

# Questions and Answers Concerning the Medicare Patient IVIG Access Act

## **1. *What is intravenous immune globulin (IVIG)?***

Immune globulin is a naturally occurring collection of highly specialized proteins known as antibodies. Antibodies initiate the body's immune response against foreign antigens. IVIG is a biological product that is transfused intravenously. It is derived from human plasma donations.

## **2. *Who uses IVIG?***

The FDA has approved IVIG to treat several conditions, including primary immunodeficiency disease, bone marrow transplantation, chronic inflammatory demyelinating polyneuropathy, chronic lymphocytic leukemia, idiopathic thrombocytopenic purpura, and Kawasaki disease. In addition, the medical literature supports using IVIG to treat several autoimmune, dermatological, and neurological conditions, such as Guillain-Barre syndrome, multiple sclerosis, myasthenia gravis, myositis, pemphigus, pemphigoid, stiff-person syndrome, neuropathies, and infection-related diseases.

## **3. *Why is Medicare reimbursement not adequate?***

Plasma is a very expensive raw material representing between 40-60% of the costs of plasma products. There also is a very long lead time in making the product and special handling is required for distribution. Many large hospital systems command better prices in comparison to other health providers because a large majority of them have contracts through group purchasing organizations (GPO). ASPE found that IVIG purchases by outpatient clinics, surgical centers, and other outpatient facilities do not fare as well in getting lower prices. Many physicians do not have access to the discounts that GPO contracts can provide large purchasers.

## **4. *Why can't CMS handle this problem administratively?***

Medicare law requires that the Secretary pay for IVIG (and all other Medicare Part B drugs) using the average sales price (ASP) methodology. A statutory change is necessary to allow any additional payment. The Medicare Patient IVIG Access Act modeled the payment provision included in the bill after a similar authority granted in the Medicare Modernization Act (MMA) for the furnishing of hemophilia clotting factor – another plasma derived therapy.

## **5. *Why is Medicare's home infusion benefit for IVIG inadequate?***

Although current Medicare law provides a home infusion benefit specific to patients with a primary immunodeficiency diagnosis, coverage for the related "items and services" are excluded. As a result, a 2007 ASPE report found that home infusion providers generally do not take new patients with only Medicare coverage – leaving Medicare patients with prohibitive out-of-pocket costs or no access to home infusion. The Medicare Patient IVIG Access Act seeks to address the absence of coverage for the required items and services for IVIG home infusion for PIDD patients.

## **6. *Isn't there another home infusion bill that will take care of this?***

Reps. Engel/Granger/Baldwin and Senators Lincoln/Snowe/Isakson introduced H.R. 574 and S. 254, which address shortfalls in home infusion coverage for drugs provided through Medicare Part D. This bill will help those patients receiving IVIG under Part D which excludes primary immunodeficiency disease because they receive IVIG through Medicare Part B. The goal of this legislation is similar, but for a broader group of patients receiving their therapy through Medicare Part D.

## **7. *Is this bill different from what was introduced last year?***

Yes, it includes minor changes to H.R. 2914 introduced in the 110<sup>th</sup> Congress and includes a new provision asking the HHS Secretary to review the current infusion codes and determine which of the complexity codes is most appropriate for IVIG administration and requires MedPAC to report after 2 years on the changes in access to IVIG for Medicare beneficiaries, as well as recommend any further policy or administrative changes to improve access.

## **8. *How much does the bill cost?***

In the 110<sup>th</sup> Congress, CBO scored H.R. 2914 at \$170-180 million over five years.

## **9. *Is there an offset?***

Yes. The bill includes a provision to help offset new spending. The offset provision allows Medicare to pay for disposable elastomeric infusion pumps, in place of a durable pump, for the treatment of colorectal cancer when prescribed by a physician.