



IMMUNE DEFICIENCY FOUNDATION

The National Patient Organization Dedicated to Advocacy, Education and Research for Primary Immunodeficiency Diseases

Questions and Answers Concerning the Medicare Patient IVIG Access Act

1. What is intravenous immunoglobulin (IVIG)?

Immunoglobulin 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 infused 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 (a group of disorders in which the immune system fails to produce enough antibodies); chronic lymphocytic leukemia, Kawasaki disease, and bone marrow transplantation. In addition, the medical literature supports using IVIG to treat several neurological conditions, such as Guillain-Barre syndrome and some neuropathies, autoimmune conditions, dermatological disorders, 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. Large hospitals 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. What is so bad about going to the hospital to get this treatment?

Because PIDD patients have compromised immune systems, they should not be exposed to the kinds of microorganisms you might find in places with sick people. This is also why home infusion is an appropriate option. In addition, because of overhead, hospitals are more expensive settings to get treatment, with higher cost-sharing for Medicare beneficiaries than would be the case if the patient were infused in the physician's office. Also having to go to a hospital can delay or create barriers to access for many Medicare beneficiaries, particularly in rural areas.

The OIG report found that 61% of physicians had sent patients to hospitals for IVIG treatment "because of the inability to acquire adequate amounts of IVIG or problems with Medicare payment." In addition, ASPE reported that physicians "described situations in which patient health was compromised when they were shifted from a physician's office to a hospital setting for ... infusions and/or when patients had difficulties and delays in receiving ... infusions."

5. 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.

6. 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 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.

7. 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. If this bill passes, it will help some patients receiving IVIG. However, it will not help patients with a primary immunodeficiency disease because they receive IVIG through Medicare Part B. While similar to the Medicare Patient IVIG Access Act, the goal of H.R. 574 and S. 254 is for a broader group of patients receiving their therapy through Medicare Part D.

In addition, it's our understanding some Members of Congress are considering introducing a bill addressing coverage for the related items and services currently excluded from Medicare Part B for patients with a primary immunodeficiency disease. We're told this legislation will include language identical to section 4 of the Medicare Patient IVIG Access Act.

8. Is the Medicare Patient IVIG Access Act different from what was introduced last year?

Yes. The Medicare Patient IVIG Access Act is closer to the Senate bill introduced in the 110th Congress (S. 2990) which sunsets the authority to provide an additional payment for IVIG after 2 years. Previously, the House bill had unlimited authority. Also, the bill 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.

9. Why not change how IVIG is paid rather than seek a temporary solution?

We recognize that ASP works for many drugs. However, there has been evidence of access difficulties for IVIG. The Medicare Patient IVIG Access Act is data-driven. In the short-term, it collects data and provides the HHS Secretary with time limited authority to provide an add-on payment, if necessary. Also, the bill directs MedPAC to review IVIG payment policy and make recommendations to Congress on alternative payment policies. A new payment policy may be appropriate for IVIG and/or all Part B drugs. However, we recognize any sweeping changes will take time to implement and the IVIG patient community would want to participate in any such efforts to ensure access to all formulations in all sites of care is not compromised. The Medicare Patient IVIG Access Act provides a transitional policy to address IVIG access issues.

10. How much does the bill cost?

In the 110th Congress, CBO scored a broader House bill (H.R. 2914) providing unlimited authority to update IVIG payment at \$170-180 million over five years. CBO separately scored the home infusion provision in the bill at \$25-30 million/5 years. The Medicare Patient IVIG Access Act in the 111th Congress limits authority for an add-on payment to 2 years, recognizing that broader Part B drug policy changes may take place in the future. Thus, the cost of the bill is expected to be less than the estimate in the 110th Congress.

11. Is there an offset?

Yes. The Senate and House bills include an offset allowing Medicare to pay for disposable elastomeric infusion pumps, in place of a durable pump, for the treatment of colorectal cancer.

12. Since sub-cutaneous Ig is available, why can't people use this therapy instead of IVIG?

While sub-cutaneous immunoglobulin is now available in a limited quantity, not all patients can use this form of therapy. It is medically appropriate for some patients and not medically appropriate for other patients. IVIG is used by a majority of primary immunodeficiency patients.