relatively long, and return to a high-level of function is a major goal of treatment. Therefore, approaches to pain developed in the context of malignant pain may not be transferable to chronic non-malignant pain. Opioids are generally not the best choice of medication for controlling neuropathic pain. Tricyclics, SNRIs, and anticonvulsants should be tried before considering opioids for neuropathic pain.

[a]. In most cases, analgesic treatment should begin with acetaminophen, aspirin, NSAIDs, and possibly Baclofen or Tizanidine. While maximum efficacy is modest, they may reduce pain sufficiently to permit adequate function. When these drugs do not satisfactorily reduce pain, medications specific to the diagnosis should be used (e.g., neuropathic pain medications as outlined in Section G.10, Medications).

[b]. There is good evidence from a prospective cohort study that in the setting of common low back injuries, when baseline pain and injury severity are taken into account, a prescription for more than seven days of opioids in the first six weeks is associated with an approximate doubling of disability one year after the injury. Therefore, prescribing after two weeks in a non-surgical case requires a risk assessment. If prescribing beyond four weeks, a full opioid trial is suggested including toxicology screen. Best practice suggests that whenever there is use of opioids for more than seven days, providers should follow all recommendations for screening and follow-ups of chronic pain use.

[c]. Consultation or referral to a pain specialist behavioral therapist should be considered when the pain persists but the underlying tissue pathology is minimal or absent and correlation between the original injury and the severity of impairment is not clear. Consider consultation if suffering and pain behaviors are present and the patient manifests risk behaviors described below, or when standard treatment measures have not been successful or are not indicated.

[d]. A psychological consultation including psychological testing (with validity measures) is indicated for all chronic pain patients as these patients are at high risk for unnecessary procedures and treatment and prolonged recovery.

[e]. Many behaviors have been found related to prescription-drug abuse patients. None of these are predictive alone, and some can be seen in patients whose pain is not under reasonable control; however, the behaviors should be considered warning signs for higher risk of abuse or addiction by physicians prescribing chronic opioids. Refer to Subsection, High Risk Behavior, below.

(ix). Recommendations for Opioid Use. When considering opioid use for moderate to moderately severe chronic pain, a trial of opioids must be accomplished as described below and the patient must have failed other chronic pain management regimes. Physicians should complete the education recommended by the FDA, risk evaluation and mitigation strategies (REMS) provided by drug manufacturing companies.

[a]. General Indications. There must be a clear understanding that opioids are to be used for a limited term in the first instance (see trial indications below). The patient should have a thorough understanding of all of the expectations for opioid use. The level of pain relief is expected to be relatively small, two to three points on a VAS pain scale, although in some individual patients it may be higher. For patients with a high response to opioid use, care should be taken to assure that there is no abuse or diversion occurring. The physician and patient must agree upon defined functional goals as well as pain goals. If functional goals are not being met, the opioid trial should be reassessed. The full spectrum of side effects should be reviewed. The shared decision making agreement signed by the patient must clarify under what term the opioids will be tapered. Refer to Subsection on the shared decision making agreement, below.

[b]. Therapeutic Trial Indications. A therapeutic trial of opioids should not be employed unless the patient has begun multi-disciplinary pain management.

The trial shall last one month. If there is no functional effect, the drug should be tapered. Chronic use of opioids should not be prescribed until the following have been met:

[i]. the failure of pain management alternatives, including active therapies, cognitive behavioral therapy, pain self-management techniques, and other appropriate medical techniques;

[ii]. physical and psychological and/or psychiatric assessment including a full evaluation for alcohol or drug addiction, dependence or abuse, performed by two specialists with one being the authorized treating physician. The patient should be stratified as to low, medium, or high risk for abuse based on behaviors and prior history of abuse. High risk patients are those with active substance abuse of any type or a history of opioid abuse. These patients should generally not be placed on chronic opioids. If it is deemed appropriate to do so, physician addiction specialists should be monitoring the care. Moderate risk factors include a history of non-opioid substance abuse disorder, prior trauma particularly sexual abuse, tobacco use, widespread pain, poor pain coping, depression, and dysfunctional cognitions about pain and analgesic medications (see below). Pre-existing respiratory or memory problems should also be considered. Patients with a past history of substance abuse or other psychosocial risk factors should be co-managed with a physician addiction specialist;

