

## ORIGINAL RESEARCH

# The Economic Value of Customized versus Off-the-Shelf Knee Implants in Medicare Fee-for-Service Beneficiaries

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**BACKGROUND:** The amount of total knee arthroplasty (TKA) procedures performed in the United States has been increasing steadily and is projected to reach 3 million procedures annually by 2030 in patients aged  $\geq 65$  years. A rise in TKA procedures will increase spending on osteoarthritis treatments, which is currently the second highest category of spending for Medicare patients. Because TKA procedures account for a substantial amount of total osteoarthritis spending, payers and providers are examining methods to reduce spending on the procedure while improving clinical outcomes. Customized individually made implants have been shown to improve clinical outcomes, such as physical function and limb alignment, compared with off-the-shelf implants; however, the economic impact of customized implants has yet to be established.

**OBJECTIVE:** To analyze TKA episode expenditures among Medicare fee-for-service (FFS) members who received a customized or an off-the-shelf implant.

**METHODS:** Members undergoing a TKA procedure using the customized implant technology were identified in the Medicare FFS database and were propensity matched (1:5) to a cohort of members who received off-the-shelf implants. Reimbursement for the initial procedure (ie, customized and off-the-shelf procedure), a preoperative computed tomography scan, and 12-month postoperative healthcare utilization were analyzed. The overall episode expenditures were used to construct a budget impact model to calculate the per-member per-month (PMPM) spending for Medicare FFS beneficiaries.

**RESULTS:** The average total episode spending was significantly lower among the customized implant cohort (\$18,585) compared with the off-the-shelf implant cohort (\$20,280; a \$1695 difference;  $P < .0001$ ). This savings resulted in \$0.08 PMPM savings for the Medicare FFS program when a portion (10%) of eligible members received the customized implant technology. A sensitivity analysis, which varied with the customized implant market penetration and the percent of customized implant-eligible procedures, indicated that the savings could be as great as \$0.28 PMPM.

**CONCLUSION:** The results of this analysis demonstrate that the use of customized implants in TKA procedures can achieve substantial savings versus off-the-shelf procedures for the Medicare FFS program, and this savings is primarily driven by a lower average initial procedure cost and lower postoperative spendings for inpatient services and skilled-nursing facility costs.

**KEY WORDS:** customized knee implant, Medicare fee-for-service, off-the-shelf implants, osteoarthritis, per-member per-month spending, total knee arthroplasty, value

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**K**nee osteoarthritis, the deterioration of cartilage and bone, affects 14 million adults in the United States.<sup>1</sup> Although knee osteoarthritis is prevalent in people of all ages, the prevalence rate increases with age, reaching approximately 16% in people aged  $>65$  years.<sup>1</sup> The early management of knee osteoarthritis typically involves multiple nonsurgical treatment strategies,

including weight loss, the use of a cane or other support device, physical therapy, and medications.<sup>2</sup>

Surgery, such as total knee arthroplasty (TKA), may be considered when nonsurgical management of osteoarthritis is unsuccessful.<sup>3</sup>

Although generally reserved as a last recourse, the use of primary and revision (ie, redoing a procedure performed for failure of the primary surgery) of knee arthroplasty is projected to reach approximately 3 million procedures annually by 2030 among those aged  $>64$  years, which is 4 times greater than the estimated 751,000 procedures performed in 2010.<sup>4</sup> The estimated number of people aged  $>64$  years during 2011-2012 who

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## KEY POINTS

- The use of total knee arthroplasty (TKA) is increasing and is associated with significant costs to the healthcare system.
- Customized TKA implants have been shown to improve clinical outcomes compared with off-the-shelf implants, but no study has compared the economic impact of these procedures.
- This study is the first to compare TKA episode spending among Medicare fee-for-service (FFS) members who received a customized or an off-the-shelf knee implant.
- The average total episode spending was \$1695 lower for patients who received a customized implant than for those who received an off-the-shelf implant.
- The customized implant group also had lower average healthcare spending on inpatient, skilled-nursing facility, and home health services than the off-the-shelf implant group.
- As a result of the potential savings for the Medicare FFS program, the use of customized implants may reduce healthcare spending for those undergoing a TKA procedure.

