IG Reimbursement: How Did We Get Where We Are Today?

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Immune globulin reimbursement is a critical and complex problem, affecting the lives of thousands of people living with chronic diseases. On Jan. 1, Medicare reimbursement for hospital outpatient IVIG therapy was reduced, a potentially life-threatening change—and a confusing one, given the recent history of IVIG reimbursement. …

IVIG

Immune globulin products (intravenous, IVIG; subcutaneous, SCIG; and intramuscular, IMIG) are manufactured from plasma, a component of human blood, pooled from thousands of donors. IG products are expensive to manufacture and distribute, yet life-long IVIG therapy is critical to the health and well-being of patients with a wide variety of chronic and often rare diseases.

This sets the stage for expensive treatment for conditions with which few practitioners, decision makers or insurers are familiar—which, in turn, sets the stage for challenges to fair, reliable reimbursement for a lifesaving treatment.

A Convoluted History

But this is not such a new problem. It didn't begin with passage of the IVIG reimbursement method mandated by the Medicare Modernization Act of 2003 (MMA). In fact, reimbursement for IVIG has been a longer-term problem for the immune globulin community, because of the historical debate about how to define immune globulin: blood product, biologic, or single or multiple source drug. Each of the three categories bears with it a different method for calculating its Medicare reimbursement rate.

In 2002, the Balanced Budget Refinement Act (BBRA) resulted in implementation of a new method for reimbursement for drugs, including IVIG, in the hospital outpatient setting. The new methodology miscategorized IVIG as a multisource drug, which is equivalent to a generic drug category. The IVIG community attempted to explain to the Centers for Medicare and Medicaid Services (CMS) that there are no generic IVIGs and, therefore, IVIG could not be classified as a multisource drug.

Eventually, CMS changed the IVIG status to single source drug, and its reimbursement was based on a percentage of average wholesale price. Although this reimbursement method did typically cover the cost of both the product and its administration, IVIG is literally a blood product, and changing market and supply conditions of blood products could reverse the effectiveness of this type of reimbursement.

With the understanding that inadequate reimbursement for blood, blood products, and plasma-based and recombinant therapies could present a barrier to patient access, the BBRA called for the secretary of the U.S. Department of Health and Human Services (HHS) to create a separate payment category for these products.

So, in September 2002, the Advisory Committee on Blood Safety and Availability (ACBSA), of HHS, directed the CMS to create a reimbursement system for blood products based on current-year acquisition cost plus the actual total cost of administering such products and related services, rather than on the cost of the previous year's hospital outpatient claims. According to ACBSA, this acquisition and administration cost formula is critical to ensuring fair reimbursement of blood products, including IVIG, because their cost is affected by the varying supply of donated blood and plasma in the United States. A market-based formula assures that reimbursement reflects market price changes.

In the meantime, the ACBSA, the Food and Drug Administration (FDA), the House Appropriations Subcommittee on Labor and HHS consistently defined IVIG as a blood product and recommended that CMS recognize it as such. And, in May and August of 2003, the Protein Plasma Therapeutics Association and the Immune Deficiency Foundation (IDF) requested that the ACBSA recommend CMS once again recognize IVIG as a blood product. The ACBSA members agreed and made the recommendation to CMS.

However, when CMS released its blood product reimbursement formula in the 2003 Medicare hospital outpatient prospective payment system, the agency excluded IVIG from its list of blood products.

Formidable Obstacles

The IVIG community challenged the CMS classification. The hurdle to achieving a solution at first seemed small, but it ultimately proved formidable: When Congress passed the MMA in 2003, the 415-page bill contained a small provision that adopted the CMS classification, excluding IVIG from the list of therapies identified as blood products. Instead, Congress included IVIG under the regular drug reimbursement formula, despite the House Appropriations Committee's 2003 recommendation otherwise.

Classification as a regular drug drastically reduced IVIG's reimbursement rate, lowering reimbursement in all sites of care (hospital, physician practice and home). The reduced reimbursement has prevented many healthcare providers from purchasing IVIG, because the total cost of acquisition and administration exceeds the Medicare reimbursement rate.

Consequently, when the MMA reimbursement formula for IVIG was implemented in 2005, many Medicare patients were transferred from their physician's office or infusion suite to the hospital outpatient setting, often causing poor health outcomes for patients whose diseases cause them to be at high risk of acquiring infections in hospital settings.

According to an HHS report by the Assistant Secretary of Planning and Evaluation (ASPE), by 2006, 42 percent of Medicare beneficiaries were shifted from the physician's office to the hospital outpatient setting to receive IVIG. A report by the HHS Office of the Inspector General (OIG) also reported that 61 percent of responding physicians indicated they had sent patients to hospitals for IVIG treatment, largely because of their inability to purchase IVIG at or below the Medicare reimbursement amounts. Despite the reports' findings, no policy recommendations were made by either agency.

The hospital outpatient reimbursement rate was then reduced in January 2006, and many hospitals could no longer afford to continue treating with IVIG. A survey conducted by the IDF of hospital pharmacy directors found that 32 percent of hospitals reported turning away patients for IVIG treatment at some point during 2006.

Through each of the reimbursement reductions mandated by the MMA, members of the IVIG community have offered many solutions to help restore access to IVIG, including declaration of a public health emergency to allow CMS to adjust the reimbursement rate, reclassification of IVIG as a blood product, asking the secretary of HHS to determine an add-on payment to the average sales price (ASP) formula, classifying IVIG as a biologic response modifier under the chemotherapy administration code, etc.

Current Situation

Still no solution has been achieved, and now CMS has reduced reimbursement for all drugs offered in the hospital outpatient setting, including IVIG, from ASP + 6 percent to ASP + 5 percent. CMS has also reduced the IVIG hospital outpatient pre-administration fee by 50 percent. Both of these changes are effective Jan. 1. This is a devastating blow to IVIG patients who have been shifted to hospitals as the site of care of last resort. CMS is also scheduled to eliminate coverage for treatment of certain infections that are acquired while patients are hospitalized, effective October 2008. This is yet another blow to immune-compromised patients, many of whom have no other site-of-care options.

Knowing late in 2007 that these reimbursement reductions were coming, and in response to three years of failed attempts to resolve the IVIG reimbursement and access crisis, the Alliance for Plasma Therapies organized a critical meeting of the minds, held on Sept. 18, 2007. Alliance representatives of patient and physician organizations, professional societies, manufacturers, distributors and specialty pharmacies met with Deputy Secretary of HHS Tevi Troy, CMS Administrator Kerry Weems, Deputy Administrator of CMS Herb Kuhn and HHS Senior Advisor for Blood Policy and Executive Secretary for the Advisory Committee on Blood Safety and Availability Jerry Holmberg.

Participants in the meeting, including the CMS representatives, agreed the meeting was the first step toward creating and maintaining a productive working group, including members of Congress and the IG community, with the goal of finding the best solution to restoring access to IVIG for all patients who rely on this therapy in all sites of care.

However, until this emerging collaboration achieves a solution, patients will continue to experience difficulty accessing their IVIG therapy—and the Jan. 1 reduction in hospital outpatient reimbursement is exacerbating the crisis.

We encourage you to share any immune globulin access problems you experience. We want to help! Contact *IG Living*, your elected representatives, your national disease state organization and the Alliance for Plasma Therapies at www.plasmaalliance.org.

Note: For updates on changes to reimbursement or if you need assistance in finding a site of care for your IG treatment, please contact us at editor@igliving.com.