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September 16, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Response on Proposed Changes to the Hospital Outpatient
PPS-CMS-1501-P.

Four Winds Saratoga is a freestanding private psychiatric hospital and is a long standing provider of Partial Hospitalization services. This program provides an essential service to the upstate New York Region. During the year 2004, we served 497 clients. For 2005 we are expecting to have served over 500 clients. The continued existence of this program will be threatened if our facility must absorb the amount of revenue reduction currently proposed.

We are requesting that the proposed 15% cut for Partial Hospitalization Services be reconsidered. The proposed rate is not sufficient to cover the costs needed to provide our intensive programs. We strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations.

Please consider not cutting the Partial Hospitalization Program reimbursement rate so drastically when most medical costs are actually increasing by 3.5% annually. These programs need to be supported by reasonable reimbursement rates that sufficiently cover the costs of providing services to such an at risk population.

Thank you for your consideration.

Sincerely,

Michael F. O'Neil, M.S.P.S.
Administrator

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The Alliance of Dedicated Cancer Centers:

- Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
- City of Hope National Medical Center
- Dana-Farber Cancer Institute
- Fox Chase Cancer Center
- Fred Hutchinson Cancer Research Center
- H. Lee Moffitt Cancer Center and Research Institute
- M.D. Anderson Cancer Center
- Memorial Sloan-Kettering Cancer Center
- Roswell Park Cancer Institute
- Seattle Cancer Care Alliance
- Sylvester Comprehensive Cancer Center

September 16, 2005

By Hand

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

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SPOLYER
Heigster
Kushnirova

**Re: File Code CMS-1501-P
Medicare Program; Proposed Changes to the
Hospital Outpatient Prospective Payment
System and Calendar Year 2006 Payment Rates;
Proposed Rule**

Dear Administrator McClellan:

On behalf of the Alliance of Dedicated Cancer Centers, an alliance of ten nationally recognized institutions focusing exclusively on the care of cancer patients, I am writing to comment on the Proposed Rule that would revise the Medicare prospective payment system for hospital outpatient services, as published in the *Federal Register* on July 25, 2005 (70 Fed. Reg. 42,674) (the "Proposed Rule"). The Cancer Centers, individually listed above, appreciate the opportunity to submit these comments.

I. EXECUTIVE SUMMARY

The Cancer Centers applaud CMS for its efforts to improve the reimbursement methodology for care provided in hospital outpatient departments. However, we have concerns about a number of significant changes the agency is proposing that could impede patient access to necessary therapies. We outline these concerns below.

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

2% of ASP for pharmacy handling. In the Proposed Rule, CMS announced its intent to provide an add-on payment that is designed to reimburse hospitals for the pharmacy overhead costs associated with separately payable drugs. This proposal responds to a MedPAC finding that an adjustment is needed to the OPPS payment amount to reflect these costs. In that report, MedPAC found that pharmacy overhead represents between 25 and 28 percent of a hospital's pharmacy department costs. Similarly, a study conducted by the Centers found that their pharmacy overhead costs represented between 27 and 36 percent of pharmacy department costs. However, the agency is proposing to only pay 2 percent of a drug's average sales price (ASP) to cover these costs. Further, the proposal only addresses separately payable drugs and does not provide any payment for the overhead associated with packaged drugs.

We are concerned that the proposed payment amount is insufficient to reimburse hospitals for these costs. Consequently, we recommend that CMS implement a dampening formula so that separately payable drugs are reimbursed at the higher of ASP+8% or 90 percent of the 2005 APC payment rate. We believe that this will provide hospitals with adequate reimbursement until the agency collects sufficient pharmacy overhead charge data to establish accurate cost-based reimbursement rates.

Capturing Drug Handling/Overhead Cost Data Using C-Codes in 2006. In order to collect data on pharmacy overhead costs, CMS proposed creating three new C-codes that hospitals will use to report these costs. While the Centers support the collection of data on drug handling/pharmacy overhead, we disagree with this proposal. These codes represent a conflation of the six categories that MedPAC recommended in its report. Consequently, hospitals will be required to consolidate a variety of disparate overhead costs into fewer categories rather than differentiating among the types of overhead costs incurred. As a result, the data collected will be less accurate than it otherwise might be.

We also believe that implementing the codes as proposed may create administrative difficulties for hospitals. Specifically, we are concerned about the burdens on hospitals if private payers do not adopt or delay adoption of the C-codes. We agree with the recommendation of the APC Advisory Panel that CMS delay implementation of this provision, and instead, we recommend using hospital cost report data to set OPPS pharmacy overhead payment rates.

Other Drug Issues. We generally support CMS's proposal with regard to the proposed changes for innovator and noninnovator multiple source drugs, new drugs without HCPCS codes, and anti-emetics. However, with regard to the anti-emetic proposals, we recommend that CMS implement the dampening formula described above to minimize the proposed payment decreases.

We support the new trimming methodology proposed by CMS to calculate the per day median cost of drugs for purposes of establishing separately payable status for 2006. However, for 2007, we recommend that CMS eliminate the separately payable drug threshold. We also request that CMS restore the J-codes for IVIG, or, at a minimum, maintain the current payment rates.

B. Drug Administration

In 2005, CMS implemented a new coding system for drug administration services provided in physician offices that used temporary G-codes. In the Proposed Rule, CMS is proposing to implement the same system for hospital outpatient departments using the new 2006 CPT codes. We have a number of concerns about this proposal. First, under this system, hospitals must identify “initial,” “concurrent,” and “sequential” drug administrations. Because patients may receive a variety of administrations in different hospital departments, it may be difficult to identify which service is the “initial” service at the time of administration. Additionally, because all administrations that are not “initial” have the “N” status indicator, services for which hospitals now receive payment will not be payable under this new system. To resolve this situation, we recommend providing hospitals with clear coding guidance, including a directive to disregard the “initial” service distinction when administering multiple drugs in a single encounter.

C. Other Issues

- Multiple Diagnostic Imaging Procedures
 - The Centers request that the agency delay implementation of its proposal to apply a 50 percent reduction when two or more diagnostic imaging procedures from the same family are provided during the same session.
- APC Relative Weights
 - The Centers support CMS’s continuing efforts to increase the number of single procedure claims, including use of the bypass list. However, the agency should ensure that the data from single procedure claims is accurate and should continue to evaluate other mechanisms to create additional single claims. We also seek clarification from the agency regarding its treatment of line items for purposes of establishing single and “pseudo” single claims.
- New Technology APCs
 - The Centers are concerned that CMS is proposing to move the codes for smoking cessation programs to a lower-paying new technology APC. We recommend that CMS maintain these codes in their existing APC until the

agency collects sufficient data to demonstrate that such a change is appropriate.

- We also recommend that CMS maintain separate codes and payment for stereotactic radiosurgery planning and treatment because these codes are separate modalities.
- Vaccines and Vaccine Administration
 - The Centers support CMS's proposal to pay separately for vaccine administration services and seek to clarify what we believe to be a typographical error at 70 Fed. Reg. 42,674, 42,739 (July 25, 2005).
- Observation Services
 - We support the agency's efforts regarding billing for the separately payable observation APC and ask that CMS continue reviewing additional diagnoses that may warrant separate observation payment.
- Status Indicators
 - The Centers support the creation of status indicator "Q" to indicate packaged services that are subject to separate payment under OPSS payment criteria and recommend that the indicator be assigned to the newly created CPT code for irrigation of an implanted venous access device.
- Interrupted Procedures
 - We disagree with CMS's proposal to reduce the discounting percentage associated with modifier -52 indicating a procedure has been terminated prior to completion because hospitals still expend significant resources prior to terminating the procedure. In addition, we request that CMS revise the definition of modifier -73.
- Implementing an Outpatient Coding and Billing Governing Body to Address Provider Questions
 - The Centers continue to urge CMS to establish an outpatient coding and billing guidance committee to answer questions about OPSS in a timely fashion.

II. BACKGROUND

The Cancer Centers play a pivotal role in the National Cancer Program, which was enacted by Congress in 1971 to improve the detection, prevention, diagnosis, and treatment of cancer. The Centers are the National Cancer Program's cornerstones for deepening the understanding of the causes and cures for cancer; developing new treatments for cancer; and disseminating this knowledge to the provider community at-large. The Centers' state-of-the-art therapies and research activities offer the greatest possibility for successful treatment of cancer patients. Much of the recent progress in understanding cancer's biology and successful treatment is directly attributable to the work of the Centers.

Within the Medicare Program, the Centers have been afforded protected status beginning with the implementation of the inpatient prospective payment system (PPS) in 1983. In enacting the Social Security Act amendments of 1983, which established inpatient PPS, Congress authorized hospitals "involved extensively in treatment for and research on cancer" to continue to be reimbursed under the Medicare reasonable cost system (subject to the TEFRA cost limits). See Social Security Act Amendments of 1983, § 601(e) (adding 1886(d)(5)(c)(iii)); 48 Fed. Reg. 39,752, 39,782 (Sept. 1, 1983); 49 Fed. Reg. 234, 272-73 (Jan. 3, 1984).

In the Balanced Budget Refinement Act (BBRA) of 1999, Congress also afforded the Centers protection under the new outpatient prospective payment system (OPPS). Specifically, in the BBRA, Congress enacted, on a permanent basis, a hold harmless floor on the Centers' payments under OPPS. See 42 U.S.C. § 1395l(t)(7). Under this hold harmless provision, the Centers' outpatient services are assigned to the appropriate APCs and corresponding payment amounts are calculated as with all other hospitals subject to OPPS. However, a floor on these payments is set so that each Center's reimbursement for these services does not fall below its "pre-BBA [Balanced Budget Act of 1997] amount." A Center's "pre-BBA amount" for a year is determined by multiplying the Center's reasonable costs for that year by the ratio of the Center's payments for its cost reporting period ending in 1996 to its reasonable costs in that period. See 42 U.S.C. § 1395l(t)(7).

III. DISCUSSION

In the following comments, the Cancer Centers identify a number of concerns about payment for cancer services under the Proposed Rule. Our primary concerns center on two issues: first, the proposed payment model for paying all separately payable drugs under OPPS on the basis of average sales price, including a 2% add-on for handling costs; and second, the proposed use of the 2006 CPT codes for reporting drug administration services. See Fed. Reg. at 42,730-37. While the Centers have historically supported the use of CPT codes by CMS for OPPS, we are very troubled by the latest developments regarding the changes in CPT coding. We describe our concerns on these and other issues more fully below.

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

CMS is proposing to pay for specified covered outpatient drugs in 2006 on the basis of average sales price (ASP), with ASP + 6% reflecting the average acquisition cost, and 2% of the ASP reflecting CMS's estimate of the corresponding pharmacy overhead or handling costs. See

70 Fed. Reg. at 42,730. Since the 2% of ASP add-on for drug handling is subject to budget neutrality, the actual payment rates CMS published in Addendum B are somewhat lower than ASP + 8%.

The Centers are fully aware that CMS is required by the Medicare Modernization Act (MMA) to change how it pays for drugs starting in 2006 and that, in the absence of average acquisition cost data, CMS is using ASP data. However, while we understand that CMA intends to implement the 2 % of ASP add-on until the agency collects sufficient pharmacy handling charge data, we also believe that CMS has the authority to implement “adjustments” to this payment methodology now. Given the inadequacy of the current payment proposal, we strongly urge the agency to exercise this authority,. We are also concerned about the financial and operational impact that providers will face if they are required to report drug handling C-codes starting on January 1, 2006. These issues are discussed separately below.

1. Issue 1: 2% of ASP for Pharmacy Handling

The Centers strongly believe that 2% of ASP is insufficient to cover pharmacy handling costs. See 70 Fed. Reg. at 42,730. These costs include services such as reviewing drug orders and dosage calculations, preparing and storing medications, checking for errors, and other clinical work performed by pharmacists. As you are aware, the recent MedPAC study on pharmacy handling costs attributed 26% to 28% of pharmacy department costs to overhead costs. Further at the APC Advisory Panel meeting in August, CMS itself stated that the current 2005 payment rates are equivalent to ASP + 22% (inclusive of the cost of the drug and pharmacy handling). Consequently, we simply do not understand how CMS can reasonably propose to reimburse separately payable drugs using ASP + 8%.

The Centers conducted a study to determine our own individual pharmacy handling costs, using cost report data to capture both direct and indirect pharmacy costs. Based on this investigation, we determined that our pharmacy handling costs range from 27.23% to 36.90% of our total pharmacy costs. Our numbers, while slightly higher than MedPAC’s estimates, clearly show that 2% of ASP is woefully inadequate to cover pharmacy handling costs.

The Centers are also very concerned about how CMS intends to pay for handling costs of packaged drugs, which can be significant, depending on the type and volume of drugs administered. CMS may believe that these costs for packaged drugs are reflected in the payment for drug administration APCs, but the Centers disagree with this assumption given the low payment rates assigned to drug administration APCs. Further, these APCs are generated on a per visit basis, meaning that one drug administration APC payment is made even if multiple injections or hours of infusion are provided during the same visit. Additionally, there may be multiple drugs that require reconstitution, dose calculation, and quality assurance checks that are mixed in a single bag of sterile solution which would generate a single administration charge. Therefore, we do not believe that the drug administration APC payment rates are sufficient to reimburse providers for the administration service, let alone the acquisition and handling costs associated with packaged drugs.

In addition to reporting the aforementioned findings on the costs attributable to pharmacy overhead, MedPAC also reported that such costs are inconsistently reported in hospital charge

data. We, therefore, do not believe that CMS's analysis of the HCPCS drug charge data from 2004 provider claims accurately and consistently reflects pharmacy handling charges. However, this appears to be the approach CMS has taken, based on the Proposed Rule's explanation of why CMS believes that 2% of ASP will adequately reimburse hospitals for drug handling costs. The Centers ask that CMS reconsider its underlying assumptions in light not only of the information presented above, but also of the MedPAC study, which stated that providers are not consistent in reporting drug charges.

Furthermore, CMS should be aware that hospitals are facing increased pharmacy handling costs as a result of at least one, and possibly two new unfunded mandates described below. The first, entitled U.S. Pharmacopeia 797 (USP797) reflects new criteria for compounding sterile products in hospital pharmacies. The second, the National Institute for Occupational Safety and Health (NIOSH) Alert of September 2004, recommends the introduction of complex and wide-ranging new procedures in the interest of staff and patient safety, but in the absence of scientific data proving the need for such procedures.

USP797: In January 2004, without opportunity for public comment, the United States Pharmacopeia, in response to isolated but highly publicized cases of patient harm resulting from contaminated medications produced outside of hospital pharmacies and, in some cases, shipped across state lines, revised their recommendations for the preparation of sterile intravenous medications. See U.S. Pharmacopeia, Proposed Revisions to USP Chapter 797, <http://www.usp.org/healthcareInfo/pharmInfo/revisions797.html>; see also Medrep Technologies, Inc., available at <http://www.medrep.us/usp797/index.html> (last visited Sept. 15, 2005). In addition to longstanding and well-respected guidelines for proper staff training in aseptic preparation techniques using laminar air flow hoods – including proper staff training and certification, USP797 also requires creation of clean room facility standards similar to those in the pharmaceutical industry and dramatic and costly changes in staff procedures. The physical plant, heating, ventilation and air conditioning, and air filtration changes alone can amount to hundreds of thousands of dollars. In some respects, the requirements for pharmacy staff clothing (e.g., gowns, booties, and facial make-up) are more stringent than requirements for nurses and surgeons in operating rooms. Although various state boards of health and/or pharmacy had not yet evaluated this new document, in April 2004 the Joint Commission for Accreditation of Health Care Organizations (JCAHO) unilaterally announced that JCAHO-accredited hospitals would be expected to be in compliance with USP797 by July 1, 2004, although hospitals were granted a delay in implementing the physical plant renovation requirements. The fact that JCAHO has declared USP797 to be valid and fully enforceable means that the Centers must take steps to comply to remain accredited by JCAHO. USP797 does not address either the negative impact on staff efficiency (e.g., needing to re-gown every time one enters or leaves the clean room) or the resulting need for pharmacy staff expansion just to comply with the new physical plant cleaning requirements (too detailed to delineate here), which result in increased pharmacy costs in ways not reflected in the most recent cost report data (FY 2004). At a minimum, the new USP797 requirements will add hundreds of thousands of dollars of infrastructure costs, not yet reflected in hospital claims or cost report data.

NIOSH Alert, September 2004 – available for download at <http://www.cdc.gov/niosh/docs/2004-165/>, introduces new recommendations for pharmacy and nursing handling of hazardous drugs, including, but not limited to, conventional chemotherapy agents, including nearly all of the

agents used for systemic therapy by the Centers. Interestingly, the panel, which authored the Alert includes members from industries that sell some of the products included in the recommendations (e.g., glove boxes and PhaSeal containment devices). Glove box isolator devices are promoted as improvements over the longstanding gold standard of biological safety cabinets, despite the fact that any contamination within the glove box would accompany the medication product as it is removed. Moreover, the bulky elbow length or longer gloves which must be used by the operator lack the dexterity of the wrist/cuff length flexible gloves that are generally used today. An additional recommendation of the NIOSH Alert includes PhaSeal devices, which are commercially available devices that attach to hazardous medication vials, as well as to syringes and intravenous bags. On average, hospitals using the PhaSeal devices face a cost increase of \$10-\$15 for disposable gloves for each and every dose of antineoplastic medication therapy. In some cases, where the drug manufacturers produce relatively small vials (e.g., cetuximab or Erbitux-®, where 7-8 vials are needed for each patient dose), the cost per dose is even higher.

The mandates described above result in hospital pharmacies facing increased handling costs and overhead expenses that are currently un-reimbursed. For several of the Centers, these costs are forecasted to be in the order of \$1 million dollars per year, and include, but are not limited to, the purchase of new disposable equipment, storage of additional devices, disposal of new devices, staff training, and lowered efficiency due to extra steps required for the preparation of some drugs. We urge CMS to carefully consider the impact of these unfunded mandates on pharmacy handling costs since these costs are not yet reflected in CMS's estimate that 2% of the ASP will cover such costs.

