CMS-1427-FC-1 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Douglas Faigel** **Date & Time:** **12/02/2004**

Organization : **OHSU**

Category : **Physician**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

The Hospital Outpatient Prospective Payments System (OPPS) pass-through program.
Implantable devices placed through a natural orifice should be treated the same as devices placed through an artificial incision, with regard to reimbursement (e.g., pass through payment). It is nonsensical to treat the method of delivery (natural orifice vs. incision) differently. The current policy is a worrisome policy in that it rewards more invasive surgical apporoaches over less invasive. This policy also retards the development of minimally invasive techniques to achieve therapeutic ends. The final result will be medicare patients being subjected to more invasive procedures with the attendant higher risks and costs. Clearly, this is in no one's interest.

CMS-1427-FC-2 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Charles Filipi** **Date & Time:** **12/06/2004**

Organization : **Creighton University School of Medicine**

Category : **Physician**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

RE: Allowance of less invasive devices to qualify for Medicare OPPS pass-through payments

Device Categories File Code: CMS-1427-FC

Dear Sirs:

In response to the questions find my corresponding responses:

1. The comments?refer to devices introduced in the body through natural orifices. CMS is seeking comments on whether this includes orifices that are either naturally or surgically created, as in the case of ostomies. If you believe this includes only natural orifices, why do you distinguish between natural and surgically created orifices?

Transoral endoscopic or swallowed devices will alter medical and surgical therapy irreversibly. Patients inherently seek less painful diagnostic or therapeutic procedures. Natural orifices diagnostic technology has recently revolutionized pH monitoring and the detection of occult small bowel bleeding. Transoral surgical/endoscopic hybridization and even paradigm shifts will occur in the very near future. Introduction of devices should be reimbursable either surgically through skin incision or through natural orifices. This will encourage development of new technologies but more importantly promote the compassionate care of patients. I see no reason to distinguish how an enabling device is introduced.

2. How would you define ?new? with respect to time and to predecessor technology? What additional criteria and characteristics do you believe distinguish ?new? devices that are surgically introduced through an existing orifice from older technology that is also inserted through an orifice?

The definition of an acceptable new device that qualifies for pass through payments should be those devices that required only an IDE clearance. At the time of FDA release they should be granted acceptable ?new? status. If a PMA was required the device should be reviewed on a case by case for the designation acceptable ?new? device.

3. What characteristics do you consider to distinguish a device that might be eligible for a pass-through category even if inserted through an existing orifice from materials and supplies such as sutures, clips or customized surgical kits that are used incident to a service or procedure?

The device must be an integral part of the procedure without which the procedure could not be performed. The device functions for a specific

procedure but supplies can be used for many and are not unique for any one procedure.

4. Are there differences with respect to instruments that are seen as supplies or equipment for open procedures when those same instruments are passed through an orifice using a scope?

I do not find any distinguishing features of supplies/equipment introduced through a surgical incision vs. a natural orifice. Supplies should be recognized as supplies.

Sincerely,

Charles Filipi, MD, FACS
Professor of Surgery
Director of Esophageal Center

CMS-1427-FC-03

Submitter: Dr. Douglas Rex
Date & Time: 12/09/2004
Organization: Indiana University Medical Center
Category : Critical Access Hospital
Issue Areas/Comments GENERAL

Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates

I am writing regarding the opportunity to comment on whether to allow less invasive devices to qualify for Medicare OPPS pass-through payments.I believe it is critical for the development of less invasive procedures and ones that will allow very rapid patient recovery and thereby a reduction of cost and risk to patients, that Medicare policy should not distinguish between devices that are introduced through natural orifices and those introduced through surgical incisions. New devices should be those that allow the performance of a procedure in a way that could not be done if the device were not available. This would be true regardless of the orifice that is used to introduce the device. This would also characterize types of devices that would be eligible for a pass-through category, i.e. the device is an integral part of the procedure and without it the procedure cannot be performed. This is different from supplies, whether they are sutures, clips, or customized surgical kits, that are not eligible for a pass-through category and may be necessary regardless of the orifice that is used for the procedure.

Sincerely,
Douglas K. Rex, M.D.
Professor of Medicine
Division of Gastroenterology/Hepatology
DKR:lsb:mm T:12/7/04

CMS-1427-FC-4 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. David Bjorkman** **Date & Time:** **12/16/2004**

Organization : **American Society for Gastrointestinal Endoscopy**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

The ASGE wishes to submit the attached comments on criteria for establishing new pass-through device categories and the appropriate APC for Stretta (43257).

CMS-1427-FC-4-Attach-1.DOC

CMS-1427-FC-04-ATttach

December 16, 2004

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445–G, HHH Bldg.
200 Independence Ave., SW
Washington, DC 20201

Dear Dr. McClellan:

The American Society for Gastrointestinal Endoscopy appreciates the opportunity to comment on the 2005 hospital outpatient prospective payment system rule. We would like to comment on two issues: the policy for determining a pass through for a costly device and the APC payment classification for code 43257.

Criteria for Establishing New Pass-Through Device Categories

We urge CMS to modify its policy and eliminate the requirement that a device be implanted through a surgically created incision for it to quality for pass through treatment. We frankly have never understood the objective of this policy nor appreciated why CMS felt it necessary to distinguish between devices implanted though a surgically created incision as opposed to a natural or a surgically created orifice. In our judgment, the criteria for pass through should rely on the fact that the device is not reusable, that it represents new technology and that it is costly. In connection with this last requirement, along with the device representing in excess of 25 percent of the cost of the related procedure, we would think the device should also be more costly than whatever device might be "bundled" into the current APC rate. We agree with CMS that the device pass through should be available when a new technology APC is not being established and there is no current clinical APC to which it is "fits" appropriately from a clinical and a cost standpoint.

We would also want to point out that the terminology "implanted through a surgical incision" is confusing in the context of endoscopic and laparoscopic surgery as opposed to traditional open surgical procedures. We recall, for example, the amount of time and effort that was expended on the issue of whether a device for measuring pH levels which is inserted into the esophagus though an endoscope was implanted through a surgical incision. After several meetings and a number of pieces of correspondence, CMS agreed that the device did satisfy the requirement and a pass through code was ultimately assigned (C9712). With all due respect, we just do not see what is gained by the requirement.
With reference to the specific four questions you asked commenters to address, we would respond as follows:

1) As stated above, we would recommend entirely eliminating the requirement for how a device is implanted. Thus, in our judgment it does not really matter whether the device is introduced into the body through a surgical incision, a natural orifice or a surgically created orifice such as a stoma. The key is whether the device otherwise meets the pass through criteria.
2) We do not have specific suggestions to offer as to the definition of the term "new" in terms of prescribed time frames. However, we think it might be reasonable to entertain applications for pass through treatment only for devices that have been marketed for, less than 3 years. Moreover, since the method of introducing the device into the body is irrelevant in our judgment, the criteria for allowing a pass through should be based on other considerations such as the fact that the new device and the related procedure is substantially more costly.
3) In general, we do not think the pass through provision should be intended to cover routine supplies such as sutures, staples or clips used in conjunction with the placement of a surgical device. For this purpose, we would suggest the characteristics of a device should include the fact that it has a diagnostic or therapeutic purpose as opposed to being a minor supply used as an adjunct in inserting the device. Having said that, we appreciate the fact that surgical kits that include the device and the related supplies present some real problems. The line is not very easy to draw since some of the supply items might represent fairly costly supply items such as guide wires used to place a device as opposed to, say, suturing material. Perhaps CMS could "encourage" manufacturers to unbundle their routine supply items from the devices kits as a condition for receiving pass through approval.
4) We are not sure we fully understand what CMS has in mind on this issue exactly. We would think that most devices that qualify for pass through treatment are those that have a therapeutic or diagnostic objective as opposed to being an instrument that is used in performing surgery. However, it seems to us that if there is a device that would otherwise qualify for pass through treatment it should be allowed even if some analogous device was used as an instrument of surgery.

Appropriate APCs - Stretta

Code 43257, which is a new 2005 code, is defined as, "Upper gastrointestinal endoscopy, including esophagus, stomach and either the duodenum or jejunum as appropriate; with delivery of thermal energy to the muscle of the lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease." It is commonly known as the Stretta procedure. We offered comments on the APC classification of this code in the proposed rule; unfortunately, CMS did not accept our comments. For 2004, this service is assigned to a new technology APC with a payment rate of $1,850. Based on a total of 33 single claims, CMS plans to assign this service to APC 422 with a payment level of $1,274. This payment rate will not remotely cover the cost of providing this procedure. The disposable supplies alone cost almost as much as the APC rate. The problem is that CMS ignored the much more numerous claims for endoscopy procedures billed with C9701.

Briefly, this procedure involves the use of a single use catheter with needle electrodes to create thermal lesions in the esophageal sphincter as a treatment for gastroesophageal reflux disease. The procedure involves three separate passages of an endoscope to perform this procedure. While we, of course, understand why CMS generally relies on single claims to determine median costs, in this case the charge

data for the EGD procedures is clearly related to the costs of providing the Stretta procedure. Not only does this result in a substantial underestimate of the costs of providing this service but it is inconsistent with CMS's own instructions on how this procedure should be billed. In this connection, CMS instructed hospitals in 2002 that in billing for Stretta, they should bill for both an initial EGD and C9701. Thus, it is inappropriate to exclude the charge data for EGD procedures billed with C9701. Moreover, the code descriptor for CPT code 43257, supported by the vignette for this procedure, would certainly suggest that charge data for both C9701 and for the accompanying EGD procedures should be included in determining the APC rate for code 43257.

Based on the analysis of claims data by the Moran Group, which we understand have been shared with CMS, when the additional charge data for EGD services are included in the calculation, the median cost of the procedure goes up substantially. We therefore urge CMS to either (1) retain this procedure in the current new technology APC or (2) recalculate the median costs by including all the related upper GI endoscopy billings. Furthermore, since CMS clearly erred in not including the EGD charge data in the calculation, we would ask for this change to be made as a correction of the 2005 APC rates to be effective January 1, 2005.

Thank you for the opportunity to offer these comments.

Sincerely yours,

David Bjorkman, MD
President

Maurits Wiersema, MD
Chairman, Practice Management Committee

CMS-1427-FC-5 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Carol Kelly** **Date & Time:** **12/16/2004**

Organization : **Advanced Medical Technology Association**

Category : **Device Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Ambulatory payment classification assignments of HCPCS codes

Definition of items eligible for device category pass-through payments, see Federal Register, 11/15/04, page 65774

CMS-1427-FC-5-Attach-1.DOC

CMS-1427-FC-5-Attach-1.DOC

CMS-1427-FC-6 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Kenneth McKusick** **Date & Time:** **12/22/2004**

Organization : **AMI/SNM/ACR/ACNP jointly**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Issues

Ambulatory payment classification assignments of HCPCS codes

See attachment

CMS-1427-FC-6-Attach-1.DOC

CMS-1427-FC-6-Attach-1.DOC

Carol A. Kelly
Executive Vice President
Health Care Systems and Federal Legislative Policy
Direct: 202 434 7203
ckelly@AdvaMed.org

December 16, 2004 * Filed Electronically *

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-FC
Room 445–G, HHH Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Hospital Outpatient Prospective Payment System
Final Rule, November 15, 2004 (CMS-1427-FC)
Update for Calendar Year 2005; Comments on Device Pass-Through Categories

Dear Dr. McClellan,

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) Final Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2005, regarding the definition of items eligible for new device category pass-through payments (CMS-1427-FC, Federal Register, Vol. 69, No.219, Monday, November 15, 2004, p. 65774). The purpose of this letter is to respond to the questions posed in the final regulations regarding a recommended amendment to the definition.

AdvaMed is the largest medical technology trade association in the world, representing more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $71 billion health care technology products consumed annually in the United States, and nearly 50 percent of $169 billion purchased around the world annually.

AdvaMed believes that CMS should change its policy to allow new devices that are implanted or inserted through a surgical incision or an existing surgical or natural orifice to be eligible for pass-through payment status, if the device

meets other existing cost and clinical criteria.

Question 1: Should this extend to existing surgical orifices, such as ostomies?
Answer: Yes, we would agree that this should extend to existing surgical orifices, such as ostomies, if the device meets other existing cost and clinical criteria.

Question 2: How would you define "new" with respect to time and to predecessor technology?
Answer: Generally, we believe that the current clinical and cost criteria are sufficient; no additional definitions are needed. The timeframe for “new” could be clarified to indicate that if the device was not approved or in use in the outpatient department during the year used for that calendar year’s update, it should be considered “new.” For example, since claims from calendar year 2003 were used to develop the 2005 update, an item would be considered new in 2005 if it was not approved or in use in the outpatient department in 2003. This means that if CMS drops the surgical incision requirement in 2005, devices approved by the FDA and in use in the outpatient department in 2003 or before would not be eligible, while devices approved by the FDA in 2004 and after, which are used in outpatient settings would be eligible for pass-through consideration.

Question 3: What characteristics do you consider to distinguish a device that might be eligible for a pass-through category even if inserted through an existing orifice from materials and supplies such as sutures, clips or customized surgical kits that are used incident to a service or procedure?
Answer: We believe that the current cost thresholds and clinical criteria are sufficient to distinguish devices that have a specific therapeutic use that would be eligible for pass-through payments from general materials and supplies that would not be eligible.

Question 4: Are there differences with respect to instruments that are seen as supplies or equipment for open procedures when those same instruments are passed through an orifice using a scope?
Answer: We believe that the definition of supplies, and the definition of pass-through eligible devices, are independent and unrelated to the use of a “’scope” during a procedure. As noted above, we believe that the current cost thresholds and clinical criteria are sufficient to distinguish devices that have a specific therapeutic use that would be eligible for pass-through payments from general materials and supplies that would not be eligible for such payments, and the presence or absence of a “scope” would have no bearing on this.

We look forward to working with you on this important program.

Sincerely,

/s/

Carol A. Kelly

CMS-1427-FC-7 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Bergein Overholt** **Date & Time:** **12/22/2004**

Organization : **Gastrointestinal Associates, PC**

Category : **Physician**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

Sirs:
The existing CMS policy that prevents reimbursement for new technologies that are inserted or implanted through natural orifices deserves changing to a policy that does not prevent/discourage such care. Patient care with these new technologies can be improved but implementation of these diagnostic or therapeutic modalities is prevented due to the policy. A new policy that provides reimbursement for "new category" technologies that are implanted or inserted through natural orifices would provide patient benefits. As such, we are requesting your consideration of such a change.

