Submitter : **Dr. Gregory Thomas** **Date: 01/23/2007**

Organization : **American Society of Nuclear Cardiology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-FC-16-Attach-1.PDF

#16

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

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Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

January 22, 2007

Administrator Leslie Norwalk
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-FC

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final Rule

Dear Administrator Norwalk:

We are writing in response to the 2007 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule, which was published November 24, 2006. **The American Society of Nuclear Cardiology (ASNC)** appreciates the opportunity to participate in the rulemaking process to assist the Centers for Medicare & Medicaid Services (CMS) in further refining the HOPPS. Unfortunately, **ASNC is troubled that the agency chose to disregard many of the comments from the cardiology community regarding appropriate pricing of myocardial PET and Cardiac Computed Tomography Angiography (CCTA) studies.** In the interest of brevity, we will not reiterate our previous October 10 comments on the proposed rule, but do feel the following points should be stressed.

As you know, ASNC is a nearly 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology, develops standards and guidelines for training and practice, promotes accreditation and certification in this sub-specialty field, and is the principal advocacy voice for nuclear cardiology.

Myocardial PET Studies

ASNC is extremely disappointed by the agency's decision to move all myocardial PET studies into one single APC (0307) – particularly lumping single (78491) and multiple (78492) studies together. The CMS proposition that a rest and stress myocardial perfusion PET study can be equated in cost to a single rest study lacks both face-validity, and an understanding of the respective procedures. In addition, given that this will result in the largest cut in APC history, we are shocked that CMS did not include some kind of dampening mechanism to at least provide some relief to those nuclear cardiology practices that are heavily invested in this growing modality for assessing coronary artery disease.

Cardiac CTA Studies

ASNC also shares the concern of the American College of Cardiology, the Society of Cardiovascular Computed Tomography, and the Society for Cardiovascular Angiography and Interventions over CMS's choice to not move the Category III codes for CCTA into appropriate new technology APCs. We believe that the October 10 joint comment letter provided by the above four members of the cardiology community provided solid reasoning and rationale for the agency to place the CCTA imaging codes in the new technology pricing category. Furthermore, ASNC believes that the 2007 APC rates for these codes are far below the true costs of providing CCTAs and fail to recognize the unique clinical benefits of this expanded use of this non-invasive modality for evaluating cardiovascular patients.

Future of Cardiac Imaging

Myocardial PET and CCTA are an integral part of the future of cardiac imaging – providing yet another non-invasive avenue for evaluating and monitoring coronary artery disease in the Medicare population. The payment policies for both of these modalities that CMS plans to implement in 2007 will have a chilling effect on expansion and innovation of these technologies.

Recent congressional action, in the form of the Deficit Reduction Act, has now further blurred the lines between Medicare's payment systems for the hospital outpatient department and the physician office setting. Given this fact, it is now more important than ever for CMS to adopt payment policy based on solid data, guidance from the medical community, and particularly an eye toward what is best for the Medicare patient. ASNC hopes that CMS will reconsider its direction on both of these payment decisions to protect continued patient access to myocardial PET and CCTA studies.

Thank you again for this opportunity to be part of the rulemaking process. If you need additional information, please contact Christopher Gallagher, ASNC Director of Health Policy, at 301-215-7575 or via email at Gallagher@asnc.org.

Sincerely,

Greg Thomas, MD, MPH
President

Submitter : **Mr. Paul Wickline** **Date: 01/23/2007**

Organization : **HCA**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment for comment on HCPCS codes identified in Addendum B with the NI comment code.

CMS-1506-FC-17-Attach-1.DOC

#17

CY 2007 Proposed and Final Payment Policy for Drugs and Biologicals with HCPCS Codes But without OPPS Hospital Claims Data ("New Drugs without Hospital Claims Data"), 68098

"Table 26 below lists the new CY 2007 HCPCS codes for drugs, biologicals and radiopharmaceuticals that were not available during the development of the proposed rule. In addition, we note that these codes are included in Addendum B this final rule with comment period and are identified with comment indicator "NI"".

We commend CMS on pricing these drugs and biologicals without having any hospital claims data but we think that the payment rate listed for HCPCS code J1324 – Enfuvirtide injection in Addendum B of this final rule is incorrect.