In an effort to identify an appropriate payment for pharmacy overhead costs, the Centers have spent considerable time evaluating alternative options that would be fair and reasonable for both providers and CMS. While it is tempting to suggest that CMS reimburse us for our full pharmacy handling costs by paying ASP + 25% or 30%, we realize that such a proposal would pull hundreds of millions of dollars away from other APC payable services. Consequently, as an alternative payment methodology, the Centers recommend that CMS implement a transition mechanism for APC drug payment rates for 2006 while it studies the issue of drug handling costs. This mechanism will protect current payment rates for drug therapy and beneficiary access to important outpatient drug administration services. The Centers believe that CMS can implement a transition mechanism similar to that used to dampen payment fluctuations for device-related procedure APCs, blood and blood products, and other APCs over the past several years. See, e.g., 70 Fed. Reg. at 42,714 (discussing CMS's history of dampening payment fluctuations). We are merely encouraging CMS to use this same process for the category of separately payable drugs.

Specifically, for 2006, the Centers recommend that CMS pay the higher of ASP + 8% (the proposed method for reimbursing separately payable drugs in 2006) or 90% of the 2005 APC payment rates for each separately payable APC with the exception of radiopharmaceuticals (which the Centers agree should be paid at cost in 2006 since ASP data does not exist). The Centers also urge CMS to pay a handling fee for all packaged drugs with HCPCS codes. The Centers believe 90% of the current 2005 APC payment rates is more appropriate than 85% as this extra dampening provides a mechanism to cover some of the costs associated with the

unfunded mandates mentioned above as well as the costs associated with packaged drugs without HCPCS codes.

The Centers believe that the agency can exercise its authority by implementing dampening as a transition step, which would be consistent with past practice in other contexts. For example, CMS provided numerous transition mechanisms to physicians in their private practice settings when it transitioned them away from the average wholesale price methodology to ASP. The Centers believe similar transition mechanisms should have been proposed for hospitals. In the absence of such mechanisms, the Centers believe it is reasonable for CMS to pay the higher of ASP + 8% or 90% of the current APC payment rate for each separately payable drug APC. By implementing our recommendation, CMS can provide hospitals with a transition mechanism as it moves towards an ASP based payment methodology.

2. Issue 2: Capturing Drug Handling/Overhead Cost Data Using C-codes in 2006

The Centers also have a number of concerns related to the use and implementation of the proposed category C-codes for drug handling. See 70 Fed. Reg. at 42,730. While the Centers support the collection of charge data on drug handling for use in developing more accurate estimates of drug handling costs in the future, we do not support the implementation of the three newly proposed drug handling C-codes starting January 1, 2006.

a. *C-code Categories*

The Centers do not believe that three drug handling categories are sufficient to cover the wide range of drug handling costs for all of the separately payable drugs used by hospital outpatient departments. The categories MedPAC proposed would allow greater differentiation of drug handling costs, despite some of the questions raised about which category certain drugs should be assigned to. While the Centers recognize the difficulty in assigning each drug to a single category because of the multiple forms and routes of administration that require the drugs to be placed in different categories, we are also aware that MedPAC was able to gain consensus on the assignment of more than 90% of the drugs into a single drug-handling category, after working with a group of pharmacists and an expert panel. Despite lingering concerns and the fact that some drugs may not be perfectly assigned to a category, the Centers believe that CMS should explore the use of more than three categories. Additional categories are more likely to generate greater differentiation among the pharmacy handling costs of the majority of drugs provided by hospital outpatient departments.

By requiring providers to use more categories at the outset, CMS will be able to collect more detailed data resulting in a more robust database of drug handling charges to use in estimating drug handling costs and establishing future drug handling APCs and payment rates. Conversely, starting with fewer categories limits CMS's ability to collect this data from the start. Furthermore, requiring providers to use six (or even ten) categories compared to three will not result in any appreciable increased administrative burden for hospitals as they have experience reporting HCPCS C-, G-, and other codes that CMS requires. Any administrative burden that CMS is concerned about regarding the implementation of these C-codes can be mitigated by the release of detailed coding and billing guidance.

The Centers also disagree with CMS's proposal to collapse categories five and six from the MedPAC report into a single category. See 70 Fed. Reg. 42,729. The relative median costs of these two categories are very different (i.e., category 5 equals 2.7 and category 6 equals 5.33), and while merging them does not violate the two times rules, it certainly approaches the limit. Because MedPAC developed these relative median costs using data from only four hospitals, we are opposed to collapsing these two categories together simply because it would not violate the mathematical two times rule.

As an alternative, the Centers believe that more refined categories can, and should, be developed. Therefore, the Centers urge CMS to work the American Society of Health System Pharmacists (ASHP), the Hematology-Oncology Pharmacy Association, and other stakeholders to create the most appropriate set of drug handling categories for use in the future. At a minimum, we urge CMS to reevaluate the use of the MedPAC categories and to release a listing of the drugs assigned to each drug handling category for hospital review.

b. *Difference in charging across payers and beneficiaries*

The Centers would like to remind CMS that Medicare providers must charge all payers the same amount or, as CMS states in the Proposed Rule, "Medicare providers are required to maintain uniform charges for all payers." See 70 Fed. Reg. at 42,693. CMS may expect that other payers will follow Medicare's lead and implement pharmacy handling C-codes, yet this is unlikely to occur by January 1, 2006. As a result, providers are likely to face problems in setting their charges for CMS and other payers. Specifically, if providers are required to report the drug HCPCS code to Medicare along with the handling C-code, then they will need to submit two line items, instead of one, with the charges split between them. The same provider may or may not be able to report in the same way to other payers.

Further, even if other payers accept both the HCPCS code (for the drug) and a C-code (for the handling charge), providers may suffer financial losses if they are currently being paid on a percentage of charges associated with the HCPCS drug code. To stay revenue neutral, hospitals would have to charge CMS a lower charge for the J-code while charging other payers as they currently do, which may result in the same J-code being reported with a higher charge. As noted above, however, this is not allowable because providers must bill all payers consistently. For this reason, the Centers urge CMS to reconsider its proposal to require drug handling C-codes as it could result in hospitals being forced to charge other payers the lower charge for the J-code in order to be consistent with Medicare and thereby result in underreimbursement from non-Medicare payers, particularly if payments are based on a percentage of charges.

CMS should also consider that many hospitals use the same Charge Description Master (CDM) for billing inpatient and outpatient services. If hospitals are required to carve out a handling charge from the drug charge, and report it separately in the outpatient setting, it is unclear how CMS intends for providers to report the same drug charges in the inpatient setting. This is another example where the proposed use of the drug handling C-codes may result in hospitals charging differently. In this case, however, the difference is that Medicare beneficiaries who are treated by the same hospital in two different settings (outpatient and inpatient) may be charged different amounts. This also is not allowed under Medicare rules.

CMS does not address either of these issues in the Proposed Rule, which the Centers believe is a significant oversight.

c. Coding, billing, and charging issues

The proposed use of the drug handling C-codes raises a number of additional questions that CMS must consider before moving forward with its proposal. If not, the aim of this proposal – collection of accurate drug handling charge data – will be severely compromised. Below are some of these additional issues for your consideration.

- Should providers report multiple line items of the drug handling C-code per date of service if multiple drugs from the same drug handling family are provided or does CMS expect that only one drug handling C-code from each category, as applicable, would be reported on a given date of service with multiple units reported in the units of service field to correspond to multiple drugs administered from the same drug handling category?
- Will CMS define which revenue code(s) providers are to use in reporting the drug handling C-codes? This is an important question as it impacts how the CDM should be set up and maintained. Although CMS has stated that it does not like to dictate which revenue codes providers should use to bill different codes, the Centers urge the agency to define the revenue codes if it proceeds with the implementation of the drug handling C-codes in 2006, since this will impact the accuracy of the data providers report.
- When a medication is prepared for administration, the charge is sent electronically from the pharmacy system to the hospital's billing system. Therefore, unless providers can establish a methodology for the drug handling C-codes to be automatically generated, which may or may not be possible, they will have to be added manually on the back end of the billing process. This is likely to lead to errors as well as claims processing delays.
- Does CMS expect a one-to-one relationship between the drug and the handling charge; meaning, that if two drugs are administered two handling charges would be reported, even if they are administered together (i.e., only one administration charge is reported), since both medications were "handled" prior to being administered?
- Will CMS create OCE edits requiring a one-to-one match between a drug HCPCS code and a drug handling C-code?
- Will CMS allow providers to report a drug handling charge even if a drug is not administered? CMS has clearly stated that providers cannot charge for drugs that are not administered, yet providers incur a cost for having prepared the drug, which should permit payment for a handling charge.
- How does CMS propose to capture handling cost data for drugs that do not have HCPCS codes and that are reported only with a revenue code?
- What status indicator will CMS assign these codes if implemented in 2006? Since these

codes do not generate any additional reimbursement, they are essentially packaged services, but we urge CMS to assign a status indicator other than “N” for packaged services to facilitate analysis and review of the data in future years.

- Will CMS provide an explicit definition of “drug handling” so that providers can build their C-code drug handling charges in a consistent manner by including and excluding the same things? If CMS does not clarify what is included in pharmacy handling/overhead, the reported charges likely will vary considerably across hospitals, compromising CMS’s ability to create accurate drug handling APCs and payment rates in the future.

The above list is by no means complete with regard to the different questions providers are likely to raise. In fact, CMS should expect to receive many more questions from pharmacy charging staff, finance, billing, and other departments. Without clear answers and guidance from CMS, the implementation of the drug handling C-codes will resemble the nightmare providers have faced in reporting device C-codes.

While the use of separate codes to capture pharmacy handling costs may ultimately be a useful approach, the Centers believe it should be delayed until these attendant issues are addressed and resolved. In the absence of such delay, the implementation of the drug handling C-codes may raise issues similar to those observed when CMS required providers to report packaged C-codes (i.e., device C-code reporting) without sufficient implementation time or guidance. That data was flawed and unusable for future OPSS rules. The Centers are concerned that a similar result may occur if CMS rushes the implementation of the drug handling C-codes without addressing the operational and financial issues identified above.

The Centers, therefore, concur with the APC Advisory Panel’s recommendation that CMS should delay the implementation of the three new drug handling C-codes. In the meantime, CMS should work with stakeholders to generate alternate mechanisms to collect the data it needs, perhaps by refining the three drug handling C-code categories, addressing the payer charging issues, and preparing detailed coding and billing guidance to give providers clear instructions about how to implement the C-codes if that is the method selected for the future.

As an alternative, or until the above methodological issues are resolved, the Centers believe that CMS could study hospital cost report data to obtain handling cost data. CMS can still comply with the statutory requirement of the MMA by requiring each Fiscal Intermediary (FI) to provide a “drug handling” survey to the hospitals it services, collect the completed surveys from the hospitals, and transmit the data back to CMS. This approach has been used to collect data for the payment-to-cost ratio used in the transitional outpatient payment calculations (see Program Memorandum A-01-51, April 13, 2001), the wage index and occupational mix information for both OPSS and IPPS, and most recently for the outpatient cost to charge ratio (see Program Memorandum A-03-004, January 17, 2003). In these cases, hospitals submitted the requested calculations using a very prescriptive method to their respective FIs who, in turn, used this data for payment purposes.

The Centers believe CMS can use a similar approach to obtain data on provider drug handling charges and costs. Collecting this data using the same formula, cost report line numbers, and overall methodology would allow CMS to establish a more realistic

pharmacy/drug handling fee either by creating either a flat add-on percentage or APC payment rates. Although the 2004 cost reports will not contain cost data related to the impact of the two unfunded mandates (USP797 and NIOSH) mentioned above, it will provide CMS a much better starting point for estimating pharmacy handling costs. As more current cost report data becomes available, CMS should update its estimates of pharmacy handling costs if this approach is selected as a method to set drug handling APC payments.

3. Innovator and Noninnovator Multiple Source Drugs

By using the ASP model, CMS no longer needs to collect drug data distinguishing between innovator and noninnovator multiple source drugs and has, therefore, proposed to eliminate the use of the brand name drug C-codes. See 70 Fed. Reg. at 42,732. The Centers support this recommendation, as it will simplify how hospitals charge for these drugs. We do, however, request that CMS clarify and describe in detail how it will determine a single average sales price for multiple source drugs since the availability of these drugs in the marketplace varies, and they are now proposed to be paid at the same rates.

4. New Drugs without HCPCS

The Centers continue to support CMS's proposal to pay for new drugs without HCPCS codes by using C9399 and other necessary data as outlined in the instructions provided in Transmittal 188. See 70 Fed. Reg. at 42,733. These instructions allow the Centers and other providers to receive payment for newer (and typically more expensive) drugs in a timely fashion.

5. Anti-emetics

The Centers continue to support CMS's proposal to make separate payment for anti-emetic drugs, which are vital to the success of aggressive cancer treatment protocols. See 70 Fed. Reg. at 42,723. We are very concerned, however, about the drastic payment reductions proposed for five of the seven drugs listed in Table 21. See id. Table 1 below clearly shows the dramatic impact of CMS's 2006 proposed payment rates. The Centers find this type of payment fluctuation unacceptable, and urge CMS to dampen the negative payment impact in order to maintain beneficiary access to care to these important supportive care cancer drugs.

Table 1

CPT/ HCPCS	Description	July 2005 APC Payment	2006 Proposed Payment Rate	2006 Proposed Payment Rate Impact	Proposed Percentage Decrease from 2005 to 2006
J1260	Dolasetron mesylate	\$14.38	\$6.55	-\$7.83	-54.45%
J1626	Granisetron HCl injection	\$16.20	\$7.24	-\$8.96	-55.31%
J2405	Ondansetron hcl injection	\$5.54	\$3.80	-\$1.74	-31.41%
J2469	Palonosetron HCl	\$17.76	\$18.42	\$0.66	3.72%
Q0166	Granisetron HCl 1 mg oral	\$39.04	\$33.51	-\$5.53	-14.16%
Q0179	Ondansetron HCl 8mg oral	\$26.12	\$32.02	\$5.90	22.59%
Q0180	Dolasetron mesylate oral	\$63.28	\$48.54	-\$14.74	-23.29%

As recommended above, CMS should pay for all separately payable drugs using the higher of ASP + 8% or 90% of the 2005 payment rates, applied at the HCPCS/APC level. If CMS implements our recommendation, then the negative payment impact shown in Table 1 will be dampened as shown below in Table 2.

Table 2

CPT/ HCPCS	Description	July 2005 APC Payment	2006 Proposed Payment Rate	New Payment Rates as a Result of Dampening (higher of ASP + 8% or 90% of 2005 APC Payment Rate)	Proposed Percentage Decrease from 2005 to 2006 After Dampening
J1260	Dolasetron mesylate	\$14.38	\$6.55	\$12.94	-10.00%
J1626	Granisetron HCl injection	\$16.20	\$7.24	\$14.58	-10.00%
J2405	Ondansetron hcl injection	\$5.54	\$3.80	\$4.99	-10.00%
J2469	Palonosetron HCl	\$17.76	\$18.42	\$15.98	N/A
Q0166	Granisetron HCl 1 mg oral	\$39.04	\$33.51	\$35.14	-10.00%
Q0179	Ondansetron HCl 8mg oral	\$26.12	\$32.02	\$23.51	N/A
Q0180	Dolasetron mesylate oral	\$63.28	\$48.54	\$56.95	-10.00%

6. Non-Pass Through Drugs (determining how to set a threshold for packaged drugs in the future)

The Centers have two specific comments to provide in this section. The first regards calculating the per day cost for drugs, biologicals, and radiopharmaceuticals, and the second addresses CMS's request for comments on alternate thresholds for packaging drugs in 2007.

The Centers are pleased to see the addition of "Step 3" to the calculation of the per day cost for drugs, biologicals, and radiopharmaceuticals. See 70 Fed. Reg. at 42,725. In our comments to CMS on the 2004 and 2005 proposed rules, the Centers urged CMS to implement similar statistical modeling and trimming logic to remove aberrant drug units of service in order to improve the accuracy of these calculations. Our proposal centered on CMS performing trimming at the hospital level, whereas CMS has applied this at the aggregate level. Nonetheless, we agree with the addition and usefulness of Step 3 at the aggregate level as it should improve the accuracy of the per day cost calculation for drugs, radiopharmaceuticals, and biologicals.

Because trimming using +/- three standard deviations in Step 5 has historically removed more data points on the high "cost" rather than the low "cost" spectrum, the inclusion of Step 3 essentially corrects this problems because line items with very high billed units of service, which if left in the database would result in lower per unit costs, are removed first. So, in essence, the very low cost items that we would typically see in the median cost file are no longer present.

Therefore, the addition of Step 3 truly supplements Step 5 and now enables CMS to trim out very high units of service (through Step 3) associated with very low costs that may inappropriately lower the overall median cost, while also continuing to remove very high cost items (through Step 5) typically associated with very low units of service. Because hospitals have had difficulty in the past accurately reporting units of service, we believe both steps serve an important purpose and result in more accurate per day cost for drugs, radiopharmaceuticals,

and biologicals. Therefore, the Centers support the use of Step 3 and urge CMS to make it a permanent part of its per day drug cost calculation.

The second issue the Centers would like to comment on is the 2007 threshold CMS should use for identifying packaged drugs. See 70 Fed. Reg. at 42,723. Currently, drugs with a median cost per day of less than \$50.00 are packaged. Beginning in 2007, CMS will no longer have to use this threshold to identify drugs for packaging and is seeking comments on how to proceed. The Centers believe that CMS should provide separate payment for all infused and injectible drugs regardless of the “per day median” cost, and should simply continue to package oral drugs – with the exception of oral anti-emetics. This would create more consistency between the hospital and physician settings, which appears to be of interest to CMS, based on its alignment of separately payable drug payments this year, as well as its proposal to require the same drug administration CPT codes in both settings.

Packaging drugs in one setting but not another does not make sense, particularly because payment for multiple drug administration services and hours of infusion are also paid separately in the physician setting and not in the hospital setting as of yet. By un-packaging all infused and injectible drugs starting in 2007, regardless of the “median or mean” cost per day, CMS will move closer to removing the existing site of service differential. CMS has already begun this process by aligning payment for many separately payable drugs this year (and even more so in 2006), as well as by proposing to require the same drug administration CPT codes in both settings starting in 2006. Therefore, the Centers urge CMS to provide separate APC payment for all infused and injectible drugs starting in 2007 regardless of the “median or mean” cost per day.