Administrator Mark McClellan, M.D. Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

December 22, 2004

Dear Administrator McClellan:

On behalf of The Academy of Molecular Imaging (AMI), the Society of Nuclear Medicine (SNM) , the American College of Radiology (ACR), and the American College of Nuclear Physicians (ACNP) we are writing to comment on coding for Positron Emission Tomography Scans (PET scans). We appreciate the continued efforts of CMS to work with members of the nuclear medicine and oncology community on billing and reimbursement issues relating to these studies. One issue we have raised over the past several years is the billing of PET scans and the appropriate coding. We would like to recommend that CMS move to the newly established CPT 2005 codes for PET and PET /CT (for anatomical localization) procedures. These codes would replace the existing G codes.

The PET G codes create difficulties for hospitals tracking and billing not only because of their number and complexity, but also for their primary use by Medicare. Most other patients are reported using the standard CPT coding system. Recently six new CPT codes were created for tumor imaging with PET and PET/CT. These will allow CMS to track utilization of PET scans and allow for proper and uniform billing of scans by hospitals and practitioners. Our organizations would be willing to work with you to implement billing and coding changes and to assist with provider education.

The change to CPT codes from G Codes should not affect reimbursement levels for these scans. The reimbursement levels under the CPT codes should be consistent with the present reimbursement rate under the G codes.

We would appreciate meeting with CMS to discuss this issue, including the role of PET with concurrent CT for anatomical localization. If you wish you may contact me directly at mckusick@capecod.net, (508) 255-8178 or Denise Merlino at dmerlino@snm.org, 781-435-1124.

Thank you very much for your attention to this matter.

Sincerely,

Kenneth McKusick M.D. FACR FACNP
For the AMI, ACNP, ACR and SNM Inc.

cc: Herb Kuhn, Director
Center for Medicare Management
Tom Gustafson, Deputy Directory
Center for Medicare Management
List:
Dillehay, ACNP

Guiberteau and Kassing, ACR
Carey and Coleman, AMI
Merlino, Cannon, Conti, SNM

December 22, 2004 - 2 -

Page 1 of 2

CMS-1427-FC-8 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Denise Seldon** **Date & Time:** **12/23/2004**

Organization : **Denver Biomedical, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

December 22, 2004
Re: File Code CMS-1427-FC

As the Vice President of Marketing for the manufacturer of the Pleurx Pleural Catheter, I would like to comment on the recently published 2005 OPPS facility reimbursement for our product. The placement of the Pleurx is included in APC 0070. (The CPT code is 32019, insertion of an indwelling tunneled pleural catheter with cuff.) The catheter is an implanted device used for the management of refractive pleural effusions. The catheter is placed using a modified Seldinger technique requiring tunneling and the use of a catheter introducer set. Most patients then drain the effusions at home with the help of a caregiver, although some have a visiting nurse. The alternative treatments, thoracoscopy with talc poudrage and chest tube pleurodesis, require hospital stays of 3 ? 7 days. The use of the Pleurx catheter on an outpatient basis saves the Medicare system money. To my knowledge, the Pleurx Catheter is the only catheter cleared by FDA for this use.

The Outpatient Prospective Payment System (OPPS) facility reimbursement of $188.99 for 2005 for APC 0070 (CPT code 32019) is less than the cost of the procedure. The Pleurx Catheter kit costs $359. There is also the cost of the procedure room and a few supplies required, such as conscious sedation (for some patients), under pad, face mask, gauze pads, sterile gloves, scissors, a suction canister or vacuum bottle, and drape(s).

Please consider reclassifying the ?insertion of an indwelling tunneled pleural catheter with cuff? in another APC category with adequate reimbursement to cover the costs of implantation. To my knowledge, the Pleurx Catheter is the only product with FDA clearance for this application.

Thank you,

Denise Seldon

Vice President of Marketing
Denver Biomedical Inc.
14998 W. 6th Ave., Bldg. E-700
Golden, CO 80401
USA
303.279.7500 ext.304
800.824.8454
303.279.7575 (fax)

dseldon@denverbio.com

CMS-1427-FC-9 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Diane Evans** **Date & Time:** **12/27/2004**

Organization : **Carolinas Hospital System**

Category : **Nurse**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

Missing C1750 from Table 19, page 65763 Federal Register Nov 15, 2004
for HCPCS code 36558. Radiology personnel and MD brought to my attention that when 36558 procedure is done they also charge C1750 - hemodialysis cathether. This code is not on the list. The Radiologist informed me both an infusion catheter (C1751) and a hemodiaylsis catheter (C1750) can be done under this code. Your assistance in this matter is much appreciated

CMS-1427-FC-10 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mrs. Lisa Withers** **Date & Time:** **12/28/2004**

Organization : **Providence St Peter Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Regarding Table 19 - Device Codes REguired for Select Device-Dependent APC's - shouldn't device codes C1750 and C1752 also be added as allowed with CPT procedure codes 35667, 36558 and 36581?

CMS-1427-FC-11 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mr. Stephen Warren** **Date & Time:** **01/03/2005**

Organization : **Baptist Hospital East**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Ambulatory payment classification assignments of HCPCS codes

Change in APC Assignment for IVUS (non-coronary).

CMS-1427-FC-11-Attach-1.DOC

CMS-1427-FC-11-Attach-1.DOC

CMS-1427-FC-12 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Jennifer Michaels** **Date & Time:** **01/05/2005**

Organization : **Dr. Jennifer Michaels**

Category : **Physician**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

I strongly oppose your recommendation that certain plastic surgery procedures with "rationale #4" be deleted from your coverage in ambulatory surgery centers. Ambulatory surgery centers provide a safe, less expensive alternative to patients seeking this kind of care. If you stop reimbursing ambulatory surgery centers, patients will continue to have these surgeries, but will lose location (and sometimes) physician choice. These cuts will not save money, as patients will have these surgeries in the hospital. You are just hurting ambulatory surgery centers and unfarely targeting a portion of the treatment community.

CMS-1427-FC-13 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **J Michaels** **Date & Time:** **01/06/2005**

Organization : **J Michaels**

Category : **Individual**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

I strongly oppose the proposed Medicare cuts for plastic surgery procedures in ambulatory surgery centers. These proposed cuts will have a very negative impact on surgical treatment for skin cancer. If these cuts occur, patients will continue to need skin cancer surgery, but will have limited options for treaters and treatment locations. Ambulatory surgery centers provide a safe, confidential alternative for patients seeking care outside a hospital. Ambulatory surgery centers have been shown to save money to health care systems, and have a safety profile equivalent if not superior to hospitals. I therefore urge you to continue to re-imburse ambulatory surgery centers for plastic surgery procedures.

CMS-1427-FC-14 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Michael Repka** **Date & Time:** **01/06/2005**

Organization : **American Academy of Ophthalmology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached letter

CMS-1427-FC-14-Attach-1.DOC

CMS-1427-FC-15 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Michael Repka** **Date & Time:** **01/06/2005**

Organization : **American Academy of Ophthalmolgy**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached letter (supercedes prior submission)

CMS-1427-FC-15-Attach-1.DOC

CMS-1427-FC-16 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Michael Repka** **Date & Time:** **01/06/2005**

Organization : **American Acdemy of Ophthalmology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached letter regarding comments for 1427-FC

CMS-1427-FC-16-Attach-1.DOC

CMS-1427-FC-17 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Kathleen Kowalchik** **Date & Time:** **01/07/2005**

Organization : **Danbury Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for addition of C1898 to pacemaker lead insertion codes CPT 33211, 33216, 33217

Issues

Ambulatory payment classification assignments of HCPCS codes

Section III. C. 4. Required Use of C-Codes for Devices

CMS-1427-FC-17-Attach-1.DOC

CMS-1427-FC-17-Attach-1.DOC

CMS-1427-FC-18 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mrs. Cathy Meeter** **Date & Time:** **01/12/2005**

Organization : **Sutter Health**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

1. CPT code 13151 is listed with a relative weight of 1.77 but other codes in the same range have a higher relative value weight, i.e. both 13150 and 13152 show a relative value weight of 5.19. 13151 should be adjusted to be comparable with the other two code.
2. Many codes within the Prosthetic Implant code range of L8500 - L9900 are listed with an A status indicator which is defined by Addendum D1 that they are paid under a fee schedule or payment system other than OPPS, eg. Non-Implantable Prosthetic & Orthotic Devices. How can the codes of L8500-L8514, L8619, L8631, L8659 and L9900 be listed with a status indicator of A if they are categorized as implantable prosthetics? PM A- 03-035 dated 5/2/03 states: "... when furnished by an OPPS hospital, implantable orthotic and prosthetic devices and implantable DME are subject to OPPS and must be reported under another revenue code such as 0278 - implants. Non-implantable orthotic and prosthetic devices furnished by an OPPS hopsital or any other hospital are billed to you and paid under the Durable Medical Equipment and Prosthetic Orthotic and Supply (DMEPOS) fee schedule and reported under the revenue code of 0274 with the appropriate HCPCS code." So, how can the items be categorized as implantable in the HCPCS book created by CMS yet be listed on Addendum B as being paid as though they were non-implantable, i.e. based on a fee schedule? Thank you for your attention to these issues.

Issues

Ambulatory payment classification assignments of HCPCS codes

Re: C9920 Na Hyaluronate per 30mg. I am unclear why this drug is being listed as a pass-through. C9413 is for the same drug but in a different dose, i.e. 20-25mg. Both are listed as used for intra-articular injections. C9413 is separately payable but as a non-pass-through and at considerably less, i.e. payment of $53.94 for the C9413. Payment for C9220 is listed as $215.72.

CMS-1427-FC-19 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Ronny Chin** **Date & Time:** **01/13/2005**

Organization : **Alta Bates Comp Cancer Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

Dear Dr. McClellan,

We noted a slight error in the definition of the new HCPCS code C9722 APC 1502. The definition should not limit to the KV imaging with IR tracking. It should allow KV imaging with or without IR tracking. Most current technologies of KV imaging do not use the infrared tracking. I was told that the code was conceived 3 years ago with old technology in mind.

Thank you for your consideration.

Sincerely,

Ronny Chin, PhD
Chief Physicist
Alta Bates Comprehensive Cancer Center

CMS-1427-FC-20 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mrs. Rachel Craig** **Date & Time:** **01/13/2005**

Organization : **Vanderbilt-Ingram Cancer Center at Franklin**

Category : **Individual**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

Centers for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-1427-FC

To Whom it May Concern:

I noted an error in the definition of the new HCPCS code C9722 APC 1502. The definition should be stated as, 'Stereoscopic kV x-ray imaging with or without infrared tracking for localization of target volume). Without this change it would eliminate the utilization for many providers since many systems now do not use infrared tracking and the application that was submitted was dated. This is a comment on the final rule as an error in verbiage.

'We have recently concluded that the kV x-ray guidance should receive a temporary 'C' code for OPPS payment under certain circumstances described below, and that it should be placed into a new technology APC. Therefore, we are creating the following HCPCS code to describe kV x- ray guidance using infrared technology: HCPCS code C9722 (Stereoscopic kV x-ray imaging with infrared tracking for localization of target volume). We are assigning the new HCPCS code C9722 to New Technology APC 1502 at a payment of $75, effective on January 1, 2005'.

Thank you for your consideration

Thank you,

Rachel L. Craig, CPC, ROCC
Billing Coordinator
VICCAF, GVCTC, VUMC Radiation Oncology
(615)591-9890
(615)591-5899

CMS-1427-FC-21 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Michael Repka** **Date & Time:** **01/13/2005**

Organization : **American Acdemy of Ophthalmology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-1427-FC-21-Attach-1.DOC

CMS-1727-P-22

Submitter: Mr. Jim Wentz
Date & Time: 08/23/2004
Organization : St Paul and Zale Lipshy University Hospitals
Category: Hospital
Issue Areas/Comments GENERAL
Medicare Program; Provider Reimbursement Determinations and Appeals

CMS-1727-P Calculating Time PeriodsII.(B)(2)(a) the expiration of the 12-month period for issuance of the NPR-Restriction is not logical, and only creates more confusion. Under this proposed change, the Provider could only appeal Self-Disallowed items because how will it know what the FI is going to audit. Provider Hearing RightsII.(D)(1) ways to obtain a Board hearing-Need to add (iii) the Intermediary.s refusal to reopen based on material errors when the rules and regulations require them to do so. A reopening may be refused because of a personal bias of the intermediary even when a material error exists.II.(D)(1) filing a cost report under protest-By requiring Providers to follow procedures for filing a cost report under protest, this will create more administrative work for the hospitals and the FI because it has to be claimed and the impact manually calculated. The FI then must manually review each protested item and decide to remove or allow. The FI.s failure to do that would automatically reimburse ProvidersII.(D)(3) the expiration of the 12-month period for issuance of the NPR-Refer to comments under II.(B)(2)(a)II.(D)(4) hearing request to include a description of each self-disallowed item-Refer to comments under II.(D)(1)II.(D)(5) 60-day add issues period-60 days is an unreasonable amount of time because it forces people to appeal everything and then weed out as appropriate, which creates more administrative work. Further for Reopenings that are not settled, it forces reopening issues to be funneled to appeals to make sure rights are protected. 90 days prior to hearing is more reasonable.II.(M)-The Board should have to obtain the approval of the Provider or the Intermediary before assigning less than a quorum to conduct a hearing because some of the issues may be highly technical, and if a member is not there, just reviewing the written record may not enough to render an appropriate decision.Board Proceedings Prior To HearingII.(N)1. The Board should not have the authority to arbitrarily remove the reference to the 60-day timeframe, or set the deadlines for submitting position papers on a case-by-case basis as the Board deems appropriate because there would be no consistency.2. We disagree with the method of discovery, the limiting of interrogatories and depositions. Specifically the section, which states .A party would not be permitted to take an oral or written deposition of another party or a non-party, unless the proposed deponent agrees to the deposition.. It is likely that a party would never agree, so there needs to be a rule that in certain cases a party must agree to a deposition.3. We disagree that a party.s discovery request would be timely if the date of receipt of such a request by another party or non-party, as applicable, is no later than 90 days prior to hearing. We believe that a more timely date of receipt should no later than 60 days. Also, we feel that allowing a party to conduct discovery up to 45 days before the scheduled starting date of the Board hearing is in excess. Allowing 30 days for discovery is adequate. 4. In addition, we feel that limiting the duration of an automatic stay to no more than 15 days for Board Proceedings and to no more than 10 days for Intermediary hearing officer(s) proceedings is too strict. Creating limits of no more than 30 days for Board Proceedings and no more than 15 days

for Intermediary hearing officer(s) proceedings would be more effective.II.(O) time limits for requesting subpoenas-Refer to comment number 3 under II.(N).II.(P) Administrator excluding or including evidence not in the record.-The Administrator should only be able to rule on the record because it is what the Board based its decision on, and it is the only thing a court of law may use to overturn a Board/ Administrator decision.