had advanced symptomatic knee osteoarthritis is staggering: 18% non-Hispanic white females, 14% non-Hispanic black females, 13% Hispanic females, 13% non-Hispanic white males, 10% Hispanic males, and 9% non-Hispanic black males.<sup>1</sup>

The projected procedure volume increase in TKA procedures will add to the current expense of osteoarthritis treatment, which at present ranks second, after septicemia, in total spending among all health plans, including Medicare patients (those in the fee-for-service [FFS] program and in Medicare Advantage plans), in the inpatient setting.<sup>5</sup> A 2016 Healthcare Cost and Utilization Project (HCUP) report showed that payments for hospital services associated with osteoarthritis accounted for 4.3% of the total US healthcare expenditures in 2013, which amounts to approximately \$16.5 billion.<sup>5</sup> A previous HCUP report noted that more than 90% of osteoarthritis-associated hospitalizations were for hip and knee replacements.<sup>6</sup> Consequently, the cost and effectiveness of TKA are under great scrutiny by the Centers for Medicare & Medicaid Services (CMS). For example, CMS cites high healthcare spending and inconsistent quality as the impetuses for developing the Comprehensive Care for Joint Replacement model, which transfers the associated financial risk to providers.<sup>7</sup>

Customized individually made knee implants have the potential to improve patient outcomes and reduce TKA-related episode spending through reductions in complications and in post-acute care. Customized implants are designed based on a computed tomography (CT) scan of the patient's knee, which allows for the implant to be custom-built to match the individual recipient's anatomy. Previous studies have reported that implant customization can lead to improved kinematic function and alignment, smaller bone resections, less blood loss, and lower blood transfusion rates.<sup>8-13</sup>