7. Intravenous Immune Globulin (IVIG)

In April 2005, CMS eliminated two existing immune globulin (IVIG) CPT codes (J1563 and J1564) and replaced them with four new “Q” codes. See Transmittal 514, Centers for Medicare & Medicaid Services, CR 3756 (March 30, 2005). The new Q-codes are based on 1 gram and 10mg dosages, and distinguish between lyophilized and non-lyophilized forms of IVIG. The payment rates for the four new codes are the same regardless of formulation, and remain similar to the payment rates released for the J-codes in January 2005. Both the 1 gram codes have a payment rate of \$80.68, while the 10mg codes have a payment rate of \$.75. Even at current reimbursement rates, the Centers and other providers can barely cover the direct cost of the drug.

It is also important that CMS be aware of the ongoing nationwide supply shortages of IVIG. This ongoing shortage frequently necessitates that the Centers and other providers purchase IVIG “off contract” – i.e., at whatever price the secondary market suppliers believe the market can bear. In this type of environment, clinical necessity sometimes mandates that we purchase IVIG at acquisition prices much higher than the APC reimbursement rate for the product. Additionally, because of the shortage of IVIG, the Centers’ pharmacies purchase whichever formulation is available in order to be able provide this important drug therapy to patients. In fact, in most cases our pharmacy staff cannot ensure that a consistent supply of either formulation will be available and must physically check their inventory to identify which drug form is in stock before putting a charge through.

Furthermore, the Centers do not understand why CMS eliminated the IVIG J-codes and introduced the Q-codes, as this has resulted in increased burden on providers for a number of reasons. First, not all payers recognize the new IVIG Q-codes forcing providers to maintain separate codes and charges by payer type in their CDMs. We also have to manually change the Medicare Q-codes to the widely accepted IVIG J-codes in order to bill secondary insurers for the Medicare beneficiary's co-payment. Second, because payment rates for lyophilized and non-lyophilized IVIG formulations are currently exactly the same, the creation of the four new Q-codes does not make sense.

However, payment rates for lyophilized and non-lyophilized IVIG formulations are proposed to be significantly different in 2006. The Centers are very concerned about the drastic proposed payment reductions given the existing shortage of IVIG in the marketplace. In fact, on May 17, 2005, the FDA Blood Products Advisory Committee recommended that CMS declare a public health "crisis" as a result of the recent reimbursement changes that deny patient care. Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, Meeting Minutes, May 16 & 17, 2005, *available* at <http://www.hhs.gov/bloodsafety/summaries/summary.pdf>. The Centers are deeply concerned about our ability to maintain beneficiary access to this important drug therapy for our bone marrow transplant, neurology, hematology, and HIV/AIDS patients.

The tables below show the codes and payment rates for January 2005 (Table 3), April 2005 (Table 4), and the proposed payment rates for January 2006 (Table 5). It is clear that CMS's proposal to pay ASP + 6% + 2% is inadequate for IVIG. Payment reductions from 24% to 51% are simply unacceptable given patients' need for this important drug therapy.

Table 3: IVIG HCPCS J- Codes and Payment Rates for January 1 – March 31, 2005

CPT/HCPCS	SI	Description	First Quarter 2005 APC	First Quarter 2005 APC Payment Rate
J1563	K	IV immune globulin	0905	80.68
J1564	K	Immune globulin 10 mg	9021	0.75

Table 4: IVIG HCPCS Q-Codes and Payment Rates for April 1– December 31, 2005

CPT/HCPCS	SI	Description	APC	July 2005 Payment Rate
Q9941	K	IVIG lyophil 1g	0869	\$80.68
Q9942	K	IVIG lyophil 10 mg	0870	\$0.75
Q9943	K	IVIG non-lyophil 1g	0871	\$80.68
Q9944	K	IVIG non-lyophil 10 mg	0872	\$0.75

Table 5: IVIG HCPCS Q-Codes and Proposed 2006 Payment Rates and Financial Impact

CPT/HCPCS	SI	Description	APC	2006 Proposed Payment Rate	July 2005 Payment Rate	Proposed Payment Difference	Proposed Payment % Change
Q9941	K	IVIG lyophil 1g	0869	\$39.46	\$80.68	(\$41.22)	-51%
Q9942	K	IVIG lyophil 10 mg	0870	\$0.40	\$0.75	(\$0.35)	-47%
Q9943	K	IVIG non-lyophil 1g	0871	\$57.26	\$80.68	(\$23.42)	-29%
Q9944	K	IVIG non-lyophil 10 mg	0872	\$0.57	\$0.75	(\$0.18)	-24%

The Centers strongly urge CMS to revert to the original J-codes for IVIG and maintain IVIG's current 2005 payment rates. If CMS does not eliminate the Q-codes and reinstate the J-codes, at a minimum, CMS must maintain the current payment rates for IVIG in order to preserve beneficiary access to care.

B. Drug Administration

Last year, the Centers supported CMS's proposal to require providers to use CPT codes to report drug administration services and were pleased that CMS made this proposal permanent in the 2005 final OPSS rule. While the use of CPT codes this year has not been without its challenges, the operational burden of reporting Q-codes to Medicare and CPT codes to other payers has been alleviated.

CMS proposes to continue requiring hospitals to report CPT codes, and the Centers continue to support this effort, in principle. The Centers are, nonetheless, concerned about the number of new codes, the code descriptions, the narrative CPT guidance, and the simple fact that the CPT codes were created for and by physicians for use in the private office setting without regard for the educational and operational impact implementation in the hospital setting would have for hospitals setting. In addition, the Centers are concerned that the new CPT codes are conceptually different from the current 2005 CPT codes. As a result, hospitals are likely to face even greater challenges in implementing the new codes and rules in 2006 than they did when the change was made from Q-codes to 2005 CPT codes.

CMS did not release the actual 2006 CPT codes and descriptions in the Proposed Rule, but rather provided the codes' expected descriptions based on temporary HCPCS G-codes created last year for use in the physician's private office setting. The Centers are grateful to the American Medical Association (AMA) for releasing a copy of the 2006 CPT codes for use during the 2006 OPSS Proposed Rule comment period. The Centers' comments are based on a thorough review of these AMA-provided 2006 CPT codes.

The temporary G-codes were created to provide physicians a means to bill for each and every instance, or combination, of drug administration service(s) provided so as to offset the significant drug payment decreases required by the MMA. Physicians in the office setting receive payment for every G-code and, therefore, will receive payment for every 2006 CPT code billed. Conversely, hospitals will not receive payment for every CPT code billed because the agency will continue to reimburse hospitals in the same manner it does today, on a "per visit" basis. This means that, while hospitals will be required to bill all of the relevant, new CPT codes that correspond to the services provided, payment will continue to be limited

by the Outpatient Code Editor. The Centers understand that CMS must continue to make “per visit” payments for another year before being able to use CPT code level data as the basis for more refined drug administration payment rates. CMS should recognize, however, that the 2006 CPT book includes many more codes than existed in 2005, and that the vast majority of these codes will be packaged under OPPS. This will result in hospitals reporting even more codes without receiving any additional reimbursement from CMS.

The most egregious aspect of the new codes is the combination of the 2006 concept of “initial” service and CMS’s expected assignment (as outlined in the Proposed Rule) of status indicator “N” to many infusion codes which are payable today but will not be payable in 2006. The 2006 CPT book states that only one “initial” service code can be reported per encounter or date of service. The initial service is the primary service or reason for the visit. All other services provided must be reported with other codes. This concept, while applicable in the physician office setting, is inappropriate in the hospital setting.

We remind CMS that drug administration services are generally assigned (“charged”) at the departmental level or at the point of service. Thus, drug administration CPT codes are embedded in the CDM and departmental staff (typically clinical staff that is also responsible for delivering patient care) is responsible for determining the appropriate codes based on the services provided to the patients under their care. Drug administration services typically are not coded by Health Information Management/Medical Records (HIM/MR) staff or individual coders. Nor can this change be easily made, given the shortage of coding staff, the typical volume of outpatient visits, and the increased delay in submitting claims to Medicare that are likely to result if drug administration services have to be coded by HIM/MR staff.

Moreover, it will be virtually impossible for hospitals to implement separate codes for “initial,” “sequential,” and “concurrent” injections and infusions because patients “flow” through hospitals in a way that is fundamentally different from how they are treated in a physician office setting. In hospitals, patients can and do receive services in different departments, and charges are entered by each department, without one department necessarily knowing what services another has already provided and charged through the CDM. Therefore, the concept of the “initial service” reflecting the primary reason for the visit will be impossible to automate using the CDM.

Even if hospital staff are somehow able to overcome the issue of cross-departmental charging and can be trained to apply the concept of “initial” service accurately, hospitals will not be reimbursed for these services because CMS has assigned payable APCs to the initial codes, but not to the “additional hours,” “sequential,” or “concurrent” services codes. This is not necessarily a problem stemming from CPT but rather, from the disconnect that exists between how the CPT codes were created and how they are paid in the physician setting compared to how they are proposed to be paid in the hospital setting in 2006.

We set out below a number of examples to illustrate the financial, clinical, and administrative problems that the 2006 CPT codes will create in the hospital setting if implemented as proposed. Example 1 below comes from guidance released by the American Society of Clinical Oncologists based on CMS’s rules for how physicians should report the temporary HCPCS G-codes this year. We begin our discussion with this example, as used in

the physician office setting today, simply to illustrate the payment implications that will result in 2006 if the CPT concept of reporting only one “initial” service code is applied in the hospital setting.

1. Example 1

Service	Time	Explanation	2005 Physician Reporting		2005 Hosp Reporting			2006 Hosp Reporting		
			HCPCS G-Codes	Physician Payment	2005 CPT Codes	APC	APC Payment	2006 CPT Codes	APC	APC Payment
Hydration (saline)	9:00 to 9:35 (35 min)	The hydration service is reported using "each additional" hydration code. The initial hour of hydration code is NOT used because hydration does not accurately describe the key service performed. The modifier -59 is used to indicate that hydration is performed prior to the chemo infusion	G0346-59	\$20.69	90780 x 1	120	\$111.80	90761 x 1	N/A	\$0.00
Anti-emetic (first drug)	9:35 to 10:15 (40 min)	The first anti-emetic is not considered to be the key service furnished in the encounter; therefore it is reported using an "additional sequential" therapeutic/diagnostic code.	G0349	\$43.72	90781 x 1	N/A	\$0.00	90767 x 1	N/A	\$0.00
Chemotherapy (first drug)	10:15 to 11:15 (1 hour)	Chemo infusion best describes the key services performed; therefore, the first drug and first hour of service is reported using the initial hour of service	G0359	\$177.60	96410 x 1	117	\$168.29	96413 x 1	117	\$192.14
Chemotherapy (second drug)	11:15 to 12:50 (1 hour & 35 min)	The second chemo drug is reported as an "additional sequential" infusion. An additional hour of chemo infusion is also used to report the remaining 35 minute infusion of the same (2nd drug).	G0362	\$86.65	96412 x 2	N/A	\$0.00	96417 x 1	N/A	\$0.00
			G0360	\$40.20				96415 x 1		
Anti-emetic (second drug)	12:50 to 1:05 (15 min)	The second anti-emetic was infused sequentially to chemotherapy for 15 minutes. It is reported with a push/short infusion code. The "additional sequential" therapeutic/diagnostic code is reported.	G0354	\$27.72	90784 x 1	359	\$49.54	90775 x 1	359	\$49.33
TOTAL				\$396.68			\$329.63			\$241.47

This example clearly demonstrates not only how physicians report HCPCS G-codes today but also that they are paid for each service provided. Therefore, there is a clear link between what is provided, what is reported, and what is paid. If this same patient were treated in the hospital setting today, payment would be made for each of the key services, but not for the additional hours of infusion therapy. In 2006, the situation worsens, since hospitals will only be allowed to report one “initial” service code.

Consequently, hospitals will first have to determine which service should be reported as “initial,” and then use codes for all of the other services that do not contain the word “initial” as per the narrative text in the 2006 CPT drug administration section. In this example, hospitals will be forced to report CPT code 90761 for *intravenous infusion, hydration, each additional hour, up to eight (8) hours* for the pre-hydration and CPT code 90767 for *intravenous infusion, for therapeutic/diagnostic; additional sequential infusion up to one hour* for administering the anti-emetic. These codes, per the descriptions provided in the Proposed Rule, have a proposed status indicator of “N” for a packaged service. Therefore, they will generate no additional reimbursement, even though reimbursement is available today. See 70 Fed. Reg. at 42,738. The result is an aggregate reduction in reimbursement of approximately \$100.00. If hospitals select hydration as the “initial” service which makes sense intuitively since it was the first service

provided, and use the corresponding “initial, first hour” code, then the chemotherapy infusion would be reported using the “additional hours code,” resulting in even lower reimbursement.

CMS should not allow codes created for the physician office setting to be used to reduce payments in the hospital setting in 2006. Instead of closing the existing site of service differential between the physician office and hospital settings (in terms of payment for both drugs and drug administration services), this gap will increase if CMS proceeds in implementing physician-created CPT codes and rules in the hospital setting without allowing for some exceptions because these codes will result in hospitals not being reimbursed for medically necessary services that are currently reimbursed. The Centers do not believe this is CMS’s intent, and urge the agency to address and correct this issue in the Final Rule.

To help CMS better understand how a nurse or other staff charges or codes drug administration services, we have prepared a series of clinical examples. These examples clearly illustrate some of the subtle, yet critical, operational and financial issues hospitals will face after the new CPT drug administration codes are implemented on January 1, 2006, if CMS fails to provide proper guidance and make appropriate policy changes.

The Centers have spent considerable time reviewing the 2006 CPT codes, and find it most useful to use these codes in our examples. Our assumptions about what would (and would not) be paid in 2006 are derived directly from the status indicators CMS intends to assign to these services. We have used the expected 2006 codes, and cross-walked them to the G-codes and service descriptions outlined in Table 27. See 70 Fed. Reg. at 42,738.

2. Example 2

Example 2 below is for a methotrexate chemotherapy regimen in which a chemotherapy injection is provided along with an infusion. Following chemotherapy, a non-chemotherapy infusion of zoledronic acid is administered to treat the patient for secondary bone metastasis.

SAMPLE METHOTREXATE REGIMEN			2005 Hospital Reporting			2006 Hospital Reporting with CPT Codes		
			2005 CPT Codes	2005 APC	2005 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment
Service	Time	Explanation						
Chemotherapy drug injection	09:25 - 09:30	Chemo drug methotrexate given by push injection	96408 x 1	116	\$63.35	96409 x 1	116	\$67.97
Chemotherapy infusion	09:30 - 09:50	Chemo drug, Vinorelbine given by infusion method	96410 x 1	117	168.29	96415 x 1	N/A	\$0.00
Nonchemotherapy infusion	10:00 - 11:00	Zoledronic acid given after chemo to treat secondary bone mets.	90780 x 1	120	111.18	90766 x 1	N/A	\$0.00
TOTAL					\$342.82			\$67.97

The above table demonstrates that hospitals report CPT codes that currently are all reimbursable,, resulting in a total national payment of \$342.82. In 2006, hospitals will be required to first determine which service is the “initial” or the key/primary reason for the visit and then assign appropriate codes to all three of the services provided. It is likely that charging

staff (coding the record at the point of service) or coding staff (coding the record after treatment is completed) may simply select the first service provided as the “initial” service. However, while the 2006 CPT drug administration section is clear that the first service is not necessarily the key or primary service, the text does not explain how providers are to determine what the key service is. In this example, using the diagnosis code will not be helpful – as the patient is presenting for cancer treatment and receives two chemotherapy drugs by two different routes of administration. If the hospital selects 2006 CPT code 96409, *intravenous, push technique, single or initial substance/drug*, as the “initial” service code, then the others services must be reported with “non-initial” service codes. As the table above demonstrates, reporting the services provided with the chemotherapy injection as the “initial” service will force hospitals to report the other two services with additional hours’ codes – which are not separately payable. Therefore, hospitals will see a dramatic decrease in payment.

a. *Example 2(a)*

The example below presents the same clinical regimen of methotrexate described above. In this instance, however, we assume the hospital selects CPT code 96413, *chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug*, as the “initial” or key/primary reason for the visit.

SAMPLE METHOTREXATE REGIMEN			2005 Hospital Reporting			2006 Hospital Reporting with CPT Codes		
			2005 CPT Codes	2005 APC	2005 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment
Service	Time	Explanation						
Chemotherapy drug injection	09:25 - 09:30	Chemo drug methotrexate given by push injection	96408 x 1	116	\$63.35	96411 x 1	116	\$67.97
Chemotherapy infusion	09:30 - 09:50	Chemo drug, Vinorelbine given by infusion method	96410 x 1	117	168.29	96413 x 1	117	\$192.14
Nonchemotherapy infusion	10:00 - 11:00	Zoledronic acid given after chemo to treat secondary bone mets.	90780 x 1	120	111.18	90766 x 1	N/A	\$0.00
TOTAL					\$342.82			\$260.11

Because CMS has proposed to assign payable status indicators to chemotherapy and non-chemotherapy injection codes, injection services are always payable regardless of whether they are reported with the “initial” or “non-initial (i.e., each additional injection) service code. However, the 2006 CPT does not provide clear guidance on how to select the “initial” service code for other services.

The simple change of selecting the chemotherapy infusion as the “initial” service and the chemotherapy injection as the “each additional” results in a total national reimbursement of \$260.11. This is much higher than the reimbursement generated in Example 2, in which the hospital was only reimbursed \$67.97 for the chemotherapy injection. While selecting the chemotherapy infusion as the “initial” service improves hospital reimbursement, it does not resolve the issue that hospitals will still not be paid for the non-chemotherapy infusion of zoledronic acid, since it must be reported with an “each additional hour” code that is not payable under OPSS 2006 as set out in the Proposed Rule.

b. *Example 2(b)*

The example below is the last in this series. It presents the same clinical regimen of methotrexate described above but, in this example, the codes selected allow hospitals to be reimbursed in 2006 in the same way they are currently reimbursed.

