FDA’s U.S. Immunoglobulin Utilization Study
Executive Summary

In 2019, multiple healthcare providers and medical societies contacted the U.S. Food and Drug Administration’s (FDA) Drug Shortage Office and Office of Compliance and Biologics Quality regarding an acute national shortage of immunoglobulin (Ig). In response, the FDA initiated a protocol under the Center for Biologics Evaluation and Research (CBER) Office of Biostatistics and Epidemiology Biologics Effectiveness & Safety (BEST) System, part of the FDA Sentinel Initiative, to analyze and better understand the various uses of Immunoglobulin (Ig).

In February 2022, the CBER Surveillance Program BEST Initiative posted the study report, *Assessment of Immune Globulin Utilization in Commercially insured and Medicare Populations*. The aim of the study was to provide a better picture of the evolving Ig use over a 10-year longitudinal period in the context of emerging scientific evidence and clinical trends. The objectives of the study evolved from the initial study protocol, ultimately being to 1) summarize the overall Ig use patterns and trends from 2009 through 2019 among individuals with private health insurance or on Medicare, and 2) assess how Ig use may have changed over time across particular disease categories associated with Ig therapy use.

Results from the study confirm that Ig use increased between 2009 and 2019 in both the commercially insured and Medicare populations. Increases were observed in

- the number of Ig administrations
- the number of enrollees receiving Ig
- the annual number of administrations per recipient
- the average aggregate annual dose
- the average dose per administration (to a lesser extent)

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1 “Assessment of Immunoglobulin Utilization and Shortage – Protocol version 1.3” (31 August 2020)
2 Although the study is dated February 2022, the publication was not made public until April 2022.
3 “Assessment of Immunoglobulin Utilization and Shortage – Protocol version 1.3” (31 August 2020)
The study highlights several observations, including:

- Stretches of time where lower-dose Ig treatments were not observed, meaning that despite reports of limited Ig availability, the evidence does not support a short-term reduction of usage
- Increases in Ig use may be attributed in part to average body weight increases in the population since Ig is administered on a kg/weight basis
- IG use was more prevalent in Medicare than in the commercially insured population. This may reflect the higher prevalence of clinical conditions among older adults for whom IG could plausibly be used in this population. Examples include immunodeficiency, neurologic, and autoimmune, etc.
- Ig use increased across all conditions, indicating that it is unlikely one condition diverted Ig from other conditions

The FDA study concludes that most Ig administrations were received by individuals with condition categories supported by emerging evidence and approved treatment guidelines. While utilization associated with all six plausible condition categories increased, the FDA recommended that certain conditions, including immunodeficiency, neurologic, hematologic, and autoimmune/CTD disorders, need further assessment in future studies.

A 2021 roundtable on Ig use sought to address not only the issue of Ig use but also to hear the opinions of US clinical experts who use Ig therapies in their practices. The roundtable included an Ig market analysis presentation conducted by Adivo Associates, which echoes FDA conclusions that the use of Ig as treatment is for FDA-approved indications or conditions supported by evidence. Participating physicians in the Roundtable presentation identified several reasons for increased use, including the following:

- Patients on Ig therapy living longer
- Improved diagnosis rates
- Wider use in oncology-related secondary immunodeficiencies, and
- Expanding scientific knowledge of Ig benefits for patients.

One point of divergence between the FDA findings and the anecdotal evidence presented during the roundtable by physicians was product availability. While the FDA study observed no short-term reductions in usage, the physicians who prescribe Ig noted that their organizations never have enough product and have, at times, needed to lower doses or delay treatments for patients. Healthcare providers believe that increasing plasma collection is a promising approach to address access challenges to ensure adequate supply levels of Ig are manufactured to meet the growing clinical need. For more information, a [report](#) and [recording](#) of the US Ig Roundtable are available.

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