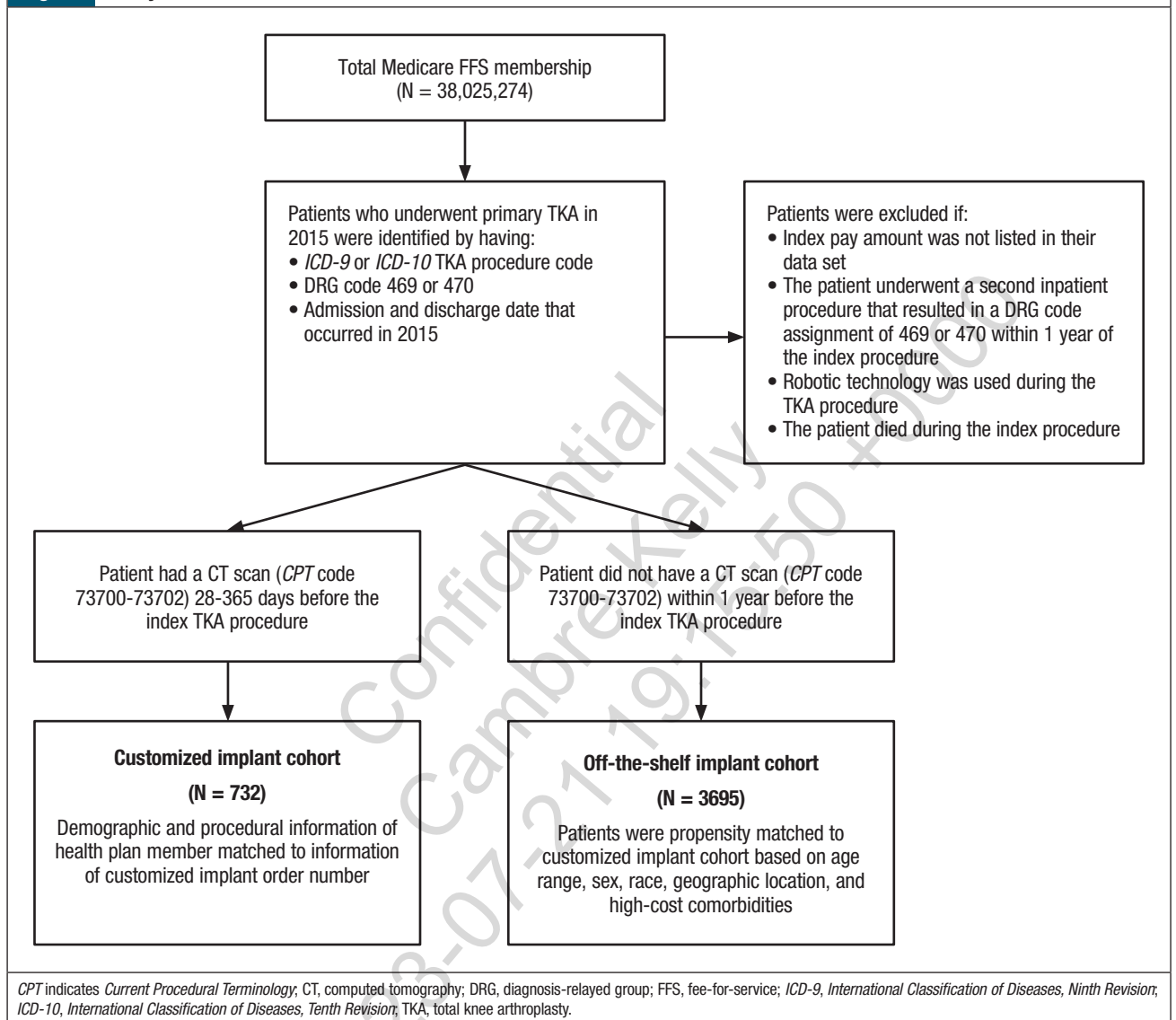
In addition to lower adverse event rates at the index date (ie, procedure date) and 90 days postdischarge, a recent retrospective medical record review of 248 TKA procedures showed that patients who had customized implant procedures were more likely to be discharged home rather than to a rehabilitation facility or a post-acute care facility.<sup>13</sup> Furthermore, although not a significant difference, the modeled episode-of-care cost per patient for health plans in that study was \$913.87 less for the customized implant cohort than for the off-the-shelf implant cohort.<sup>13</sup> However, the costs after acute care were based on previously published assessment of average costs for these settings and may therefore lack the granularity of an actual cost-based assessment that accounts for varied utilization as a result of each patient's clinical condition.<sup>14</sup>

The improved clinical outcomes and postoperative care differences associated with customized implants could result in substantial cost-savings. For example, a 2016 study showed that patients who received a blood transfusion during a TKA procedure had a 13% increased risk for hospital readmission, and patients who were discharged home after the procedure, as opposed to a skilled-nursing facility, had a 25% lower risk for readmission.<sup>15</sup> The cost of such post-acute care was highlighted in an analysis of Medicare primary joint arthroplasty procedures, which revealed that Medicare payments for post-acute care services and TKA-related hospital readmissions accounted for approximately 38% of the total 30-day episode spending for a TKA.<sup>16</sup>

Thus, the real-world economic savings associated with clinical differences when utilizing the customized implant technology versus off-the-shelf implants, particularly in patients receiving post-acute care, warrants further evaluation using actual costs. Economic studies and clinical evidence are necessary for payers and providers to make informed decisions and select cost-effective technology for TKA procedures, but the data that demonstrate the economic impact of the use of customized implants on TKA spending do not address the full episode cost among the Medicare population.

Our study sought to establish the annual cost of treatment, including the initial procedure and 12-month

**Figure** Study Patient Selection Criteria for Medicare Beneficiaries Who Had a TKA



postdischarge expenditures incurred by the Medicare FFS program for members undergoing TKA procedures with customized or off-the-shelf implants. The results may assist payers in evaluating the financial impact of customized implants among Medicare beneficiaries.