SAMPLE METHOTREXATE REGIMEN			2005 Hospital Reporting			2006 Hospital Reporting with CPT Codes			2006 Hospital Reporting with CPT Codes - Ignore the word "Initial"		
Service	Time	Explanation	2005 CPT Codes	2005 APC	2005 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment
Chemotherapy drug injection	09:25 - 09:30	Chemo drug methotrexate given by push injection	96408 x 1	116	\$63.35	96411 x 1	116	\$67.97	96409 x 1	116	\$67.97
Chemotherapy infusion	09:30 - 09:50	Chemo drug, Vinorelbine given by infusion method	96410 x 1	117	168.29	96413 x 1	117	\$192.14	96413 x 1	117	\$192.14
Nonchemotherapy infusion	10:00 - 11:00	Zoledronic acid given after chemo to treat secondary bone mets.	90780 x 1	120	111.18	90766 x 1	N/A	\$0.00	90765 x 1	120	\$119.83
TOTAL					\$342.82			\$280.11			\$379.94

This can be achieved merely by allowing hospitals to disregard the concept of “initial service” and select codes that truly represent the services provided. In this example, the charging or coding staff will have no problem selecting codes that include the language, “initial, or initial, up to one hour” as these code descriptors are directly linked to the actual services rendered. If hospitals are allowed to ignore the word “initial” in the 2006 drug administration CPT codes, then they will naturally select CPT code 96409, *chemotherapy administration, intravenous, push technique, single or initial substance/drug*; CPT code 96413, *chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug*; and CPT code 90765, *intravenous infusion, for therapeutic/diagnostic; initial, up to one hour*. Each of these services, as described in the Proposed Rule (with the temporary HCPCS G-codes), would be payable in 2006 resulting in total national reimbursement of \$379.94. Payment of all three services is appropriate and consistent with how CMS currently reimburses hospitals and should therefore be preserved in 2006.

3. Example 3

The following example presents a sample Folfox chemotherapy regimen. The chemotherapy drug Oxaliplatin is infused concurrently with a non-chemotherapy drug, Leucovorin, through “Y” tubing that allows both drugs to enter the patient at the same time. These drugs are given by infusion over a two-hour period. The documentation shows that both drugs run from 10:00 am to 12:00 pm. Following this infusion, the patient receives a chemotherapy injection of Florauracil.

SAMPLE FOLFOX REGIMEN			2005 Hospital Reporting			2006 Hospital Reporting with CPT Codes		
Service	Time	Explanation	2005 CPT Codes	2005 APC	2005 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment
Chemotherapy drug infusion	10:00 to 12:00	The drug Oxaliplatin is infused concurrently with the non-chemo Leucovorin drug through "Y" tubing. Oxaliplatin is compatible with Leucovorin, but not the second chemo drug Fluorouracil. Order reads: Oxaliplatin 85mg/m2 IVPB Run in 2 hrs.	96410 x 1	117	\$168.29	96413 x 1	117	\$192.14
			96412 x 1	N/A	N/A			
						96415 x 1	N/A	
Non-chemotherapy drug infusion	10:00 to 12:00	The non-chemo drug Leucovorin is infused concurrently with the chemo drug Oxaliplatin through "Y" tubing. Order reads: Leucovorin 200mg/m2 IVPB run in 2 hrs.mg/m2 IVPB Run in 2 hrs.	90780 x 1	120	111.8	90768 x 2	N/A	\$0.00
			90781 x 1	N/A	N/A	or 90768 x 1 and 90766 x 1	N/A	\$0.00
Chemotherapy drug injection	12:10	Fluorouracil given by the hospital as an IVP	96408 x 1	116	63.35	96411 x 1	116	\$67.97
TOTAL					\$343.44			\$280.11

This example is similar to the previous ones in terms of the reimbursement impact of selecting the chemotherapy injection versus the chemotherapy infusion as the "initial" service. If the hospital selects chemotherapy infusion as the "initial service," then payment will be made as shown above for both the chemotherapy infusion reported with CPT code 96413 (CPT code 96415 for the second hour is also reported but does not generate any separate APC reimbursement consistent with CMS's payment policy today) and chemotherapy injection code CPT code 96411 (this is reimbursed even though it is not an initial service code). Similar to the issues raised in Examples 2 and 2a, hospitals will not receive reimbursement for the non-chemotherapy infusion since the expected 2006 CPT drug administration rules would require this service to be reported with an "each additional hour" code.

The primary difference in this example, however, has to do with what codes must be reported for the non-chemotherapy infusion of Leucovorin since it is given at the same time as Oxaliplatin. This raises the question of whether to report the non-chemotherapy infusion as a "concurrent" infusion and how to report it accurately using one or more CPT codes or one or more units of service to describe the two hours of the infusion. Because both infusions are given at the same exact time and through "Y" tubing, hospitals will likely consider these concurrent, though CMS should clarify this understanding since the agency used the example of starting multiple lines in separate arms as an example of "concurrent infusions" in the drug administration transmittals released for hospital use this year. In addition, the 2006 CPT drug administration section states that CPT code 90768 can only be reported once per encounter, which may confuse hospitals regarding their ability to report the actual hours of the concurrent infusion with the units of service field in a similar manner to how units are used to report hours for other infusion codes. It is, therefore, not clear if the units of service field should be used to report the full two hours of the concurrent infusion, or if another code must be used in conjunction with one unit of CPT code 90768.

In the table above, we indicate that CPT code 90768 x 2 is one way to report a concurrent infusion, while using CPT code 90768 x 1 along with CPT code 90766 (*intravenous infusion, for therapeutic/diagnostic; each additional hour, up to eight (8) hours*) is another that may be more

consistent with the 2006 CPT drug administration guidance. Though one of the above coding options may be technically correct from a CPT coding perspective, neither will result in APC reimbursement because these services, per the Proposed Rule, have a proposed status indicator "N" assigned to them. Currently, hospitals report the non-chemotherapy infusion with CPT code 90780 for the first hour and CPT code 90781 for the second hour; Fiscal Intermediaries currently reimburse this service through APC 120 at a national rate of \$111.80.

a. Example 3(a)

The example below is the second in this series and presents the same Folfox clinical regimen described above, but goes on to demonstrate how hospitals can be reimbursed in 2006 in a manner consistent with how they are reimbursed today.

The simplest way for CMS to reimburse hospitals in 2006 for providing all three services is, once again, to allow hospitals to ignore the concept of the "initial" service when assigning codes to these services, as shown below in Table 3a (below). By allowing hospitals to ignore the concept of "initial" service and select codes that truly represent the services provided, hospital charging or coding staff will again be able to easily select the codes that include the language "initial, or initial, up to one hour," as these descriptions in the code are directly linked to the actual services rendered.

SAMPLE FOLFOX REGIMEN			2005 Hospital Reporting			2006 Hospital Reporting with CPT Codes			2006 Hospital Reporting with CPT Codes - ignore the word "Initial"		
			2005 CPT Codes	2005 APC	2005 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment
Chemotherapy drug infusion	10:00 to 12:00	The drug Oxaliplatin is infused concurrently with the non-chemo Leucovorin drug through "Y" tubing. Oxaliplatin is compatible with Leucovorin, but not the second chemo drug Fluorouracil. Order reads: Oxaliplatin 85mg/m2 IVPB Run in 2 hrs.	96410 x 1	117	\$168.29	96413 x 1	117	\$192.14	96413 x 1	117	\$192.14
			96412 x 1	N/A	N/A						
						96415 x 1	N/A		96415 x 1	N/A	
Non-chemotherapy drug infusion	10:00 to 12:00	The non-chemo drug Leucovorin is infused concurrently with the chemo drug Oxaliplatin through "Y" tubing. Order reads: Leucovorin 200mg/m2 IVPB run in 2 hrs.mg/m2 IVPB Run in 2 hrs.	90780 x 1	120	111.8	90768 x 2	N/A	\$0.00	90765 x 1	120	\$119.83
			90781 x 1	N/A	N/A	or 90768 x 1 and 90766 x 1	N/A	\$0.00	90766 x 1	N/A	\$0.00
Chemotherapy drug injection	12:10	Fluorouracil given by the hospital as an IVP	96408 x 1	116	63.35						
TOTAL					\$343.44	96411 x 1	116	\$67.97	96409 x 1	116	\$67.97
								\$260.11			\$379.94

In this example, hospitals will naturally select CPT code 96409 for the Fluorouracil, chemotherapy administration, intravenous, push technique, single or initial substance/drug; CPT code 96413, chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug; CPT code 96415, chemotherapy administration, intravenous infusion technique; each additional hour, one to eight (8) hours; CPT code 90765, intravenous infusion, for therapeutic/diagnostic; initial, up to one hour; and CPT code 90766, intravenous infusion, for therapeutic/diagnostic; each additional hour, up to eight (8) hours. Each of the above services (with the exception of the additional hours' codes) is separately payable in 2006 as described in the Proposed Rule. Not only does this remove the issue of what codes and units must be reported for the concurrent infusion code, but it also allows hospitals to be reimbursed for each of the services they provide, similar to how they are reimbursed today. While the Centers would like to see CMS collect data on concurrent infusions, we believe this can be achieved through the use of the new therapeutic/diagnostic infusion codes when multiple

substances are being infused through one IV line as opposed to two separate IV lines running concurrently (one in each arm), which could be reported using the new concurrent infusion code. If CMS agrees, then perhaps it can narrow the application of the "concurrent" infusion code to only apply to those situations when two IV lines are running in two separate sites (e.g., left arm and right arm) during the same session. In this case, CMS would instruct providers to report CPT code 90768 and no separate payment would be made.

4. Example 4

The following example presents a sample Etoposide chemotherapy regimen. An injection of Kytril is given as a pre-medication prior to the chemotherapy infusion of Etoposide. During the chemotherapy infusion, the patient complains of pain and is given an injection of morphine. Several hours following the Etoposide infusion, the patient is still in pain and receives another injection of morphine.

SAMPLE ETOPOSIDE REGIMEN			2005 Hospital Reporting			2006 Hospital Reporting with CPT Codes		
Service	Time	Explanation	2005 CPT Codes	2005 APC	2005 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment
Non-chemotherapy injection	10:40	Pre-medication of Kytril IVP	90784 x1	359	\$49.54	90775 x 1	359	\$49.33
Chemotherapy drug infusion	11:30-12:30	Etoposide IV for 1 hour 11:30-12:30	96410 x 1	117	\$168.29	96413 x 1	117	\$192.14
Non-chemotherapy injection	11:50	Patient experiencing pain Morphine 2mg IVP	90784 x1	359	\$49.54	90775 x 1	359	\$49.33
Non-chemotherapy injection	4:10PM	Patient still experiencing discomfort. Morphine 3mg IVP at 4:10PM	90784 x1	359	\$49.54	No available code per 2006 CPT drug administration code and narrative descriptions	?	?
TOTAL					\$316.91			\$290.80

The Centers share this example to demonstrate the coding and reimbursement issues related to reporting multiple injection administrations of the same drug.

Following the 2006 CPT drug administration code descriptions, hospitals will be forced to report CPT code 90775, *therapeutic, prophylactic, or diagnostic injection, intravenous push, each additional sequential intravenous push of a new substance/drug* for the Kytril injection and the first morphine injection rather than CPT code 90774, *therapeutic, prophylactic, or diagnostic injection, intravenous push, single or initial substance/drug* since the chemotherapy infusion is reported with an "initial" service code. There are two problems selecting CPT code 90775 instead of 90774. The first is that it will not be intuitive for charging staff to report a "sequential" code when an "initial" injection code has not been charged. Second, there are no 2006 CPT codes available to report the sequential infusion of the same drug. This leaves the question of what code hospitals must use to report the second Morphine injection.

The Centers do not believe it is CMS's intent to prevent hospitals from being reimbursed for the second morphine injection in this scenario since it is currently reported and reimbursed. However, if CMS does not clarify how it expects hospitals to report multiple medically necessary administrations of the same drug during the same visit, then, based on this example, hospitals will never be paid for the second and subsequent injections of the same drug resulting in a loss of revenue.

a. Example 4(a)

The example below demonstrates how hospitals can be reimbursed in 2006 in a manner consistent with how they are reimbursed today.

Again, the simplest way for CMS to reimburse hospitals in 2006 for the medically necessary services they provide is to allow hospitals to ignore the concept of the "initial" service when assigning codes to these services, as shown in the table below. Not only will this result in hospitals being able to easily select the appropriate codes, but it will also allow appropriate reimbursement.

SAMPLE ETOPOSIDE REGIMEN			2005 Hospital Reporting			2006 Hospital Reporting with CPT Codes			2006 Hospital Reporting with CPT Codes - Ignore the word "Initial"		
Service	Time	Explanation	2005 CPT Codes	2005 APC	2005 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment	2006 CPT Codes	2006 APC	2006 APC Payment
Non-chemotherapy injection	10:40	Pre-medication of Kytril IVP	90784 x 1	359	\$49.54	90775 x 1	359	\$49.33	90774 x 1	359	\$49.33
Chemotherapy drug infusion	11:30-12:30	Etoposide IV for 1 hour 11:30-12:30	96410 x 1	117	\$168.29	96413 x 1	117	\$192.14	96413 x 1	117	\$192.14
Non-chemotherapy injection	11:50	Patient experiencing pain Morphine 2mg IVP	90784 x 1	359	\$49.54	90775 x 1	359	\$49.33	90775 x 1	359	\$49.33
Non-chemotherapy injection	4:10	Patient still experiencing discomfort. Morphine 3mg IVP at 4:10	90784 x 1	359	\$49.54	No available code per 2006 CPT drug administration code and narrative descriptions	?	?	90774 x 1	359	\$49.33
TOTAL					\$316.91			\$290.80			\$340.13

In this example, hospitals will naturally select CPT code 90774 (for the Kytril), *therapeutic, prophylactic, or diagnostic injection, intravenous push, single or initial substance/drug*; CPT code 96413 (for the Etoposide), *chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug*; CPT code 90775 (for the first morphine injection), *therapeutic, prophylactic, or diagnostic injection, intravenous push, each additional sequential intravenous push of a new substance/drug*; and CPT code 90774 (for the second morphine injection), *therapeutic, prophylactic, or diagnostic injection, intravenous push, single or initial substance/drug*.

By ignoring the word "initial," hospitals will be able to report all three injections provided to the patient using two different injection codes. CPT code 90774 is charged for the

Kytril and CPT code 90775 is used to charge for the first morphine drug since the morphine is a “sequential intravenous push” of a new/substance drug. CPT code 90775 cannot be charged again for the second injection of morphine since the code definition explicitly states, “new substance/drug.” Therefore, if CMS allows hospitals to ignore the word “initial,” then they can report the second morphine injection using the intravenous push code, CPT 90774. This is the simplest way to resolve the problem of how multiple intravenous push injections of the same drug should be reported and reimbursed. Alternatively, CMS could instruct hospitals to use modifiers, allow them to ignore the CPT language “new substance/drug,” or allow them to interpret the word new in “new substance/drug” as a different administration rather than a different (i.e., new) drug. The Centers do not believe any of these alternatives is as easy to implement as simply allowing hospitals to ignore the word “initial.” Moreover, allowing hospitals to ignore the word “initial” truly allows CMS to provide one instruction regarding the 2006 CPT codes that clarifies coding and reimbursement across a number of different clinical scenarios.

5. Summary and Recommendations

The above examples clearly illustrate that the codes and descriptions created for the physician office setting, now a permanent part of the CPT book, simply will not work in the hospital setting unless certain exceptions are made. If the 2006 CPT codes are implemented without exceptions and clarification, they will result in hospitals not being reimbursed for services for which they are currently reimbursed. The result, as noted, will be a significant decrease in payment – as shown in the all of the above examples – which the Centers doubt is CMS’s intent.

If CMS allows hospitals to ignore the concept of the “initial” service in each CPT drug administration code, hospitals will be able to select codes easily to report the services provided. Ignoring the word “initial” not only allows hospitals to report payable CPT codes for the services they provide (which will mitigate the financial impact shown in the examples above), it also allows hospitals to continue charging for these services at the point of care, rather than asking HIM/MR to code these services, thereby minimizing administrative burden.

In addition, the new codes and descriptions are not intuitive, and hospitals will face an enormous operational challenge in training both clinical and coding staff to use them. The new 2006 CPT concept of reporting only one “initial” service code where initial means the “key or primary reason for the encounter” forces all other services provided to be reported with an “additional,” “sequential,” or “concurrent” code. This is a difficult concept, and CMS should be prepared to receive questions from coding staff such as who should determine what the key or primary service is, whether the “initial” service should be based on diagnosis code, and whether the “initial” service reported should be based on time of administration, duration, and intensity.

The concept is further complicated by the need for charging and coding staff to report an “additional hours” code or an “additional sequential” code despite the fact that a first hour (or first injection) code has not been reported. It will be counter-intuitive for clinical staff charging at the point of service to charge for an “additional, sequential, or concurrent” hour of infusion or injection without charging for a corresponding first hour or initial injection code simply because an “initial” service code has already been charged. Staff currently follow CMS’s guidance to

only report the additional hours' code for non-chemotherapy infusion, CPT code 90781, when the corresponding first hour code for non-chemotherapy infusion, CPT code 90780, has been reported. Training staff *not* to do this will consume considerable time for all providers, including the Centers. Forcing hospitals to select codes across routes of administration in order to have only one "initial service" code is simply an artifact left over from how the codes were created and defined by physicians for use in the office setting.

For all of the operational and financial reasons detailed above, the Centers strongly urge CMS to take immediate action in order to minimize provider burden and ensure that payments are made appropriately in 2006 for drug administration services. CMS can accomplish this by creating special logic in the OCE, or by requiring hospitals to use modifiers, but both of these solutions are cumbersome and inferior to our recommendation that providers be allowed to ignore the word "initial" in every 2006 CPT drug administration code. This simple change alleviates the majority of the operational and financial issues outlined above. It also enables CMS to assign status indicator "N" (as outlined in the 2006 OPSS Proposed Rule) to all services that do not include the word "initial" in the descriptor. This will allow CMS to collect data on "additional hours," "sequential," and "concurrent" infusions without eliminating payment for services that are currently payable. To do this, CMS would program its claims processing logic to allow multiple "initial" service CPT codes to be reported on the same date of service (i.e., *intravenous infusion, hydration, initial up to one hour* should be allowed and paid when reported with *chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance/drug*). If hospitals are instructed to ignore the concept of the "initial" service, then they will be able to use the 2006 CPT codes as they currently use the 2005 CPT codes with minimal additional education and training.

