Plasma Protein Therapeutics Association

August 29, 2008
Reference No.: FASC08037

Kerry Weems
Acting Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS–1403–P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule

Dear Acting Administrator Weems:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the *Federal Register* on July 7, 2008 ("Proposed Rule").1 As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

PPTA is the association that represents the manufacturers of plasma protein therapies. These therapies, which include albumin, blood clotting factor, alpha-1 proteinase inhibitor, and intravenous immunoglobulin ("IVIG"), are used to treat a variety of orphan diseases and serious medical conditions for a very small, fragile patient population in the United States. PPTA members produce more than 80 percent of the plasma protein therapies for the U.S. market and more than 60 percent of such therapies for global consumption.

Patient access to plasma protein therapies depends on adequate physician reimbursement for the acquisition and administration of these biologicals. PPTA continues to be concerned that the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing IVIG therapies is insufficient.

1 73 Fed. Reg. 38502 (Jul. 7, 2008).

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This concern is exacerbated by the proposal to eliminate the payment the agency has been making for IVIG preadministration-related services (G0332). Members of Congress also share our concern.[2] Therefore, PPTA urges the Centers for Medicare and Medicaid Services ("CMS") to continue reimbursing physicians for IVIG preadministration-related services because the rationale for discontinuing the payment is flawed.

DISCUSSION

I. CMS Should Continue Paying for IVIG Preadministration-Related Services ["Coding Issues"]

CMS proposes to discontinue its current policy of making separate payments to physicians for IVIG preadministration-related services. As you know, CMS established this payment, effective January 1, 2006, in order to address the significant resources necessary to manage inventory, locate and acquire product, reschedule infusions due to product availability and patient needs, and provide the proper therapy and dose to patients.[3] The agency bases the proposal to discontinue the payment on the premise that the IVIG market has stabilized (as reflected in IVIG prices, the establishment of new HCPCS codes, and increased utilization) and that the transient market conditions prompting the creation of the new policy no longer exist. CMS' rationale for discontinuing the IVIG preadministration-related services payment is faulty, as we explain below. The preadministration payment remains necessary to assure that Medicare beneficiaries have full access to their lifesaving IVIG therapy and CMS should continue making this payment.

A. Market Stability

After reviewing the history of the preadministration-related services payment, CMS describes the reasons why it decided to propose to eliminate this payment. CMS points to certain figures stated in an April 2007 Office of Inspector General Report ("OIG Report")[4] as proof that the IVIG market place has stabilized. Specifically, CMS states that the OIG Report concludes that "[d]uring the third quarter of 2006, 56 percent of IVIG sales to hospitals and over 59 percent of IVIG sales to physicians by the largest three distributors occurred at prices below the Medicare payment amounts."[5] CMS concludes, based on these figures that stability in the IVIG market had improved in late 2006.[6] PPTA finds it difficult to believe that market stability can be found in a market

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2 *See, e.g.,* Letter from Sen. John Ensign, Member, S. Comm. on Finance to Kerry Weems, Acting Administrator, CMS (July 28, 2008) (Attachment B).
3 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005).
4 Office of Inspector General, U.S. Dep't of Health and Human Services, *Intravenous Immune Globulin: Medicare Payment and Availability* (2007).
5 73 Fed. Reg. at 38519.
6 Id.

where 44% of hospitals and 41% of physicians cannot purchase product at or below the Medicare payment rate.

Moreover, CMS looked at the very same information last year, when it decided to continue to pay for preadministration-related services for calendar year 2008. The OIG Report was published in April of 2007[7] and CMS was able to review the study's findings for the 2008 physician fee schedule (PFS) rulemaking process. In last year's proposed PFS rule, CMS acknowledged the findings in the OIG report, cited the same statistics that are in this year's proposed rule and then proposed to continue the preadministration payment. Further, CMS stated that it requested that the OIG further study the IVIG marketplace.[8] In finalizing the continued preadministration-related services payment for 2008, CMS stated that it "will carefully consider all relevant information including the conditions of the IVIG drug market during CY 2008 when we address whether it would be appropriate to continue the payment policy as part of the CY 2009 PFS."[9] With no new information, there is no basis for CMS to now rely on the April 2007 OIG report in support of a claim that there is improved market stability.