**Methods**

We created a budget impact model to evaluate the economic impact of utilizing customized knee implants in the Medicare population. The budget impact model computed the annual healthcare expenditures for patients who received customized or off-the-shelf knee implants, as well as the potential per-member per-month (PMPM) financial impact of customized implants on the Medicare FFS program. We derived the expenditures by performing a

retrospective analysis of the Medicare Standard Analytical Files for Inpatient, Outpatient, Skilled Nursing Facility, and Home Health. These databases contain administrative claims data for medical services provided to approximately 37 million Medicare FFS beneficiaries.

The annual healthcare expenditures for a TKA comprised the costs for the initial total knee replacement (designated as the index procedure), the preoperative CT scan, and the 12-month postoperative spending for inpatient, outpatient, emergency department, skilled-nursing facility, and home health services. Because our model was constructed to evaluate the financial impact of customized knee implants from the viewpoint of the Medicare FFS program, payments made from Medicare to providers (ie, the pay amount) represent the costs in

the model. The pay amount does not include out-of-pocket costs paid by the patient.

With the exception of the preoperative CT scan, all costs were extracted from the previously defined Standard Analytical Files databases. Cost estimates for the preoperative CT scan were derived from the Medicare pay rate for Ambulatory Payment Classification code 5522 and the Medicare physician fee schedule for *Current Procedural Terminology* (CPT) code 73700. Although CT scans may be performed with contrast material (CPT codes 73701 and 73702), 98.9% of patients in our study received CT scans without contrast (CPT code 73700). Thus, CT scan costs in the budget impact model were solely based on the reimbursement of CPT code 73700.

To identify customized and off-the-shelf implant claims in the Medicare database, we used a 2-step process. The **Figure** illustrates the identification methodology used to select the patient population for this study.

In step 1, TKA procedure claims were identified in the Medicare Inpatient Standard Analytical File. To be included in the study, TKA procedure claims were required to meet 3 criteria, including (1) the patient underwent a primary TKA in an inpatient setting, which was identified by *International Classification of Diseases, Ninth Revision (ICD-9)* and *Tenth Revision (ICD-10)* coding manuals (for a complete list of the TKA procedure codes used, see **Appendix Table** at [www.AHDBonline.com](http://www.AHDBonline.com)); (2) the primary TKA procedure visit was assigned a diagnosis-related group (DRG) code that indicates a major joint replacement or reattachment of lower extremity with major complications or comorbidities (DRG code 469) or without major complications or comorbidities (DRG code 470); and (3) the admission and discharge dates occurred during 2015 (between January 1, 2015, and December 31, 2015).

Claims were excluded from the analysis if they met any of 4 criteria, including (1) had a paid amount associated with the primary TKA inpatient visit that was not available in the database; (2) the patient had a hip or staged bilateral knee replacement within 1 year of the index procedure (identified by DRG code 469 or 470); (3) robotic technology was used during the procedure (ICD-9 code 17.41 or ICD-10 code 8E0Y0CZ); or (4) the patient died during the index procedure.

The second step in the patient selection entailed categorizing TKA claims into 2 cohorts, based on whether the patient received a customized or an off-the-shelf implant. Because medical coding is unable to distinguish between customized and off-the-shelf implants, we developed an alternative methodology to isolate each cohort. The identification of customized knee implants was guided by 2 principal criteria.

The first criterion was the presence of preoperative imaging. Because customized implants are manufactured based on CT scans, the patients in this cohort were required to have a CT scan of the lower extremity (CPT code 73700, 73701, or 73702) on or between 28 and 365 days before the index procedure (this time frame was established based on the manufacturer-reported time necessary to create the implant before surgery).

