



Medicare Access to Intravenous Immunoglobulin (IVIG) for Primary Immunodeficiency (PI) Beneficiaries

The Medicare IVIG Demonstration (Demo) allows thousands of Medicare beneficiaries with PI to receive life-saving IVIG in their home. **Without Congressional Action, by the end of 2020, this necessary and cost-effective option will no longer be available.**

About PI and IVIG

In the United States there are an estimated 250,000 people diagnosed with PI. PIs include more than 400 types of rare, chronic disorders in which part of the body's immune system is missing or functions improperly. Fortunately, most people with PI can live healthy productive lives if they receive lifelong immunoglobulin (Ig) replacement therapy. Ig is a blood plasma product that helps prevent frequent and severe infections and may be administered subcutaneously or intravenously. With approximately 4,000 Medicare beneficiaries with PI dependent IVIG, it is essential that this small but vulnerable group have continued access to IVIG treatments in the safety of their home.

Medicare IVIG Access Background

In 2012, Congress passed the Medicare IVIG Access Act, which established a Demo that allowed enrollees with PI to receive IVIG at home by providing Part B reimbursement not just for the medication, but for the services and supplies required. The Demo began in 2014 and was extended by Congress through December 31, 2020. The Demo is capped at 4000 enrollees and as of March 2020, the Centers for Medicare and Medicaid (CMS) reported 3,394 enrolled.

At the Demo's close, CMS has one year to assess its value and cost effectiveness and report to Congress its recommendation on whether to convert it to a permanent benefit. This means, those who have been receiving in-home IVIG services will not have access for at least one year. If access to in-home IVIG is limited, then Medicare beneficiaries will only be able to receive this needed treatment at facility-based sites. Such facilities are in short supply and, when they do exist, are challenging for those with PI given their compromised immune systems. Also, private insurers have demonstrated the cost effectiveness of home-based care and frequently cover home infusions. With no Demo, many individuals will lose in-home infusions when they age into Medicare.

IVIG during the Coronavirus (COVID-19) Pandemic

The current COVID-19 pandemic demonstrates how important it is for individuals with compromised immune systems to avoid potentially dangerous environments. While Ig therapy is effective, the very nature of PI means our community is especially vulnerable to viruses including COVID-19. Ensuring that those with PI have continuous access to at-home IVIG treatments during a health emergency and beyond is essential to the well-being of this community. While the Demo will help PI beneficiaries during the current crisis, the coverage for these services is scheduled to end this year, forcing individuals with PI to take serious risks by having to receive treatments among others in facilities.

Congressional Call to Action

We urge Congress to pass legislation extending the Medicare IVIG Demonstration ensuring beneficiaries with PI continue to be able to receive IVIG at home. Legislation should; (1) extend the Demo for 2 years, (2) raise the enrollment cap, and (3) require CMS to submit its report by October 2021, using data from October 1, 2014 through September 30, 2020, to address the coverage gap and allowing Congress to assess the study and make a permanent benefit by October 1, 2022.