CMS also states that IVIG drug Healthcare Common Procedure Coding System (HCPCS) code revisions have led, in part, to increased payments for IVIG therapies resulting in a more stable marketplace.[10] PPTA appreciates that CMS made these HCPCS code revisions pursuant to a new interpretation of the ASP statute that computes the ASP payment rate of all IVIG entering the marketplace after October 1, 2003 based solely on the individual ASP information of that therapy – a process that is best facilitated by these HCPCS code revisions.[11] Although PPTA believes that this measure has improved product-specific IVIG access for patients, we do not see this measure alone as the panacea to a more stable marketplace. To the best of PPTA's knowledge, the cited increases in IVIG payment rates simply reflect the quarterly update in ASPs for each HCPCS code and not a specific measure by CMS. Thus, while the creation of new HCPCS codes for IVIG was welcome by the entire IVIG community, nothing about that decision supports the notion that it stabilized the IVIG marketplace over the past year. Moreover, by statute, product-specific reimbursement is not available for every brand of IVIG in the marketplace.

When advocating for appropriate IVIG reimbursement, particularly product-specific reimbursement pursuant to the ASP statute, it was always PPTA's position that Medicare beneficiaries that require IVIG must be able to access the product best suited for their individual needs because each brand is unique. IVIG therapies are unique not only because of their production processes, but also because of the "substantial

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7 72 Fed. Reg. 66222, 66255 (Nov. 27, 2007).
8 72 Fed. Reg. 38122, 38146 (Jul. 12, 2007). The OIG has not issued any subsequent report on IVIG. *See* 73 Fed. Reg. at 38519.
9 Id. at 66255.
10 73 Fed. Reg. at 38519.
11 *See* SSA § 1847A(c)(6)(C) (2008).

variation in manufacturing, fractionation, and bottling process times that may also influence the biological activity of the final product," as well as formulation, volume load, sodium content, sugar content, osmolality, immunoglobulin A ("IgA") content, and pH.[12] For example, physicians may prefer prescribing IVIG therapies: (1) without sugar for diabetics; (2) with low osmolality and low volume for those patients with congestive heart failure or compromised renal function; (3) with less IgA for those patients with IgA deficiencies; (4) with lower pH for those patients with small peripheral vascular access or a tendency toward phlebitis. In addition, therapies with sucrose may create a higher risk of renal failure in some patients. Because IVIG is not an interchangeable, "one-size-fits-all" therapy, patient outcomes may be adversely affected if physicians fail to administer the IVIG therapy best suited for the individual needs of a patient.[13]

Therefore, while the HCPCS code revisions, which went into effect on July 1, 2007, ensure providers will prescribe IVIG therapies that had been assigned to discontinued HCPCS code J1567 based on safety and efficacy reasons.[14] There is no evidence that these HCPCS coding revisions had an effect on the availability of any specific IVIG therapy. Moreover, it is not clear if the cited increases in IVIG payment rates that CMS noted in the CY 2009 PFS Proposed Rule were caused by the coding changes or just reflected the quarter to quarter variability in ASP payment rates. Again, we do not see a clear connection between the coding revisions and a more stable marketplace.

In this year's proposed rule, CMS states that the slight increase in utilization of IVIG and its corresponding preadministration code from 2006 to 2007 suggests that pricing of and access to IVIG may be improving, thereby indicative of a more stable market.[15] Although there was a slight increase, PPTA does not believe that this increase demonstrates an improvement in the stability of the marketplace. There are other reasons that may have contributed to the slight increase; for example, an increase in the number of Medicare beneficiaries that require the therapy. The slight increase could indicate that more beneficiaries are being treated with IVIG, not that physicians are having an easier time locating it or that any individual beneficiary is having an easier time accessing the therapy. As a result, the reported, but unanalyzed increase in utilization of IVIG from 2006 to 2007 does not signify stability in the IVIG market.