The 2007 HCPCS Manual description for HCPCS code J1324 is "Injection, enfuvirtide, 1 mg". According to the drug manufacturer documentation, enfuvirtide is only sold as a kit with the kit containing 60 vials of enfuvirtide, syringes, wipes, etc. Each vial contains 90 mg of enfuvirtide. Hence, the total number of milligrams (mg) of this drug per kit is 5,400 mg. The Average Wholesale Price (AWP) for the kit depending on the drug supplier ranges from $2,315.00 to $2,431.00. The AWP per mg for this drug ranges from **$.43** ($2,315/5400 mg) to **$.45** ($2,431/5400 mg) depending on the drug supplier.

Thus, when one vial of enfuvirtide is administered to the patient, the approximate AWP per vial should be $38.70 ($.43 x 90 mg) to $40.50 ($.45 x 90 mg). Conversely, when using the payment rate shown in CY 2007 OPPS Final Rule Addendum B – January 2007 Update of $22.91 per 1 mg, the approximate payment per vial as based on the HCPCS description is $2,061.90 ($22.91 x 90 mg).

Therefore, we recommend that CMS should change the payment rate for HCPCS J1324 to reflect the payment in the number of milligrams administered instead of what appears to be a payment per vial (90 mg).

Submitter : Ms. Kathleen J. Lester **Date:** 01/23/2007

Organization : Patton Boggs on behalf of BioSphere Medical

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-FC-18-Attach-1.PDF

#18

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January 23, 2007

Kathleen J. Lester
202-457-6562
klester@pattonboggs.com

The Honorable Leslie Norwalk
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1506-FC:** Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List.

Dear Ms. Norwalk:

I am writing on behalf of BioSphere Medical, Inc., (BioSphere) to provide you with comments about the new CPT code and reimbursement rates for Uterine Fibroid Embolization (UFE), which appear in the Final Rule on Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List (Final Rule).[1] Specifically, BioSphere is concerned that CMS has assigned the newly developed CPT code for uterine fibroid embolization (UFE), 37210, to an inappropriate Ambulatory Payment Classification (APC) for purposes of Medicare hospital outpatient payment. Additionally, because some patients do not require an overnight hospital stay, UFE should be included in the list of procedures eligible for payment when performed in an Ambulatory Surgical Center (ASC) in 2007.

BioSphere specializes in the development of embolotherapy technology, including the use of microsphere embolization for the treatment of benign uterine fibroid tumors. The company also works with physicians, patients, and patient advocates to raise awareness about UFE as a safe and effective alternative to surgical options, such as myomectomy and hysterectomy.

I. CMS Reimbursement Policies Must Encourage, Not Restrict, Access to UFE.

UFE provides women with a uterine-sparing, non-surgical option for the treatment of benign uterine fibroid tumors, one of the most prevalent women's health problems in the United States today. Uterine fibroids grow on the muscle tissue of the uterus. These tumors cause pelvic pressure, abdominal bloating, heavy menstrual bleeding, anemia, urinary pressure or incontinence, and possible infertility. Twenty to forty percent of women of childbearing age

[1] 71 *Fed. Reg.* 67960 (Nov. 24, 2006).

experience fibroids; more than five million women are symptomatic. African-American women are three times as likely to be affected by the condition.

Traditionally, women suffering from fibroids have had to have invasive, painful hysterectomies (removal of the entire uterus) or myomectomies (removal of the affected portion of the uterus) that require lengthy recovery periods. UFE is a new procedure that provides women with a non-surgical alternative treatment for uterine fibroid tumors. It is minimally invasive, clinically effective, cost-efficient, and allows women to retain their uterus and fertility.

UFE is performed by inserting two small catheters to inject tiny particles into the uterine blood stream that block the blood supply to the tumor. Clinical data demonstrate that one year after UFE 90 percent of women are symptom free; five years after the procedure 73 percent of patients remain symptom free.[2] The cost associated with UFE is generally lower than surgical treatment. A recent study found that 96 percent of women who undergo UFE are satisfied with the treatment 12 months following the procedure. All of these evidence-based attributes are remarkable for a procedure that has emerged in such a short time period.

