Plasma Protein Therapeutics Association

September 4, 2012

Reference No.: FASC12065

Marilyn Tavenner
Acting Administrator
Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

ELECTRONIC DELIVERY

Re: CMS–1589–P (Hospital Outpatient Prospective Payment System Calendar Year 2013 Proposed Rule)

Dear Acting Administrator Tavenner,

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to comment on the proposed rule that the Centers for Medicare & Medicaid Services (CMS) has promulgated detailing proposed payment policies in the Hospital Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2013 (Proposed Rule).[1] Our comments on the Proposed Rule are intended to ensure that all Medicare beneficiaries who require plasma protein therapies as part of their treatment regimen have access to the full range of therapies in each therapeutic class. PPTA respectfully urges CMS to take the following actions:

1. Finalize its proposal to pay at average sales price (ASP) + 6% for separately payable, non-pass-through drugs and biologicals in CY 2013; and
2. Continue its longstanding policy for payment of the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department at the same level as in the physician office setting.

PPTA believes these recommendations, if implemented in the final rule, will preserve access to the plasma protein therapy best suited for the individual needs of each patient.

[1] *See* Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations, 77 Fed. Reg. 45,061 (July 30, 2012).

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PPTA represents human plasma collection centers and the manufacturers of lifesaving medicinal therapies, including albumin, alpha$_1$-proteinase inhibitor, antithrombin III, blood clotting factors, C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, and protein C concentrate, from this human plasma.[2] Some PPTA members also use recombinant DNA technology to produce blood clotting factors. Collectively, these therapies – both plasma-derived and recombinant – are known as "plasma protein therapies." The manufacturer membership of PPTA in the United States (U.S.) currently includes Baxter, Biotest, Cangene, CSL Behring, Grifols, and Kedrion.

The majority of plasma protein therapies are solely approved for marketing by the U.S. by the Food and Drug Administration for the treatment of rare diseases, disorders, and conditions. In the U.S., a "rare disease or condition" is generally defined as a disease or condition that affects less than 200,000 people.[3] The majority of the rare conditions that require treatment with plasma protein therapies are genetic, chronic, and life-threatening, including alpha-1 antitrypsin deficiency, chronic B-cell lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy (CIDP), hereditary angioedema, hereditary antithrombin III deficiency, protein C deficiency, primary immune deficiency diseases (PIDDs), such as common variable immunodeficiency, X-linked agammaglobulinemia (Bruton's disease), DiGeorge syndrome, Wiskott-Aldrich syndrome, Nezelof's syndrome, severe combined immunodeficiency, graft-versus-host diseases, and bleeding disorders, such as hemophilia A, hemophilia B, congenital fibrinogen deficiency, von Willebrand disease, and factor XIII deficiency. Cytomegalovirus disease associated with transplant patients, hepatitis B reinfection in liver transplant patients, idiopathic thrombocytopenic purpura (ITP),[4] infant botulism, Kawasaki's disease, rabies, rhesus incompatible pregnancies, and tetanus are examples of acute rare conditions that are treated with plasma protein therapies.

As representatives of a segment of the drug industry with considerable experience in treating rare diseases, disorders, and conditions, PPTA recognizes the importance of adequate reimbursement levels for maintaining access to rare disease therapies. Previous reimbursement cuts for Medicare Part B drugs have resulted in some rare disease patient populations experiencing access difficulties. For example, it is well documented that PIDD patients requiring regular infusions of intravenous immune globulin (IVIG) have experienced treatment delays and shifts in site of service due to previous Medicare reimbursement cuts. Additionally, providers have switched some patients that require regular infusions of IVIG from a brand on which they had been stabilized because of the unintended consequences of payment reductions. Because of the rare, chronic, life-threatening nature of PIDDs and other rare diseases like alpha-1 antitrypsin deficiency and hemophilia, such impediments to treatment are

[2] Human plasma is the clear liquid portion of blood that remains after the red cells, leukocytes, and platelets are removed. Due to its human origin, complexity, and richness in therapeutically useful proteins, human plasma is a unique biological material. *See* Thierry Burnouf, *Plasma Proteins: Unique Biopharmaceuticals – Unique Economics*, *in* 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 209 (2005, 2006).
[3] *See* 21 U.S.C. § 360bb(a)(2) (2006).
[4] ITP can also be a chronic condition.

particularly dangerous. PPTA believes adequate reimbursement levels will prevent future patient access issues for users of plasma protein therapies.