[iii]. risk factors to consider: history of severe post-operative pain, opioid analgesic tolerance (daily use for months), current mixed opioid agonist/antagonist treatment (e.g., buprenorphine, naltrexone), chronic pain (either related or unrelated to the surgical site), psychological comorbidities (e.g., depression, anxiety, catastrophizing), history of substance use disorder, history of "all over body pain", history of significant opioid sensitivities (e.g., nausea, sedation), and history of intrathecal pump use or nerve stimulator implanted for pain control;

[iv]. employment requirements are outlined. The patient's employment requirements should also be discussed as well as the need to drive. It is generally not recommended to allow workers in safety sensitive positions to take opioids. Opioid naïve patients or those changing doses are likely to have decreased driving ability. Some patients on chronic opioids may have nominal interference with driving ability; however, effects are specific to individuals. Providers may choose to order certified driver rehabilitation assessment;

[v]. urine drug screening for substances of abuse and substances currently prescribed. Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. It is appropriate to screen for alcohol and marijuana use and have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. Alcohol use in combination with opioids is likely to contribute to death;

[vi]. review of the Prescription Monitoring Program. Louisiana Revised Statutes 40:978 and 40:1001-1014. Informed, written, witnessed consent by the patient including the aspects noted above. Patients should also be counseled on safe storage and disposal of opioids;

[vii]. the trial, with a short-acting agent, should document sustained improvement of pain control, at least a 30 percent reduction, and of functional status, including return-to-work, and/or increase in activities of daily living. It is necessary to establish goals which are specific, measurable, achievable, and relevant prior to opioid trial or adjustment to measure changes in activity/function. Measurement of functional goals may include patient completed validated functional tools. Frequent follow-up at least every two to four weeks may be necessary to titrate dosage and assess clinical efficacy.

[c]. On-Going, Long-Term Management after a successful trial should include:

[i]. prescriptions from a single practitioner;

[ii]. ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects; full review at least every three months;

[iii]. ongoing effort to gain improvement of social and physical function as a result of pain relief;

[iv]. review of the Prescription Monitoring Program (PMP);

[v]. shared decision making agreement detailing the following:

{a}. side effects anticipated from the medication;

{b}. requirement to continue active therapy;

{c}. need to achieve functional goals including return to work for most cases;

{d}. reasons for termination of opioid management, referral to addiction treatment, or for tapering opioids (tapering is usually for use longer than 30 days). Examples to be included in the contract include, but are not limited to:

{i}. diversion of medication;

{ii}. lack of functional effect at higher doses;

{iii}. non-compliance with other drug use;

{iv}. drug screening showing use of drugs outside of the prescribed treatment or evidence of non-compliant use of prescribed medication;

{v}. requests for prescriptions outside of the defined time frames;

{vi}. lack of adherence identified by pill count, excessive sedation, or lack of functional gains

{vii}. excessive dose escalation with no decrease in use of short-term medications;

{viii}. apparent hyperalgesia;

{ix}. shows signs of substance use disorder (including but not limited to work or family problems related to opioid use, difficulty controlling use, craving);

{x}. experiences overdose or other serious adverse event

{xi}. shows warning signs for overdose risk such as confusion, sedation, or slurred speech.

{e}. patient agreements should be written at a sixth grade reading level to accommodate the majority of patients;

{f}. use of random drug screening, initially, four times a year or possibly more with documented suspicion of abuse or diversion or for stabilization or maintenance phase of treatment. In addition to those four or more random urine drug screens, quantitative testing is appropriate in cases of inconsistent findings, suspicions, or for particular medications that patient is utilizing that is not in the qualitative testing;

{i}. drugs or drug classes for which screening is performed should only reflect those likely to be present based on the patient's medical history or current clinical presentation, illicit substances, the practitioner's suspicion, and without duplication;

{ii}. qualitative urine drug testing (UDT) (i.e., immunoassay to evaluate, indicates the drug is present) that is utilized for pain management or substance abuse monitoring, may be considered medically necessary for: baseline screening/Induction phase before initiating treatment or at time treatment is initiated, stabilization phase of treatment with targeted weekly qualitative screening for a maximum of four weeks. (This type of monitoring is done to identify those patients who are expected to be on a stable dose of opioid medication within a four-week timeframe.) Maintenance phase of treatment with targeted qualitative screening once every one to three months. Subsequent monitoring phase of treatment at a frequency appropriate for the risk level of the individual patient. (This type of monitoring is done to identify those patients who are noncompliant or abusing prescription drugs or illicit drugs.) Note: In general, qualitative urine drug testing should not require more than four tests in a 12-month period. Additional testing, as listed above, would require clinical justification of medical necessity;