Many women prefer UFE. First, it shortens the hospitalization period. Patients undergoing UFE typically return home the same day as the procedure or have an overnight hospital stay, rather than the two-to-four day hospitalization associated with surgical treatments. Second, it provides for a quicker recovery. Patients can usually return to their activities of daily living and work in 7-10 days, as opposed to the several weeks of recovery following surgical treatment. Third, because the uterus is not removed, a patient who undergoes UFE may be able to preserve the ability to have children, which is not possible after having a hysterectomy.

In addition to its clinical benefits and patient-friendly attributes, UFE has also been shown to be more cost-effective than traditional surgical treatments for fibroid tumors. The procedure generally allows a patient to go home the same day or the next morning, rather than requiring a three-to-four day hospital stay. This difference between the surgical options and UFE significantly reduces the costs of treating fibroid tumors. Furthermore, because a patient is typically able to return to work and normal activity within 10-11 days instead of waiting the four-to-six weeks required for recovery after a hysterectomy, there is also less expense associated with recovery costs of the procedure. Given the significant population of women who experience fibroid tumors and the number of procedures undertaken each year to treat this condition, the development of UFE as a clinically effective and cost efficient treatment method holds tremendous promise for patient benefit and savings.

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[2] James B. Spies, *et al*, "Uterine Artery Embolization for Leiomyomata," *Obstetrics & Gynecology* (March 2001), 98, 29-34; James B. Spies, *et al*, .Long-Term Outcome of Uterine Artery Embolization of Leiomyomata," *Obstetrics & Gynecology* (November 2005), 106, 933-939.

II. CMS Should Appropriately Reimburse the UFE Procedure by Assigning It to APC Group 0229.

The assignment of the newly developed CPT code for UFE, 37210, to APC group 0202 does not appropriately reflect the costs associated with providing UFE treatment and, if not changed, will result in a drastic cut for providing this procedure that could result in fewer facilities that are able to offer UFE. APC group 0202 provides for a payment rate of approximately $2,600. This amount would barely cover the cost of supplies for providing the procedure.

Cost data submitted by the Society for Interventional Radiology (SIR) to the RVS Update Committee (RUC) of the American Medical Association (AMA) during the development on practice expense component of the physician fee for 37210 demonstrated that the cost of the procedure supplies (infusion catheter, guidewire, etc.) and the microspheres (drug) alone can exceed $2000 per patient. For example, in the recent Fibroid Registry study[3], researchers found that the typical patient requires (on average) five, two-milliliter syringes of microspheres, which cost approximately $1,290. This is only one component of the cost of supplies. Both the SIR and Fibroid Registry study data demonstrate that the supply cost are higher than those that would normally be associated with procedures in APC group 0202.

Instead of the current group, CMS should place UFE in APC group 0229. The procedures in this group share more clinical similarities with UFE and its costs than those procedures in APC group 0202. For example, UFE requires similar skills and time as does the transcatheter placement of a shunt. Both procedures entail placement of a small medical device in a patient using a transcatheter. Both procedures also are "combination" codes, which mean they include in their value input the costs of the additional services, such as imaging, that are critical to the performance of the procedure. Typically, for other codes, these services would be billed separately rather than being included in the main service code. As such, it is clear that the clinical requirements and coding specifications of APC 0229 and the UFE procedure are similar. Therefore, APC 0229 is a more appropriate placement than APC 0220 for the new UFE CPT code for both clinical and cost-related reasons.

Given that UFE is more efficient and cost-effective overall than surgical options, CMS should encourage its use through appropriate reimbursement policy. Furthermore, because UFE is a relatively new treatment option that is still gaining support among patients and clinicians, a flawed reimbursement policy is even more likely to have a negative impact on the availability of this procedure, thus stifling the growth of an important treatment alternative for women.

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[3] Worthington-Kirsch R, et al., "The Fibroid Registry for Outcomes Data (FIBROID) for Uterine Artery Embolization: Short Term Outcomes", *Obstetrics and Gynecology* (2005);106:52-59.

III. CMS Should Include UFE on the CY 2007 List of Procedures Eligible For Payment in the ASC Setting.

CMS should also revise the Final Rule to include UFE in the covered procedure list. Currently, most UFE procedures require an overnight hospital stay. However, as physicians adopt and refine UFE, it appears likely that many women will be able to avoid the overnight stay. CMS should encourage the further refinement of the procedure by ensuring that physicians performing it in an ASC setting receive appropriate reimbursement for it.