The Centers believe that CMS has the authority to instruct hospitals to ignore the concept of the "initial" service as outlined in the 2006 CPT drug administration section. CMS has used this process many times in the past, and in fact instructed hospitals to essentially "ignore" the following 2005 CPT language this year with respect to drug administration services – "*administered by physician or under the direct supervision of physician*" See 69 Fed. Reg. 65,682, 65812-13 (Nov. 15, 2004). Hospitals also currently have different reporting rules for reporting conscious sedation associated with CPT bull's-eye codes, evaluation and management visit codes (not used at all as they appear in CPT), critical care visit codes (not used at all as they appear in CPT), and others. CMS has provided separate guidance to hospitals on how to "interpret," "use," and even "ignore" CPT language when codes or descriptions are not applicable in the hospital setting in the same way they are in the physician setting. The 2006 CPT drug administration codes are no different.

In summary, the Centers urge CMS to implement the recommendations outlined below:

- CMS should explicitly state – both in the final 2006 OPSS rule and in guidance it releases for hospitals – which parts of the CPT text, code descriptions, and narrative hospitals may ignore for reporting under OPSS. At a minimum, the concept of the "initial" service should be ignored for the purposes of reporting drug administration services to CMS. This also extends to the multiple references to "physician

supervision.” The Centers request that CMS follow precedent and instruct providers to disregard this language.

- CMS should not simply re-release guidance provided to physicians in 2005 for hospitals’ use in 2006. Instead, we urge CMS to carefully review the 2006 CPT codes, along with all of the previous transmittals released in relation to OPPS billing for drug administration services, to determine which guidance will apply in 2006 and which guidance needs to be updated. The hospital guidance should contain clinical examples (including combinations of services that reference documentation time) that will clearly guide hospitals in accurately determining what codes hospitals should report. Additionally, CMS should release the guidance as soon as possible after the 2006 OPPS Final Rule is published, so that providers will have time to adapt to the new codes and rules.
- CMS should clearly define the terms “sequential” and “concurrent.”. CMS should also provide clinical examples in its guidance related to the use and implementation of these codes in the hospital setting.
- CMS should instruct providers to report the solutions administered as hydration with codes 90760/90761 using revenue code 258 for IV solutions. This is necessary so that CMS will be able to package these solutions into the hydration administration CPT codes in the future.
- CMS should clearly define what is meant by “the administration of single or initial substance/drug” (e.g. 90774) and include examples in the guidance of how these terms should be applied. Currently, hospitals report an administration for each medically necessary drug administered. If two drugs are mixed together and administered via one syringe, only one administration code is reported. If the same drug is injected more than once in a period of time due to medical necessity, multiple administrations are charged, even though the same drug is being given. The Centers believe the new CPT codes will fundamentally change how these services are reported and urge CMS to include clinical examples that speak to this issue in the guidance it releases.
- Currently, CMS only expects to see modifier -59 reported with drug administration services when two or more separate and distinct visits occur on the same date of service, or when multiple IV lines are started during the same visit/session due to protocol. The Centers request that CMS confirm that this instance remains the only time hospitals would report modifier -59 with respect to drug administration services.
- Finally, we request that CMS carefully review the clinical examples provided above, along with the code level detail provided in the chart below. The Centers would be pleased to discuss our recommendations and clinical examples with CMS staff.

**Alliance of Dedicated Cancer Centers' Recommendations
For Selected 2006 Drug Administration CPT Codes**

2005 CPT Code	2005 CPT/HCPCS Level II Code	Expected 2006 CPT Code from the AMA	Description from the 2006 Proposed OPSS Rule (very similar to the expected 2006 CPT descriptions released by the AMA)	Alliance of Dedicated Cancer Centers Recommendations for 2006 Drug Administration CPT Codes
90780	G0345	90760	Intravenous Infusion, Hydration; Initial, up to one hour.	Instruct hospitals to ignore the word "initial" and to report this code with revenue code 258 for IV solutions
90781	G0346	90761	Intravenous Infusion, Hydration; each additional hour, up to eight (8) hours.	Instruct hospitals that this code cannot be reported without CPT code 90760.
90780	G0347	90765	Intravenous Infusion, for Therapeutic/Diagnostic; Initial, up to one hour.	Instruct hospitals to ignore the word "initial"
90781	G0348	90766	Intravenous Infusion, for Therapeutic/Diagnostic; each additional hour, up to eight (8) hours.	Instruct hospitals that this code cannot be reported without CPT code 90765.
90781	G0349	90767	Intravenous Infusion, for Therapeutic/Diagnostic; additional sequential infusion, up to one hour.	Define sequential in terms of whether this occurs before or after another service; Instruct hospitals whether they need to report two sequential infusions of different substances using two line items of the code each with a unit of one or one line item with two units and a modifier. The CPT definition limits the units allowed to 1 so CMS will need to determine how it will handle two sequential infusions of different substances reported on the same date of service. Instruct hospitals that this code cannot be billed without CPT code 90765 and it may be billed with CPT code 90766 to report additional hours of the sequential infusion.
90781	G0350	90768	Intravenous Infusion, for Therapeutic/Diagnostic; concurrent infusion.	CMS must define whether concurrent means two or more drugs/solutions etc. being infused at the exact same time per nursing documentation or two separate IV lines running in different arms. CMS must also define whether concurrent is applicable when two or more drugs/solutions etc. overlap in their start and stop times, but are not running for the exact same duration. This concept must be clarified.
90782	G0351	90772	Therapeutic or Diagnostic Injection; subcutaneous or intramuscular; <i>2006 CPT description expected to include: (also use this code to report non-antineoplastic hormonal therapy injections)</i>	Publish and maintain a set of anti-neoplastic hormonal drug codes on a quarterly basis
90784	G0353	90774	Intravenous Push; single or initial substance/drug	Ignore "initial" and indicate this code should be reported for the first injection provided. Clarify definition of single substance/drug.
90784	G0354	90775	Intravenous Push; each additional sequential intravenous push. <i>2006 CPT description expected to include of a new substance/drug</i>	CMS must clarify the definition of new substance/drug. If the same drug is given over time, then will CMS allow providers to report multiple units of 90774? If two drugs are mixed and provided through one injection, will CMS allow providers to report two codes to signify the "new drugs"?

**Alliance of Dedicated Cancer Centers' Recommendations
For Selected 2006 Drug Administration CPT Codes (continued)**

2005 CPT Code	2005 CPT/HCPCS Level II Code	Expected 2006 CPT Code from the AMA	Description from the 2006 Proposed OPSS Rule (very similar to the expected 2006 CPT descriptions released by the AMA)	Alliance of Dedicated Cancer Centers Recommendations for 2006 Drug Administration CPT Codes
96400	G0355	96401	Chemotherapy Administration, subcutaneous or intramuscular; non-hormonal antineoplastic	CMS should publish and maintain a set of non-hormonal anti-neoplastic drug codes on a quarterly basis
96400	G0356	96402	Chemotherapy Administration, subcutaneous or intramuscular; hormonal antineoplastic	CMS should publish and maintain a set of hormonal anti-neoplastic drug codes on a quarterly basis
96408	G0357	96409	Chemotherapy Administration Intravenous, push technique, single or initial substance/drug	CMS must instruct hospitals to ignore the word "initial" and clarify whether providers should report this code even if two drugs are mixed and injected together.
96408	G0358	96411	Chemotherapy Administration Intravenous, push technique, each additional substance/drug.	CMS should instruct hospitals to report this code for second and subsequent chemotherapy push injections (meaning that if this code is present, CMS should also expect to see 96409) rather than as a code reported with some other "initial service" code such as chemotherapy infusion.
96410	G0359	96413	Chemotherapy Administration, Intravenous Infusion Technique; up to one hour, single or initial substance/drug.	CMS should instruct hospitals to ignore the word "initial" and to report this code for the first hour of chemotherapy by infusion and clarify whether providers should report this code if two drugs are mixed and infused together
96412	G0360	96415	Chemotherapy Administration, Intravenous Infusion Technique; Each additional hour, one to eight (8) hours.	CMS should instruct providers that this code cannot be reported without CPT code 96413; This code should not be reported with 96409 to signify that chemotherapy infusion was provided, unless it appears in addition to 96415, to signify multiple hours of chemotherapy infusion.
96412	G0362	96417	Chemotherapy Administration, Intravenous Infusion Technique; Each additional sequential infusion (different substance/drug), up to one hour.	CMS must define sequential in terms of whether this occurs before or after another service. CMS must clarify whether hospitals need to report two sequential infusions of different substances using two line items of the code each with a unit of one or one line item with two units and a modifier. The CPT definition seems to limit the unit to 1 so CMS will need to determine how it will handle two sequential infusions of different substances reported on the same date of service. CMS should instruct hospitals that this code cannot be billed without CPT code 96413 and that it may be billed with CPT code 96415 to report additional hours of a sequential infusion.
96425	G0363	96523	Irrigation of Implanted Venous Access Device for Drug Delivery Systems.	Assign this code a status indicator "Q" as described in our comments so that a low level visit APC payment is made by the OCE when this is the only code reported on a claim

C. Multiple Diagnostic Imaging Procedures

CMS proposes to apply a 50% reduction when two or more diagnostic imaging procedures from the same family of codes are provided during the same session. See 70 Fed. Reg. at 42,748. This proposal is based on CMS assuming that certain economies of scale exist when multiple procedures are provided during the same session. The Centers agree that there are certain economies of scale when similar radiology procedures are performed during the same session, but we disagree with CMS's proposal to reduce the payment rate of the second and subsequent APCs by 50%.

A 50% reduction ignores the fact that some of the economies of scale are currently reflected in the cost-to-charge ratio used by CMS to arrive at the median cost data. The Centers support both the American College of Radiology's assertion that cost report data already reflects some economies of scale, and the APC Advisory Panel's recommendation that CMS should further study this proposal and delay its implementation.

The Centers are also concerned about the procedures CMS has assigned to each family of codes and urge further review of the families. For example, we do not believe that CPT code

76830 (transvaginal ultrasound, non-ob) should be discounted by 50% when provided during the same “session” as CPT code 76700 (echo exam of abdomen). Routinely, when a patient has a transvaginal ultrasound following ultrasound of the abdomen, the patient must leave the room to empty her bladder, the room must be set up again for the second procedure, and a different probe must be installed. In the above example, the Centers do not believe economies of scale exist that would warrant a 50% payment reduction for the second procedure. Therefore, if CMS chooses to move forward with its proposal, we urge CMS to remove the transvaginal procedure represented by CPT code 76830 from the list of services included in Family 1.

Another issue that concerns the Centers about CMS’s proposal to discount multiple diagnostic radiology procedures from the same family provided in the same session is that CMS has not explained what it means by the “same session.” See 70 Fed. Reg. at 42,748. In the above example, it is not clear whether CMS would consider both procedures to have been provided in the “same session.” The Centers believe that any economies of scale generated when multiple procedures are provided to the patient occur in cases when, for example, the patient does not have to be moved or the equipment does not have to be changed. In the above example, we do not believe economies of scale are generated that warrant a 50% payment reduction.

Without a definition of “same session,” it is unclear if CMS expects to apply the 50% payment reduction in the example above, or if CMS would instruct providers to report modifier -59 with the second procedure so that 100% of the APC payment is made for both procedures.

If CMS proceeds with its proposal, the term “session” must be explicitly defined so that providers know when modifier -59 can be used to signify that multiple diagnostic radiology procedures were performed on the same date of service, but not during the same session.

The Centers urge CMS to delay implementation of this proposal until it has fully studied and analyzed both provider claims and cost report data to determine if, in fact, a further reduction in payment is warranted or if economies of scale are already being captured through departmental cost-to-charge ratios. In addition, the Centers encourage CMS to consider working with the AMA to create new CPT codes that describe combined procedures so that providers can easily select the proper code when reporting services that are truly provided in the “same session.” This will not only make it easier for providers to report these services, but will also allow CMS to capture charge data that can be systematically used to create new APCs, or to propose payment policy changes that reflect economies of scale for combined procedures as reported through the claims data.

D. APC Relative Weights

1. Bypass List

The Centers continue to support using different methods to increase the number of single procedure bills available to establish payment rates, including the use of the bypass list. However, we are concerned that the criteria used by CMS to expand the bypass list – less than 5% of claims with the relevant bypass code appearing on a claim with packaged charges – may not result in an accurate list. See 70 Fed. Reg. at 42,681. While we support using a data test to identify those services that may be eligible for inclusion on the bypass list, we do not support

adding these services to the bypass list simply because they pass a “data” test. The Centers believe this is a shortsighted approach, since the list of procedures which meet the test may change from year to year based on the claims data. As a result, the list may not be consistently reliable because of the erroneous assumption that packaged charges do not occur with the services on the bypass list. For example, the proposed bypass list once again includes two evaluation and management (E/M) codes (99213 and 99214) that concern the Centers. CPT codes 99213 and 99214 appear on the bypass list, although other evaluation and management codes (such as 99211, 99212, and 99215) do not. See 70 Fed. Reg. at 42,687. The Centers do not believe that CPT codes 99213 and 99214 differ significantly from other clinic visit codes in terms of packaged services being a fundamental part of the visit. In fact, we expect the higher-level visit codes (99213 and 99214) to have packaged services associated with them more frequently than the lower-level visit codes (99211 and 99212). Therefore, the Centers recommend that CMS remove both 99213 and 99214 from the 2006 bypass list.

In addition, the Centers again urge CMS to place all add-on CPT codes on the bypass list because these codes, by definition, should never appear on a correctly coded claim without the corresponding primary procedure code. Both separately payable and packaged add-on codes should be added to the bypass list for the purpose of determining single procedure claims and assigning packaged charges more appropriately. For example, if two payable APCs are present on a claim along with a packaged add-on code, then CMS could disregard the packaged add-on code for purposes of defining a single procedure claim. By ignoring the packaged add-on code, this claim would transition from a multiple procedure claim to two singleton claims, and the charges associated with the packaged add-on code would then be allocated to the main procedure code.

Ignoring separately payable add-on codes by placing them on the bypass list will also facilitate creating additional single procedure claims. For example, a claim with two APC payable services (one of which is a separately payable add-on code) and packaged supplies currently is considered a multiple procedure claim, and is not included in the rate-setting process. If CMS ignores the add-on code (in this case a separately payable add-on code), then the agency can simply assign the packaged charges to the other payable APC and generate additional single procedure claims. Alternatively, if CMS believes the separately payable add-on code should have charges packaged with that code, it can simply apportion the packaged charges equally between the separately payable add-on APC and the other payable APC. Therefore, the Centers urge CMS to place all add-on codes, both packaged and separately payable, onto the bypass list.

2. “Pseudo-Single Claims”

The Centers are pleased that CMS has continued to make progress in generating more single procedure claims as the basis for the 2006 OPPTS proposed payment rates. See 70 Fed. Reg. at 42,681. As CMS is aware, the Centers have provided assistance in this effort through testimony to the APC Advisory Panel and directly to CMS for several years.

The Centers understand the value of using single procedure claims in the rate-setting process, and continue to urge CMS to explore avenues beyond increasing the bypass list to increase the number of “pseudo” single claims. The Centers also urge CMS to use correctly coded single procedure claims to the fullest extent possible. We believe the quality of the claims

data and the accurate assignment of packaged charges is more important than simply increasing the number of single procedure claims used to set relative weights if such an increase compromises the accuracy of the weights.

To this end, CMS should evaluate whether to create additional edits, such as the device C-codes edits implemented this year, on the front end of the claims process as part of the Outpatient Code Editor (OCE) to insure that it receives properly coded claims, or on the back end, by creating logic to allocate packaged charges to specific procedures. Either approach will facilitate more accurate assignment of packaged charges resulting in the creation of additional “pseudo” single claims that can improve the accuracy and reliability of the APC relative weights, while effectively reducing the remaining volume of multiple procedure claims.

The Centers raise this issue because we expect a large percentage of the 2005 drug administration claims to be multiple procedure claims due to the reporting of CPT drug administration codes this year. As a result of this policy, the majority of correctly coded chemotherapy infusion claims for infusions exceeding 90 minutes in duration may be multiple procedure claims. Specifically, these claims will have a separately payable first hour HCPCS code, a packaged additional hour HCPCS code, a HCPCS drug code, and one or more additional separately payable APC services (e.g., an injection code or evaluation and management visit code).

Unless CMS can convert these multiple procedure claims into “pseudo” single claims, these claims will not be used in the 2007 rate-setting process. The Centers are concerned about this outcome because we typically treat more complicated cases, both with regard to the combination of services and the duration of the services. For CMS to truly reimburse these services at the level of the average case, it would have to factor in costs from single procedure claims and find a way to convert multiple procedure claims to “pseudo” single claims. If this is not done, the APC relative weights for drug administration services in 2007 will be undervalued and will not reflect payment for the “average” case, resulting in hospitals being consistently “under-reimbursed” for providing lengthier infusions or more complicated types of care. Therefore, the Centers urge CMS to consider how to convert 2005 multiple procedure drug administration claims into “pseudo” single claims prior to the CY 2007 rulemaking. We would be willing to work with CMS in this regard to further develop the logic for creating additional “pseudo” single claims that we have previously provided to both CMS and the APC Advisory Panel.

Finally, the Centers urge CMS to assign “pseudo” single flags to line items in the public use file claims data. Currently, the agency assigns flags to single procedure claims, multiple major claims, multiple minor and other claims, but it does not provide any information about the “pseudo” single claims it was able to create using the methodology outlined in the Proposed Rule. By providing “pseudo” single flags, CMS will facilitate commenters’ ability to model various aspects of future proposed rules.

3. Proposed Calculation of Median Costs

CMS states that line item costs for drugs, blood, and devices are copied into another file for the purpose of calculating the per unit median costs for these items, and that the line item

costs were also used to calculate the per administration cost of drugs, radiopharmaceuticals, and biologicals. See 70 Fed. Reg. at 42,689. The Centers ask CMS to clarify whether the line items copied into another file (and that continue to remain on the original claim) are disregarded for the purpose of identifying single procedure bills.

We also believe CMS disregards all line items with status indicators “K” and “G” for the purpose of defining single procedure claims as these items should not have packaged dollars allocated to them. For example, if a claim contains an infusion administration code, an injection code, and a separately payable drug, the Centers assume the separately payable drug line item is ignored for the purpose of determining whether this claim can be converted into two “pseudo” single claims. The Centers request that CMS clarify in the Final Rule how it treats drug line items in the process of creating single procedure and “pseudo” single procedure claims in the final rule.