{iii}. quantitative UDT (i.e., gas chromatography and or mass spectrometry [GCMS] as confirmatory, indicates the amount of drug is present) that is utilized for pain management or substance abuse monitoring, may be considered medically necessary under the following circumstances: When immunoassays for the relevant drug(s) are not commercially available, or in specific situations when qualitative urine drug levels are required for clinical decision making. The following qualitative urine drug screen results must be present and documented: Positive for a prescription drug that is not prescribed to the patient; or Negative for a prescription drug that is prescribed to the patient; or Positive for an illicit drug;

{iv}. quantitative testing is not appropriate for every specimen and should not be done routinely. This type of test should be performed in a setting of unexpected results and not on all specimens. The rationale for each quantitative test must be supported by the ordering clinician's documentation. The record must show that an inconsistent positive finding was noted on the qualitative testing or that there was not an available qualitative test to evaluate the presence of semisynthetic or synthetic opioid, illicit drugs or other medications used for pain management in a patient. Simultaneous blood and urine drug screening or testing is not appropriate and should not be done.

{v}. urine testing, when included as one part of a structured program for pain management, has been observed to reduce abuse behaviors in patients with a history of drug misuse. Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. Clinicians should determine before drug screening how they will use knowledge of marijuana use. It is appropriate to screen for alcohol and marijuana use and have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. Alcohol use in combination with opioids is likely to contribute to death. From a safety standpoint, it is more important to screen for alcohol use than marijuana use as alcohol is more likely to contribute to unintended overdose;

{vi}. physicians should recognize that occasionally patients may use non-prescribed substances because they have not obtained sufficient relief on the prescribed regime.

[vi]. chronic use limited to two oral opioids;

[vii]. transdermal medication use, other than buprenorphine, is generally not recommended;

[viii]. use of acetaminophen-containing medications in patients with liver disease should be limited; including over-the-counter medications. Acetaminophen dose should not exceed 4 grams per day for short-term use or 2 to 3 grams/day for long-term use in healthy patients. A safer chronic dose may be 1800 mg/day;

[ix]. continuing review of overall therapy plan with regard to non-opioid means of pain control and functional status;

[x]. tapering of opioids may be necessary for many reasons including the development of hyperalgesia, decreased effects from an opioid, lack of compliance with the opioid contract, or intolerance of side effects. Some patients appear to experience allodynia or hyperalgesia on chronic opioids. This premise is supported by a study of normal volunteers who received opioid infusions and demonstrated an increase in secondary hyperalgesia. Options for treating hyperalgesia include withdrawing the patient from opioids and reassessing their condition. In some cases, the patient will improve when off of the opioid. In other cases, another opioid may be substituted;

{a}. Tapering may also be appropriate by patient choice, to accommodate “fit-for-duty” demands, prior to major surgery to assist with post-operative pain control, to alleviate the effects of chronic use including hypogonadism, medication side effects, or in the instance of a breach of drug agreement, overdose, other drug use aberrancies, or lack of functional benefit. It is also appropriate for any of the tapering criteria listed in Section E above.

{b}. Generally tapering can be accomplished by decreasing the dose 10 percent per week. This will generally take 6 to 12 weeks and may need to be done one drug class at a time. Behavioral support is required during this service. Tapering may occur prior to MMI or in some cases during maintenance treatment.

[xi]. medication assisted treatment with buprenorphine or methadone may be considered for opioid abuse disorder, in addition to behavioral therapy;

[xii]. inpatient treatment may be required for addiction or opioid tapering in complex cases. Refer to Interdisciplinary Rehabilitation Programs for detailed information on inpatient criteria;

[d]. Relative Contraindications—Extreme caution should be used in prescribing controlled substances for workers with one or more “relative contraindications”: Consultation with a pain or addiction specialist may be useful in these cases;

[i]. history of alcohol or other substance abuse, or a history of chronic, benzodiazepine use;

[ii]. sleep apnea: If patient has symptoms of sleep apnea, diagnostic tests should be pursued prior to chronic opioid use;

[iii]. off work for more than six months with minimal improvement in function from other active therapy;

[iv]. severe personality disorder or other known severe psychiatric disease per psychiatrist or psychologist;

[v]. monitoring of behavior for signs of possible substance abuse indicating an increased risk for addiction and possible need for consultation with an addiction specialist.

[e]. High Risk Behavior: The following are high risk warning signs for possible drug abuse or addiction. Patients with these findings may need a consultation by a physician experienced in pain management and/or addiction. Behaviors in the first list are warning signs, not automatic grounds for dismissal, and should be followed up by a reevaluation with the provider.