Clinicians specializing in UFE support providing the procedure in an ASC setting if a patient does not require intensive pain management. Today, it is true that it is less common for UFE to be performed in the ASC setting than in a hospital setting. Because UFE can be performed in some cases without requiring an overnight stay, including UFE in the list of ASC-eligible procedures would be consistent with CMS' criteria for determining what procedures should be included on the list. As physicians become more familiar and skilled in performing UFE, it seems likely that the number of patients requiring an overnight hospital stay will continue to decrease and more patients will be sent home on the same day as the procedure. Allowing UFE to be performed in the ASC setting may provide patients with a lower cost, higher quality option for undergoing the procedure, thus increasing access to an important treatment option for women suffering from uterine fibroid tumors. By including UFE on the list of covered procedures, CMS will be aligning the incentives in a manner that will encourage physicians to use the less costly ASC setting when appropriate for the patient. This approach is the correct one because it is exactly how the ASC setting is supposed to be used.

IV. Conclusion

BioSphere appreciates the opportunity to comment on this important issue for women. It is imperative that CMS ensure that its reimbursement policies do not threaten access to UFE and thwart the desire of many Members of Congress who are working to educate more women about this important and effective new alternative to surgery. To ensure access to the UFE procedure for patients, CMS must accurately account for the costs of the procedure and reimburse providers at an appropriate level. We hope the information provided above will encourage your staff to revisit the APC assignment for UFE as well as its eligibility for performance in an ASC. We look forward to working with you to provide effective and efficient services for women with fibroid tumors. Please do not hesitate to contact me at 202-457-6562 if you have questions or would like additional information.

Sincerely,

Kathleen J. Lester

Submitter : **Date: 01/23/2007**

Organization :

Category : **Drug Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

#20

KIDNEY CARE
PARTNERS

JAN 2 3 2007

January 23, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-FC Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates

Dear Ms. Norwalk:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the changes to the Ambulatory Surgery Center payment methodology for CY 2007 Payment Rates. KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[1]

KCP is pleased that CMS recognizes the importance of expanding the types of procedures performed in the ASC setting to include those related to the repair and maintenance of AV fistula and grafts, as evidenced by the inclusion of G0392 and G0393 in the November 1, 2006 Final Rule for the Hospital Outpatient Prospective Payment System (OPPS). In reviewing the public use files of supplies, labor and equipment for the most common dialysis access procedures, there appear to be some errors. We would like to request that the technical group review the data files (equipment and supplies) for the 35475, 35476 and 36870 codes. Be advised that 35475 and 35476 are the map codes for the new G codes in 2007:

G0393-Dialysis Access Angioplasty-venous (35476 old code)

[1]A list of Kidney Care Partners coalition members is included in Attachment A.

G0392-Dialysis Access Angioplasty-arterial (35475 old code)

Specifically, we are asking for consideration of the following:

- **RVU adjustment for new G codes (G0392 and G0393)** - The corresponding CPT codes (35475 and 35476) were last reviewed in 2004. Since then, technology advances, particularly in the advent of angioplasty balloons, have improved success rates as well as decreased complications. The low profile, high pressure balloons are routine in these types of angioplasties.

- **Adjustment to equipment and supply items for common dialysis access procedures** – In reviewing the public use files, we found several missing items on the angioplasty procedure list as well as missing items pertaining to the declot code that were included in last years' public use files. In the dialysis access declot code (36870), there is nothing in the cost files to note the use of a room with angiographic equipment, table and imaging. In addition, the angioplasty procedures would need a power table in the angio room.

As always, KCP appreciates CMS' review of these comments and look forward to working with you as you finalize this regulation. Please feel free to contact Kathy Lester (202) 457-6562 if you have any questions.