I. PPTA Urges CMS to Finalize Its Proposed Payment Level of ASP + 6% for Separately Payable, Non-Pass-Through Drugs and Biologicals in the OPPS

Adequate Medicare reimbursement is vital to preserve patient access to therapeutic interventions for rare diseases. It affects not only existing therapies, but also decisions by manufacturers to invest in the research and development required to improve formulations and routes of administration for existing therapies or to bring new therapies to market. CMS has proposed to discontinue its policy of setting reimbursement on the basis of claims data for separately paid drugs and biologicals without pass-through status. Instead, CMS is proposing to set the payment level for these drugs and biologicals at ASP + 6% for CY 2013.[5] We commend CMS for this proposal and urge CMS to adopt this proposed payment rate for separately payable, non-pass-through drugs and biologicals in the OPPS.

Pursuant to section 1833(t)(14)(A)(iii)(II) of the Social Security Act (SSA), CMS has broad statutory authority to set the payment level for specified covered outpatient drugs administered or dispensed in the hospital outpatient department. This broad authority has resulted in the reimbursement level for separately payable, non-pass-through drugs and biologicals constantly changing over the last several years – ASP + 6% in CYs 2006 and 2007, ASP + 5% in CY 2008, ASP + 4% in CYs 2009 and 2010, ASP + 5% in 2011, and ASP + 4% in 2012. For CY 2010 through CY 2012, CMS arrived at the payment rate through a complicated methodology that included redistributing some overhead costs from packaged drugs and biologicals to separately paid products.

Based on the last several years of basing reimbursement on claims data, CMS believes that the range between ASP + 4% and ASP + 6% is an appropriate payment rate for separately payable drugs and biologicals. However, CMS is concerned that the continued use of its standard drug payment methodology still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate for hospitals as they could be due to limitations in the submitted hospital charge and claims data for drugs.[6]

In response to these concerns, for CY 2013, CMS is proposing to discontinue its policy of setting reimbursement on the basis of claims data for separately paid drugs and biologicals without pass-through status. Instead, CMS is proposing to use ASP + 6%, which is a statutory default amount, as provided in §1833(t)(14)(A)(iii)(II) of the SSA, when data on drug acquisition cost are not available. This reimbursement rate matches the payment amounts provided for drugs in the physician office. The agency

[5] 77 Fed. Reg. at 45,140.
[6] *Id.*

believes this policy will improve payment predictability for separately payable, non-pass-through drugs and biologicals under the OPPS.[7]

We agree that CMS has the authority to adopt a payment rate of ASP + 6% for these drugs and biologicals and strongly support the adoption of this proposed payment rate under the OPPS. We concur with CMS's reading of the hospital outpatient statute - that SSA § 1833(t)(14)(A)(iii)(II) authorizes CMS to set payment rates for separately payable, non-pass-through drugs at ASP + 6%. This provision specifically cites to SSA § 1847A, which is the section that sets forth payment for drugs and biologicals at ASP + 6%.

We also believe that there are strong policy reasons to reimburse for separately payable, non-pass-through drugs at ASP + 6% at this time. Adequate Medicare reimbursement is imperative for the preservation of patient access to plasma protein therapies in the hospital outpatient setting. Both the U.S. Department of Health and Human Services (HHS)[8] and the Immune Deficiency Foundation (IDF)[9] issued reports in 2007 that concluded insufficient reimbursement was a leading factor in the difficulties patients faced in accessing IVIG. At that time, reimbursement differences resulted in patient migration from the physician office to the hospital outpatient department.[10] We believed then and continue to believe that it is imperative that Medicare beneficiaries be able to obtain IVIG and other plasma protein therapies best suited for their individual needs in the most appropriate site of service, and thus hospital outpatient departments must remain a viable option for beneficiaries to receive IVIG. Thus, we applaud the proposal to pay hospital outpatient departments at ASP + 6%, just as these products are reimbursed in physicians' offices. Just as CMS has correctly decided to pay the same furnishing fee for blood clotting factors in physician offices and hospital outpatient departments to avoid a financial advantage for one setting over another, so too should CMS set payments at ASP + 6% in hospital outpatient departments. By establishing payment equity across settings, CMS helps to ensure that the choice of setting will be driven by clinical, rather than financial, considerations – as it should be.