The second criterion in identifying customized knee implant claims was to identify the patients who had a customized implant within the group of patients who had a CT scan. To do this, Medicare claims were matched against deidentified patient data provided by the customized implant manufacturer (Conformis). The manufacturer provided 10,631 deidentified records for procedures performed within the United States. Potential customized implant claims identified in the Medicare Inpatient Standard Analytical File database were required to match the physician National Provider Identifier number, hospital Medicare provider number, surgery date, and the patient's age range (as listed in the database, which is grouped in 5-year increments) of a customized implant order number.

We used a precise methodology to ensure that for each individual knee implant order provided by the manufacturer only 1 member was matched in the claims data. When more than 1 order number matched the information associated with a distinct claim number or when more than 1 claim number matched the information associated with a distinct order number, such claim numbers were excluded from this analysis.

The criteria for patients with off-the-shelf implants included the absence of a CT scan within 1 year of the index procedure to reduce the likelihood that these patients received a technology other than a customized implant, that requires preoperative imaging, such as robotic-assisted TKA.

The 2 patient cohorts were then propensity matched, a technique often used in retrospective analyses to limit the differences in baseline characteristics of the populations and to allow for high confidence that observed differences are the result of the intervention.<sup>17-19</sup>

Propensity matching was performed using the Fisher's scoring methodology and k-nearest neighbors machine learning algorithm at a 1 (ie, customized implant) to 5 (ie, off-the-shelf implant) ratio, meaning that for every 1 patient with a customized implant there were 5 patients with an off-the-shelf implant and a similar demographic and comorbidity profile included in the analysis. This 1:5 ratio was used to enhance the precision of the matching.<sup>20</sup>

The patients were matched based on their age range, sex, race, geographic location within the United States (based on US Census Bureau divisions), and high-cost

**Table 2** Average Episode Expenditures by Healthcare Setting Among All Medicare Members Undergoing TKA with Customized or Off-the-Shelf Implants

Type of cost	Off-the-shelf implant, \$	Customized implant, \$	Expenditure difference, \$	P value
Index costs				
Preoperative CT scan	N/A	166	166	
Initial TKA procedure	12,386	11,579	-807	
12-month postindex costs				
Inpatient	2711	2012	-699	
Outpatient	1806	2117	311	
Emergency department	251	263	13	
Skilled-nursing facility	784	264	-520	
Home health	2343	2184	-159	
Total TKA episode spending	20,280	18,585	-1695	<.0001

CT indicates computed tomography; N/A, not applicable; TKA, total knee arthroplasty.

comorbidities (ie, chronic obstructive pulmonary disease, coronary artery disease, diabetes, hypertension, obesity, oncology, pneumonia, and smoking).

**Model Calculations**

Our budget impact model estimates the average spending per cohort for each healthcare setting analyzed and computes the total annual cost of care (including the preoperative CT cost). The total health plan savings amount is calculated by multiplying the annual number of TKA procedures that are candidates for a customized implant by an assumed 10% market penetration rate of customized implants and the average cost difference between the customized and off-the-shelf implant cohorts. The annual TKA procedure volume was derived from an analysis of the 2016 Inpatient Standard Analytical File database, which was the latest Medicare claim file containing a complete 12 months of administrative claims data.

Patients were required to have a TKA procedure code and a DRG code (Figure). Claims with a revenue code indicating that the member entered through the emergency department were excluded, because customized implants cannot be used in these instances. The annual procedure volume was further limited to procedures that are candidates for a customized implant, which we estimated (based on our clinical expertise) to be 80% to 85% of TKA procedures as a result of exclusions, including difficult TKA procedures needing augments and highly constrained polyethylene, or patients with suspected metal sensitivity to nickel. To be conservative, our base-case analysis applied 80% to the annual TKA procedure volume.

The PMPM savings were determined by dividing the total plan savings by the total members per month (total plan members multiplied by 12 months).

A sensitivity analysis was performed to account for variations in market adoption (range, 3%-30%), as well as for the percent of TKA procedures that are candidates for a customized implant (range, 75%-90%).