Sincerely,

Edward R. Jones

Edward R. Jones
Chairman
Kidney Care Partners

Attachment A

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

Submitter : **Date: 01/23/2007**

Organization :

Category : **Drug Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-FC-21-Attach-1.PDF

#21

PPTA
Plasma Protein Therapeutics Association

January 23, 2007
Reference No.: FASC07005

Leslie V. Norwalk, 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-1506-FC; CMS-4125-F (Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates)

Dear Administrator Norwalk:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the final rule with comment period concerning the 2007 hospital outpatient prospective payment system ("OPPS") rates that was published in the Federal Register on November 24, 2006 ("Final Rule").[1] As an association deeply committed to the health and safety of the patients it serves, these comments on the Final 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 hospital outpatient setting.

PPTA is the association that represents the commercial producers of plasma protein therapies. These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80 percent of the plasma protein therapies for the United States market and more than 60 percent worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins ("IVIG") used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

[1] 71 Fed. Reg. 67960.

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PPTA Offices in Washington · Annapolis · Brussels · Tokyo

PPTA commends the Centers for Medicare and Medicaid Services ("CMS") for its decisions to pay separately for additional hours, beyond the first hour, for intravenous infusions and to continue to pay for drugs and biologicals under OPPS at the average sales price ("ASP") plus six percent rate updated quarterly. At the same time, however, PPTA is very concerned that the manner in which hospitals are reimbursed for the costs they incur in furnishing IVIG is jeopardizing patient access to IVIG. Because access to these life-saving therapies is essential for all patients, including the more than 10,000 Medicare beneficiaries who rely upon them, PPTA urges CMS to act now to improve reimbursement so that it does not continue to impede access to IVIG. In addition to maintaining the payment for preadministration-related services for IVIG, CMS will ensure patient access to IVIG by taking further action, including implementing a payment adjustment for IVIG and recognizing that the administration of IVIG should be billed under the same codes as other biological response modifiers.

DISCUSSION

CONTINUING THE PAYMENT FOR IVIG PREADMINISTRATION-RELATED SERVICES

IVIG is the only effective treatment for primary immunodeficiency disease and has also been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States-licensed IVIG therapies are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals afflicted with diseases or conditions treated with IVIG must depend on this life-saving therapy for the duration of their lives. Each individual patient requires maximum access to the specific formulation that not only best meets their unique needs, but also significantly limits the risk of exposure to serious and potentially life threatening complications.

After first proposing to discontinue the payment for the preadministration-related services for IVIG for 2007, 71 Fed. Reg. 49506, 49604 (Aug. 23, 2006), in the Final Rule, the agency said that it will continue this payment in 2007. In doing so, CMS noted that it "will continue to review IVIG access during CY 2007 as additional information becomes available, and we will discontinue this temporary preadministration-related service payment during CY 2007 through rulemaking if we determine it is no longer warranted." 71 Fed. Reg. at 68092. While PPTA appreciates the continuation of the payment and the recognition that the payment cannot be discontinued without rulemaking, we believe it would be inappropriate for CMS to discontinue this payment during 2007. This payment ensures that hospitals are adequately reimbursed for providing IVIG to their patients and access throughout 2007 must be maintained. Further, any change to payments related to IVIG should not be done in isolation, which would be the case if the preadministration-related services were to be eliminated during 2007. Ensuring beneficiary access to IVIG requires an examination of the total payments for IVIG, including the payment for administration services, the preadministration-related services payment, and the payment for the product. Altering

one component without considering the other components could further jeopardize patient access and, thus, would be inappropriate.

PAYMENT ADJUSTMENT FOR IVIG

As CMS acknowledged in the Final Rule, there are continuing concerns about access to IVIG. According to a survey done by a patient advocacy group, patients have been increasing their intervals between doses and reducing the dosages of IVIG they take. 71 Fed. Reg. at 68092. While these access concerns are cited as the basis for continuing the payment for p readministration-related s ervices, t he net r esult i s t hat payments to hospitals will not be materially different in 2007 than they have been in 2006. As such, the Final Rule does not provide any mechanism to enhance access to IVIG, as CMS has been told is needed.

PPTA believes a payment adjustment to the ASP payment rates for IVIG, used for OPPS rates, is required to remove the reimbursement disincentives that hospitals currently encounter in the provision of IVIG. This payment adjustment needs to be reflective of the true costs to hospitals of making IVIG available to their patients. We recognize that CMS is awaiting data from the two current IVIG access studies being conducted by the Department of Health and Human Services – one by the Office of Inspector General and one by Assistant Secretary of Planning and Evaluation. Beneficiaries who rely upon IVIG, however, do not have the luxury of waiting for the completion of these studies, much less the agency's subsequent policy decisions based on these studies. A payment adjustment is needed at the beginning of 2007 to ensure beneficiary access to IVIG. The agency's assertion that an adjustment to the ASP rates is not needed at this time, 71 Fed. Reg. at 68092, is contrary to the evidence before the agency that there are access problems under the current payment scheme.