CMS-1427-FC-23 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Molly Rogers** **Date & Time:** **01/13/2005**

Organization : **St. Elizabeth Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1427-FC-23-Attach-1.DOC

CMS-1427-FC-24 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Melissa Feig** **Date & Time:** **01/13/2005**

Organization : **UCH**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-1427-FC
P.O. Box 8010,
Baltimore, MD 21244-8018

Dear Dr. McClellan:

We noted a slight error in the definition of the new HCPCS code C9722 APC 1502. The definition should state, "Stereoscopic kV x-ray imaging with or without infrared tracking for localization of target volume). Without this change this would eliminate the utilization as many systems now do not use infrared tracking and the application that was submitted was dated. This is a comment on the final rule as an error in verbiage.

"We have recently concluded that the kV x-ray guidance should receive a temporary "C" code for OPPS payment under certain circumstances described below, and that it should be placed into a new technology APC. Therefore, we are creating the following HCPCS code to describe kV x- ray guidance using infrared technology: HCPCS code C9722 (Stereoscopic kV x-ray imaging with infrared tracking for localization of target volume). We are assigning the new HCPCS code C9722 to New Technology APC 1502 at a payment of $75, effective on January 1, 2005".

Thank you for your consideration

Thank you

Issues

Ambulatory payment classification assignments of HCPCS codes

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-1427-FC
P.O. Box 8010,

CMS-1427-FC-25 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Anthony Berson** **Date & Time:** **01/13/2005**

Organization : **Saint Vincents Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dr. McClellan
When this code was initially proposed the technology required infrared tracking with stereoscopic kv xray imaging. The latest technology does NOT require infrared tracking. Please change the definition to kv imaging WITH OR WITHOUT infrared tracking.
Thank you. Anthony Berson MD

Issues

Ambulatory payment classification assignments of HCPCS codes

see comments

CMS-1427-FC-26 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Lawrence Tena** **Date & Time:** **01/13/2005**

Organization : **St. Vincent's Comprehensive Cancer Center**

Category : **Physician**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

The definition of the new HCPSC code C9722, 'Stereoscopic KV x-ray imaging with infrared tracking' should be changed to 'Stereoscopic KV x- ray imaging with OR WITHOUT infrared tracking'. The technology that is available today does not require infrared tracking when using stereoscopic KV x-ray imaging.

CMS-1427-FC-27 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Kenneth McKusick** **Date & Time:** **01/14/2005**

Organization : **Nuclear Medicine APC Task Force**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1427-FC-27-Attach-1.DOC

CMS-1427-FC-28 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mr. Craig McNabb** **Date & Time:** **01/14/2005**

Organization : **US Oncology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-1427-FC
P.O. Box 8010,
Baltimore, MD 21244-8018

Dear Dr. McClellan:

We noted a slight error in the definition of the new HCPCS code C9722 APC 1502. The definition should state, "Stereoscopic kV x-ray imaging with or without infrared tracking for localization of target volume). Without this change this would eliminate the utilization as many systems now do not use infrared tracking and the application that was submitted was dated. This is a comment on the final rule as an error in verbiage.

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Thank you for your consideration

CMS-1427-FC-29 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mr. Todd Howard** **Date & Time:** **01/14/2005**

Organization : **Elekta Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attached Word document

Issues

Ambulatory payment classification assignments of HCPCS codes

Thank you for the opportunity to comment on the CMS-1427-FC final rules with comment period. On behalf of Elekta Inc., we are submitting comments concerning the implementation of a new HCPCS code (HCPCS code C9722 Stereoscopic kV X-ray imaging with infrared tracking for localization of target volume) as outlined for the Hospital Outpatient Prospective Payment System (HOPPS) for calendar year 2005. This particular HCPCS code is addressed in the November 15, 2004 Federal Register, Volume 69, Number 219 on page 65714.

CMS-1427-FC-29-Attach-1.DOC

CMS-1427-FC-29-Attach-2.DOC

CMS-1427-FC-29-Attach-1.DOC

CMS-1427-FC-29-Attach-2.DOC

Via electronic submission

January 13, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-FC
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Comments regarding HCPCS code C9722 Stereoscopic kV X-ray imaging with infrared tracking for localization of target volume

Dear Administrator:

Thank you for the opportunity to comment on the CMS-1427-FC final rules with comment period. On behalf of Elekta Inc., we are submitting comments concerning the implementation of a new HCPCS code (HCPCS code C9722 Stereoscopic kV X-ray imaging with infrared tracking for localization of target volume) as outlined for the Hospital Outpatient Prospective Payment System (HOPPS) for calendar year 2005. This particular HCPCS code is addressed in the November 15, 2004 Federal Register, Volume 69, Number 219 on page 65714.

The issue with this HCPCS code is that the definition is actually two technologies combined into one HCPCS code. This definition as currently worded excludes other superior technological methods of acquiring kV x-ray images for localization of target volume that do not rely on infrared tracking. The key to this technology is the kV x-ray imaging that is used for localization of the target volume. Infrared or cameras are not used for positioning and localization but are only used as a monitoring mechanism to ensure immobilization similar to what specialized immobilization devices, such as vacuum fixation devices.

The concern is that based on the current definition of this HCPCS code as defined by CMS, some Medicare beneficiaries will not have the same valuable access to new technologies utilizing kV x-ray imaging for positioning and localization of the target volume. Thus providing a vendor specific code that only benefits a fraction of the Medicare Beneficiaries and not all of them. Medicare has the responsibility to offer affordable quality healthcare with equal access to all of its beneficiaries, regardless of who manufactured the hospitals' equipment.

One simple solution to remedy this issue would be to modify the definition of C9722 to read as follows:

C9722 Stereoscopic kV X-ray imaging with or without infrared tracking for localization of target volume

This modification would allow hospitals, regardless of the vendor offering kV x-ray imaging, to have

equal access and offer this technology to Medicare patients and be reimbursed under HOPPS.

Thank you again for the opportunity to comment on this rule. If there is anything in these comments that CMS would like to discuss, please feel free to contact me at (800) 535-7355, or (770) 300-9725.

Sincerely,

Todd Howard, MBA
Business Services Manager
Elekta, Inc.

Via electronic submission

January 13, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-FC
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Comments regarding HCPCS code C9722 Stereoscopic kV X-ray imaging with infrared tracking for localization of target volume

Dear Administrator:

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equal access and offer this technology to Medicare patients and be reimbursed under HOPPS.

Thank you again for the opportunity to comment on this rule. If there is anything in these comments that CMS would like to discuss, please feel free to contact me at (800) 535-7355, or (770) 300-9725.

Sincerely,

Todd Howard, MBA
Business Services Manager
Elekta, Inc.

Via electronic submission

January 13, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-FC
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Comments regarding HCPCS code C9722 Stereoscopic kV X-ray imaging with infrared tracking for localization of target volume

Dear Administrator:

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The concern is that based on the current definition of this HCPCS code as defined by CMS, some Medicare beneficiaries will not have the same valuable access to new technologies utilizing kV x-ray imaging for positioning and localization of the target volume. Thus providing a vendor specific code that only benefits a fraction of the Medicare Beneficiaries and not all of them. Medicare has the responsibility to offer affordable quality healthcare with equal access to all of its beneficiaries, regardless of who manufactured the hospitals' equipment.

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C9722 Stereoscopic kV X-ray imaging with or without infrared tracking for localization of target volume

This modification would allow hospitals, regardless of the vendor offering kV x-ray imaging, to have

equal access and offer this technology to Medicare patients and be reimbursed under HOPPS.

Thank you again for the opportunity to comment on this rule. If there is anything in these comments that CMS would like to discuss, please feel free to contact me at (800) 535-7355, or (770) 300-9725.

Sincerely,

Todd Howard, MBA
Business Services Manager
Elekta, Inc.

CMS-1427-FC-30 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Date & Time:** **01/14/2005**

Organization : **Biotechnology Industry Organization**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1427-FC-30-Attach-1.DOC

January 14, 2005

BY ELECTRONIC DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1427-FC (Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment period regarding changes to the hospital outpatient prospective payment system (OPPS) and calendar year 2005 payment rates, published in the Federal Register on November 15, 2004 (the Final Rule).1 BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO consistently has expressed concerns that OPPS could create substantial access and quality of care issues for Medicare beneficiaries. As we acknowledged in our comments to the proposed rule,2 however, we are pleased to see that the agency has made significant progress in addressing many of our concerns this year. Specifically, we appreciate the agency finalizing the following and believe that these improvements will go a long way to helping ensure beneficiary access to critical drugs and biological therapies in the hospital outpatient setting:

* Setting the pass-through payment amount for drugs and biologicals at zero and using the excess funds from the pass-through pool to increase the conversion factor;3
* Paying separately for all new drugs with Healthcare Common Procedure Coding System (HCPCS)

codes using the same methodology as for pass-through therapies, regardless of whether an application for pass-through status has been filed;4
* Verifying that payment for pass-through drugs and biologicals will be based on the latest average sales price (ASP) data available and will be updated quarterly;5
* Paying separately for all six injectible and oral forms of anti-emetics.6
* Implementing the payment methods required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) for "specified covered outpatient drugs" (SCODs) in a straightforward manner and recognizing that all biological products are sole source;7
* Treating three expiring pass-through drugs as SCODs;8
* Implementing the MMA's provision requiring immediate reimbursement for drugs and biologicals for which HCPCS codes have not yet been assigned;9
* Continuing to reimburse vaccines under the reasonable cost methodology;10
* Setting payment rates for certain orphan drugs at the higher of 88 percent of their average wholesale price (AWP) or 106 percent of their ASP, updated quarterly;11
* Basing the payment rate for J0256, Alpha 1-Proteinase Inhibitor, on the volume-weighted average of all three brands currently available on the market, updated quarterly;12 and
* Acknowledging that radiopharmaceuticals are indeed drugs and biologicals and paying for radiopharmaceuticals with transitional pass-through status using the same methodology as for SCODs.13

We continue to be concerned, however, that the MMA's significant changes in Medicare payment for drugs and biologicals could have negative consequences for patient access to important, innovative therapies. As you are aware, the Medicare statute ties reimbursement for pass-through therapies in the hospital outpatient setting to the rates applicable in physician offices. Neither the new drug administration G-codes nor the demonstration project on improved quality of care for cancer patients undergoing chemotherapy are applicable in the hospital outpatient setting though. Thus, we believe it is critically important for CMS to monitor patient access to these pass-through therapies closely and to act immediately if access is compromised. Hospital outpatient departments are an extremely important part of the drug and biological delivery infrastructure in this country, particularly for high-risk patients with comorbidities and for patients previously enrolled in clinical trials. CMS needs to do what is necessary to preserve patient access to drug and biological therapies in this critical setting.

Moreover, as we discussed in our comments to the Medicare physician fee schedule final rule for 2005,14 we are deeply concerned that paying for new drug and biologicals at wholesale acquisition cost (WAC) until a rate based on ASP can be implemented could jeopardize patients' access to new therapies. Accordingly, we urge the agency to pay for these single source drugs and biologicals at 95 percent of their AWP – as they currently are paid in the hospital outpatient setting until a HCPCS code is assigned – or at a WAC-based rate appropriate to ensure beneficiary access to them.

BIO raises the following concerns stemming from the Final Rule. First, although we appreciate CMS' willingness to permit outlier payments for the compounding costs of the radiopharmaceutical therapies Bexxar® and Zevalin®,15 we continue to be concerned that the final payment rates for these therapies and their related preparation and administration costs and associated procedures are not adequate. We ask the agency to work with the manufacturers and hospitals involved in this issue to find

a way to ensure that patient access to these lifesaving therapies will not be compromised. Second, we do not believe functional equivalence, an "equitable adjustment," or any similar standard should be applied to the payment rate of any product and are disappointed CMS did so in the final rule. Third, we urge CMS to apply its special single-indication orphan drug payment rules to additional deserving therapies used to treat rare diseases and disorders, including Elitek™ (J2783) and Fabrazyme® (C9208).

Finally, we are concerned about the packaging threshold and payment for SCODs and other separately paid drugs and biologicals in 2006 and beyond. Although we recognize that CMS believes these issues are outside the scope of the Final Rule,16 we urge the agency to become more actively engaged on them today to ensure that the future rate-setting methodology is appropriate and that the agency will have the information it needs to proceed. Rather than wait until the comment period on next year's proposed rule, we hope CMS will have an open dialogue with us, other stakeholders, and the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) as soon as the Government Accountability Office's (GAO) study on hospital acquisition costs and the Medicare Payment Advisory Commission's (MedPAC) study on pharmacy service costs have been completed. We welcome the opportunity to work with you to create a new rate-setting methodology for 2006 and thereafter that will help ensure beneficiary access to important drug and biological therapies in hospital outpatient departments.

Rather than repeating our extensive comments on the proposed rule, supporting numerous proposals that CMS now has finalized, we instead focus these comments on only those aspects of the Final Rule about which we continue to have concerns.

I. Transitional Pass-Through Payment for Additional Costs of Drugs and Biologicals

Consistent with the Social Security Act (SSA), CMS will pay for drugs and biologicals with transitional pass-through status at 106 percent of ASP in 2005 – the same rate applicable in physician offices.17 As discussed in depth in our comments to the proposed rule18 and to the proposed and final Medicare physician fee schedule rules for 2005,19 BIO continues to be concerned that these rates may not adequately compensate hospitals for the costs of providing innovative drug and biological therapies, however. This is particularly true because the neither the new drug administration G-codes nor the demonstration project on improved quality of care for cancer patients undergoing chemotherapy are applicable in the hospital outpatient setting.