[i]. repeated behaviors in the first list may be more indicative of addiction and behaviors in the second list should be followed by a substance abuse evaluation:

{a}. First List: Less suggestive for addiction but are increased in depressed patients- Frequent requests for early refills; claiming lost or stolen prescriptions; Opioid(s) used more frequently, or at higher doses than prescribed; Using opioids to treat non-pain symptoms; Borrowing or hoarding opioids; Using alcohol or tobacco to relieve pain; Requesting more or specific opioids; Recurring emergency room visits for pain; Concerns expressed by family member(s); Unexpected drug test results; Inconsistencies in the patient’s history.

{b}. Second List: More suggestive of addiction and are more prevalent in patients with substance use disorder- Buying opioids on the street; stealing or selling drugs; Multiple prescribers (“doctor shopping”); Trading sex for opioids; Using illicit drugs; Positive urine drug tests for illicit drugs; Forging prescriptions; Aggressive demands for opioids; Injecting oral/topical opioids; Signs of intoxication (ETOH odor, sedation, slurred speech, motor instability, etc.).

[ii]. both daily and monthly users of nicotine were at least three times more likely to report non-medical use of opioid in the prior year. At least one study has

demonstrated a prevalence of smokers and former smokers among those using opioids and at higher doses compared to the general population. It also appeared that smokers and former smokers used opioids more frequently and in higher doses than never smokers. Thus, tobacco use history may be a helpful prognosticator;

[iii]. in one study, four specific behaviors appeared to identify patients at risk for current substance abuse: increasing doses on their own, feeling intoxicated, early refills, and oversedating oneself. A positive test for cocaine also appeared to be related;

[iv]. one study found that half of patients receiving 90 days of continuous opioids remained on opioids several years later and that factors associated with continual use included daily opioid greater than 120 MED prior opioid exposure, and likely opioid misuse;

[v]. One study suggested that those scoring at higher risk on the screener and opioid assessment for patients with pain-revised (SOAPP-R), also had greater reductions in sensory low back pain and a greater desire to take morphine. It is unclear how this should be viewed in practice.

[f]. Dosing and Time to Therapeutic Effect. Oral route is the preferred route of analgesic administration because it is the most convenient and cost-effective method of administration. Transbuccal administration should be avoided other than for buprenorphine. A daily dosage above 50 MED may be appropriate for certain patients. However, when the patient's dosage exceeds 50 MED per day and/or the patient is sedentary with minimal function, consideration should be given to lowering the dosage. Some patients may require dosages above 90 MED per day. However, if the patient reaches a dosage above 90 MED per day, it is appropriate to taper or refer to a pain or addiction specialist. The provider should also adhere to all requirements in this guideline and closely monitor the patient as this is considered a high risk dosage. In some cases, buprenorphine may be a preferred medication for pain control in those patients. Consultation may be necessary.

[g]. Major Side Effects—There is great individual variation in susceptibility to opioid-induced side effects and clinicians should monitor for these potential side effects. Common initial side effects include nausea, vomiting, drowsiness, unsteadiness, and confusion. Occasional side effects include dry mouth, sweating, pruritus, hallucinations, and myoclonus. Rare side effects include respiratory depression and psychological dependence. Constipation and nausea/vomiting are common problems associated with long-term opioid administration and should be anticipated, treated prophylactically, and monitored constantly. Stool softeners, laxatives, and increased dietary fluid may be prescribed. Refer to Section G.10.g, Opioid Induced Constipation. Chronic sustained release opioid use is associated with decreased testosterone in males and females and estradiol in pre-menopausal females. Patients should be asked about changes in libido, sexual function, and fatigue. Appropriate lab testing and replacement treatment should be completed.

[h]. Naloxone or oral and injection Naltrexone: may be prescribed when any risk factors are present. The correct use of Naloxone and Naltrexone should be discussed with the patient and family.

[i]. Benzodiazepines: should not be prescribed when opioids are used.

[j]. Sedation: Driving and Other Tasks. Although some studies have shown that patients on chronic opioids do not function worse than patients not on medication, caution should be exerted, and patients should be counseled never to mix opioids with the use of alcohol or other sedating medication. When medication is increased or trials are begun, patients should not drive for at least five days. Chronic untreated pain, sedatives especially when mixed with opiates or alcohol, and disordered sleep can also impair driving abilities.

[k]. Drug Interactions. Patients receiving opioid agonists should not be given a mixed agonist-antagonist such as pentazocine [Talacen, Talwin] or butorphanol [Stadol] because doing so may precipitate a withdrawal syndrome and increase pain.

