

# IVIIG Medicare Policy Review

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In October, the Centers for Medicare & Medicaid Services (CMS) issued its final rules for reimbursement changes that will go into effect on Jan. 1, 2009. These changes include the elimination of the preadministration fee for the hospital outpatient setting and the physician's office that was established to help locate product for patients who had shifted to other treatment sites because of earlier reimbursement changes. Additionally, CMS has further reduced the reimbursement for the hospital outpatient setting from the manufacturer's average sales price (ASP) + 5 percent to ASP + 4 percent. Both rules are of great concern to the immune globulin (IG) community, as many patients have been shifted to the hospital outpatient setting and will surely be affected by the new rate.

The Alliance for Plasma Therapies, an advocacy group formed by members of the IG community, submitted comments to CMS in September stating its concern with CMS' continued lack of understanding of the IVIG industry, the patients who rely on IVIG, and the providers who continue to be unable to afford to treat patients because they can't purchase IVIG below Medicare's reimbursement rates.

As indicated by the above issues, problems with Medicare reimbursement are not new. As reported previously in *IG Living*, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) has led to a reimbursement shortfall for IVIG therapies given in

physician offices. This shortfall is due to basing payment for most drugs under Medicare Part B (including IVIG) on the market-based ASP.

In 2005, when the ASP methodology went into effect for treatment in physician offices, the majority of physicians were unable to continue to offer IVIG therapies to patients in this setting because 106 percent of the ASP does not adequately reimburse providers for the acquisition of IVIG.

As a result, patient organizations, providers and other members of the IG community have reported thousands of patients negatively affected. Numerous studies have also been done. According to a May 2007 Department of Health and Human Services (DHHS) report from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) titled "Analysis of Supply, Distribution, Demand, and Access Issues Associated With Immune Globulin Intravenous (IGIV)," after new reimbursement rules for physicians were instituted in 2005, 42 percent of Medicare beneficiaries who had received their IVIG treatment in their physicians' offices at the end of 2004 were shifted to the hospital outpatient setting by 2006. This shift caused a lack of continuity of care, adversely affecting health outcomes and quality of life.

Another study published by the Office of Inspector General (OIG) documented that 50 percent of providers at best were able to afford to treat patients with IVIG. The

study predicted that access would be reduced to 25 percent because of increases in prices of IVIG that are not immediately accounted for in reimbursement rates. (Manufacturers price their products quarterly; however, Medicare's reimbursement rates are based on prices two quarters prior, creating a six-month lag that only exacerbates the above issues when prices increase.)

Despite these reports, CMS has stated that there is stability in the marketplace and providers are continuing to administer IVIG; therefore there is no need for a continuation of the preadministration fee. As we know, patient care continues to be disrupted by change of location, change in IVIG brand, reduction in IVIG dosage, or elimination of treatment altogether due to no site of care available.

### What to Expect in 2009?

Congress is determined to reform Medicare in 2009 and IVIG must be on that agenda. It's critical that legislation be introduced that will help restore access to IVIG for all patients in all sites of care, including patients in the Part D program, which will undoubtedly be a target for reform as well. To effect the changes that will improve IVIG access, the voice of the IG community must be heard. The more organized the IG community is, the stronger our voice will be and the better chance we will have to restore access for all patients.

It's inevitable that coverage determinations under the Medicare program and in the private insurance sector will continue to be a problem. Signs of that sector following Medicare's lead are increasingly evident. If you are a Medicare beneficiary and have trouble finding a site of care willing to administer IVIG due to the continued cuts in reimbursement and/or if your insurance company has stated that it now considers IVIG experimental for your condition and has denied access to IVIG, please contact your patient organizations, *IG Living* or the Alliance for Plasma Therapies for help in finding a site of care and appealing your case. ■

## A Recap of Pricing Methodology

Before the MMA went into effect, Medicare payment for Part B drugs was based on the average wholesale price (AWP), "a term that had never been defined by statute or regulation."<sup>1</sup> Historically, manufacturers published AWP's for their drugs in industry publications such as the *Red Book*, *Blue Book* and *MediSpan*. The CMS used these prices to determine reimbursement. In fact, oftentimes physicians were able to acquire drugs at prices below the AWP (sometimes well below). Regardless of what they paid, they were still able to be reimbursed at 95 percent of AWP (however, the reimbursement for IVIG was later reduced to 85 percent of AWP). This apparent play in the system is what brought about change to the CMS' reimbursement formula: "This gap between the provider's cost for the drug and the reimbursement based on AWP, termed the 'spread,' has led prosecutors to contend that drug manufacturers have inflated the AWP of their drugs in order to entice physicians to buy their products based on the profit to be made on the spread."<sup>2</sup>

To tighten up standards, Congress changed the reimbursement methodology under the MMA. In a three-step process that was phased in over three years, the new methodology called for using the ASP in 2005 as its basis for reimbursement: "Multiple source drugs will be reimbursed at 106 percent of the volume-weighted average of the ASP at which all manufacturers of the drug sold the product."<sup>3</sup> This does not include markup for distribution. The three steps required to calculate the volume-weighted average of the ASP ensure that providers are reimbursed the same amount for a multiple source drug regardless of the price charged by the manufacturer. Single source drugs and biologicals, however, were treated differently, as there's generally only one manufacturer for the product. For these, the amount reimbursed was either the lesser of the manufacturer's ASP or the wholesale acquisition cost (WAC), which is the most recent list price reported in wholesale price guides or other publications.<sup>4</sup> However, since the implementation of the change in 2005, all pricing for IVIG has been predicated on the ASP plus model.

<sup>1</sup> "What Physicians Should Know About the Medicare Modernization Act Part B Drug Reimbursement," *Healthcare Review*, Winter 2005, p. 1, [www.duanemorris.com/newsletters/static/HealthcareNewsletter\\_Winter2005.pdf](http://www.duanemorris.com/newsletters/static/HealthcareNewsletter_Winter2005.pdf).

<sup>2</sup> *ibid.*

<sup>3</sup> *ibid.*

<sup>4</sup> *ibid.*