Hospital outpatient departments are a critical part of the drug delivery infrastructure. Frequently they treat patients who are higher-risk or have complicating comorbidities, such as a history of infusion reactions. Hospitals also tend to be early adopters of new technologies, particularly if they participate in clinical trials. Often patients who previously were enrolled in clinical trials in a hospital setting will want to continue treatment at that setting where staff are familiar with the therapy, the patient's medical history, and any complexities involved in the drug or biological's administration. Because most pass-through therapies are new with recently completed clinical trials, this is another reason why access to them in a hospital outpatient setting is so imperative.

In our previous comments, BIO has urged CMS to monitor patient access to drug and biologicals proactively as the MMA's new payment methodologies are implemented and to act immediately if access is compromised. We appreciate CMS' statements that it is committed to ensuring beneficiary access and request that the agency add a form to its website to facilitate the reporting of access issues. In addition, we firmly believe that CMS should inform patients and providers that the 1-800-Medicare number and website form are available to report any problems. Unless beneficiaries know that these avenues exist to give feedback, CMS will not be able to collect the information it needs to fully evaluate access issues. This is particularly important in the hospital outpatient setting where neither the new drug administration codes nor the demonstration project will be available to cushion the impact of the ASP-based payment rates. As part of each annual rulemaking, we also encourage CMS to state explicitly what measures it proposes to use to assess access and to report its findings from such assessment. The agency should solicit comment on both such methodology as well as its findings.

The Final Rule provides that in the absence of ASP data, the agency will use WAC to establish the initial payment rate.20 The Final Rule continues, "If WAC is also unavailable then we will calculate payment at 95 percent of the May 1, 2003 AWP or the first reported AWP for the product."21 Although the statute authorizes payment based on WAC or the methodology in effect on November 1, 2003 – 95 percent of AWP,22 we are deeply concerned that payment at WAC – as appears to be the case with the physician office payment rates recently released by CMS – will jeopardize patients' access to new therapies, particularly in hospital outpatient departments. As articulated in our comments to the Medicare physician fee schedule final rule,23 we urge CMS to pay for these single source therapies at 95 percent of AWP or at a WAC-based rate appropriate to ensure beneficiary access to them. Because pass-through therapies for which a unique HCPCS code has not been assigned are paid at 95 percent of AWP in the hospital outpatient setting,24 we believe that continued payment at 95 percent of AWP makes the most sense in this situation particularly given the limited period of time until ASP data are available. We urge CMS to make this change immediately. Unless payment rates are adequate, patients will not have access to cutting-edge therapies that may provide their best hope for treatment.

II. Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

A. Ensuring Patient Access to Bexxar® and Zevalin®

In our comments to the proposed rule,25 we expressed concern that the 2005 payment rates for the radiopharmaceutical therapies Bexxar® and Zevalin® and their related preparation and administration costs and associated procedures may not be adequate to ensure patient access to them. In the Final Rule, CMS acknowledged that it shares our concerns but that these radiopharmaceuticals meet the definition of sole source SCODs and must be paid in accordance with the MMA.26 The Final Rule also states that outlier payments are permitted for the substantial compounding costs of these radiopharmaceutical therapies, however.27

Although BIO appreciates CMS' willingness to permit outlier payments for the compounding costs of these radiopharmaceutical therapies, we continue to be concerned that the final payment rates for Bexxar® and Zevalin® and their related preparation and administration costs and associated procedures

are not adequate. We request that the agency work with the manufacturers and hospitals involved in this issue to find a way to ensure that patient access to these lifesaving therapies will not be compromised.

B. Equitable Adjustments to Payment Rates

In the proposed rule, CMS solicited comment on whether the agency should again apply an equitable adjustment to the payment rate of darbepoetin alfa (Q0137).28 BIO commented – as we repeatedly have done in the past – that we do not believe functional equivalence, and equitable adjustment, or any similar standard should be applied to the payment rate of any product.29 We are disappointed that CMS now has applied such an adjustment in the Final Rule30 and ask the agency to reconsider its decision.

III. Changes in Payment for Single Indication Orphan Drugs

BIO applauds CMS for recognizing the unique concerns for patients with rare disorders and for continuing to making separate payments for orphan drugs based on their currently assigned ambulatory payment classifications (APCs).31 We firmly believe that CMS' setting payment rates for certain orphan drugs at the higher of 88 percent of their AWP or 106 percent of their ASP, updated quarterly,32 will help ensure that patients with certain rare disorders have access to the life-saving therapies they so desperately need. We are concerned, however, that CMS' criteria for determining which orphans will be eligible for this special treatment is overly narrow. First, we urge CMS to include drugs and biologicals that also are eligible for transitional pass-through status. Second, we ask that the agency expand its special payment rules to all drugs and biologicals designated as orphan therapies by the Food and Drug Administration (FDA) and used for orphan indications.

In the Final Rule, CMS declined to extend single-indication orphan status to Elitek™ (J2783) because it has an off-label, non-orphan use as indicated by the 2004 United States Pharmacopoeia Drug Information (USPDI).33 We have attached the USPDI's listing for Elitek™, however, and only the orphan use is reported. We ask CMS to make this correction.

Elitek™ also is a current pass-through therapy. In the Final Rule, CMS determined that Fabrazyme® (C9208), another single-indication orphan drug that also is a pass-through, should be paid at 106 percent of ASP.34 Given the unique concerns CMS has articulated about orphan drugs used solely for orphan conditions and the need to ensure patient access to these critical therapies, we ask the agency to expand its special payment rules to include single-indication orphan drugs that also have been granted pass-through status. This would mean that single-indication pass-through drugs and biologicals such as Elitek™ and Fabrazyme® would be paid the higher of 88 percent of their AWP or 106 percent of their ASP, updated quarterly. We believe such treatment is consistent with CMS' objective to ensure that patients suffering from rare diseases continue to have access to the treatments they need.

Even more broadly, we sincerely hope CMS will consider expanding the number of orphan therapies that qualify for special payment. As addressed in depth in our comments to the proposed

rule,35 we ask CMS to extend its special payment rules to all drugs and biologicals designated as orphan therapies by the FDA and used for orphan indications. We believe such treatment supports the goals of the Orphan Drug Act – creating incentives for the research, development, production, and distribution of therapies to treat patients with rare disorders – and will help ensure that patients suffering with rare disorders have access to the life-saving treatments they need.

IV. Payment Methodology for Drugs and Biologicals in 2006 and Beyond

In years 2006 and thereafter, the MMA requires CMS to develop a payment methodology for SCODs that takes into account a GAO study of hospital acquisition cost data and a MedPAC study of pharmacy service and overhead costs. BIO firmly believes that a rate-setting methodology based on actual hospital acquisition costs for drugs and biologicals is far more appropriate than a rate-setting methodology based on deriving costs from hospital charges based on claims data. The GAO recently confirmed what BIO has said in our comments on previous OPPS proposed rules – CMS' methodology for deriving costs from charge data may under or overestimate costs and that CMS's application of a constant cost-to-charge ratio may not result in an accurate calculation of hospital costs.36 Accordingly, we hope that CMS will apply the MMA's acquisition cost-based payment methodology to all separately paid drugs and biologicals. Moreover, we encourage the agency not to increase the $50 packaging threshold in 2007 and beyond unless it can show with a thorough study that patient care will not be affected by such a change. Both of these issues are discussed in depth in our comments to the proposed rule.37

In the Final Rule, CMS acknowledges the comments on the MMA-mandated surveys and on the future payment methodology for drugs and biologicals, but explains that these issues fall outside the scope of the Final Rule.38 Similarly, the agency states that it will take all the commenters' recommendations regarding the packaging threshold as the agency works on its proposal for 2007.39 Although we understand the agency's hesitance to discuss these issue in the 2005 Final Rule, we urge the agency to consider them carefully today to ensure that the future rate-setting methodology is appropriate and that the agency will have the information it needs to proceed.

Specifically, should CMS decide to extend the MMA's acquisition cost-based payment methodology to all separately paid drugs and biologicals – as we urge the agency to do – these therapies will need to be included in the acquisition cost survey GAO now is administering. If the agency waits until next fall to request this information from GAO, we are concerned that it will be too late to collect the reliable data necessary. Moreover, we encourage CMS to work with GAO and MedPAC today to ensure that their studies provide CMS with the data the agency needs in the format it needs to set appropriate payment rates in the future.

Rather than waiting until the comment period on next year's proposed rule, BIO hopes CMS will have an open dialogue with us, other stakeholders, and the APC Panel as soon as the GAO and MedPAC studies have been completed. We encourage the agency to use the sub-regulatory process – similar to what it has done to seek input on the Medicare Part D prescription drug benefit – to seek comment, schedule working group meetings, and provide other opportunities for transparency and public input regarding the payment methodology for drugs and biologicals in 2006 and beyond. We also recommend

that CMS continue to accept external cost data that may be submitted by knowledgeable stakeholders, such as manufacturers, providers or patients to provide verification of hospital acquisition costs for specific drugs and biologicals. We are hopeful that the future rate-setting methodology will help ensure beneficiary access to important drug and biological therapies in hospital outpatient departments. We welcome the opportunity to work with you to make this occur.

V. Conclusion

In conclusion, BIO commends CMS for making important improvements to the OPPS, and we urge the agency to continue to make patient access to quality care its primary focus as it implements the MMA. To ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies in appropriate hospital outpatient settings, we urge CMS to:

* Monitor patient access closely for pass-through drugs and biologicals during the transition to ASP-based payment and to react quickly to any access problems;
* Add a form to the CMS website to facilitate the reporting of access issues and inform Medicare beneficiaries and providers that the form and the 1-800-Medicare number are available to give feedback;
* Pay for new single source drugs and biologicals at 95 percent of their AWP or at a WAC-based rate appropriate to ensure beneficiary access to them;
* Ensure that the final payment rates for Bexxar® and Zevalin® and their related preparation and administration costs and associated procedures are adequate to ensure beneficiary access;
* Reconsider the application of an equitable adjustment to the payment rate for darbepoetin alfa and never apply it or a similar standard again;
* Apply the agency's special single-indication orphan drug payment rules to additional deserving therapies used to treat rare diseases and disorders, such as Elitek™, Fabrazyme®, and other drugs and biologicals designated as orphan drugs by the FDA and used for orphan indications;
* Expand the future rate-setting methodology for SCODs to include all separately-paid drugs;
* Do not increase the $50 packaging threshold in 2007 and beyond unless a thorough study shows that patient care will not be affected;
* Work with GAO and MedPAC now to ensure that their studies of the acquisition costs and pharmacy service and overhead costs include all the data the agency needs in the format it needs to set appropriate payment rates in the future; and
* Begin an open dialogue with BIO and other stakeholders as soon as the GAO and MedPAC studies have been completed and work with them to create a payment methodology for 2006 and thereafter that will help ensure beneficiary access to important drug and biological therapies in hospital outpatient departments.

BIO appreciates this opportunity to comment on the Final Rule, and we look forward to working with CMS to protect Medicare beneficiaries' access to life-improving drug therapies both now and in the future. Please contact Jayson Slotnik at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Michael Werner, Esq.
Chief of Policy

1 69 Fed. Reg. 65682 (Nov. 15, 2004).
2 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS (Oct. 8, 2004) available at http://www.bio.org/letters/.
3 69 Fed. Reg. at 65776.
4 Id. at 65776, 65798.
5 Id. at 65777.
6 Id. at 65781.
7 Id. at 65781-94, 65803.
8 Id. at 65795.
9 Id. at 65807.
10 Id. at 65807.
11 Id. at 65807-09.
12 Id. at 65809.
13 Id. at 65799, 65810-11.
14 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 5-6 (Dec. 27, 2004) available at http://www.bio.org/letters/.
15 69 Fed. Reg. at 65787.
16 Id. at 65801.
17 SSA § 1833(t)(6)(D)(i).
18 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 4-5 (Oct. 8, 2004) available at http://www.bio.org/letters/.
19 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS at 4-5 (Sept. 24, 2004); Letter from Michel Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 3-4 (Dec. 27, 2004) available at http://www.bio.org/letters/.
20 69 Fed. Reg. 65798.
21 Id.
22 SSA § 1847A(c)(4)
23 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 5-6 (Dec. 27, 2004) available at http://www.bio.org/letters/.
24 69 Fed. Reg. at 65807.
25 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 8-9 (Oct. 8, 2004) available at http://www.bio.org/letters/.
26 69 Fed. Reg. at 65786-87.
27 Id. at 65787.
28 69 Fed. Reg. 50448, 50513 (Aug. 16, 2004).
29 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 9-10 (Oct. 8, 2004) available at http://www.bio.org/letters/.
30 69 Fed. Reg. at 65796.
31 Id. at 65807-09.