B. Transient Market Conditions

CMS concludes its comments on the preadministration-related services payment by stating that it now believes that the "transient market conditions that led us to adopt

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12 *See* ASPE ANALYSIS OF THE IVIG MARKET, *supra* note 13, at 2-17.
13 *Id.* at 2-18 (describing the recommendations of the Clinical Immunology Society of the appropriate IVIG therapy for certain patient risk factors).
14 *Id*. (suggesting that providers may argue a degree of substitutability exists among IVIG therapies to justify their preference to purchase or prescribe certain IVIG therapies for economic reasons).
15 Id.

the payment preadministration-related services have improved."16 Based on a review of the final rule in which CMS adopted the preadministration-related services payment, PPTA respectfully disagrees, as many of the initial conditions that led CMS to create the payment still exist.

In that final rule, the agency said it was concerned "about reports of patients experiencing difficulties in accessing timely IVIG treatments and reports of providers experiencing difficulties in obtaining adequate amounts of IVIG products on a consistent basis to meet their patients' need in the current marketplace."17 CMS seemed to believe that this marketplace condition occurred, at least in part, because most brands of IVIG were put on allocation by manufacturers in 2005.18 Currently, just as they did in 2005, PPTA member companies allocate to customers and providers the amount of IVIG they receive based on historical usage in order to meet demand throughout the manufacturing process. Manufacturers determine allocations of IVIG to these various customers and providers to ensure supply will meet contractual obligations. To the extent that CMS viewed IVIG allocation as a "transient market condition" that warranted the establishment of the IVIG preadministration-related services payment, this market condition remains.

Further, in concluding that it will implement a preadministration payment, CMS stated that the patterns of utilization of IVIG are different than for other drugs and biologicals due to the many indications that it treats.19 CMS then adds that there are also new emerging indications for IVIG that differentiate this therapy from others. PPTA agrees with CMS' statement and appreciate that CMS has historically recognized the many treatment options that IVIG provides for Medicare beneficiaries. PPTA believes that these market conditions have not changed; IVIG is still used to treat many conditions and is being studied to treat many more. The utilizations patterns that existed for calendar year 2006 still exist, if not increased, for calendar year 2009.

Lastly, CMS cited an increase in IVIG infusion days from calendar years 2002 through 2004 to further support its decision to create a preadministration payment for IVIG.20 Specifically, CMS stated that "[i]n the face of growing demand for IVIG in the absence of significant changes in the prevalence of medical conditions for which there is high quality evidence regarding the effectiveness of IVIG therapy, we are concerned that all patients with medical need for IVIG continue to have access to this expensive and valuable therapy."21 As a result of this concern, the agency established the IVIG preadministration-related services payment to help assure that Medicare beneficiaries

16 73 Fed. Reg. at 38519.
17 70 Fed. Reg. 70116, 70219-70220 (Nov. 21, 2005).
18 Id.
19 Id.
20 Id.
21 Id.

could access IVIG. Demand for IVIG is still high today, which is supported by CMS' own statements in the Proposed Rule and also evidenced by the record setting distribution by IVIG manufacturers for CY 2007 of 34,188 kg. Therefore, it is inconsistent for CMS to use the same fact of increased utilization of IVIG from 2004 to 2006 to support the establishment of the payment, and then use the same fact that IVIG utilization increased from 2006 to 2008 to support the elimination of the payment.

PPTA appreciates the agency's hard work over the past three years to ensure that physicians can acquire IVIG and provide access to this critical therapy for the Medicare beneficiaries that they treat. Simply put, physicians furnishing IVIG to their patients encounter the same costs and difficulties now that they did when the payment was first established. There has been no new data or study presented over the past year that would illustrate the need for eliminating the preadministration code for IVIG. In fact, one could make the case that the elimination of the code will return the IVIG access environment to where it was in 2005, prior to the implementation of G0332. Accordingly, PPTA urges CMS to continue to make a payment for IVIG preadministration-related services so that beneficiaries will continue to have access to the product upon which they are so dependent.