4. 2 Times Rule

The Centers do not understand why CMS included APC 120 in Table 8 of the Proposed Rule. See 70 Fed. Reg. at 42,705. In order to apply the two times rule, two or more CPT codes must exist in the same APC. CPT code 90780 is the only CPT code assigned to APC 120. The Centers believe it is impossible for CMS to apply the two times rule to APC 120 or place this APC on the two times rule exception list. Therefore, the Centers request that CMS remove APC 120 from Table 8.

E. **New Technology APCs**

1. Smoking Cessation Codes

The Centers are concerned with the proposal to move smoking cessation codes G0375 and G0376 from the existing New Technology APCs, where they have a payment rate of \$25.00, to two much lower-paying new technology APCs in 2006. See 70 Fed. Reg. at 42,936, 42,707.

When HCPCS code G0375 and G0376 were implemented in March of 2005, hospitals began to create programs to provide these services. The current payment rate of \$25.00 is not, however, sufficient to cover the resources associated with this type of visit. CMS should recognize that counseling services are similar to clinic visits and reimbursement for smoking cessation should therefore be more closely aligned with APC 600 (low-level clinic visit). The services should certainly not be reduced in payment from \$25.00 to \$5.00, or even \$15.00, as outlined in the Proposed Rule. We do not believe that CMS should make such drastic payment rate reductions without any claims data, particularly since smoking cessation counseling is a new service and one that we believe CMS would like to see more beneficiaries receive.

Consequently, the Centers urge CMS to maintain the current payment rate of \$25.00 until it has received provider claims data, at which time placement of these codes into a clinically and resource homogenous APC can be made. We believe that CMS will eventually see claims data reflecting charges, when reduced to cost, that will justify placing these codes into APC 600 with a payment rate closer to \$52.00. While we would prefer for CMS to make this change now, we recognize that CMS relies on claims data before moving CPT codes into new APCs. CMS should observe its own principles and leave these codes in their current APC.

Finally, CMS should clarify the final payment rates and assignment of G0375 and G0376, since Table 10 and Addendum B are inconsistent and show different payment rates for the codes. Table 10 shows HCPCS code G0375 assigned to APC 1491 with a payment rate of \$5.00 and G0376 assigned to APC 1492 with a payment rate of \$15.00. See 70 Fed. Reg. at 42,707. Addendum B shows both codes assigned to APC 1491, the APC with the lower payment rate of \$5.00. See 70 Fed. Reg. at 42,936. At a minimum, the Centers urge CMS to keep the payment rate for these HCPCS codes at the current rate of \$25.00 by assigning these codes to either APC 1493, 1494, or 1495. A better solution is to reassign these codes to APC 600.

2. Stereotactic Radiosurgery (Cobalt-60)

CMS's proposal to combine the Cobalt 60-based SRS planning code (G0242) and delivery code (G0243) is of concern to the Centers. See 70 Fed. Reg. at 42,709. These are two separate modalities and should be considered as such. By combining the planning and treatment codes, CMS assumes that both planning and treatment delivery occur together during the same patient visit. While this is often the case, there are instances when the planning is conducted, but treatment is not delivered on the same date of service. The Centers urge CMS to recognize that planning can occur without treatment, although treatment fundamentally cannot occur without planning.

There are also times when a patient has been framed and had a complete MRI scan, and then a problem arises that precludes the treatment delivery. CMS needs to clarify how providers should report one service without the other if separate codes are not maintained for planning and treatment. In other words, if CMS combines planning and treatment delivery codes for Cobalt-60, then the only way providers will be able to report planning without treatment delivery is to report the single combined code with a modifier to indicate the service was reduced (i.e., planning completed but not delivery). This raises the question of whether the same combined code would be reported a second time when the treatment occurs, again with a modifier to indicate that the full service was not provided. These issues can be easily avoided if CMS continues to allow providers to report separate codes for planning and treatment delivery.

If CMS is proposing this change because it is concerned about generating enough single procedure bills for the purpose of future rate setting for these services, then the Centers recommend that CMS review the appropriateness of placing the planning code on the bypass list. This will enable CMS to generate single procedure bills, while allowing hospitals to continue reporting separate codes for planning and treatment delivery.

While the use of CPT codes is almost always preferable to the use of HCPCS codes, the Centers urge CMS to be cautious in making annual changes to how these services are reported. Frequent changes increase the administrative burden and workload on hospitals, and can lead to coding confusion. Therefore, we recommend that CMS retain the separate codes for reporting planning and treatment delivery services, whether through the use of existing G-codes or through the available CPT codes.

F. Vaccines and Vaccine Administration

The Centers appreciate CMS's proposed changes for vaccines and urge the agency to implement these changes in the Final Rule. See 70 Fed. Reg. at 42,739. In addition, the Centers strongly support CMS's proposal to pay separately for vaccine administration services, as shown in Table 28, and urge the agency to make these changes final for 2006. See 70 Fed. Reg. at 42,740. The Centers also ask CMS to clarify what we believe to be a typographical error in the middle column of page 42,739. We believe the agency intends for hospitals to report administration of the hepatitis B vaccine using codes 90741 and 90742, not codes 96471 and 96472 as listed in the Proposed Rule. Please confirm that this is the case.

G. Observation Services

The Centers applaud CMS for its continued thoughtful work in studying the administrative issues related to coding and billing and the payment criteria for the separately payable observation APC. See 70 Fed. Reg. at 42,742. We also appreciate CMS taking additional steps to propose a set of changes for 2006 that will result in further streamlining the reporting of these services.

The Centers also fully support and appreciate CMS's use of programming logic to determine whether separate payment is warranted, rather than requiring providers to make that determination as a part of their coding and billing process. This process will simplify how providers report separately payable observation and result in providers reporting all observation services more completely and accurately. This, in turn, will provide CMS with the data it needs to determine if additional conditions warrant separate payment for observation in the future. To that end, the Centers urge CMS to continue reviewing additional diagnoses that may warrant separate observation payment, particularly if CMS does not plan to implement the APC Advisory Panel's recommendation to make payment for all medically necessary observation services.

The patient population treated by the Centers continues to become more complex as new drugs and technologies become available, and patients present with more advanced disease. The overall physical condition and the number of co-morbidities being seen in cancer patients with advanced disease increases the risk of toxicity. State-of-the-art treatments rely on higher level toxicities, increasing the likelihood of adverse reactions. As a result, oncology patients frequently warrant intense observation that goes above and beyond the routine monitoring required by all patients receiving chemotherapy.

The Centers again urge CMS to study the following diagnoses because patients with these conditions require intensive monitoring not unlike the current separately payable observation APC conditions (e.g., chest pain, asthma, and congestive heart failure), and therefore warrant separate reimbursement through observation APC 339 when criteria for the separately payable observation APC is met. The Centers appreciate CMS's continued focus on the area of observation and ask that the following conditions be reviewed by both CMS and the APC Advisory Panel's Observation Subcommittee.

- *Febrile Neutropenia*

- *Chemotherapy hypersensitivity reaction*
- *Hypovolemia, electrolyte imbalance*

H. Status Indicators

The Centers support the creation of status indicator “Q” to indicate packaged services that are subject to separate payment under OPSS payment criteria. See 70 Fed. Reg. at 42,748. Our understanding of the payment implications of codes with status indicator “Q” is that they will be paid through APC 600 when no other separately payable OPSS services are present on the claim on the same date of service. If other OPSS payable services were provided, then the OCE would not make separate payment for codes with status indicator “Q” and would instead consider the service packaged. If our understanding is incorrect, then the Centers support assigning status indicator “Q” to services that can be and truly are provided as the only OPSS payable service. Currently, CMS has not proposed to assign this status indicator to any CPT/HCPCS codes.

The Centers believe that CMS should assign status indicator “Q” to the 2006 CPT code for irrigation of implanted venous access device for drug delivery systems (expected to be 96523 in the 2006 CPT book), even though in Table 27 CMS proposes to assign this new service/code a status indicator “N”. See 70 Fed. Reg. at 42,739. The Centers request that CMS not implement this proposal because occasions exist when irrigation of an implanted venous access device is the only service rendered to hospital outpatients. If this service is not separately payable, then hospitals will be faced with the problem of having to report an E/M visit code in order to receive payment.

Private practice physicians often send patients to the hospital with an order to “flush the venous access device.” This situation typically occurs when the device is newly implanted, there has been a sluggish response by the device when blood is being withdrawn, when infusions are being administered, or after the device has been declotted. In such scenarios, it is imperative to ensure that the device stays patent. Without this service, there is a risk of the device clotting. These conditions, if untreated, could necessitate more invasive and expensive procedures, including removal of the existing device and implantation of a new device.

A registered nurse assesses the patient and uses a sterile kit and sterile needle to access the device in order to ascertain whether it is patent by receiving blood flow with aspiration and flushing of the device. With a new device, additional time is spent removing the original dressing and redressing the site. This service would not be expected to generate separate reimbursement when it is provided on the same day as other services such as IV infusion therapy, IV push medications, blood transfusions, or blood draws. As described above, however, there are times when this is truly the only service rendered and it would be more intuitive for hospitals to just charge for this service rather than being forced to submit an E/M code simply to receive payment.

The Centers appreciate the creation of both status indicator “Q” and the new code for irrigation of implanted venous access devices for drug delivery systems, and urge CMS to assign

the newly proposed status indicator "Q" to this service so that separate payment can be made when this is the only service provided on a given date of service.

I. Interrupted Procedures (modifiers 52, 73 and 74)

Since implementation of the OPPS in 2000, CMS has required hospitals to report modifiers -52, -73, and -74 to indicate procedures terminated before completion. For CY 2006, CMS is proposing to decrease payment for services when modifiers -52 and -74 are reported. See 70 Fed. Reg. at 42,751. The Centers disagree with this proposal.

1. Modifier -52

The Centers request that CMS continue making 100% of the APC payment for services reported with modifier -52. The Centers reject CMS's view that a 50% reduction in payment is warranted because fewer resources are consumed when a procedure is discontinued compared to when it is provided in full. This is simply not the case.

Procedures that are most often reported with modifier -52 are already underway and cancelled due to factors such as unforeseen complications. In these cases, the same resources are consumed as if the procedure had been completed. In some cases, the time, resources, and supplies required for the failed procedure are actually *higher* than for an uncomplicated completed procedure. Therefore, the Centers disagree with CMS's proposal to reduce payment from 100% to 50% for procedures reported with modifier -52. Because of the relatively low frequency of this modifier in the claims database, it would be shortsighted of CMS to reduce payment, as this would financially impact providers who truly must discontinue procedures and who have incurred the expense that will not be covered if only 50% of the APC payment is made.

2. Modifier 73

The Centers agree with the APC Advisory Panel's recommendation that CMS make full APC payment for services reported with modifier -73. Significant hospital resources are expended in preparing patients who will be treated in an operating or treatment room. The Centers further request CMS to remove the language "taken into the treatment room," from the current policy. It is simply not practical to expect that all patients whose procedures are discontinued are already in the operating or treatment room. Patients are often prepared for surgery in other various settings in the hospital based on space constraints that include pre-operative suites or holding areas close to the operating or treatment rooms.

Preparation in these areas requires the same level of resources, and providers incur the costs as if the preparation had occurred in the actual treatment or operating room. The current definition of modifier -73 requires the surgery to be cancelled in the room where the surgery is to occur, which essentially precludes the use of modifier -73 for procedures that are discontinued in a holding room or pre-operative suite. CMS should also recognize that just because the patient is not taken into the treatment room does not mean that sterile surgical supplies have not been opened or other resources expended (including staff time, registration of the patient, initial assessment, supplies, and drugs). In fact, scheduling constraints necessitate that the procedure room already have been prepared for the patient and sterile supplies opened, in order to expedite

the start of the procedure as soon as the patient is taken into the procedure room and positioned on the table.

Based on the current definition of modifier -73, providers cannot recoup the costs associated with discontinuing procedures prior to the administration of anesthesia if the patient has not been taken into the operating or treatment room. Providers that report an E/M code in these situations recoup a fraction of their costs, but this is only a band-aid solution with which not all providers are familiar or comfortable. Therefore, the Centers urge CMS to allow providers to use modifier -73 for cancellation of procedures for patients in a holding room or a pre-operative suite when resources have been utilized. When a procedure is cancelled prior to resource utilization, modifier -73 would be inappropriate and CMS should make this clear through written guidance.

3. Modifier -74

The Centers again agree with the APC Advisory Panel's recommendation that 100% of the APC payment should be made for services reported with modifier -74. This is CMS's current policy. The Centers urge CMS to keep it in place as providers typically face full, and often increased, costs when procedures are cancelled or discontinued after anesthesia has been administered. Providers currently report these cases with a modifier -74 and should continue to receive 100% of the APC Payment.

The majority of the upfront costs in procedure cases involving anesthesia occur in the procedure's first hour. When the physician reaches a point at which a procedure cannot be completed, the resources have already been expended. In fact, once anesthesia is administered, there is every expectation that the procedure will be completed and, therefore, supplies are opened and ready for use during the procedure. Once the usual supplies are opened and the patient has entered the room, the supplies cannot be used for a different patient. To wait to open each item until the physician is ready to use it would increase procedure time, require additional staff in the procedure room to anticipate the physician's needs, and could cause the patient to be anesthetized longer than necessary. Post-procedure care for the patient does not change when a procedure is discontinued or cancelled. In fact, the anesthesia must be reversed, the patient recovered, and post-operative pain control managed. Complications that cause a procedure to be interrupted often require longer recovery times than completed procedures, which results in increased cost to the hospital that is not covered.

Since this happens infrequently, as reported by CMS, providers absorb these extra costs, which are un-reimbursed, even if payment is made at 100%. They should not be expected to absorb even more costs because of CMS's proposal to reduce the payment of procedures reported with modifier -74 from 100% to 50%. Therefore, the Centers urge CMS to maintain its current payment policy with respect to modifier -74.

J. Implementing an Outpatient Coding and Billing Governing Body to Address Provider Questions

The Centers continue to urge CMS to release detailed coding guidance to the provider community in a timely fashion, particularly on topics for which CMS has promised guidance.

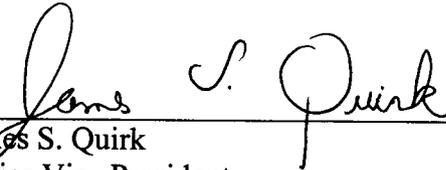
The Centers recognize the enormous amount of work required to analyze data, respond to questions, and release new rules for various PPS systems each year.

Without proper coding and billing guidance, CMS cannot expect to see comparable data from providers. Coding and billing differences will exist even in the best of worlds, but they need not be provider-driven or result from incomplete, conflicting or absent guidance from CMS. The Centers strongly believe that CMS can help improve coding and billing through greater responsiveness to provider questions, particularly in the arena of reporting drug administration services which is likely to be an operational challenge for providers in 2006 given the latest wave of changes. Therefore, the Centers recommend that CMS establish an outpatient coding and billing guidance committee that is responsible for providing answers to OPPS questions in a timely fashion and disseminating this information through a dedicated section of the CMS website.

IV. CONCLUSION

Thank you for your willingness to consider our views. We hope that CMS will address the concerns described above and make the necessary adjustments to OPPS to ensure equitable reimbursement for state-of-the-art cancer care. If you have any questions or require additional information, please contact the Cancer Centers' technical consultant, Ms. Jugna Shah, at (215) 888-6037.

Sincerely yours,



James S. Quirk
Senior Vice President
Memorial Sloan-Kettering Cancer Center



NATIONAL PATIENT ADVOCATE FOUNDATION

A National Network for Healthcare Reform

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RPT DR
Att: M. J.
Kane

VIA HAND DELIVERY

September 16, 2005

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

Re: CMS-1501-P

Dear Dr. McClellan:

The National Patient Advocate Foundation (NPAF) is a non-profit organization dedicated to improving access to health care services through policy reform. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive counseling and case management services from our companion organization, the Patient Advocate Foundation (PAF), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from diagnosis with a chronic, debilitating or life-threatening disease. From July 1, 2003 to June 30, 2004, PAF received 3.2 million requests for information and/or direct professional intervention in the resolution of access disputes.

On behalf of the people with cancer we serve, we are writing to respond to the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding the calendar year (CY) 2006 Medicare hospital outpatient prospective payment system (outpatient PPS or OPPS), CMS-1501-P, published on July 25, 2005.¹

NonPass-Throughs - Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Pursuant to section 1833(t)(16)(B) of the Social Security Act (the Act), the threshold for establishing separate Ambulatory Payment Classifications (APCs) for drugs and biologicals, currently set at \$50 per administration, will expire at the end of CY 2006 and CMS will be evaluating other packaging thresholds for these products for the CY 2007 OPPS update. CMS is requesting comments on the use of alternative thresholds for packaging drugs and radiopharmaceuticals in CY 2007.

¹ 70 Fed. Reg. 42674 (July 25, 2005).

Nancy Davenport-Ennis
Chief Executive Officer

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Doris Simonson

In comments submitted to CMS on October 6, 2003, in response to the proposed rule setting out changes to the hospital outpatient prospective payment system and CY 2004 payment rates, NPAF recommended that “[a]ll drugs should continue to have separate ambulatory payment classifications.” Our concern remains that any proposed packaging price that does not adequately reimburse providers and fairly represent market price will result in the likelihood that Medicare beneficiaries will be deprived of drug therapies. NPAF respectfully recommends that, in its consideration of the use of alternative thresholds for packaging drugs and radiopharmaceuticals in CY 2007, CMS determine appropriate reimbursement levels that will be sufficient to ensure patient access. We commend CMS for the continuation of its policy of exempting anti-emetic drugs from the \$50 per day packaging requirement, in recognition of the therapeutic importance of anti-emetic drugs in helping to alleviate the debilitating impact of chemotherapy.