32 Id. at 65809.
33 Id. at 65808.
34 Id. at 65809.
35 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 11-13 (Oct. 8, 2004) available at http://www.bio.org/letters/.
36 U.S. GAO, "Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services," No. GAO-04-772 (Sept. 2004), at 16, 18.
37 Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 6-8 (Oct. 8, 2004) available at http://www.bio.org/letters/.
38 69 Fed. Reg. at 65801.
39 Id. at 65779-80.
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CMS-1427-FC-31 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mr. Carl Wilcox** **Date & Time:** **01/14/2005**

Organization : **Inovise Medical, Inc.**

Category : **Device Industry**

Issue Areas/Comments

Issues

Ambulatory payment classification assignments of HCPCS codes

See Attachment

CMS-1427-FC-31-Attach-1.JPG

CMS-1427-FC-33 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Frederick Cahn** **Date & Time:** **01/14/2005**

Organization : **BioMedical Strategies LLC**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Ambulatory payment classification assignments of HCPCS codes

Additional HOPPS codes or payment correction needed for Collagen Glycosaminoglycan Bilayer Matrix

CMS-1427-FC-33-Attach-1.RTF

CMS-1427-FC-33-Attach-1.RTF

CMS-1427-FC-32 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Sarah Wells** **Date & Time:** **01/14/2005**

Organization : **Boston Scientific Corporation**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter

Issues

Ambulatory payment classification assignments of HCPCS codes

See attached comment letter

CMS-1427-FC-32-Attach-1.JPG

CMS-1427-FC-32-Attach-1.JPG

CMS-1427-FC-33 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Frederick Cahn** **Date & Time:** **01/14/2005**

Organization : **BioMedical Strategies LLC**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Ambulatory payment classification assignments of HCPCS codes

Additional HOPPS codes or payment correction needed for Collagen Glycosaminoglycan Bilayer Matrix

CMS-1427-FC-33-Attach-1.RTF

CMS-1427-FC-33-Attach-1.RTF

CMS-1427-FC-34 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Kathleen Smith** **Date & Time:** **01/14/2005**

Organization : **Fresenius Medical Care**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1427-FC-34-Attach-1.DOC

CMS-1427-FC-34 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Kathleen Smith** **Date & Time:** **01/14/2005**

Organization : **Fresenius Medical Care**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1427-FC-34-Attach-1.DOC

VIA ELECTRONIC AND FIRST CLASS MAIL

Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018
Attention: CMS-1427-FC

Re: CMS-1427-FC:
APC Classification of CPT Code 36515 in the 2005 Hospital Outpatient Prospective Payment System Final Rule

Dear Dr. McClellan:

Fresenius HemoCare ("Fresenius"), a division of Fresenius Medical Care – NA, hereby submits these comments to Final Rule CMS-1427-FC, "Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates" (the " HOPPS Final Rule"), published in the Federal Register November 15, 2004.1 Specifically, Fresenius' comments relate to the decision by the Centers for Medicare and Medicaid Services ("CMS") in the Final Rule to reclassify CPT Code 36515 ("therapeutic apheresis, with extracorporeal immunoadsorption and plasma reinfusion") from APC 0112 ("Blood Product Exchange") to APC 0111 ("Apheresis, Photopheresis, and Plasmapheresis").

As set forth in further detail below, we believe that this decision was inappropriate because it was made under the mistaken assumption that the majority of claims for Extracorporeal Immunoadsorption ("ECI") using Protein A columns were billed to the Medicare program under CPT Code 36515 in 2003, when, in fact, the national CPT coding book utilized by CMS and providers, and policies issued by some CMS contractors, instructed providers to bill this procedure under CPT Code 36516 ("therapeutic apheresis, with extracorporeal selective adsorption or selective filtration and plasma reinfusion"). As a result of these erroneous directives, a substantial majority of apheresis procedures performed to treat patients with rheumatoid arthritis were billed under CPT Code 36516 (instead of 36515) in 2003. The costs associated with those procedures were substantially in excess of the reimbursement assigned to the new APC to which CPT Code 36515 was assigned in the Final Rule.

Accordingly, Fresenius respectfully requests that CMS issue a technical correction to the HOPPS Final Rule, reassigning CPT Code 36515 to APC 0112 in the Outpatient Code Editor ("OCE"). Ideally this change should be made retroactive to the beginning of 2005, but, at a minimum, made effective for services furnished on or after April 1, 2005. Further, to the extent that CMS decides that a correction cannot be made for services provided in 2005, Fresenius respectfully requests that a more detailed analysis of claims billed under Codes 36515 and 36516 in 2004 be used to determine the proper APC assignment for code 36515 under the 2006 HOPPS fee schedule.

Background on PROSORBA® and Apheresis

Fresenius manufactures and distributes the PROSORBA® Column, which is a single-use immunoadsorption therapeutic medical device approved by the Food and Drug Administration ("FDA") for the treatment of rheumatoid arthritis ("RA") and idiopathic thrombocytopenic purpura ("ITP"). The device contains approximately 200 mg of highly purified protein A covalently bound to a silica matrix. Protein A is a component of certain strains of the bacterium Staphylococcus Aureus. The protein A binds to, and selectively adsorbs and removes from the blood, immuno-globulins – commonly called antibodies – and circulating immune complexes – antibodies bound to antigens – that contribute to the symptoms characteristic of rheumatoid arthritis.

RA is a chronic and often debilitating autoimmune disease in which the body's immune system attacks its own tissue, often leading to painful inflammation and deformity of the joints. The disease affects more than approximately 2.5 million Americans, 70% of them women, most between the ages of 25 and 60. It has been estimated that 10% of the 2.5 million RA patients in the United States may benefit from PROSOBRA® Column treatment.

Medicare covers the use of Protein A columns for the treatment of ITP as well as for the treatment of RA under certain conditions.2 Payment for claims with dates of service on or after August 1, 2000 is made under the OPPS. Starting in 2005, payment for these procedures is also made when they are performed in a physician's office. The ICD-9 codes that support the medical necessity of Protein A columns include 287.3 ("primary thrombocytopenia") and 714.0 ("rheumatoid arthritis").

Because the PROSORBA® Column works through selective adsorption, treatment with it arguably could be coded under CPT Code 36516 ("therapeutic apheresis; for white blood cells with extracorporeal selective adsorption or selective filtration and plasma reinfusion"). However, because it selectively adsorbs immunoglobulins and immune complexes, treatment with the PROSORBA® Column also could be considered an "extracorporeal immunoadsorption and plasma reinfusion" which matches the definition of CPT Code 36515. We understand the American Society for Hematology takes the position that CPT Code 36515 is the better fit.3 So too does CMS. Furthermore, it recently has issued a Transmittal to clarify this fact with the provider community.4

The 2005 HOPPS Final Rule

In the 2005 HOPPS Final Rule, CMS remapped CPT Code 36515 from APC 0112 to APC 0111. APC 0111 is assigned a payment rate of $725.16 in 2005, and the payment rate for APC 0112 in 2005 is $2,127.26. In response to public comments on the HOPPS proposed rule, which, among other things, articulated that the apheresis procedure described by CPT Code 36515 involved an expensive disposable supply item (presumably the PROSORBA® Column)5 that costs more than the proposed payment rate for APC 0111, and noted that the proposed HOPPS payment rate would be substantially less than the physician's office payment, CMS stated as follows:

APC assignments are based on clinical homogeneity and comparable resource utilization for all CPT and

HCPCS codes within an APC. After careful review, we disagree with the commenters that CPT code 36515 should be reassigned to APC 0112. We believe that the resources required for CPT Code 36515 are more similar to the other CPT codes in APC 0111. Thus, for CY 2005, we are adopting as final our proposal to assign CPT Code 36515 to APC 0111, effective January 1, 2005.

69 Fed. Reg. 65,681, at 65,704 (Nov. 15, 2004)

When Fresenius met with CMS to discuss the remapping of Code 36515 to APC 111, the agency confirmed that its remapping decision was informed by a review of claims filled under CPT Code 36515. No data associated with claims filled under CPT Code 36516 was considered.

Conflicting Instructions Issued By The American Medical Association and CMS Contractors Resulted In Inconsistent Billing For Therapeutic Apheresis

There has been significant confusion over which CPT Code to use for apheresis treatments with the PROSORBA® Column since 2003, and this confusion underlies the inappropriate reclassification of CPT Code 36515 from APC 0112 to APC 0111. Specifically, in 2002, the American Medical Association's ("AMA") CPT Code Book, which is utilized by CMS and its contractors under a licensing agreement with the AMA, and is relied upon, and, in fact, considered an "authoritative" source, by CMS, its contractors, and providers in determining the proper coding for a particular service or procedure, contained only one code for therapeutic apheresis ? Code 36521, which was defined as "therapeutic apheresis; with extracorporeal affinity column adsorption and plasma reinfusion." In 2003 the CPT Panel deleted Code 36521 and established two new CPT Codes for therapeutic apheresis – 36515 for apheresis that involves extracorporeal immunoadsorption and 36516 for apheresis that involves selective adsorption or selective filtration. Despite the CPT Panel's intent to implement two new therapeutic apheresis codes, the 2003 CPT Code book contained an error that made it appear that Code 36516 alone had replaced Code 36521. This error was not corrected in the 2004 edition of the CPT Code Book. Rather, both the 2003 and the 2004 CPT Code Books contained the following statement where CPT Code 36521 had been located: "(36521 has been deleted. To report, use 36516)". Because of the selective nature of the adsorption resulting from PROSORBA® Column use, it is unlikely that clinicians or coders looking at this instruction and then reading the definition of Code 36516 would have questioned the advice. Thus, in both 2003 and 2004, many providers who had previously billed aphresis treatments with the PROSORBA® Column under CPT Code 36521 were specifically instructed to bill for the same procedures under CPT Code 36516. By contrast, the 2005 CPT Code book directs those looking at CPT Code 36521 to review both 36515 and 36516 before making a coding decision.

Contributing to this confusion over the proper CPT Code to use for billing apheresis procedures using the Protein A column is the fact that some local coverage policies issued by Carriers and Intermediaries instructed (and, in fact, still do instruct) physicians and hospitals to use CPT Code 36516 (or the now defunct 36521) when billing for apheresis procedures using the Protein A column. Indeed, of the 14 Medicare Carriers with Local Coverage Policies for ECI for ITP and RA, five direct providers to bill using CPT Code 36516, three direct providers to bill using CPT Code 36515, six direct providers to bill using CPT Code 36521, and one instructs providers to bill using either CPT Code 36515 or 36516.

Although the Carrier policies apply only to the professional services of physicians associated with the apheresis procedure, as opposed to the technical component, they are still instructive in that they highlight the confusing and contradictory nature of the instructions that were being disseminated to providers regarding billing for the apheresis procedure. In addition, of the four Intermediaries that have issued local coverage policies, one instructs providers to bill using CPT Code 36516, two instruct providers to use CPT Code 36515, and one mentions both codes. A table summarizing our review of local coverage policies is attached as Exhibit 1.

As discussed below, the conflicting billing and coding instructions issued to providers regarding apheresis procedures using the Protein A Column resulted in CMS utilizing incomplete and unrepresentative data when it decided to reclassify CPT Code 36515 to an APC group that has a payment rate of only one-third of the average costs associated with these procedures.

An Analysis of 2003 Hospital Claims Data Shows that CMS Relied upon Incomplete and Unrepresentative Data When It Set the APC Assignment for CPT Code 36515

In order to determine how hospital providers coded for apheresis claims for patients with RA (ICD-9-CM diagnosis code 714.0) and ITP (ICD-9-CM diagnosis code 287.3) during 2003, Fresenius engaged the services of The Moran Group to conduct an analysis of hospital claims data for CPT Codes 36515 and 36516 for outpatient services provided from January 1, 2003 through December 31, 2003, linking costs to the aforementioned diagnosis codes listed on the claims forms. The Moran Group's report is attached as Exhibit 2. As a result of this analysis, which is attached, The Moran Group concluded that a substantial majority of apheresis procedures performed to treat patients diagnosed with RA or ITP were billed under CPT Code 36516, as opposed to CPT Code 36515, and that these cases had materially higher costs than the APC 0111 payment rate.6 Specifically, they concluded as follows:

* Of the 959 claims billed in 2003 to either CPT Code 36515 or 36516, 300 claims were coded with a diagnosis of 714.0 or 287.3, and 213 of these 300 claims (or 71%) were billed to CPT Code 36516;

* These cases have materially higher average costs (between $2,500 and almost $3,000) than the APC 0111 payment rate of $725.16; and

* The median procedure-level costs for these cases is materially higher than the median costs of cases being used to set the payment rates for APC 0111.

This report clearly demonstrates that the claims data examined by CMS when determining what APC group to classify CPT Code 36515 into was incomplete and unrepresentative, and that the charges for the apheresis procedures which were billed under CPT Code 36516 were substantially in excess of the reimbursement for the new APC to which PROSORBA® therapy was designated in the Final Rule. As further evidence of the fact that incomplete data was analyzed when setting the 2005 HOPPS rates is the fact that the current APC 0111 rate of $725.16 is less than one-third of the rate established for the same procedure furnished in a physician's office under the 2005 final physician fee schedule rule.

If CMS had reviewed and evaluated complete data for therapeutic apheresis using the Protein A column, drawn from claims filed under both CPT Codes 36515 and 36516 in 2003, when it developed the 2005 HOPPS Final Rule, the observed levels of resource utilization for this treatment would have supported continued mapping of 36515 to APC 112. This mapping should be reestablished by matching Code 36515 with APC 112 in the 2005 OCE. Ideally, the revised mapping should be applied to claims with dates of service beginning January 1, 2005, but, at a minimum, made effective for the second quarter of 2005. Such a change will result in 2005 reimbursement more closely approximating the average costs in 2003 associated with apheresis with the PROSORBA® Column. This type of technical correction is necessary and appropriate because the coding confusion that led to the inappropriate reassignment of CPT Code 36515 to APC 111 stemmed in large part from a mistake in the 2003 and 2004 CPT Code Books that was further exacerbated by errors in local coverage policies published by a number of CMS contractors.

Conclusion

As a result of erroneous and conflicting instructions issued by the AMA's CPT Code Book as well as several CMS contractors, a substantial majority of hospitals in 2003 and 2004 filed claims for apheresis therapy using the PROSORBA® Column under CPT Code 36516, not CPT Code 36515. Because CMS, in setting the 2005 HOPPS final rates for this procedure, only considered costs associated with CPT Code 36515 (and not those associated with CPT Code CPT Code 36516), it did not accurately determine the true cost of this therapy, which resulted in a new APC classification that imposes an unrealistically low relative value to the procedure. If CMS were to consider costs associated with the CPT Code 36516 claims for patients diagnosed with RA in 2003, it would be evident that PROSORBA® Column therapy is more appropriately grouped with APC 0112 from a resource utilization perspective as well as a clinical homogeneity perspective.

Accordingly, for the reasons outlined above, Fresenius respectfully requests that CMS issue a technical correction to the 2005 HOPPS Final Rule remapping CPT Code 36515 to APC 0112. Ideally this change should be made retroactive to the beginning of 2005, but, at a minimum, made effective for services furnished on or after April 1, 2005. Further, to the extent that CMS decides that a correction cannot be made for services provided in 2005, Fresenius respectfully requests that a more detailed analysis of claims billed under CPT Codes 36515 and 36516 in 2004 be used to determine the proper APC assignment for 36515 in the 2006 HOPPS fee schedule. Otherwise, CMS will again be using unrepresentative base-year data when it decides on the APC with which to group CPT Code 36515 next year.

