

# Medicare Patient IVIG Access Demonstration Project

## 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-Barre syndrome, multiple sclerosis, myasthenia gravis, myositis, pemphigus, pemphigoid, stiff-person syndrome, neuropathies, and infection-related diseases.

### **3. *Why is the current Medicare home infusion benefit for IVIG inadequate?***

Current Medicare Part B law provides a home infusion benefit specific to patients with a primary immunodeficiency diagnosis. However, coverage for the related "items and services" is 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. The bill establishes a 3 year demonstration project to provide coverage of items and nursing services necessary to infuse IVIG in the home. Without such a change, the current law benefit is inadequate.

### **4. *Why are studies of Medicare IVIG reimbursement necessary?***

In 2007, government-sponsored studies by ASPE and the OIG demonstrated the difficulty Medicare patients routinely experience trying to locate providers willing to provide IVIG infusions. The April 2007 OIG report stated that Medicare reimbursement for IVIG many times did not cover the cost providers must pay for the product. In fact, the OIG found that 44 percent of hospitals and 41 percent of physicians were unable to purchase IVIG at the Medicare reimbursement rate during the 3<sup>rd</sup> quarter of 2006. The previous quarter had been even worse: 77.2% of hospitals and 96.5% of physicians were unable to purchase IVIG at the Medicare reimbursement rate. The studies in the bill will analyze the appropriateness of implementing a new Medicare payment methodology for IVIG and the feasibility of reducing the lag time with respect to data used to determine the Medicare Part B Average Sales Price and report to Congress recommendations for legislative and administrative action, as well as update the 2007 ASPE study. These reports are necessary because an astounding 61 percent of responding physicians indicated they had no choice but to send patients to hospitals for IVIG treatment, instead of providing this therapy in a physician's office, due to their inability to purchase IVIG at prices below Medicare reimbursement. Some physicians reported that they stopped providing IVIG altogether to patients with Medicare. Indeed, the current situation seriously jeopardizes patient care for individuals with compromised health.

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

An independent analysis of the bill by Dobson/DaVanzo estimates a cost of \$9.6 million over five years.

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

Yes. 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. Currently, Medicare only reimburses for a durable pump, while private insurance generally covers both. The disposable pump is cheaper and improves patient quality of life. The offset is estimated to save \$216.8 million over ten years.

### **7. *How does this bill differ from H.R. 1765 and H.R. 2002/S.701?***

During consideration of the health care reform bills, Rep. Matsui and Senator Kerry modified their IVIG bills to provide greater certainty of the cost of the provisions to the Medicare program and assure that the proposed offset covered any increased Medicare spending. Unfortunately, the amendment did not receive an official estimate by the Congressional Budget Office (CBO) before final passage of the Patient Protection and Affordable Care Act. HR 5597 contains the same language as the floor

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amendment introduced by Senator Kerry, providing for a demonstration project and study. This bill also contains an offset for the cost.