II. PPTA SUPPORTS CMS' CAUTION IN CONSIDERING WHETHER IT IS APPROPRIATE TO APPLY THE WAMP AND AMP THRESHOLD ["ASP ISSUES"]

Under the ASP statute, if the OIG finds that the ASP for a product exceeds the widely available market price ("WAMP") or the Average Manufacturer Price ("AMP") by a percentage threshold, the OIG informs CMS and the agency, in the next quarter, shall replace the ASP amount with the lesser of the WAMP or 103 percent of the AMP.[22] The OIG must conduct studies, which can include surveys, to determine the WAMP.[23] In the Proposed Rule, CMS proposes to continue to set the WAMP and AMP threshold at 5 percent for CY 2009.[24]

Although PPTA does not oppose this threshold generally, we caution CMS that any decision to apply this statutory provision to the reimbursement of IVIG could exacerbate existing difficulties a fragile patient population is experiencing in attempting to access these therapies in the physician office. We appreciate the statement in the Proposed Rule that the agency is cognizant of the complicated operational issues associated with payment substitutions and thus it "will continue to proceed cautiously in this area and provide stakeholders, particularly manufacturers of drugs impacted by potential price substitutions, with adequate notice of our intentions." [25] PPTA believes that this is a sound approach for the agency to take in this area, and that it is especially

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22 Social Security Act ("SSA") § 1847A(d)(3).
23 Id. at § 1847A(d)(1).
24 73 Fed. Reg. at 38521.
25 Id. at 38521-22.

appropriate for all plasma protein therapies, given their importance to the patients that take them.

III. CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. For the reasons discussed above, we believe that there is no basis for discontinuing the IVIG preadministration-related services payment, and that the agency should continue this payment for 2009. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer
Vice President, North America

Attachment B

JOHN ENSIGN
NEVADA

COMMITTEES:
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July 28, 2008

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Weems:

I am writing to express my concern regarding the Centers for Medicare and Medicaid Services (CMS) proposal to discontinue payments for pre-administration-related services for intravenous infusion of immunoglobulin (IVIG) as part of the Medicare Physician Fee Schedule for 2009 and the Hospital Outpatient Prospective Payment System for 2009. Such a change could significantly reduce patient access to IVIG.

As you know, CMS established a temporary pre-administration-related service payment in 2006 for physicians and hospital outpatient departments that administer IVIG to Medicare beneficiaries. This add-on payment, which has been available for three years now, is intended to help cover the effort required to locate and acquire adequate IVIG product during a period of market instability.

I recognize that the pre-administration payment was intended to be temporary; however, I am seriously concerned that the CMS proposal to discontinue these payments could negatively impact Medicare beneficiaries who suffer from Primary Immune Deficiency Disorder and other life-threatening ailments. This could result in patients experiencing delays in treatment and being shifted to more expensive care settings.

In the past, the HHS Office of the Inspector General and the HHS Assistant Secretary for Planning and Evaluation studied IVIG and concluded that payment problems exist. Although studies on IVIG payment issues have not been published since April 2007, CMS has apparently reviewed national claims data for IVIG drug utilization to develop its proposal to discontinue pre-administration payments. According to the proposed rule, national claims data "show modest increases in the utilization of IVIG drugs and the pre-administration-related service code which suggests that pricing and access may be improving." I would appreciate a more thorough description of the data CMS reviewed which led the Agency to propose to discontinue pre-administration payments.

In closing, I urge you to reconsider your proposal to discontinue payments for pre-administration-related services for IVIG. A change of this nature could significantly reduce patient access to this life-saving therapy. Thank you in advance for your prompt attention to this important matter.

Sincerely,

John Ensign

JOHN ENSIGN
United States Senator