Respectfully submitted,

Kathleen T. Smith, RN
Vice President, Government Affairs

EXHIBIT 1

Local Coverage Policies for Extracorporeal Immunoadsorption (ECI) For ITP and RA

Name

Primary Geographic Jurisdiction
Payor Type

Policy or Article Type and Number

Effective
Date / revisions

CPT Code

Comments

Arkansas BC/BS of Rhode Island

Rhode Island

FI

LMRP
L2998

3/2000
1/2003

36516

Use Q0068 prior for services prior to 12/1999
Use 36521 for services 1/2000 to 12/31/2002
Use 36516 for services after 1/2003

BC/BS of Arkansas

Arkansas

FI

LMRP
L10279

8/2000
10/2003

36515

First Coast Services Options

Florida

FI

LMRP
L2999

9/2002
2/2003

36515

36516

HGS Administrators

Pennsylvania

Carrier

LMRP
L5201

10/1992
10/2003

36515

General Apheresis policy includes coverage for ECI for ITP and RA

Empire Medicare Services

New York Downstate

Carrier

LMRP
L3470

10/2000
1/2002

36516

BC/BS of Rhode Island

Rhode Island

Carrier

LMRP
L2807

3/2000
1/2003

36516

HealthNow

New York Upstate

Carrier

LMRP
L4242

7/2001
1/2003

36516

Group Health

New York – Queens

Carrier

LMRP
L4398

10/2000
1/2003

36516

First Coast

Florida

Carrier

LMRP
L6255

5/1991
1/2003

36515

36516

BC/BS of Kansas

Kansas

Carrier

LMRP
L9247

4/2001
2/2003

36516

Palmetto GBA

Ohio and West Virginia

Carrier

LMRP
L6943
and
Article
A24624

7/2000
10/2002

9/2004

36515

36515

BC/BS of Arkansas

Oklahoma

Carrier

LMRP
L11818

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Missouri

Carrier

LMRP
L11884

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Louisiana

Carrier

LMRP
L11942

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Arkansas

Carrier

LMRP
L12132

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

New Mexico

LMRP
L9397

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

Cahaba Government Benefit Administrators

Mississippi

Carrier

LMRP
L6140

6/1995
10/2003

36521

Policy not updated to change 36521 to 36516

AdminiStar

Indiana

FI

Article
A23491

11/2004

36515

Trailblazers

Texas

Carrier

Article
A4821

1/2003

36515

There are numerous policies for LDL apheresis listing 36516 as the appropriate CPT code after Jan 1, 2003

EXHIBIT 2

Memorandum 1/6/05

TO: Kathleen Smith
Vice President
Government Affairs
Fresenius Medical Care North America

FROM: Don Moran

SUBJECT: Findings from Analysis of Prosorba® Claims

The Moran Company was engaged to evaluate data from the 2005 Medicare Outpatient Prospective Payment System ratesetting file to determine how providers are coding apheresis claims for patients with rheumatoid arthritis7. Per your direction, we evaluated claims with ICD-9 CM diagnosis codes 714.0 (Rheumatoid Arthritis) and 287.3 (Idiopathic Thrombocytopenic Purpura). In summary, are findings are as follows:

o As you suspected, a substantial majority of these cases (71%) were billed to CPT 36516 (Apheresis, selective), rather than 36515 (Apheresis, adsorp/reinfuse).

o The median cost for these cases is materially higher than the median cost of cases being used to set the payment rates for APC 111.

o A revision of the APC mapping to code 36515 claims to APC 112 would result in payment more typical of the average cost of these cases.

Detailed Findings

Descriptive statistics on cases billed to 36515-6 are as follows:

As indicated in the table, of the 959 claims billed in 2003 to either code, 300 claims were coded with a diagnosis of either 714.0 or 287.38. Of this latter group of claims, 213, or 71.0%, were billed to CPT 36516, and hence mapped to APC 112. In its ratesetting methodology, CMS restricts its analysis to so-called “single bills,” where it has the capacity to attribute the “packaged” charges to a single procedure mapping to an APC. Of the 300 RA apheresis claims, only 164, or 55%, qualified as “single bills”. Of these claims, 99, or 60.4%, were billed to 36516 rather than 36515.

These claims lines exhibited average costs in the range of $2,500-3,000; the median procedure-level costs were $1,217.37 for procedures billed to 36515, and $1,677.66 for procedures billed to 36516. In comparison, the 2005 OPPS payment rate for APC 111 is $725.16.

In our analysis, we considered whether reassigning the RA apheresis cases to APC 111 would have improved the payment rate for APC 111. It would not. The median cost finding for APC 111 is dominated by the data for claims coded with CPT 36514, “apheresis plasma”. These 12,552 claims, 8,652 of which qualify as single bills, have a median cost of $745.41. Adding 99 RA apheresis cases billed to CPT 36516 to the analysis would not move the median cost finding. Similarly, the median calculation for APC 112, which is dominated by the 3,344 single bills for CPT 36522, “photopheresis,” would not be affected by adding the 65 RA apheresis claims billed to CPT 35515.

To complete our evaluation, we analyzed the total recorded costs found on the 164 RA apheresis single bills, including the costs associated with the "packaged" charges on the claim.

As these data indicate, the costs recorded for the procedure are the dominant factor in determining the cost of these claims; the median cost for the 36515 claims represents 93.4% of the median costs found, for RA apheresis claims mapping to APC 111, for the total claims. For the RA apheresis claims billed to 36516, the procedure cost represents 97.6% of the median total cost on the claim.

As these data indicate, the relationship between cost and payment are totally determined by how rheumatoid arthritis apheresis claims are coded. At present, if these cases are coded to 36515 and mapped to APC 111, total reimbursement for these cases in 2005 will be only about one-third of the average cost observed for these cases in 2003. If, by contrast, CPT 36515 were remapped to APC 112, the payment rate for neither APC would change, but the RA cases billed with CPT 36515 would receive reimbursement more closely reflecting the actual costs hospital experience in performing this procedure.

1 69 Fed. Reg. 65681 (Nov. 15, 2004).
2 National Coverage Decision for Apheresis (Therapeutic Pheresis), Pub. 100-3 §110.14.
3 See discussion of HOPPS on the American Society for Hematology website at www.hematology.org/practice/hopps_impact.cfm
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5 See discussion of HOPPS on the American Society of Hematology website at www.hematology.org/practice/hopps_impact.cfm.
6 A copy of the complete report is attached to this letter.
7 This data set, which CMS used to establish the 2005 payment rates promulgated in the recent Final Rule, comprise a 100% sample of all OPPS claims for calendar year 2003.
8 Throughout our analysis, we refer to claims with these two diagnoses coded to either 36515 or 36516 as "RA apheresis claims." There is, of course, no certainty that your product was, in fact, used with these cases, since there is not separate reimbursement (and hence, observable coding) for the device.
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Fresenius Medical Care North America
Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

VIA ELECTRONIC AND FIRST CLASS MAIL

Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018
Attention: CMS-1427-FC

Re: CMS-1427-FC:
APC Classification of CPT Code 36515 in the 2005 Hospital Outpatient Prospective Payment System Final Rule

Dear Dr. McClellan:

Fresenius HemoCare ("Fresenius"), a division of Fresenius Medical Care – NA, hereby submits these comments to Final Rule CMS-1427-FC, "Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates" (the " HOPPS Final Rule"), published in the Federal Register November 15, 2004.1 Specifically, Fresenius' comments relate to the decision by the Centers for Medicare and Medicaid Services ("CMS") in the Final Rule to reclassify CPT Code 36515 ("therapeutic apheresis, with extracorporeal immunoadsorption and plasma reinfusion") from APC 0112 ("Blood Product Exchange") to APC 0111 ("Apheresis, Photopheresis, and Plasmapheresis").

As set forth in further detail below, we believe that this decision was inappropriate because it was made under the mistaken assumption that the majority of claims for Extracorporeal Immunoadsorption ("ECI") using Protein A columns were billed to the Medicare program under CPT Code 36515 in 2003, when, in fact, the national CPT coding book utilized by CMS and providers, and policies issued by some CMS contractors, instructed providers to bill this procedure under CPT Code 36516 ("therapeutic apheresis, with extracorporeal selective adsorption or selective filtration and plasma reinfusion"). As a result of these erroneous directives, a substantial majority of apheresis procedures performed to treat patients with rheumatoid arthritis were billed under CPT Code 36516 (instead of 36515) in 2003. The costs associated with those procedures were substantially in excess of the reimbursement assigned to the new APC to which CPT Code 36515 was assigned in the Final Rule.

Accordingly, Fresenius respectfully requests that CMS issue a technical correction to the HOPPS Final Rule, reassigning CPT Code 36515 to APC 0112 in the Outpatient Code Editor ("OCE"). Ideally this change should be made retroactive to the beginning of 2005, but, at a minimum, made effective for services furnished on or after April 1, 2005. Further, to the extent that CMS decides that a correction cannot be made for services provided in 2005, Fresenius respectfully requests that a more detailed analysis of claims billed under Codes 36515 and 36516 in 2004 be used to determine the proper APC assignment for code 36515 under the 2006 HOPPS fee schedule.

Background on PROSORBA® and Apheresis

Fresenius manufactures and distributes the PROSORBA® Column, which is a single-use immunoadsorption therapeutic medical device approved by the Food and Drug Administration ("FDA") for the treatment of rheumatoid arthritis ("RA") and idiopathic thrombocytopenic purpura ("ITP"). The device contains approximately 200 mg of highly purified protein A covalently bound to a silica matrix. Protein A is a component of certain strains of the bacterium Staphylococcus Aureus. The protein A binds to, and selectively adsorbs and removes from the blood, immuno-globulins – commonly called antibodies – and circulating immune complexes – antibodies bound to antigens – that contribute to the symptoms characteristic of rheumatoid arthritis.

RA is a chronic and often debilitating autoimmune disease in which the body's immune system attacks its own tissue, often leading to painful inflammation and deformity of the joints. The disease affects more than approximately 2.5 million Americans, 70% of them women, most between the ages of 25 and 60. It has been estimated that 10% of the 2.5 million RA patients in the United States may benefit from PROSOBRA® Column treatment.

Medicare covers the use of Protein A columns for the treatment of ITP as well as for the treatment of RA under certain conditions.2 Payment for claims with dates of service on or after August 1, 2000 is made under the OPPS. Starting in 2005, payment for these procedures is also made when they are performed in a physician's office. The ICD-9 codes that support the medical necessity of Protein A columns include 287.3 ("primary thrombocytopenia") and 714.0 ("rheumatoid arthritis").

Because the PROSORBA® Column works through selective adsorption, treatment with it arguably could be coded under CPT Code 36516 ("therapeutic apheresis; for white blood cells with extracorporeal selective adsorption or selective filtration and plasma reinfusion"). However, because it selectively adsorbs immunoglobulins and immune complexes, treatment with the PROSORBA® Column also could be considered an "extracorporeal immunoadsorption and plasma reinfusion" which matches the definition of CPT Code 36515. We understand the American Society for Hematology takes the position that CPT Code 36515 is the better fit.3 So too does CMS. Furthermore, it recently has issued a Transmittal to clarify this fact with the provider community.4

The 2005 HOPPS Final Rule

In the 2005 HOPPS Final Rule, CMS remapped CPT Code 36515 from APC 0112 to APC 0111. APC 0111 is assigned a payment rate of $725.16 in 2005, and the payment rate for APC 0112 in 2005 is $2,127.26. In response to public comments on the HOPPS proposed rule, which, among other things, articulated that the apheresis procedure described by CPT Code 36515 involved an expensive disposable supply item (presumably the PROSORBA® Column)5 that costs more than the proposed payment rate for APC 0111, and noted that the proposed HOPPS payment rate would be substantially less than the physician's office payment, CMS stated as follows:

APC assignments are based on clinical homogeneity and comparable resource utilization for all CPT and

HCPCS codes within an APC. After careful review, we disagree with the commenters that CPT code 36515 should be reassigned to APC 0112. We believe that the resources required for CPT Code 36515 are more similar to the other CPT codes in APC 0111. Thus, for CY 2005, we are adopting as final our proposal to assign CPT Code 36515 to APC 0111, effective January 1, 2005.

69 Fed. Reg. 65,681, at 65,704 (Nov. 15, 2004)

When Fresenius met with CMS to discuss the remapping of Code 36515 to APC 111, the agency confirmed that its remapping decision was informed by a review of claims filled under CPT Code 36515. No data associated with claims filled under CPT Code 36516 was considered.

Conflicting Instructions Issued By The American Medical Association and CMS Contractors Resulted In Inconsistent Billing For Therapeutic Apheresis

There has been significant confusion over which CPT Code to use for apheresis treatments with the PROSORBA® Column since 2003, and this confusion underlies the inappropriate reclassification of CPT Code 36515 from APC 0112 to APC 0111. Specifically, in 2002, the American Medical Association's ("AMA") CPT Code Book, which is utilized by CMS and its contractors under a licensing agreement with the AMA, and is relied upon, and, in fact, considered an "authoritative" source, by CMS, its contractors, and providers in determining the proper coding for a particular service or procedure, contained only one code for therapeutic apheresis ? Code 36521, which was defined as "therapeutic apheresis; with extracorporeal affinity column adsorption and plasma reinfusion." In 2003 the CPT Panel deleted Code 36521 and established two new CPT Codes for therapeutic apheresis – 36515 for apheresis that involves extracorporeal immunoadsorption and 36516 for apheresis that involves selective adsorption or selective filtration. Despite the CPT Panel's intent to implement two new therapeutic apheresis codes, the 2003 CPT Code book contained an error that made it appear that Code 36516 alone had replaced Code 36521. This error was not corrected in the 2004 edition of the CPT Code Book. Rather, both the 2003 and the 2004 CPT Code Books contained the following statement where CPT Code 36521 had been located: "(36521 has been deleted. To report, use 36516)". Because of the selective nature of the adsorption resulting from PROSORBA® Column use, it is unlikely that clinicians or coders looking at this instruction and then reading the definition of Code 36516 would have questioned the advice. Thus, in both 2003 and 2004, many providers who had previously billed aphresis treatments with the PROSORBA® Column under CPT Code 36521 were specifically instructed to bill for the same procedures under CPT Code 36516. By contrast, the 2005 CPT Code book directs those looking at CPT Code 36521 to review both 36515 and 36516 before making a coding decision.

