

August 28, 2015
Reference No.: FASC15022

Andrew Slavitt
Acting Administrator
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–1633–P (Hospital Outpatient Prospective Payment System Calendar Year 2016 Proposed Rule)

Dear Acting Administrator Slavitt:

The Plasma Protein Therapeutics Association (PPTA) is pleased to have this opportunity to comment on the proposed rule that the Centers for Medicare & Medicaid Services (CMS) has issued regarding the Hospital Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2016 (Proposed Rule).¹ As a representative of human plasma collection centers and the manufacturers of plasma protein therapies used to treat rare disorders and conditions, PPTA strives to ensure that Medicare beneficiaries who depend on these vital therapies will continue to have appropriate access to them. We note that our U.S. membership includes leading manufacturers of plasma protein treatments, such as Baxalta, Biotest, CSL Behring, Grifols Inc., and Kedrion SpA. To preserve patient access to these essential treatments, we urge CMS to finalize the following two proposals:

1. CMS should pay average sales price (ASP) + 6% for separately payable, non-pass-through drugs and biologicals in CY 2016; and
2. CMS should 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.

BACKGROUND

Most of the rare conditions that require treatment with plasma protein therapies are genetic, chronic, and life-threatening, including alpha-1 proteinase inhibitor deficiency, hemophilia, von Willebrand disease, and primary immune deficiency

¹ See 80 Fed. Reg. 39199 (July 8, 2015).

diseases (PIDDs).² Plasma protein therapies includes albumin, alpha₁-proteinase inhibitor, antithrombin III, plasma-derived and recombinant blood clotting factors,³ C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, prothrombin complex concentrate and protein C concentrate.⁴

Due to their unique nature, plasma protein therapies face distinct challenges and regulatory treatment. First, the vast majority of plasma proteins treat rare diseases, and in some cases, prevalence may be fewer than 100 patients. In light of these circumstances, patients can struggle to access providers that have sufficient expertise to treat their conditions, and patients may experience challenges in accessing treatment at their preferred site of care. Reductions in payment for these treatments can further compound these issues. For instance, PIDD patients requiring regular infusions of intravenous immune globulin (IVIG) have experienced treatment delays and shifts in site of service due to previous reductions in Medicare reimbursement.

The non-interchangeable nature of plasma protein therapies is also a unique aspect of these therapies that highlights the importance of reimbursement mechanisms that ensure uninterrupted access to all brands of plasma protein therapies. Distinct fractionation processes are used to generate each brand within a plasma protein therapeutic class. The result is plasma protein therapies that are non-interchangeable, sole source biologicals that produce different therapeutic outcomes depending on the patient. In some cases, payment cuts have caused providers to switch some patients that require regular infusions of IVIG from a brand on which they had been stabilized. Such patient access issues underscore the value of ensuring adequate reimbursement levels for these therapies.⁵

² Diseases treated with plasma protein therapies also include chronic B-cell lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy (CIDP), hereditary angioedema, hereditary antithrombin III deficiency, protein C deficiency, 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, and factor XIII deficiency. Cytomegalovirus disease associated with transplant patients, hepatitis B reinfection in liver transplant patients, idiopathic thrombocytopenic purpura (ITP), infant botulism, and Kawasaki's disease. Rabies, rhesus incompatible pregnancies, and tetanus are examples of acute rare conditions that are treated with plasma protein therapies.

³ Recombinant blood clotting factor therapies are those created using recombinant DNA technologies, which entail the integration of genes coding for the production of human blood clotting factor proteins into laboratory cell cultures. The cell cultures produce the blood clotting factor proteins, which are subsequently collective, purified, and further refined into safe and effective biologic medicines.

⁴ 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).

⁵ The Moran Group, 2003-2010 IVIG [Intravenous Immune Globulin/SCIG [Subcutaneous Immune Globulin] Utilization by PID [Primary Immune Deficient] Patients By Site of Service (Dec. 21, 2012) (noting a significant shift in the site of service of IVIG utilization after implementation of reimbursement cuts as a result of the Medicare Modernization Act).

A third unique characteristic of plasma protein is that its manufacturers depend upon donated human plasma as the raw material for therapeutic production. The process for collecting human donated plasma is highly regulated, resource-intensive, and time-consuming, with a production process spanning seven to nine months. These unusual factors again highlight the importance of minimizing disruptions to patient access by providing appropriate payment.

