

SENATOR KERRY MEDICARE PATIENT IVIG ACCESS AMENDMENT

Medicare IVIG Access Studies

Requires the Secretary to report to Congress within 2 years after enactment regarding the following IVIG access and reimbursement issues:

- (1) Update the February 2007 ASPE report entitled "Analysis of Supply, Distribution, Demand and Access Issues Associated with Immune Globulin Intravenous (IGIV)"; and
- (2) 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.

Medicare Demonstration Project

The current Medicare Part B IVIG home benefit for beneficiaries with Primary Immune Deficiency Disease (PIDD) fails to cover the items and services necessary to administer IVIG in the home. The Kerry amendment establishes a three-year Medicare demonstration project to address this inequity by providing reimbursement for the items and services necessary to administer IVIG in the home. The demonstration project would begin on January 1, 2011 and enrollment would be capped at no more than 4,000 beneficiaries. An interim report of the demonstration project would be due within 2 years of enactment and a final report would be due in 2014.

Cost/Offset

The estimated cost of the amendment is \$9.58 million. The amendment is offset by allowing Medicare patients undergoing chemotherapy for colorectal cancer the option to use disposable elastomeric infusion pumps when prescribed by a physician in place of a durable pump. Currently, Medicare only reimburses for a durable pump, while private insurance 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.

Background

Intravenous immune globulin (IVIG) therapy is vital in treating patients with frequent life-threatening infections and debilitating illnesses, including those with primary immunodeficiency diseases, autoimmune and neurological conditions such as: chronic inflammatory demyelinating polyneuropathy, Guillain-Barré syndrome, idiopathic thrombocytopenic purpura, myasthenia gravis, myositis, multiple sclerosis, pemphigus; as well as certain types of cancer and other chronic illnesses. Without regular access to IVIG therapy, these patients experience a poor quality of life, disability and potentially death. In January 2005, the basis for Medicare Part B drug reimbursement was changed to average sales price (ASP) and soon after reports of access problems were reported to patient groups. The OIG and ASPE studied IVIG issues and reported to Congress in 2007. The OIG reported that even after the 6 month time lag allowed Medicare payment to adjust to changes in product cost, 44% of hospital outpatient departments and 41% of physicians were unable to purchase IVIG at the Medicare reimbursed rate. In addition, the ASPE report concluded that home infusion providers generally do not accept new PIDD patients with only Medicare coverage noting that limitations in service are caused because health care providers: (1) are not able to acquire IVIG at prices at or below the Medicare Part B reimbursement level, and (2) are not reimbursed for the infusion services (*i.e.*, nursing time). Home treatment is an appropriate setting for many Medicare beneficiaries with PIDD because of the risk of infection in other health care settings. Many private insurers recognize this fact and provide home coverage for IVIG.

Unfortunately, current law specifically excludes from Medicare coverage the items and services necessary to administer IVIG in the home, including the services of a nurse to perform the infusion. The average length of infusion for Medicare patients with a primary immune deficiency diagnosis (PIDD) is 3 hours and patients are typically infused once each month.