Contributing to this confusion over the proper CPT Code to use for billing apheresis procedures using the Protein A column is the fact that some local coverage policies issued by Carriers and Intermediaries instructed (and, in fact, still do instruct) physicians and hospitals to use CPT Code 36516 (or the now defunct 36521) when billing for apheresis procedures using the Protein A column. Indeed, of the 14 Medicare Carriers with Local Coverage Policies for ECI for ITP and RA, five direct providers to bill using CPT Code 36516, three direct providers to bill using CPT Code 36515, six direct providers to bill using CPT Code 36521, and one instructs providers to bill using either CPT Code 36515 or 36516.

Although the Carrier policies apply only to the professional services of physicians associated with the apheresis procedure, as opposed to the technical component, they are still instructive in that they highlight the confusing and contradictory nature of the instructions that were being disseminated to providers regarding billing for the apheresis procedure. In addition, of the four Intermediaries that have issued local coverage policies, one instructs providers to bill using CPT Code 36516, two instruct providers to use CPT Code 36515, and one mentions both codes. A table summarizing our review of local coverage policies is attached as Exhibit 1.

As discussed below, the conflicting billing and coding instructions issued to providers regarding apheresis procedures using the Protein A Column resulted in CMS utilizing incomplete and unrepresentative data when it decided to reclassify CPT Code 36515 to an APC group that has a payment rate of only one-third of the average costs associated with these procedures.

An Analysis of 2003 Hospital Claims Data Shows that CMS Relied upon Incomplete and Unrepresentative Data When It Set the APC Assignment for CPT Code 36515

In order to determine how hospital providers coded for apheresis claims for patients with RA (ICD-9-CM diagnosis code 714.0) and ITP (ICD-9-CM diagnosis code 287.3) during 2003, Fresenius engaged the services of The Moran Group to conduct an analysis of hospital claims data for CPT Codes 36515 and 36516 for outpatient services provided from January 1, 2003 through December 31, 2003, linking costs to the aforementioned diagnosis codes listed on the claims forms. The Moran Group's report is attached as Exhibit 2. As a result of this analysis, which is attached, The Moran Group concluded that a substantial majority of apheresis procedures performed to treat patients diagnosed with RA or ITP were billed under CPT Code 36516, as opposed to CPT Code 36515, and that these cases had materially higher costs than the APC 0111 payment rate.6 Specifically, they concluded as follows:

* Of the 959 claims billed in 2003 to either CPT Code 36515 or 36516, 300 claims were coded with a diagnosis of 714.0 or 287.3, and 213 of these 300 claims (or 71%) were billed to CPT Code 36516;

* These cases have materially higher average costs (between $2,500 and almost $3,000) than the APC 0111 payment rate of $725.16; and

* The median procedure-level costs for these cases is materially higher than the median costs of cases being used to set the payment rates for APC 0111.

This report clearly demonstrates that the claims data examined by CMS when determining what APC group to classify CPT Code 36515 into was incomplete and unrepresentative, and that the charges for the apheresis procedures which were billed under CPT Code 36516 were substantially in excess of the reimbursement for the new APC to which PROSORBA® therapy was designated in the Final Rule. As further evidence of the fact that incomplete data was analyzed when setting the 2005 HOPPS rates is the fact that the current APC 0111 rate of $725.16 is less than one-third of the rate established for the same procedure furnished in a physician's office under the 2005 final physician fee schedule rule.

If CMS had reviewed and evaluated complete data for therapeutic apheresis using the Protein A column, drawn from claims filed under both CPT Codes 36515 and 36516 in 2003, when it developed the 2005 HOPPS Final Rule, the observed levels of resource utilization for this treatment would have supported continued mapping of 36515 to APC 112. This mapping should be reestablished by matching Code 36515 with APC 112 in the 2005 OCE. Ideally, the revised mapping should be applied to claims with dates of service beginning January 1, 2005, but, at a minimum, made effective for the second quarter of 2005. Such a change will result in 2005 reimbursement more closely approximating the average costs in 2003 associated with apheresis with the PROSORBA® Column. This type of technical correction is necessary and appropriate because the coding confusion that led to the inappropriate reassignment of CPT Code 36515 to APC 111 stemmed in large part from a mistake in the 2003 and 2004 CPT Code Books that was further exacerbated by errors in local coverage policies published by a number of CMS contractors.

Conclusion

As a result of erroneous and conflicting instructions issued by the AMA's CPT Code Book as well as several CMS contractors, a substantial majority of hospitals in 2003 and 2004 filed claims for apheresis therapy using the PROSORBA® Column under CPT Code 36516, not CPT Code 36515. Because CMS, in setting the 2005 HOPPS final rates for this procedure, only considered costs associated with CPT Code 36515 (and not those associated with CPT Code CPT Code 36516), it did not accurately determine the true cost of this therapy, which resulted in a new APC classification that imposes an unrealistically low relative value to the procedure. If CMS were to consider costs associated with the CPT Code 36516 claims for patients diagnosed with RA in 2003, it would be evident that PROSORBA® Column therapy is more appropriately grouped with APC 0112 from a resource utilization perspective as well as a clinical homogeneity perspective.

Accordingly, for the reasons outlined above, Fresenius respectfully requests that CMS issue a technical correction to the 2005 HOPPS Final Rule remapping CPT Code 36515 to APC 0112. Ideally this change should be made retroactive to the beginning of 2005, but, at a minimum, made effective for services furnished on or after April 1, 2005. Further, to the extent that CMS decides that a correction cannot be made for services provided in 2005, Fresenius respectfully requests that a more detailed analysis of claims billed under CPT Codes 36515 and 36516 in 2004 be used to determine the proper APC assignment for 36515 in the 2006 HOPPS fee schedule. Otherwise, CMS will again be using unrepresentative base-year data when it decides on the APC with which to group CPT Code 36515 next year.

Respectfully submitted,

Kathleen T. Smith, RN
Vice President, Government Affairs

EXHIBIT 1

Local Coverage Policies for Extracorporeal Immunoadsorption (ECI) For ITP and RA

Name

Primary Geographic Jurisdiction
Payor Type

Policy or Article Type and Number

Effective
Date / revisions

CPT Code

Comments

Arkansas BC/BS of Rhode Island

Rhode Island

FI

LMRP
L2998

3/2000
1/2003

36516

Use Q0068 prior for services prior to 12/1999
Use 36521 for services 1/2000 to 12/31/2002
Use 36516 for services after 1/2003

BC/BS of Arkansas

Arkansas

FI

LMRP
L10279

8/2000
10/2003

36515

First Coast Services Options

Florida

FI

LMRP
L2999

9/2002
2/2003

36515

36516

HGS Administrators

Pennsylvania

Carrier

LMRP
L5201

10/1992
10/2003

36515

General Apheresis policy includes coverage for ECI for ITP and RA

Empire Medicare Services

New York Downstate

Carrier

LMRP
L3470

10/2000
1/2002

36516

BC/BS of Rhode Island

Rhode Island

Carrier

LMRP
L2807

3/2000
1/2003

36516

HealthNow

New York Upstate

Carrier

LMRP
L4242

7/2001
1/2003

36516

Group Health

New York – Queens

Carrier

LMRP
L4398

10/2000
1/2003

36516

First Coast

Florida

Carrier

LMRP
L6255

5/1991
1/2003

36515

36516

BC/BS of Kansas

Kansas

Carrier

LMRP
L9247

4/2001
2/2003

36516

Palmetto GBA

Ohio and West Virginia

Carrier

LMRP
L6943
and
Article
A24624

7/2000
10/2002

9/2004

36515

36515

BC/BS of Arkansas

Oklahoma

Carrier

LMRP
L11818

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Missouri

Carrier

LMRP
L11884

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Louisiana

Carrier

LMRP
L11942

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Arkansas

Carrier

LMRP
L12132

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

New Mexico

LMRP
L9397

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

Cahaba Government Benefit Administrators

Mississippi

Carrier

LMRP
L6140

6/1995
10/2003

36521

Policy not updated to change 36521 to 36516

AdminiStar

Indiana

FI

Article
A23491

11/2004

36515

Trailblazers

Texas

Carrier

Article
A4821

1/2003

36515

There are numerous policies for LDL apheresis listing 36516 as the appropriate CPT code after Jan 1, 2003

EXHIBIT 2

Memorandum 1/6/05

TO: Kathleen Smith
Vice President
Government Affairs
Fresenius Medical Care North America

FROM: Don Moran

SUBJECT: Findings from Analysis of Prosorba® Claims

The Moran Company was engaged to evaluate data from the 2005 Medicare Outpatient Prospective Payment System ratesetting file to determine how providers are coding apheresis claims for patients with rheumatoid arthritis7. Per your direction, we evaluated claims with ICD-9 CM diagnosis codes 714.0 (Rheumatoid Arthritis) and 287.3 (Idiopathic Thrombocytopenic Purpura). In summary, are findings are as follows:

o As you suspected, a substantial majority of these cases (71%) were billed to CPT 36516 (Apheresis, selective), rather than 36515 (Apheresis, adsorp/reinfuse).

o The median cost for these cases is materially higher than the median cost of cases being used to set the payment rates for APC 111.

o A revision of the APC mapping to code 36515 claims to APC 112 would result in payment more typical of the average cost of these cases.

Detailed Findings

Descriptive statistics on cases billed to 36515-6 are as follows:

As indicated in the table, of the 959 claims billed in 2003 to either code, 300 claims were coded with a diagnosis of either 714.0 or 287.38. Of this latter group of claims, 213, or 71.0%, were billed to CPT 36516, and hence mapped to APC 112. In its ratesetting methodology, CMS restricts its analysis to so-called “single bills,” where it has the capacity to attribute the “packaged” charges to a single procedure mapping to an APC. Of the 300 RA apheresis claims, only 164, or 55%, qualified as “single bills”. Of these claims, 99, or 60.4%, were billed to 36516 rather than 36515.

These claims lines exhibited average costs in the range of $2,500-3,000; the median procedure-level costs were $1,217.37 for procedures billed to 36515, and $1,677.66 for procedures billed to 36516. In comparison, the 2005 OPPS payment rate for APC 111 is $725.16.

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To complete our evaluation, we analyzed the total recorded costs found on the 164 RA apheresis single bills, including the costs associated with the "packaged" charges on the claim.

As these data indicate, the costs recorded for the procedure are the dominant factor in determining the cost of these claims; the median cost for the 36515 claims represents 93.4% of the median costs found, for RA apheresis claims mapping to APC 111, for the total claims. For the RA apheresis claims billed to 36516, the procedure cost represents 97.6% of the median total cost on the claim.

As these data indicate, the relationship between cost and payment are totally determined by how rheumatoid arthritis apheresis claims are coded. At present, if these cases are coded to 36515 and mapped to APC 111, total reimbursement for these cases in 2005 will be only about one-third of the average cost observed for these cases in 2003. If, by contrast, CPT 36515 were remapped to APC 112, the payment rate for neither APC would change, but the RA cases billed with CPT 36515 would receive reimbursement more closely reflecting the actual costs hospital experience in performing this procedure.

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Fresenius Medical Care North America
Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

CMS-1427-FC-35 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Ms. Kathleen Smith** **Date & Time:** **01/14/2005**

Organization : **Fresenius Medical Care No America**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1427-FC-35-Attach-1.DOC

VIA ELECTRONIC AND FIRST CLASS MAIL

Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018
Attention: CMS-1427-FC

Re: CMS-1427-FC:
APC Classification of CPT Code 36515 in the 2005 Hospital Outpatient Prospective Payment System Final Rule

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As set forth in further detail below, we believe that this decision was inappropriate because it was made under the mistaken assumption that the majority of claims for Extracorporeal Immunoadsorption ("ECI") using Protein A columns were billed to the Medicare program under CPT Code 36515 in 2003, when, in fact, the national CPT coding book utilized by CMS and providers, and policies issued by some CMS contractors, instructed providers to bill this procedure under CPT Code 36516 ("therapeutic apheresis, with extracorporeal selective adsorption or selective filtration and plasma reinfusion"). As a result of these erroneous directives, a substantial majority of apheresis procedures performed to treat patients with rheumatoid arthritis were billed under CPT Code 36516 (instead of 36515) in 2003. The costs associated with those procedures were substantially in excess of the reimbursement assigned to the new APC to which CPT Code 36515 was assigned in the Final Rule.

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HCPCS codes within an APC. After careful review, we disagree with the commenters that CPT code 36515 should be reassigned to APC 0112. We believe that the resources required for CPT Code 36515 are more similar to the other CPT codes in APC 0111. Thus, for CY 2005, we are adopting as final our proposal to assign CPT Code 36515 to APC 0111, effective January 1, 2005.

69 Fed. Reg. 65,681, at 65,704 (Nov. 15, 2004)

When Fresenius met with CMS to discuss the remapping of Code 36515 to APC 111, the agency confirmed that its remapping decision was informed by a review of claims filled under CPT Code 36515. No data associated with claims filled under CPT Code 36516 was considered.

Conflicting Instructions Issued By The American Medical Association and CMS Contractors Resulted In Inconsistent Billing For Therapeutic Apheresis

There has been significant confusion over which CPT Code to use for apheresis treatments with the PROSORBA® Column since 2003, and this confusion underlies the inappropriate reclassification of CPT Code 36515 from APC 0112 to APC 0111. Specifically, in 2002, the American Medical Association's ("AMA") CPT Code Book, which is utilized by CMS and its contractors under a licensing agreement with the AMA, and is relied upon, and, in fact, considered an "authoritative" source, by CMS, its contractors, and providers in determining the proper coding for a particular service or procedure, contained only one code for therapeutic apheresis ? Code 36521, which was defined as "therapeutic apheresis; with extracorporeal affinity column adsorption and plasma reinfusion." In 2003 the CPT Panel deleted Code 36521 and established two new CPT Codes for therapeutic apheresis – 36515 for apheresis that involves extracorporeal immunoadsorption and 36516 for apheresis that involves selective adsorption or selective filtration. Despite the CPT Panel's intent to implement two new therapeutic apheresis codes, the 2003 CPT Code book contained an error that made it appear that Code 36516 alone had replaced Code 36521. This error was not corrected in the 2004 edition of the CPT Code Book. Rather, both the 2003 and the 2004 CPT Code Books contained the following statement where CPT Code 36521 had been located: "(36521 has been deleted. To report, use 36516)". Because of the selective nature of the adsorption resulting from PROSORBA® Column use, it is unlikely that clinicians or coders looking at this instruction and then reading the definition of Code 36516 would have questioned the advice. Thus, in both 2003 and 2004, many providers who had previously billed aphresis treatments with the PROSORBA® Column under CPT Code 36521 were specifically instructed to bill for the same procedures under CPT Code 36516. By contrast, the 2005 CPT Code book directs those looking at CPT Code 36521 to review both 36515 and 36516 before making a coding decision.