DISCUSSION

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

Maintaining appropriate reimbursement rates for plasma protein therapies is critical to protecting the health of patients who need them. As it did for CY 2015, CMS is proposing to set the payment for separately paid drugs and biologicals without pass-through status at ASP + 6% for CY 2016.⁶ We applaud CMS for this proposal and urge CMS to finalize the proposed payment rate and mechanism for separately payable, non-pass-through drugs and biologicals.

In addition to preserving patient access, adequate payment for these therapies fosters innovation by encouraging manufacturers to invest in research that focuses on plasma protein therapy advancements. We also agree with CMS that this policy offers payment predictability for separately payable, non-pass-through drugs and biologicals under the OPSS.⁷

Policy considerations provide additional support for continuing to reimburse separately payable, non-pass-through drugs at ASP+6%. This payment rate establishes parity with payment in physician offices and thereby affords Medicare beneficiaries freedom to seek plasma protein therapies in the setting that best suits their needs. In 2007, the U.S. Department of Health and Human Services (HHS)⁸ and the Immune Deficiency Foundation (IDF)⁹ issued reports finding that insufficient reimbursement was a leading factor in the challenges patients faced in accessing IVIG. Due to the differences in the payments provided in the physician office versus hospital

⁶ 80 Fed. Reg. at 39281.

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).

outpatient settings, patients migrated from the physician office to the hospital outpatient department.¹⁰ We therefore agree with CMS's proposal to pay hospital outpatient departments at ASP+6%, which is equal to payment in physician offices. We believe this policy helps to ensure that receiving plasma protein therapies in hospital outpatient departments remains a viable option for beneficiaries. Further, this proposal is properly aligned with CMS's proposal 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. Payment equity across care settings helps to ensure that clinical considerations, rather than financial ones, dictate the choice of setting.

II. PPTA Urges CMS to Continue Its Longstanding Policy of Applying the Furnishing Fee for Blood Clotting Factors under the OPPS

PPTA strongly supports CMS's proposal to continue paying for blood clotting factors at ASP + 6%, plus a furnishing fee using an updated amount based on the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year.¹¹

Pursuant to the Medicare statute, a "furnishing fee" is required for blood clotting factors provided in the physician office.¹² This fee is updated annually according to inflation for medical care.¹³ The fee for CY 2015 is \$0.197 per unit.¹⁴

Since 2006, CMS has rightly established payment parity in the hospital outpatient setting by providing hospitals with the same furnishing fee that is available in the physician office setting.¹⁵ CMS originally adopted this policy on the grounds that similar resources are required to furnish blood clotting factors regardless of the service setting.¹⁶ According to the CMS, "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 strongly agrees with CMS's conclusion that the furnishing fee should be provided across care settings. The furnishing fee has played an essential role in preserving patient access to blood clotting therapies, so we are pleased to see the

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).

¹¹ 80 Fed. Reg. at 39282.

¹² See Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), Pub. L. 108-173, 117 Stat. 2066, 2252 (2003); Social Security Act ("SSA") § 1842(o)(5) (2006).

¹³ SSA, § 1842(o)(5)(C).

¹⁴ See CMS, Annual Clotting Factor Furnishing Fee Update 2015, Transmittal 3055 (Aug. 29, 2014), accessible at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R3055CP.pdf> (announcing the blood clotting factor furnishing fee for CY 2015).

¹⁵ See 70 Fed. Reg. 68516, 68661 (Nov. 10, 2005).

¹⁶ *Id.* at 68661.

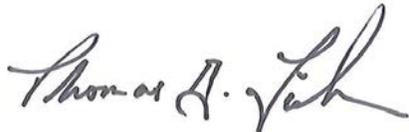
¹⁷ *Id.*

proposal once again included in the Proposed Rule. We urge CMS to finalize its proposal to continue applying the furnishing fee for blood clotting factors under the OPPS in CY 2016.¹⁸

Conclusion

We are grateful for this opportunity to offer comments to CMS on its Proposed Rule implementing payment policies in the OPPS for CY 2016. We urge CMS to finalize its proposal to adopt a payment level for separately payable, non-pass-through drugs and biologicals of ASP + 6%. We also encourage the agency to finalize its proposal to continue the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department. Thank you for considering our comments, and please feel free to contact Thomas Lilburn, Director of Government Relations at (443) 458-4682 or tlilburn@pptaglobal.org if you have any questions.

Sincerely,



Thomas B. Lilburn
Director, Government Relations

¹⁸ 80 Fed. Reg. at 39282.