

Senator Kerry Amendment C-5

Medicare IVIG Access -- Frequently Asked Questions

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-Barré 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. The Assistant Secretary of Planning & Evaluation (ASPE) commissioned a study (2007) which 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 provided to large purchasers because they cannot buy at bulk rate. . The Kerry Amendment requires ASPE to update its study and make recommendations to Congress regarding payment options.

4. *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 Kerry Amendment seeks to address the absence of coverage for the required items and services for IVIG home infusion for PIDD patients.