CMS is also seeking comments on its proposal to establish a drug payment rate using the Average Sales Price (ASP) methodology rather than applying an equitable adjustment methodology. NPAF commends CMS for providing an opportunity to comment on this proposed payment policy. On November 14, 2002, and on October 8, 2004, NPAF provided comments to CMS on the potential use of a functional equivalence standard to set reimbursement levels for drugs, biologicals and radiopharmaceuticals, expressing concern that such a reimbursement methodology would be detrimental to patient access. As stated in our comments of October 8, 2004, the “elimination of equitable adjustment assures patients that CMS understands the need to support a process of discovery that encourages innovators to continue their quest to eliminate and control the advance of disease through biologic research.” NPAF continues to support the elimination of equitable adjustment and any comparable standards, such as functional equivalence, that restrict patient access to therapeutic alternatives and discourage innovation in biologic research and innovation in life-saving therapies.

CMS proposes payment based on 2 percent of the ASP, scaled for budget neutrality, for overhead costs associated with the acquisition and handling of drugs and biologicals. CMS has stated that it will collect hospital charge data for two years, pursuant to the establishment of three distinct HCPCS C-codes and three corresponding APCs for drug handling categories. CMS will then consider basing payment for the corresponding drug handling APCs on the charges reduced to costs in CY 2008.

As you may remember, in February, 2005, NPAF presented to CMS a study convened by the Global Access Project (GAP), and conducted by the University of Utah, Pharmacotherapy Outcomes Research Center, that identified “true cost” associated with drug-related handling for the preparation and delivery of chemotherapy doses. The GAP study was conducted within two academic medical outpatient infusion centers and two community cancer centers to collect fixed cost data. The GAP study also looked at the top fifteen drugs and regimens used across

the four sites to determine what tasks were conducted by pharmacy staff and how much time was spent in the preparation of these agents. The study's findings indicate that "the oncology pharmacist spends almost their entire day related to tasks associated with the preparation of chemotherapeutic agents," and that the "fixed costs analysis confirmed significant costs across all sites . . ." thus validating the need for the consideration of these services for reimbursement.² NPAF is pleased that CMS has recognized these costs and commends CMS for the addition of payment for overhead and related expenses, such as pharmacy services and handling costs, associated with separately payable drugs and biologicals, along with paying ASP+6 percent for specified covered outpatient drugs.

NPAF is concerned, however, that the 2% may not be sufficiently representative and that actual overhead costs associated with drugs and biologicals may exceed this proposed percentage, and also vary over time. We support adjusting this overhead cost determination based on reported hospital charges and also recommend that the findings in this study as well as further studies may assist in the determination of appropriate reimbursement for overhead costs.

NPAF would like to thank CMS for the opportunity to offer comments on CMS - 1501-P. If you require additional information, please do not hesitate to call me at (202) 347-8009.

Respectfully submitted,



Nancy Davenport-Ennis
CEO
National Patient Advocate Foundation

² *Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices*, Final Report, University of Utah, Pharmacotherapy Outcomes Research Center (on behalf of the National Patient Advocate Foundation), February 2005, p 31.



VIA HAND DELIVERY

September 16, 2005

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Jordan J. Cohen, M.D.
President

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Attention: CMS-1501-P

Dear Dr. McClellan:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "*Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (outpatient PPS or OPPS) and Calendar Year 2005 Payment Rates.*" 70 Fed. Reg. 42674 (July 25, 2005).¹ The AAMC represents approximately 400 major teaching hospitals and health systems; all 125 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

Our comments focus on the following areas: the financial impact of the OPPS on major teaching hospitals, the outlier payment policy, the multiple imaging discount, the proposed payment for overhead and handling costs of separately payable drugs, and the "inpatient-only" list.

I. CMS Should Study the Impact of OPPS on Teaching Hospitals

The outpatient PPS is the only major Medicare payment system that does not include a teaching adjustment. Teaching adjustments are included in the inpatient, psychiatric and rehabilitation facilities prospective payment systems. We urge CMS to conduct a study to determine whether teaching hospitals incur higher outpatient service costs compared to other hospital types, thereby supporting the addition of a teaching adjustment to the OPPS.

¹ I also will be referring to the correction notice for the proposed rule, which was published on August 26, 2005 (70 Fed. Reg. 50680).

The outpatient department is critical to fulfilling the missions of teaching hospitals. In addition to providing a site for clinical education for all types of health professional trainees, teaching hospital outpatient departments provide an environment in which clinical research can flourish, and are a source for specialized, unique, and referral/standby services. Because of their education and research missions, teaching hospitals offer the newest and most advanced services and equipment, and care for the nation's sickest patients. In addition, teaching hospital outpatient departments often serve as a primary source of health care for low-income Medicare beneficiaries and other individuals.

Medicare payments for hospital outpatient services represent an important source of reimbursement for teaching hospitals. Yet, according to the financial impact table contained in the correction notice of the proposed rule (70 Fed. Reg. at 50682), CMS estimates that average payment increases for major teaching hospitals in calendar year 2006 will lag significantly behind those of other hospital groups: 0.6 percent compared to 2.3 percent for non-teaching and other teaching hospitals.

The 2006 figure represents the fourth consecutive year exhibiting this disturbing disparity.² These financial impacts are particularly troublesome because teaching hospitals are more dependent on outlier, pass-through, and device-dependent APC payments, yet these payments are not stable, predictable funding sources. Through 2003, teaching hospitals could depend on transitional corridor payments to help protect against significant financial losses, but the availability of these payments expired at the end of 2003.

In the initial OPSS Final Rule, published April 7, 2000, CMS stated that it would "conduct analyses and studies of cost and payment differential among different classes of hospitals, including teaching facilities, when sufficient data under the PPS have been submitted. We will carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire." (65 Fed. Reg. at 18500). In addition, the Balanced Budget Act of 1997 requires the Secretary to establish adjustments "as determined to be necessary to ensure equitable payments . . . for certain classes of hospitals." (Section 4523 of the BBA). Pursuant to a mandate in the Medicare Modernization Act (MMA), CMS has conducted an analysis to determine whether rural hospital outpatient costs exceed those of urban hospitals. Although the regression analysis did not support an adjustment for all rural hospitals, it did support an adjustment for sole community hospitals. As a result, CMS is proposing that sole community hospitals receive a payment adjustment of 6.6 percent.

² CMS also estimated that the OPSS payment increase for major teaching hospitals would be less than that of other hospital categories in 2003, 2004 and 2005. See OPSS final rules in 67 Fed. Reg. at 66810 (Nov. 1, 2002), 68 Fed. Reg. at 63475 (Nov. 7, 2003), and 69 Fed. Reg. at 65857 (Nov. 15, 2004).

We are unaware whether CMS has done an analysis of teaching hospital costs. In the discussion accompanying the financial impact table, the Agency seems to state that the expiration of pass-through drug payments is a key factor in the low payment increases for major teaching hospitals. If the expiration of pass-through payments for drugs does play such a major role in decreased payments for teaching hospitals, we believe it is incumbent upon CMS to provide a more in-depth analysis of how the drug payment policy affects teaching hospitals.

In addition, since CMS has estimated that OPPS payments for teaching hospitals are lagging behind those of other teaching and non-teaching hospitals, we believe a comprehensive analysis is overdue. Such an analysis should not only examine the impact of other payments, such as outlier, transitional corridor and device-dependent APC payments, but also the impact of the costs associated with teaching hospitals' teaching and research missions on their outpatient cost structure. If such an analysis concludes that teaching hospitals have higher costs, like sole community hospitals, we believe a teaching adjustment would be warranted.

II. CMS Should Not Reduce the Outlier Payment Pool

Outlier payments are an important component of the OPPS because they provide some financial cushion when hospitals provide high cost services. Currently, CMS targets these payments to be 2 percent of total outpatient payments, financed by a corresponding reduction in the APC conversion factor. A hospital receives an outlier payment for a service if the hospital's cost for that service exceeds 1.75 times the APC payment rate and the cost exceeds the APC payment rate plus a fixed dollar threshold of \$1,175.

CMS proposes to decrease the outlier pool from 2 percent of total payments to 1 percent. In order to achieve this reduction, CMS would increase the fixed dollar threshold by \$400 (from \$1,175 to \$1,575). Thus, for CY 2006, payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and the cost exceeds the APC payment rate plus a \$1,575 fixed dollar threshold. The outlier payment would remain the same -- 50 percent of the service cost is above the threshold.

We oppose the reduction of the outlier pool. First, the APC payment rates continue to fluctuate, widely in some cases. We believe there should not be changes to the outlier pool until there is more stability among and across APC payment rates. Secondly, CMS has provided no data to support the proposed reduction or its impact on various classes of hospitals; the only rationale provided is a MedPAC recommendation to eliminate the outlier pool. We believe these data must be made available to allow providers to make meaningful comments as to whether the outlier pool should be increased or decreased. It is only fair to ask that if payment reductions are made, there are data to support the hypothesis that the outlier pool has been underspent and that this information is made available to the public.

As we have written in the past, we continue to believe that outpatient services that qualify for outlier payments should receive 80 percent of their costs above the threshold, rather than the current level of 50 percent. While teaching hospitals would still incur significant unreimbursed costs, increasing the payment level would help ameliorate the level of these losses for hospitals, such as teaching hospitals, that provide complex outpatient services. Increasing the payment level would also make the OPSS consistent with the policy under the inpatient PPS.

III. CMS Should Rescind the Proposal To Discount Multiple Diagnostic Imaging Procedures

Under the OPSS, hospitals receive a full APC payment per imaging procedure, regardless of how many scans the patient may have during a single episode (one day) of care.

CMS is proposing to reduce the payments for multiple imaging procedures within the same "imaging family" provided to a patient in the same encounter. Specifically, a hospital would receive full payment for the highest APC-weighted imaging procedure and then 50 percent of the APC payment for subsequent procedures.

We urge CMS to rescind this proposal pending further study. Two issues in particular highlight the need for an in-depth analysis of the proposed pricing methodology before it becomes part of the payment system. First, CMS's rationale for this proposal is that this payment would be consistent with the pricing methodology already used for multiple imaging procedures in the physician's office. However, it is unclear whether the cost structure and practice pattern (i.e. complexity of cases and imaging procedures) in the hospital setting are the same as those in the physician's office.

Secondly, even if additional procedures performed in the same encounter are less costly, CMS's proposal misses an important point: this cost efficiency is already built into each hospital's cost structure and therefore already accounted for in CMS's rate determination.

As the Agency knows, outpatient service costs, which are the basis for the APC rate determinations, are calculated by multiplying the charges on the claim by the appropriate hospital department's cost-to-charge ratio (CCR). We understand that most hospitals charge the same for single procedures as they charge for any additional procedure performed during a multiple procedure test. To the extent this is the case, then the hospital's departmental CCR is lower than it should be because the denominator is higher than it otherwise would be if the hospitals had charged less for the subsequent services. This results in a cost determination at the individual service level that is likely too low for single scans, and possibly too high for subsequent scans. As a result, the APC payment rate also is likely too low for single scans, and too high for multiple scans. However, since most hospitals do both single and multiple scans, the overall payments may be adequate.

By discounting subsequent tests performed during multiple procedures, the proposed rule essentially eliminates the amount that it possibly is overpaying for subsequent scans. However, it is still underpaying when only a single imaging procedure is performed, as well as underpaying the procedure that receive the full APC payment when it occurs in the same session with other imaging procedures. Consequently, if finalized, the proposed rule methodology would underpay all procedures, whether single procedures or multiple procedures.

We believe these issues need to be studied in more detail before any type of discounting policy is contemplated. Depending on the results of these analyses, CMS may decide that it is suitable to have no discount or a discount less than 50 percent for subsequent tests performed during multiple imaging procedures.

IV. CMS Should Reconsider Its Proposal for Drug Handling Costs

Currently under the OPDS, payments for certain separately payable drugs, biologicals and radiopharmaceuticals are based on the average wholesale price (AWP).

For 2006, CMS proposes to end payments based on the average wholesale price. Instead, it proposes to pay based on the average sales price (ASP). To cover acquisition costs, the Agency proposes to pay hospitals ASP plus 6 percent -- the same as what is paid when the drug is provided in the physician's office setting.

To cover overhead and handling costs, CMS is proposing to pay an additional amount equal to ASP plus two percent. This amount appears to be an estimate based on an analysis of overall drug costs since CMS does not have hospital charge data on handling costs incurred by hospitals' pharmacy departments when administering separately payable drugs and biologicals. In order to acquire data on drug handling and overhead costs, CMS is proposing to establish C-codes for drug handling categories and to instruct hospitals to charge the appropriate handling C-code for handling costs associated with each administration of each drug and biological.

We appreciate CMS's effort to establish accurate payment to cover drug handling and overhead costs. However, we strongly oppose the proposal to mandate the use of C-codes. According to our members, such a requirement is unduly burdensome and would create organizational "chaos" in outpatient departments. Among the many complex administrative obstacles to implementing the proposal, three issues stand out. First, implementing the C-codes would force hospitals to change their billing systems to separate out handling charges for separately payable drugs, while retaining these charges within the overall charge for those items in which the drug cost is packaged. Second, the new C-codes would be recognized by and acceptable only to Medicare, thus requiring hospitals to modify their systems to separate out these costs for Medicare, but continue to combine them with acquisition costs and bill them as a single item for other payers. Third, many hospitals use the same charge master for inpatient and outpatient services. Implementing this proposal, which is specific to the outpatient payment system, would

seemingly require modifications to the charge master to recognize drug delivery in the inpatient versus outpatient setting.

For these reasons, we strongly recommend that CMS look into other methods of gathering data for the purpose of studying handling costs. We would be eager to assist the Agency in this endeavor.

With regard to CMS's specific proposal to pay two percent of ASP to cover handling costs, we believe that this payment rate may not be adequate to cover the overhead and handling costs of drugs and biologicals, particularly those that require more intricate preparation. As the two studies conducted by the Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) demonstrated, handling costs vary greatly depending upon the type of drug involved (example: oral tablet versus compounded preparation). If a hospital has a higher utilization of drugs whose handling costs are at the high end of the spectrum, two percent of ASP would not cover those costs. Given the lack of sound handling cost data and the consequent uncertainty associated with any payment methodology ultimately adopted by the Agency, we urge CMS to compare the payment rates under the payment methodology it ultimately finalizes to the 2005 payment rates and provide an appropriate adjustment for those drugs that experience significant payment reductions.

V. "Inpatient-Only" List

Under current OPSS policy, CMS deems certain procedures as "inpatient-only" for which hospitals will not receive an OPSS payment if these procedures are performed in the hospital outpatient department. Under the proposed rule, 25 procedures would be taken off the "inpatient-only" list and paid under the OPSS in 2006.

While we appreciate that CMS has removed a significant number of procedures, we also urge CMS (as we have in the past) to accept the recommendation made by the APC Advisory Panel at the February 2004 meeting, and eliminate the "inpatient-only" list altogether. The determination of whether a patient should be admitted as an inpatient or treated as an outpatient should not be made by CMS, but rather be based on the professional judgment of the physician overseeing the patient.

If the Agency decides to retain an "inpatient-only" list, we also believe CMS must revise the criteria to determine when a procedure is removed from that list. Two of these criteria require that the procedure is being performed in "most outpatient departments" or that "most outpatient departments" are equipped to provide the service. Major teaching hospital outpatient departments often are the first places to perform services that heretofore had been performed only in an inpatient setting. Thus, there likely will be a time gap between when these services are performed safely in teaching hospital outpatient departments and "most" hospitals' outpatient departments. The criterion should be whether a procedure can be performed safely in an outpatient department, *not*

Administrator McClellan

September 16, 2005

Page 7 of 7

the number of outpatient departments in which the procedure is performed. We urge CMS to reconsider its current policy on this issue.

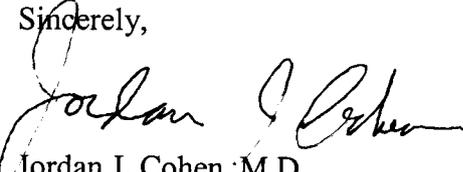
We also agree with the comments of the American Hospital Association that if the "inpatient-only" list is not eliminated, there should be an appeals process to address those circumstances in which an OPPS payment for a service provided in an outpatient setting is denied because it is on the "inpatient-only" list. These hospitals are not eligible to receive payments under the inpatient PPS, because the service was not provided in that setting. Consequently, unless hospitals have an opportunity for reconsideration, they will continue to receive no reimbursement for these services. As a result of this policy and because teaching hospitals are the first places to perform services that had previously only been performed in an inpatient setting, they will continue to be denied payment until these services are performed by "most" hospitals' outpatient departments. An appeals process could provide payments to hospitals, such as teaching hospitals, whose cutting edge technology permits them to be on the front lines of performing procedures previously considered inpatient-only, in an outpatient setting.

* * * * *

Teaching hospital's outpatient departments are critical to providing needed services to beneficiaries as well as fulfilling the mission of teaching hospitals. Medicare outpatient payments are critical for teaching hospitals to continue their missions in the outpatient setting, including serving important access roles for outpatient services that range from clinic and emergency room visits to technically-advanced innovations. We would be happy to work with CMS as it continues to refine and improve this important Medicare payment system.

If you have questions concerning these comments, please contact Karen Fisher at kfisher@aamc.org, or 202-862-6140 or Diana Mayes, at dmayes@aamc.org, 202-828-0498.

Sincerely,



Jordan J. Cohen, M.D.

cc: Robert Dickler, AAMC
Karen Fisher, AAMC
Diana Mayes, AAMC

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Outlier
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Imaging
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SEP 16 P 2:35

September 14, 2005

The Honorable Mark W. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C., 20201

RE: CMS-1501-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

On behalf of the Providence Health System, I want to offer our formal comment to CMS' Notice of Proposed Rulemaking that sets forth the proposed regulations to update payment rates and policies for the Hospital Outpatient Prospective Payment System ("HOPPS") for 2006.

The Providence Health System is a not-for-profit, Catholic health system that includes 18 acute care hospitals, 18 freestanding long term care facilities, clinics and physician groups, a health plan and home health agencies serving communities in Alaska, Washington, Oregon and California. Nearly 40% of the Providence Health System's gross revenue comes from the Medicare program with an increasingly significant portion of that total derived from the hospital outpatient prospective payment system. While these payments are an important part of the system's revenue, more importantly they enable the provision of services for tens of thousands of Medicare beneficiaries. Medicare beneficiaries represent approximately one-third of Providence's total outpatient volume.

In this letter, we offer our perspectives and recommendations to CMS on specific policy proposals made in the July 25th Notice of Proposed Rulemaking. These are:

1. The recalibration of APC average relative weights and continued instability of those relative weights from year to year;
2. Changes to the outlier payment policy;
3. A proposal to remove 25 procedures from the "Inpatient-Only" list;
4. A change in payment policy for multiple imaging services.