Contributing to this confusion over the proper CPT Code to use for billing apheresis procedures using the Protein A column is the fact that some local coverage policies issued by Carriers and Intermediaries instructed (and, in fact, still do instruct) physicians and hospitals to use CPT Code 36516 (or the now defunct 36521) when billing for apheresis procedures using the Protein A column. Indeed, of the 14 Medicare Carriers with Local Coverage Policies for ECI for ITP and RA, five direct providers to bill using CPT Code 36516, three direct providers to bill using CPT Code 36515, six direct providers to bill using CPT Code 36521, and one instructs providers to bill using either CPT Code 36515 or 36516.

Although the Carrier policies apply only to the professional services of physicians associated with the apheresis procedure, as opposed to the technical component, they are still instructive in that they highlight the confusing and contradictory nature of the instructions that were being disseminated to providers regarding billing for the apheresis procedure. In addition, of the four Intermediaries that have issued local coverage policies, one instructs providers to bill using CPT Code 36516, two instruct providers to use CPT Code 36515, and one mentions both codes. A table summarizing our review of local coverage policies is attached as Exhibit 1.

As discussed below, the conflicting billing and coding instructions issued to providers regarding apheresis procedures using the Protein A Column resulted in CMS utilizing incomplete and unrepresentative data when it decided to reclassify CPT Code 36515 to an APC group that has a payment rate of only one-third of the average costs associated with these procedures.

An Analysis of 2003 Hospital Claims Data Shows that CMS Relied upon Incomplete and Unrepresentative Data When It Set the APC Assignment for CPT Code 36515

In order to determine how hospital providers coded for apheresis claims for patients with RA (ICD-9-CM diagnosis code 714.0) and ITP (ICD-9-CM diagnosis code 287.3) during 2003, Fresenius engaged the services of The Moran Group to conduct an analysis of hospital claims data for CPT Codes 36515 and 36516 for outpatient services provided from January 1, 2003 through December 31, 2003, linking costs to the aforementioned diagnosis codes listed on the claims forms. The Moran Group's report is attached as Exhibit 2. As a result of this analysis, which is attached, The Moran Group concluded that a substantial majority of apheresis procedures performed to treat patients diagnosed with RA or ITP were billed under CPT Code 36516, as opposed to CPT Code 36515, and that these cases had materially higher costs than the APC 0111 payment rate.6 Specifically, they concluded as follows:

* Of the 959 claims billed in 2003 to either CPT Code 36515 or 36516, 300 claims were coded with a diagnosis of 714.0 or 287.3, and 213 of these 300 claims (or 71%) were billed to CPT Code 36516;

* These cases have materially higher average costs (between $2,500 and almost $3,000) than the APC 0111 payment rate of $725.16; and

* The median procedure-level costs for these cases is materially higher than the median costs of cases being used to set the payment rates for APC 0111.

This report clearly demonstrates that the claims data examined by CMS when determining what APC group to classify CPT Code 36515 into was incomplete and unrepresentative, and that the charges for the apheresis procedures which were billed under CPT Code 36516 were substantially in excess of the reimbursement for the new APC to which PROSORBA® therapy was designated in the Final Rule. As further evidence of the fact that incomplete data was analyzed when setting the 2005 HOPPS rates is the fact that the current APC 0111 rate of $725.16 is less than one-third of the rate established for the same procedure furnished in a physician's office under the 2005 final physician fee schedule rule.

If CMS had reviewed and evaluated complete data for therapeutic apheresis using the Protein A column, drawn from claims filed under both CPT Codes 36515 and 36516 in 2003, when it developed the 2005 HOPPS Final Rule, the observed levels of resource utilization for this treatment would have supported continued mapping of 36515 to APC 112. This mapping should be reestablished by matching Code 36515 with APC 112 in the 2005 OCE. Ideally, the revised mapping should be applied to claims with dates of service beginning January 1, 2005, but, at a minimum, made effective for the second quarter of 2005. Such a change will result in 2005 reimbursement more closely approximating the average costs in 2003 associated with apheresis with the PROSORBA® Column. This type of technical correction is necessary and appropriate because the coding confusion that led to the inappropriate reassignment of CPT Code 36515 to APC 111 stemmed in large part from a mistake in the 2003 and 2004 CPT Code Books that was further exacerbated by errors in local coverage policies published by a number of CMS contractors.

Conclusion

As a result of erroneous and conflicting instructions issued by the AMA's CPT Code Book as well as several CMS contractors, a substantial majority of hospitals in 2003 and 2004 filed claims for apheresis therapy using the PROSORBA® Column under CPT Code 36516, not CPT Code 36515. Because CMS, in setting the 2005 HOPPS final rates for this procedure, only considered costs associated with CPT Code 36515 (and not those associated with CPT Code CPT Code 36516), it did not accurately determine the true cost of this therapy, which resulted in a new APC classification that imposes an unrealistically low relative value to the procedure. If CMS were to consider costs associated with the CPT Code 36516 claims for patients diagnosed with RA in 2003, it would be evident that PROSORBA® Column therapy is more appropriately grouped with APC 0112 from a resource utilization perspective as well as a clinical homogeneity perspective.

Accordingly, for the reasons outlined above, Fresenius respectfully requests that CMS issue a technical correction to the 2005 HOPPS Final Rule remapping CPT Code 36515 to APC 0112. Ideally this change should be made retroactive to the beginning of 2005, but, at a minimum, made effective for services furnished on or after April 1, 2005. Further, to the extent that CMS decides that a correction cannot be made for services provided in 2005, Fresenius respectfully requests that a more detailed analysis of claims billed under CPT Codes 36515 and 36516 in 2004 be used to determine the proper APC assignment for 36515 in the 2006 HOPPS fee schedule. Otherwise, CMS will again be using unrepresentative base-year data when it decides on the APC with which to group CPT Code 36515 next year.

Respectfully submitted,

Kathleen T. Smith, RN
Vice President, Government Affairs

EXHIBIT 1

Local Coverage Policies for Extracorporeal Immunoadsorption (ECI) For ITP and RA

Name

Primary Geographic Jurisdiction
Payor Type

Policy or Article Type and Number

Effective
Date / revisions

CPT Code

Comments

Arkansas BC/BS of Rhode Island

Rhode Island

FI

LMRP
L2998

3/2000
1/2003

36516

Use Q0068 prior for services prior to 12/1999
Use 36521 for services 1/2000 to 12/31/2002
Use 36516 for services after 1/2003

BC/BS of Arkansas

Arkansas

FI

LMRP
L10279

8/2000
10/2003

36515

First Coast Services Options

Florida

FI

LMRP
L2999

9/2002
2/2003

36515

36516

HGS Administrators

Pennsylvania

Carrier

LMRP
L5201

10/1992
10/2003

36515

General Apheresis policy includes coverage for ECI for ITP and RA

Empire Medicare Services

New York Downstate

Carrier

LMRP
L3470

10/2000
1/2002

36516

BC/BS of Rhode Island

Rhode Island

Carrier

LMRP
L2807

3/2000
1/2003

36516

HealthNow

New York Upstate

Carrier

LMRP
L4242

7/2001
1/2003

36516

Group Health

New York – Queens

Carrier

LMRP
L4398

10/2000
1/2003

36516

First Coast

Florida

Carrier

LMRP
L6255

5/1991
1/2003

36515

36516

BC/BS of Kansas

Kansas

Carrier

LMRP
L9247

4/2001
2/2003

36516

Palmetto GBA

Ohio and West Virginia

Carrier

LMRP
L6943
and
Article
A24624

7/2000
10/2002

9/2004

36515

36515

BC/BS of Arkansas

Oklahoma

Carrier

LMRP
L11818

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Missouri

Carrier

LMRP
L11884

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Louisiana

Carrier

LMRP
L11942

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

Arkansas

Carrier

LMRP
L12132

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

BC/BS of Arkansas

New Mexico

LMRP
L9397

8/2000
8/2001

36521

Policy not updated to change 36521 to 36516

Cahaba Government Benefit Administrators

Mississippi

Carrier

LMRP
L6140

6/1995
10/2003

36521

Policy not updated to change 36521 to 36516

AdminiStar

Indiana

FI

Article
A23491

11/2004

36515

Trailblazers

Texas

Carrier

Article
A4821

1/2003

36515

There are numerous policies for LDL apheresis listing 36516 as the appropriate CPT code after Jan 1, 2003

EXHIBIT 2

Memorandum 1/6/05

TO: Kathleen Smith
Vice President
Government Affairs
Fresenius Medical Care North America

FROM: Don Moran

SUBJECT: Findings from Analysis of Prosorba® Claims

The Moran Company was engaged to evaluate data from the 2005 Medicare Outpatient Prospective Payment System ratesetting file to determine how providers are coding apheresis claims for patients with rheumatoid arthritis7. Per your direction, we evaluated claims with ICD-9 CM diagnosis codes 714.0 (Rheumatoid Arthritis) and 287.3 (Idiopathic Thrombocytopenic Purpura). In summary, are findings are as follows:

o As you suspected, a substantial majority of these cases (71%) were billed to CPT 36516 (Apheresis, selective), rather than 36515 (Apheresis, adsorp/reinfuse).

o The median cost for these cases is materially higher than the median cost of cases being used to set the payment rates for APC 111.

o A revision of the APC mapping to code 36515 claims to APC 112 would result in payment more typical of the average cost of these cases.

Detailed Findings

Descriptive statistics on cases billed to 36515-6 are as follows:

As indicated in the table, of the 959 claims billed in 2003 to either code, 300 claims were coded with a diagnosis of either 714.0 or 287.38. Of this latter group of claims, 213, or 71.0%, were billed to CPT 36516, and hence mapped to APC 112. In its ratesetting methodology, CMS restricts its analysis to so-called “single bills,” where it has the capacity to attribute the “packaged” charges to a single procedure mapping to an APC. Of the 300 RA apheresis claims, only 164, or 55%, qualified as “single bills”. Of these claims, 99, or 60.4%, were billed to 36516 rather than 36515.

These claims lines exhibited average costs in the range of $2,500-3,000; the median procedure-level costs were $1,217.37 for procedures billed to 36515, and $1,677.66 for procedures billed to 36516. In comparison, the 2005 OPPS payment rate for APC 111 is $725.16.

In our analysis, we considered whether reassigning the RA apheresis cases to APC 111 would have improved the payment rate for APC 111. It would not. The median cost finding for APC 111 is dominated by the data for claims coded with CPT 36514, “apheresis plasma”. These 12,552 claims, 8,652 of which qualify as single bills, have a median cost of $745.41. Adding 99 RA apheresis cases billed to CPT 36516 to the analysis would not move the median cost finding. Similarly, the median calculation for APC 112, which is dominated by the 3,344 single bills for CPT 36522, “photopheresis,” would not be affected by adding the 65 RA apheresis claims billed to CPT 35515.

To complete our evaluation, we analyzed the total recorded costs found on the 164 RA apheresis single bills, including the costs associated with the "packaged" charges on the claim.

As these data indicate, the costs recorded for the procedure are the dominant factor in determining the cost of these claims; the median cost for the 36515 claims represents 93.4% of the median costs found, for RA apheresis claims mapping to APC 111, for the total claims. For the RA apheresis claims billed to 36516, the procedure cost represents 97.6% of the median total cost on the claim.

As these data indicate, the relationship between cost and payment are totally determined by how rheumatoid arthritis apheresis claims are coded. At present, if these cases are coded to 36515 and mapped to APC 111, total reimbursement for these cases in 2005 will be only about one-third of the average cost observed for these cases in 2003. If, by contrast, CPT 36515 were remapped to APC 112, the payment rate for neither APC would change, but the RA cases billed with CPT 36515 would receive reimbursement more closely reflecting the actual costs hospital experience in performing this procedure.

1 69 Fed. Reg. 65681 (Nov. 15, 2004).
2 National Coverage Decision for Apheresis (Therapeutic Pheresis), Pub. 100-3 §110.14.
3 See discussion of HOPPS on the American Society for Hematology website at www.hematology.org/practice/hopps_impact.cfm
4 Transmittal 419, Change Request 3632 (Dec. 30, 2004) instructs hospitals billing for therapeutic apheresis with the Protein A column to use CPT Code 36515.
5 See discussion of HOPPS on the American Society of Hematology website at www.hematology.org/practice/hopps_impact.cfm.
6 A copy of the complete report is attached to this letter.
7 This data set, which CMS used to establish the 2005 payment rates promulgated in the recent Final Rule, comprise a 100% sample of all OPPS claims for calendar year 2003.
8 Throughout our analysis, we refer to claims with these two diagnoses coded to either 36515 or 36516 as "RA apheresis claims." There is, of course, no certainty that your product was, in fact, used with these cases, since there is not separate reimbursement (and hence, observable coding) for the device.
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Fresenius Medical Care North America
Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

CMS-1427-FC-36 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Mrs. Terese Ghio** **Date & Time:** **01/14/2005**

Organization : **Ligand Pharmaceuticals Incorporated**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

Comments attached regarding payment rates for single indicationorphan products.

CMS-1427-FC-36-Attach-1.DOC

CMS-1427-FC-37 **Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates**

Submitter : **Dr. Nick Poulios** **Date & Time:** **01/14/2005**

Organization : **Elan Pharmaceuticals**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1427-FC-37-Attach-1.DOC