Furthermore, the agency and its contractors have experience with the type of payment adjustment PPTA is seeking such that it should not be administratively burdensome for the Medicare program. Specifically, as directed by statute,[1] CMS provides an add-on payment to the ASP rate for the furnishing of blood clotting factors. This payment adjustment has been in place since CY 2005, and has been adjusted for inflation to $0.152 for CY 2007. As commenters have told CMS, the payment rates for IVIG are not sufficient to ensure access for Medicare beneficiaries such that a payment adjustment is also needed for IVIG. Given the success of the blood clotting factor payment adjustment in maintaining beneficiary access to these therapies and the ease of the implementation of such payment adjustment, PPTA urges CMS to implement a similar payment adjustment for IVIG as soon as practicable.

[1] 42 U.S.C. § 1395u(o)(5) (2006).

IVIG SHOULD BE TREATED AS A BIOLOGICAL RESPONSE MODIFIER FOR PURPOSES OF PAYMENT FOR THE ADMINISTRATION OF IVIG

In 2006, new Current Procedural Terminology ("CPT") codes were implemented for drug administration services, and these codes will be fully integrated into OPPS in 2007. Under these new codes, chemotherapy administration codes apply to parenteral administration of biological response modifiers, according to the language contained in the CPT book. As a result, any product that is a "biological response modifier" should be billed under such codes. IVIG is such a therapy and PPTA asks CMS to explicitly clarify that the service of administering IVIG should be billed as such.

According to the U.S National Library of Medicine, biological response modifier therapy is defined by reference to "immunotherapy," which is defined as "treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases."[3] IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki's disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Thus, IVIG qualifies as a biological response modifier.

In the Final Rule, CMS notes that the term "biological response modifier" appears in the text preceding certain CPT codes and thus it is for the American Medical Association ("AMA") to address whether IVIG should be treated as a biological response modifier. 71 Fed. Reg. at 68093, 68117. CMS' position that this is for the AMA to decide is contradicted by the ac tions of its own contractors. Contractors such as Empire Medicare Services recognize that the AMA has not specified what products are "biological response modifiers" and it has moved to fill this gap by establishing a listing of biological response modifiers.[4] Since a Medicare contractor can identify which products are biological response modifiers, CMS's deferral to the AMA of the identification of IVIG as a biological response modifier is not appropriate. Accordingly, PPTA urges CMS to identify IVIG as a biological response modifier so that hospitals administering the product are paid appropriately for such service.

SEPARATE HCPCS CODES FOR IVIG THERAPIES

As you know, PPTA has advocated for the establishment of separate HCPCS codes for plasma protein therapies because of the significant clinical differences among the brand name IVIG products. We believe that setting payment rates for each IVIG product based on its own ASP information could help to alleviate the reimbursement hurdles that hospitals encounter in furnishing IVIG to their patients. We are aware that CMS recently considered a similar issue related to sodium hyaluronate products in conjunction with the ASP statutory structure. Because of our belief that unique products should be paid based on ASP information specific to them, we continue to pursue this

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[3] *See* http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy.

[4] *See* http://www.empiremedicare.com/news/nynews05/030405charts.pdf (chart 4).

objective and would like to work with the agency to that end as we learn more about the ramifications of the decision on the sodium hyaluronate products.

CONCLUSION

PPTA appreciates the opportunity to comment on the Final Rule. While we appreciate the agency's reversal of the proposal to eliminate the preadministration-related services payment for IVIG, unfortunately, that merely preserves the status quo for IVIG. Given the access concerns discussed above, preserving the status quo is not good enough. CMS must utilize the mechanisms discussed herein to improve payments for IVIG. The lives of many beneficiaries depend upon access to IVIG, and we must ensure that reimbursement is not an impediment to access. 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
Executive Director
PPTA North America