

September 29, 2020

The Honorable Chuck Grassley
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden:

We are writing as patients, healthcare providers, product manufacturers and other stakeholders to request that you include within any “must pass” 2020 legislative package [H.R. 7839: the Continuing Access to In-Home IVIG Act](#). H.R. 7839 is bipartisan legislation sponsored by Congresswoman Doris Matsui (D-CA) and Congressman Kevin Brady (R-TX) that will ensure Medicare beneficiaries diagnosed with a primary immunodeficiency (PI) will retain access to in-home administration of life-sustaining intravenous immunoglobulin (Ig) medications. It will do so by extending a previously enacted and once-extended demonstration project until December 31, 2022 at which time we hope a permanent Medicare benefit for this necessary service is in place.

Individuals with PI have one of the over 400 rare disorders in which a person’s immune system fails to function properly because of genetic or intrinsic defects. People with PI are more susceptible to infections, and even the mildest of illnesses present a significant threat. To help overcome this impediment, many people with PI rely on Ig replacement therapy to replace the antibodies their bodies are unable to produce. These medications, derived from donated blood plasma that undergoes a rigorous purification and manufacturing process, are delivered intravenously (IVIG) or subcutaneously (SCIG).

While Medicare has covered IVIG in beneficiary homes under Part B for over 15 years, coverage was limited to just the medication, but not the nursing services or the supplies needed to infuse the drug. This made Medicare an outlier to most other payers and most Medicare beneficiaries were unable to afford in-home treatment. In late 2012, Congress addressed this problem by creating a Medicare IVIG demonstration (demo) that provided for a bundled payment to cover the therapy, supplies and treatment, which began operating in 2014 and was extended in 2017. Unfortunately, this project is scheduled to end on December 31, 2020 unless Congress acts to extend it again.

In addition, in order to ensure patients have uninterrupted access to home IVIG, the Centers for Medicare and Medicaid (CMS) must be directed to conduct their evaluation of the demo before the project concludes. Currently, at the demo’s close, CMS has one year to assess its value and report its recommendation to Congress on creating a permanent benefit. Without legislative action, those who have been receiving in-home IVIG will lose access for at least one year while CMS conducts this study.

It is our hope that Congress will ultimately enact legislation to make the in-home IVIG bundled payment permanent, especially given the impact on beneficiary health as well as on program costs by

keeping a service in the home rather than a community setting. However, given the challenges before us today, the near-term need is to extend this demonstration so beneficiaries do not lose access to in-home IVIG care at the end of 2020. **H.R. 7839 will do this by:**

- Extending the demonstration program until December 2022, subject to available funds.
- Requiring CMS to provide Congress with an interim report on the first six years of the demonstration to inform further Congressional actions.
- Increasing the beneficiary cap from the current 4,000 to 6,500 to prevent beneficiaries from being shut-out from the program.

CMS has recently begun efforts to notify beneficiaries of the looming end to the demonstration, making clear the need for Congressional action to prevent this from occurring. **We urge you to include H.R. 7839 within any legislative package that will be enacted this year to ensure Medicare beneficiaries with PI do not lose access to this service.** Taking this action is particularly important as we continue to navigate the COVID-19 pandemic and its serious impact on immunocompromised individuals such as those with PI. While CMS has taken actions to enhance the ability of beneficiaries to access care in the home, the process to obtain in-home infusions remains challenging and expiration of the demo would leave many without in-home options.

We thank you in advance for giving this request your fullest consideration. If you have any questions, please feel free to reach out to any of our organizations or to Lynn Albizo, Associate Vice President of Public Policy, Immune Deficiency Foundation at lalbizo@primaryimmune.org.

Sincerely,

American Academy of Allergy, Asthma, and Immunology (AAAAI)
American Plasma Users Association (APLUS)
CSL Behring
GBS|CIDP Foundation International
Grifols
Immune Deficiency Foundation (IDF)
Jeffrey Modell Foundation
Pharmaceutical Care Management Association
Plasma Protein Therapeutics Association (PPTA)
Takeda Pharmaceuticals U.S.A.