[l]. All sedating medication, especially benzodiazepines, should be avoided or limited to very low doses. Over-the-counter medications such as antihistamines, diphenhydramine, and prescription medications such as hydroxyzine (Anx, Atarax, Atazine, Hypam, Rezine, Vistaril) should be avoided except when being used to manage withdrawal during tapering of opioids. Alcohol should not be used.

[m]. Recommended Laboratory Monitoring. Primary laboratory monitoring is recommended for acetaminophen/aspirin/ibuprofen combinations (renal and liver function, blood dyscrasias) although combination opioids are not recommended for long-term use. Morphine and other medication may require renal testing and other screening. A comprehensive genetic testing panel may be ordered by treating physician for these multiple P450 genes once in a lifetime and utilized whenever there is a question of metabolism or unusual response of any drugs used to treat pain conditions, because multiple drugs and associated genes can cause problems with opioid metabolism.

[n]. Sleep Apnea Testing: Both obstructive and central sleep apnea are likely to be exaggerated by opioid use or may occur secondary to higher dose chronic opioid use and combination medication use, especially benzodiazepines and sedative hypnotics. Patients should be questioned about sleep disturbance and family members or sleeping partners questioned about loud snoring or gasping during sleep. If present, qualified sleep studies and sleep medicine consultation should be obtained. Portable sleep monitoring units are generally not acceptable for diagnosing primary central sleep apnea. Type 3 portable units with two airflow samples and an O2 saturation device may be useful for monitoring respiratory depression secondary to opioids, although there are no studies on this topic.

[o]. Regular consultation of the Prescription Monitoring Program (PMP). Physicians should review their patients on the system whenever drug screens are done. This information should be used in combination

with the drug screening results, functional status of the patient, and other laboratory findings to review the need for treatment and level of treatment appropriate for the patient.

[o]. Addiction. If addiction occurs, patients will require treatment. Refer to Section G.12, Opioid Addiction Treatment. After detoxification, they may need long-term treatment with naltrexone (Depade, ReVia, Vivitrol), an antagonist which can be administered in a long-acting form or buprenorphine which requires specific education per the Drug Enforcement Agency (DEA).

[p]. Potentiating Agents. There is some evidence that dextromethorphan does not potentiate the effect of morphine opioids and therefore is not recommended to be used with opioids.

v. - v.(d). ...

vi. Other Agents

(a). Agents not listed which may be useful in the treatment of CRPS and SMP include propranolol, nifedipine, calcitonin, bisphosphonates and short-term oral steroids, during the acute phase of the disease. Although propranolol, nifedipine, oral steroids, and calcitonin are used in practice, at this time there is a lack of well-designed studies to support their effectiveness compared to placebo. In individual patients, they may be effective. There is some evidence to support the use of intravenous bisphosphonate drugs, currently licensed for use in malignant bone disease and Paget's disease, in CRPS patients with abnormal bone scans. Oral use of bisphosphonates has not been studied in CRPS.

7. - 11.b.vi. ...

vii. Vocational Assistance. Formal vocational assistance is a generally accepted intervention and can assist disabled persons to return to viable employment. Assisting patients to identify vocational goals will facilitate medical recovery and aid in the maintenance of MMI by increasing motivation towards treatment and alleviating the patient's emotional distress. Chronic pain patients may benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment may be utilized to identify rehabilitation program goals, as well as optimize both patient motivation and utilization of rehabilitation resources.

11.b.vii.(a). - 13.b.vi.(d). ...

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§2133. Therapeutic Procedures—Operative

A. - C.2. ...

3. Sympathectomy

a. ...

b. Indications. Single extremity CRPS-I or SMP; distal pain only (should not be done if the proximal extremity is involved). Local anesthetic Stellate Ganglion Block, Kuntz Fiber Block or Lumbar Sympathetic Block consistently gives 90 to 100 percent relief each time a technically good block is performed (with measured rise in temperature). The procedure may be considered for individuals who have limited duration of relief from blocks. Permanent neurological complications are common.

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§2135. Maintenance Management

A. - D.6.e.i. ...

7. Therapy management. Some treatment may be helpful on a continued basis during maintenance care if the therapy maintains objective function and decreases medication use. Aggravation of the injury may require intensive treatment, including injections, PT and/or OT to get the patient back to baseline. In those cases, treatments and timeframe parameters listed in Section H, 13 and 14, Active and Passive Therapy.

7.a. - 9.a. ...

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