**Statistical Analysis**

The difference in annual healthcare spending between the study cohorts was tested for statistical significance. Furthermore, differences between the 2 cohorts in the probability of having postoperative healthcare utilization and the total spending associated with each postoperative healthcare category were tested for significance. As is often the case, our cost data were not normally distributed. Accordingly, a generalized linear model was chosen as the appropriate method to test the statistical significance of skewed distributions.

The statistical analyses were performed by means of the GENMOD procedure, with a gamma distribution and log-link function using SAS Enterprise Guide 7.1 software (SAS Institute Inc; Cary, NC). Statistical analyses to test the probability of having costs, as well as the total healthcare spending in each postoperative cost category, were performed using a 2-part model to account for members who did not have healthcare utilization in a given category. The first part of the model used a logistics model to test the probability of having costs and was followed by a generalized linear model to test the cost distributions.

**Results**

A total of 739 members with a customized knee implant and 228,697 with an off-the-shelf implant were identified in the Medicare Inpatient Standard Analytical File. After conducting propensity score matching to ensure that the study cohorts had similar baseline demographic and comorbidity profiles, a total of 4434 patients—739 who received a customized implant and 3695 who received an off-the-shelf implant—were selected for analysis. **Table 1** (available at [www.AHDBonline.com](http://www.AHDBonline.com)) shows the demographics and comorbidity profiles of the matched study cohorts. No significant differences were found in the study cohorts' age range, sex, race, geographic location within the United States, or high-cost comorbidity profile.

**Table 2** presents the average TKA episode spending by healthcare setting among all patients for each cohort. The overall episode expenditures, which include the preoperative CT scan, index procedure, and 12-month postoperative healthcare spending, were \$1695 less for the customized implant cohort (\$18,585) than for the off-the-shelf implant cohort (\$20,280;  $P < .0001$ ). This savings was driven by lower average healthcare spending in the customized implant group versus the off-the-shelf

implant group in postindex settings, including inpatient costs, \$2012 versus \$2711, respectively; skilled-nursing facility, \$264 versus \$784, respectively; and home health, \$2184 versus \$2343, respectively.

As described above, a 2-part statistical model was used to test the significance of postoperative spending to account for members without spending in a particular healthcare setting. The results showed significance in the probability of having costs and the average cost among patients with spending in the category. The results for each postoperative healthcare setting are presented in **Table 3**.

Although the probability of having postindex inpatient spending was not significantly different between the study cohorts (15.7% for customized implants vs 15.4% for off-the-shelf implants;  $P = .9437$ ), the average inpatient expenditure among patients who had a customized implant was significantly lower than patients with an off-the-shelf implant (\$12,817 vs \$17,605, respectively;  $P = .0008$ ). Furthermore, patients who had a customized implant were significantly less likely to have 12-month healthcare spending for skilled-nursing facility services (3% vs 4.8%;  $P = .0241$ ). In addition, patients with a customized implant had significantly lower spending for skilled-nursing facility services than members with an off-the-shelf implant (\$8882 vs \$16,183, respectively;  $P = .0236$ ).

Conversely, patients with a customized implant were significantly more likely to incur outpatient costs than the off-the-shelf implant cohort (90.9% vs 85.7%, respectively;  $P = .0005$ ). Moreover, patients with a customized implant had significantly higher outpatient spending (\$2328 vs \$2106;  $P = .0377$ ). No significant differences were seen between the 2 cohorts with regard to the probability of incurring costs or average spending related to emergency department use and home health services.

PMPM calculations were made with the assumption that the customized implant market penetration would be 10% of customized implant-eligible procedures. Under these base-case population, procedure volume, and customized implant market penetration rate assumptions, the Medicare FFS program could have a \$0.08 PMPM savings.

To assess the PMPM impact of customized implant use under various market scenarios, a sensitivity analysis was performed altering 2 model inputs: market penetration rate and the percent of TKA procedures that are candidates for a customized implant. The market penetration rate ranged from 3% to 30%, and the percent of TKA procedures that would be candidates for a customized implant varied from 75% to 90%. The PMPM impact for each scenario is presented in **Table 4** and ranges from \$0.02 to \$0.28 PMPM savings.