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[7] *Id.*

[8] OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERVS., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV): FINAL REPORT (2007), at Section 4 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites). OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007), at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices equal to or above the Medicare payment rate for the third quarter of 2006).

[9] IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

[10] See, e.g., Ricardo Alonso-Zaldivar, Crucial But Costly Treatment Is Drying Up With Funding: Thousands Of Elderly Patients Who Need Intravenous Antibodies Are Hurt By Medicare Cutbacks - More Pain Could Be On The Way, L.A. TIMES, February 28, 2006, at A8 (illustrating the challenges, including shifts in sites of service, patients must overcome to receive IVIG therapies because of the Medicare reimbursement cuts).

II. PPTA Applauds CMS for Continuing Its Longstanding Policy of Applying the Furnishing Fee for Blood Clotting Factors under the OPPS

Section 303(e) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) established a "furnishing fee" for blood clotting factors provided in the physician office.[11] Pursuant to the statute, this fee is updated annually according to inflation for medical care.[12] The fee for CY 2012 is $0.181 per unit.[13]

Since 2006, CMS has rightly paid hospitals the same furnishing fee[14] and again provides for a furnishing fee for hospital outpatient departments in the Proposed Rule.[15] In arriving at its original decision to also provide for the furnishing fee under the OPPS, CMS determined that similar resources were required to furnish blood clotting factors "across all types of service settings."[16] As such, the agency concluded that, moving forward, "it is appropriate to adopt a methodology for paying for clotting factors under the OPPS that is consistent with the methodology applied in the physician office setting and the inpatient hospital setting."[17]

PPTA agrees that the agency's conclusion continues to be the correct one. Indeed, we believe this furnishing fee has been instrumental in preserving patient access to blood clotting factors since its inception in the physician office in 2005; thus, PPTA appreciates CMS' inclusion of the furnishing fee under OPPS to date. We urge CMS to finalize its proposal and continue the furnishing fee for blood clotting factors administered in the hospital outpatient department in CY 2013.

III. Conclusion

PPTA greatly appreciates the opportunity to provide comments to CMS on its proposed rule implementing payment policies in the OPPS for CY 2013. We strongly support the agency's proposal to adopt a payment level for separately payable, non-pass-through drugs and biologicals of ASP + 6%. We also appreciate the agency's proposal to continue the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department. PPTA would like to underscore the importance of appropriate reimbursement levels for ensuring patient access to rare disease therapies like alpha$_1$-proteinase inhibitor, blood clotting factors, and intravenous immune globulin. The hospital outpatient department must remain a viable site of service for patients suffering from rare disorders like alpha-1 antitrypsin deficiency, bleeding disorders, chronic B-cell lymphocytic leukemia, CIDP, ITP and PIDDs. Please

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[11] *See* MMA, 117 Stat. 2066, 2252 (2003); Social Security Act ("SSA") § 1842(o)(5) (2006).
[12] SSA, § 1842(o)(5)(C).
[13] CMS, Blood Clotting Factor Furnishing Fee, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/ClotFactorFurnishFee.html.
[14] *See* Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 Fed. Reg. 68,516, 68,661 (Nov. 10, 2005).
[15] 77 Fed. Reg. 45,141 (July 30, 2012).
[16] 70 Fed. Reg. at 68,661.
[17] *Id*.

do not hesitate to contact Kym H. Kilbourne at 443-458-4682 or by email (kkilbourne@pptaglobal.org) if you have any questions regarding these comments.

Sincerely,

Julie Birkofer
Senior Vice President, North America