**Table 3** Probability of Costs and Average Spending, by Healthcare Setting

Postindex healthcare setting	Off-the-shelf implant cohort	Customized implant cohort	Difference	P value
<b>Inpatient</b>				
Probability of healthcare spending, %	15.4	15.7	0.3	.9437
Average healthcare spending, \$	17,605	12,817	-4787	.0008
<b>Outpatient</b>				
Probability of healthcare spending, %	85.7	90.9	5.2	.0005
Average healthcare spending, \$	2106	2328	222	.0377
<b>Emergency department</b>				
Probability of healthcare spending, %	27.0	30.2	3.2	.0671
Average healthcare spending, \$	929	872	-57	.6748
<b>Home health</b>				
Probability of healthcare spending, %	66.2	63.9	-2.3	.3145
Average healthcare spending, \$	3540	3419	-120	.1026
<b>Skilled-nursing facility</b>				
Probability of healthcare spending, %	4.8	3.0	-1.9	.0241
Average healthcare spending, \$	16,183	8882	-7301	.0236

**Table 4** Sensitivity Analysis: Per-Member per-Month Savings on Customized Implants

Customized implant market penetration rate	Percent of TKA procedures that are candidates for a customized implant			
	75%	80% <sup>a</sup>	85%	90%
3%	\$0.02	\$0.03	\$0.03	\$0.03
5%	\$0.04	\$0.04	\$0.04	\$0.05
10% <sup>a</sup>	\$0.08	\$0.08 <sup>b</sup>	\$0.09	\$0.09
15%	\$0.12	\$0.13	\$0.13	\$0.14
20%	\$0.16	\$0.17	\$0.18	\$0.19
25%	\$0.20	\$0.21	\$0.22	\$0.24
30%	\$0.24	\$0.25	\$0.27	\$0.28

<sup>a</sup>Indicates base-case assumptions.  
<sup>b</sup>Indicates base-case per-member per-month.  
 TKA indicates total knee arthroplasty.

**Discussion**

The current expense of TKA treatment, which is already one of the highest categories of spending in the Medicare FFS program, is projected to continue to grow as a result of the aging US population and the increasing obesity rate. Consequently, identifying solutions to reduce spending while maintaining or increasing the quality of care is paramount. Previous studies have demonstrated that customized implants are associated with

reduced complications and improved function and implant alignment.<sup>8-10,13</sup>

To our knowledge, our study is the first to evaluate the economic impact of customized implant performance compared with off-the-shelf implants on the Medicare FFS program.

The PMPM financial impact on the Medicare FFS program when customized implants are used in a proportion of TKA procedures was modeled using the TKA episode expenditures per cohort, Medicare enrollment figures, and the volume of TKA procedures that are candidates for a customized implant. The most recent beneficiary enrollment statistics published by CMS in February 2019 indicate that 38,442,107 beneficiaries are currently participating in the Medicare FFS program.<sup>21</sup> In addition, our analysis of the 2016 Inpatient Standard Analytical File database in conjunction with our expert estimate regarding the percent of TKA procedures that are candidates for a customized implant resulted in 230,150 custom implant–eligible TKA procedures.

Consistent with previous findings that show lower adverse event rates during the index and postindex time frames for patients who received customized implants,<sup>13</sup> our study showed that the 12-month average episode spending was \$1695 less for members who received a customized implant than for a propensity-matched cohort of members who received an off-the-shelf implant. Lower average episode expenditures among members with a customized implant were largely a function of a reduced index procedure cost and less average spending in the inpatient and skilled-nursing facility settings during the postoperative time frame.

Our findings are consistent with the results of Culler and colleagues, who identified lower episode-of-care spending and less skilled nursing facility utilization among patients who received customized implants than in those who received off-the-shelf implants.<sup>13</sup> The modeled PMPM savings in our study, which used the average episode spending among members with customized or off-the-shelf implants, showed that the Medicare FFS program could result in substantial savings of \$0.08 PMPM (range, \$0.02 PMPM–\$0.28 PMPM savings) when a customized implant is used in a selection of members who currently have an off-the-shelf implant.

It may be suggested that new technologies, such as customized implants, are more likely to be used in a healthier population, and therefore the results demonstrated in our study may not be applicable to the wider Medicare population who undergo TKA procedures. However, patients included in this present analysis are largely similar to those in the full Medicare TKA population. Table 1 presents the demographics, comorbidities, and DRG procedures of all Medicare FFS beneficia-

ries who underwent TKA compared with patients in each of the study cohorts.

Although some characteristics differ between the full Medicare TKA population and the study cohorts, such as the percent of members located in certain Census Bureau division categories, the majority of characteristics are similar between each of the 3 populations. For example, the percent of total Medicare beneficiaries who are classified as having major complications or comorbidities (DRG code 469) is extremely similar among each population (2.3% of total Medicare-covered patients with TKA, 2.1% of total patients with TKA who had an off-the-shelf implant, 1.6% of total patients with TKA who had a customized implant). As such, we are confident in generalizing the study findings to the full Medicare population with TKA.

Our study findings indicate that the use of customized implants in the Medicare population can reduce 12-month episode spending compared with the use of off-the-shelf implants. Given the significant increase in the volume of TKA procedures in the United States, advances in care that lower costs while maintaining or improving quality merit our attention.

### Limitations

This study has some limitations. Because medical coding does not distinguish between customized and off-the-shelf implants in administrative claims data, the customized implant cohort was identified through matching health plan members to multiple demographic and procedural characteristics of customized implant order numbers provided by the manufacturer to ensure that members who were identified as having a customized implant actually received the implant. The coding methodology used could have limited impact on study findings.

The study selection criteria only allowed for exact matches; therefore, there is an extremely low chance that a patient who did not receive a customized implant was included in the customized implant cohort. However, it is possible for a patient who received a customized implant to be included in the off-the-shelf implant cohort if the patient did not receive a preoperative CT scan in the outpatient setting, which was therefore not listed in the Medicare database. Because the off-the-shelf implant cohort was selected from a large population (ie, 228,697 procedures), the chance of incorrect categorization is low and is unlikely to have any impact on the study's results.

In addition, as a result of the conservative nature of patient selection used in the study, not all customized implant order numbers were identified in the Medicare FFS database and/or were included in the analysis.

Finally, the driving factor of the index procedure pay

amount differences between the 2 cohorts was not identified during the analysis. We examined multiple factors that could potentially increase or decrease a hospital's DRG pay amount. The factors we examined include the percent of patients with a short stay (which reduces DRG payments in some instances), the outlier payments (made when hospital costs exceed a certain threshold), and the percent of patients whose index visit was classified with DRG code 469 (reimbursed at a higher rate than DRG code 470). Although the results of these analyses suggested that each factor may slightly contribute to the index differences observed between the 2 cohorts, no one factor made a meaningful impact that fully explained these differences.

### Conclusion

The results of the present study suggest that compared with off-the-shelf implants, customized knee implants can reduce healthcare spending among patients undergoing TKA. These findings may help to assess the economic impact of customized knee implant technology on specific health plan populations. In addition, the results may be of benefit for providers who are taking on financial risk for patients undergoing TKA procedures, such as those participating in accountable care organizations or bundled payment programs.

Our study did not investigate the financial impact of receiving a customized implant in a commercial population with TKA. Given the positive results in the Medicare population, a similar review is recommended to be completed in a commercial population among younger patients aged <65 years, because the findings may indicate that customized implants could also result in substantial savings for a commercial health plan. It is also suggested that future studies conduct subanalyses by sex, race, and comorbidities to understand the economic impact on these specific populations. ■

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