APC Relative Weights

For the CY 2006 proposed rule, CMS proposes to continue to use the same methodology as it used for the previous year to determine the medians on which the APC relative payment weights will be based. This includes a process to create “pseudo” single claims to capture data from claims that include multiple separately paid procedures. CMS then uses a series of adjustments and calculations to determine the median costs for CY 2006.

Despite its continuing and commendable effort to refine its processes to accurately capture median costs and the corresponding average relative weights for APCs, nonetheless the relative weights again show significant volatility in comparison with their weights from the previous two years. As noted in the proposed rule, for 65 APCs, the 2006 weights would decrease by 10 percent or more; for 11 of the APCs the reduction is greater than 20 percent. In total, 235 APCs would experience reduced weights. Alternatively, 175 APCs would increase their relative weights – with 46 APCs increasing by 10 percent or more and weights for 21 APCs growing by 30 percent or more.

This level of volatility and fluctuation in payment rates is not only difficult for hospitals to manage; it undermines the credibility of the payment system and threatens access to needed services. Furthermore, these significant changes bear no relationship to actual cost trends experienced by providers or the beneficiaries who pay the wildly-fluctuating deductibles associated with these services.

Recommendation:

In our view, the problem of continuing volatility of APC average relative weights is one that requires fundamental changes to the *billing* system. **We strongly urge, as we did in our comments on the CY 2005 proposed rule, that CMS convene a panel to look at additional data submission requirements that could greatly enhance both the reliability of these data and their subsequent use for rate-setting.** For example, many of our information systems have the ability to group data submitted on our claims and, using a “grouper,” assign an APC code at the hospital, a capability that allows us to properly manage our recording of gross receivables and contractual allowances. Therefore, we can identify the appropriate APCs represented on multi-procedure claims even though we do not submit them with identification of an APC. CMS should explore either requiring claims be submitted with an APC identified or by developing a system that groups multi-procedure claims in a fashion that is analogous to the Inpatient Prospective Payment System.

In the interim, we recommend that CMS adjust medians derived from claims data to limit the amount of change that occurs from year-to-year; a stabilization policy that adjusts medians from claims data to ensure that no APC medians fall more than five percent above or below medians used for payment in CY 2005.

Outlier Payments

In the July 25 proposed rule, CMS proposes to set the projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under the OPSS. In order to

achieve that target, CMS also proposes to modify the outlier threshold so that outlier payments are triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$1,575 fixed dollar threshold.

CMS cites in its rationale for this change the Medicare Payment Advisory Commission's (MedPAC) recommendation that the outlier policy under OPSS be eliminated altogether. CMS states that "many of the reasons cited by MedPAC for the elimination of the outlier policy are equally applicable to any reduction in the size of the percentage of total payments dedicated to outlier payments..."

Recommendation:

While we continue to support a policy direction that targets outlier payments to only the most expensive cases and have strongly argued for policies that prevent "gaming" the system to capture outlier payments, we are concerned that CMS provides no supporting data analysis to justify a reduction in the target amount, other than citing MedPAC's recommendation. Because the outlier policy is an important component of the HOPPS – particularly as more and more procedures move from the inpatient to outpatient setting, **it is incumbent upon CMS to provide data analysis to support its proposal so that stakeholders can conduct their own analyses.**

Inpatient Procedures

CMS proposes to remove an additional 25 procedures from the Inpatient-Only list in the CY 2006 proposed rule and assign 23 of those procedures to a clinically appropriate APC. We support CMS' decision to remove these procedures from the list and its ongoing evaluation of whether the procedures on the list have shifted to the outpatient setting.

However, as stated in previous comment letters, we agree with the APC panel that the Inpatient-Only list is unnecessary and should be eliminated altogether. This list is highly problematic for hospitals, due largely to the fact that physicians determine the setting in which they will perform any procedure, irrespective of whether the hospital receives payment. Providence has experience with cases involving a physician ordering an outpatient procedure that was performed at our hospital only to later discover that it was unfortunately on the Inpatient-Only List. Moreover, because the physician fee schedule and HOPPS are not linked, there is no reason for physicians to perform a procedure in the inpatient setting unless it is clinically appropriate. As a provider of health plan services in a portion of the country with one of the most efficient hospital delivery systems as measured by both utilization and length of stay, we would note that this list continues to lag behind many similar utilization expectations in the commercial and Medicaid markets. Since the Inpatient-Only List was developed under the broad authority of the Secretary to determine the services to be covered and paid for under the OPSS, **we urge CMS to eliminate the list completely and allow coverage and payment to instead be based on clinical decision-making by the physician.**

Multiple Diagnostic Imaging Procedures

In the July 25 proposed rule, CMS proposes to change the way Medicare reimburses for multiple diagnostic imaging procedures performed on contiguous areas of the body and in concurrent sessions. CMS cites its policy of paying for separate surgeries performed on the same patient in the same session at 100 percent of the highest APC rate and 50 percent for the subsequent APC as a precedent for establishing the same policy for multiple diagnostic imaging procedures performed on the same patient in the same session.

CMS would change its payment policy for CY 2006 such that for 11 "families" of diagnostic procedures by imaging modality, the APC payment will be reduced for the second and some subsequent imaging procedures performed during the same session. Full payment will be made for the highest-paying APC, with 50 percent reductions for the additional APCs if they are within the diagnostic imaging "families," not across families.

We agree with CMS' analysis that cost efficiencies can be gained by hospitals performing concurrent imaging procedures in the same session, particularly to the technical component of the costs. Moreover, it is generally in the best interest of the patients to perform these procedures in the same session whenever possible. While we do not challenge CMS' underlying premise, we are concerned with the payment policy proposed.

Our imaging center experts inform us that reducing the subsequent APC payments in these cases by 50 percent far exceeds the value of the efficiencies gained by performing them in the same session and will result in a 10 to 25 percent reduction in payment for imaging services overall. Providence Health System imaging departments estimate that subsequent imaging procedures during the same session on average cost about 25 percent less in terms of the technical component or approximately one-half of the amount proposed by CMS.

This reduction will have a greater impact on hospital outpatient imaging departments than a 50 percent cut in cases of more than two studies. For example, a triple study in CT (Chest, Abdomen, and Pelvis) would require 15 to 20 minutes of room time for room turnover and the exam; with the second and third studies reimbursed at 50 percent of the APC payment. Whereas a hospital could perform at least two fully-reimbursed, single studies in the room within the same time frame, if staged properly. As a result of these opportunity costs, the hospital is doubly affected by the reduction in reimbursement for the multiple-study session.

Consequently, we are concerned that such a change, unlike that of multiple surgical procedures, creates an incentive to change the sequence in which studies are performed and to separately schedule procedures in order to avoid a 50 percent cut in reimbursement for all but one of the procedures performed. This is particularly the case for procedures that do not involve a contrast injection (i.e., multiple spine studies or joint studies). This would be inefficient in terms of resource use and inconvenient for patients. However, the

nature of imaging – unlike surgeries – creates that potential for a change in behavior based on economic factors.

Below is an analysis of the financial impact of this proposed rule for one of our hospitals, Providence St. Peter Hospital in Olympia, Washington:

APC Code	Department Procedure	APC Rate 2006 Proposed*	PSPH Labor & Supplies	APC Rate 2006 50% **	Deficit For 2 nd Study
76705	Abdominal Ultrasound	19.46	34.53	9.73	(24.80)
76856	Pelvic ultrasound complete	19.46	34.53	9.73	(24.80)
74150	CT Abdomen without contrast	38.80	34.30	19.40	(14.90)
74160	CT Abdomen with contrast	52.52	111.67	26.26	(85.41)
72192	CT Pelvis without contrast	38.80	34.30	19.40	(14.90)
72193	CT Pelvis with contrast	52.52	111.67	26.26	(85.41)
72126	CT neck & spine with contrast	52.52	111.12	26.26	(85.41)
72130	CT Chest spine combined	62.71	44.87	31.34	(13.51)

*1st exam in sequence

**2nd exam in sequence

In proposing this policy change, CMS cited the recent analysis conducted by MedPAC¹ concerning the explosive growth of imaging services. However, that report demonstrated that the high growth of imaging services is a function of *physician* behavior and practice patterns: All of the imaging provided in the hospital outpatient setting is ordered by physicians with the hospital's role simply to provide these physician-ordered imaging tests. While productivity is appropriately concern of our hospitals, the hospital does not control utilization. Consequently, it appears to us as if the proper policy solution to the cost of imaging is first – as MedPAC recommended – to engage physicians in better understanding the appropriate, evidence-based utilization for these services. As that occurs, a more refined and targeted policy can be simultaneously developed for the proper coding and reimbursement of these tests in the outpatient setting.

Recommendation:

Consequently, we urge CMS to withdraw this proposal while more physician education and cost analysis is conducted. To the extent the agency elects not to proceed with our recommendation, the agency should at a minimum consider a higher level of reimbursement (75%) for the lesser cost procedures performed within the same family of imaging services. While CMS refers to its analysis of the costs of subsequent imaging procedures in these circumstances as supporting the 50 percent reduction in payment, it does not make the data available for view by stakeholders. Because this is such a dramatic reduction in payment for those APCs, we believe it is imperative that CMS show its justification and allow for provider input based on the CMS analysis. Our internal analysis suggests that a 25 percent reduction would be more appropriate in such instances.

¹ "Issues in Physician Payment Policy," Report to the Congress: Medicare Payment Policy, MedPAC, March 2005, p. 159.

Dr. Mark McClellan re CMS-1501-P
September 16, 2005
Page 6

Thank you for your consideration of our comments and should you have any questions on these remarks feel free to contact Charles Hawley, Vice President of Government Affairs at 206.464.4237 or e-mail at chuck.hawley@providence.org.

Sincerely,

A handwritten signature in black ink that reads "John Koster MD". The signature is written in a cursive style with a large initial "J" and "K".

John Koster, M.D.
Chief Executive Officer
Providence Health System



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September 15, 2005

Hand Delivered

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: Comments concerning Stereotactic Radiosurgery as presented in the CMS-1501-P (Proposed Rule)

Dear Administrator:

Thank you for the opportunity to comment on the CMS-1501-P proposed rule. On behalf of Elekta, Inc., we are submitting comments concerning the coding and reimbursement of stereotactic radiosurgery. We specifically address the coding changes that are being proposed for the linac and Cobalt-60 based, multi-source photon technologies. The changes that we refer to are posted in the July 25, 2005 Federal Register, pages 42708-42709. For reference, the HCPCS codes involved include: G0242, G0243, G0173, G0338, 77295, 77300, 77315 and 77370.

Elekta manufactures and sells the Leksell Gamma Knife, a Cobalt-60 based, multi-source photon device, dedicated for intracranial stereotactic radiosurgery. The company also manufactures linear accelerators used for both radiation therapy and stereotactic radiosurgery.

CMS's Proposal:

CMS is proposing to change the following codes to report stereotactic radiosurgery.

- 1.) The code used to report treatment planning for the linac based procedure (G0338), replace with 77295, 77300, 77315 and 77370;
- 2.) The code used to report treatment planning for the Cobalt-60 based, multi-source photon procedure (G0242), replace with 77295, 77300, 77315 and 77370; and
- 3.) The paired codes used to report the entire Cobalt-60 based, multi-source photon procedure (G0242 and G0243) would be replaced with one bundled code.



Introductory Summary:

- 1.) Elekta encourages CMS to keep linac based stereotactic radiosurgery coding separate and distinct from Cobalt-60 based, multi-source photon stereotactic radiosurgery coding due to the significant clinical and cost differences discussed below.
- 2.) We recommend one unique code for reporting the entire Cobalt-60 based, multi-source photon stereotactic radiosurgery procedure. There are several reasons for a single code, which include: (1) more accurate claims data collection for Cobalt-60 based radiosurgery; (2) more accurate representation of the integrated procedure (e.g. not being limited to the false dichotomy of treatment planning and treatment delivery); (3) more accurate payment for the procedure. Additional reasons are listed below.
- 3.) We also request that payment for Cobalt-60 based, multi-source photon stereotactic radiosurgery be increased so that payment is consistent with the cost of this procedure. We suggest that the procedure be placed in a higher paying New Technology APC classification until more accurate cost data are available to CMS for determining an appropriate clinical APC.

1.) Separate and Distinct Coding:

a.) Clinical Differences Between Cobalt-60 and Linac Based Radiosurgery

While the APC Panel and CMS have recommended using the same CPT codes (77295, 77300, 77370 and 77315) for treatment planning of both linac and Cobalt-60 based radiosurgery, Elekta believes that these generic radiotherapy codes do not adequately describe Cobalt-60 (Gamma Knife) based radiosurgery treatment planning. Furthermore, these codes would not sufficiently distinguish Cobalt-60 based radiosurgery treatment planning from that of linac-based radiosurgery and that which is used for hypofractionated (few fractions) radiation therapy.

The significant differences between Cobalt 60 treatment planning and linac treatment planning are discussed in a recent report by clinicians at Wake Forest University School of Medicine's Department of Radiation Oncology¹. The authors discuss in detail the differences between these two modalities. In particular, with respect to treatment planning, the authors state: "The resources used in Gamma Knife and linear accelerator radiosurgery treatment planning have inherent differences due to the fundamental design and physical properties of each particular treatment unit."²

- 1.) Personal communication with Department of Radiation Oncology, Wake Forest University School of Medicine, Winston-Salem, NC, July 2005.
- 2.) *ibid*



For example, Gamma Knife Cobalt 60-based units, which are used exclusively for intracranial, single session radiosurgery, utilize a fixed arrangement of 201 isocentrically arranged non-opposing beams. Treatment planning involves a proprietary 'shot' (irradiation placement) packing algorithm to fill the target volume with varying spheres of dose. "Complex treatments, e.g. pituitary tumors with cavernous sinus extension and approximation to the optic chiasm requiring custom plugging of individual collimators for each shot,"³ may require several hours for treatment planning.

Due to their physical design, linear accelerator systems (linacs) are used for both intracranial and extracranial applications and for single session (radiosurgery) and multi-session (fractionated radiation therapy) protocols. Linac based radiosurgery/radiation therapy systems use a variety of treatment planning systems. Some systems involve shot packing algorithms, similar to the Gamma Knife, but several systems involve static fields of fixed shapes, dynamic arcs with changing field shapes, and intensity modulated radiation therapy (IMRT). These alternative planning methods require different resources from that of Cobalt 60-based systems.

As more hospitals gain access to multiple different SRS technologies, we are seeing greater differences in patient selection and clinical applications between linac based radiosurgery/radiation therapy and Cobalt-60 based radiosurgery. The Gamma Knife is more widely used in functional neurosurgery applications (e.g. trigeminal neuralgia) and in situations where lesions are located near critical structures (e.g. pituitary tumors). In contrast, linac systems are used to treat intracranial lesions that are remote from critical structures and extracranial targets (e.g. lung metastases, liver metastases and spine tumors). Nearby critical structures require more careful and time consuming planning. Cobalt-60 based SRS is the modality of choice for lesions near critical intracranial structures.

In addition, there are important staffing differences between linac and Cobalt-60 based treatment planning procedures. In Cobalt-60 based radiosurgery, treatment planning typically involves a neurosurgeon and a medical physicist. In linac based radiosurgery/radiation therapy, either a dosimetrist or radiation oncologist performs treatment planning. Hence, there are distinct staffing differences between Cobalt-60 based radiosurgery and linac based radiosurgery/radiation therapy treatment planning processes.

3.) Personal communication with Department of Radiation Oncology, Wake Forest University School of Medicine, Winston-Salem, NC, July 2005.



In the report from Wake Forest University's School of Medicine, the authors describe the clinical differences between treating intracranial and extracranial (linacs only) targets. During the treatment planning process, one of the primary considerations for clinicians is the organs at risk, or OAR. When treating the brain, "the main OAR is neural tissue and the dose calculation assumes homogeneity throughout the brain."⁴ "With extracranial radiosurgery, the OARs are multiple."⁵ For instance, when treating lung cancer the OARs "include thoracic spinal cord, esophagus, heart and pericardium and normal lung."⁶ "There is dosimetric heterogeneity due to the air-tissue-interfaces, which need to be considered in the dose calculation."⁷ Therefore, there are planning consideration and dose calculation differences between Cobalt-60 based radiosurgery and linac based radiosurgery/radiation therapy.

In addition, Cobalt 60 based radiosurgery and linac-based radiosurgery/radiation therapy treatment planning have different billing characteristics, which we believe is an indication of the different processes of care. For example, in 2004, the percentage of total claims representing single frequency claims for Cobalt-60 based radiosurgery treatment planning (G0242) was 22% and that for linac-based radiosurgery/radiation therapy treatment planning (G0338) was 70% (more discussion on this topic in the next section; see Table 3). We believe this large difference is a reflection of the unique processes of care associated with these two treatment planning procedures (e.g. differences in dates of service, clinical protocols, hospital resources, etc.). These are just a few of the clinical differences between Cobalt-60 based radiosurgery and linac based radiosurgery/radiation therapy treatment planning.

b.) Cost Differences Between Cobalt-60 and Linac-Based Radiosurgery

Elekta maintains that, based on the Medicare claims data over the past several years, the costs of treatment planning for Cobalt-60 and linac-based radiosurgery (G0242 and G0338, respectively) are significantly different. The treatment planning code (G0242) for Cobalt-60 based radiosurgery was instituted in January 2002. At that time, there was some confusion among hospitals as to whether this code should be used for Cobalt-60 treatment planning only, or both Cobalt-60 and linac based radiosurgery treatment planning (refer to November 30, 2001 Federal Register, Vol. 66, No. 231, pages 59867 - 59869, and Program Memorandum Transmittal A-02-026, March 28, 2002). Regardless, the code had a single frequency use of 243 counts and a median cost of \$1,543 (refer to Tables 1 and 2).

- 4.) Personal communication with Department of Radiation Oncology, Wake Forest University School of Medicine, Winston-Salem, NC, July 2005.
- 5.) ibid
- 6.) ibid
- 7.) ibid



The alternative treatment planning code was CPT 77295 (hospitals typically use this code to bill for computer generated, three dimensional, radiation therapy treatment planning). Radiation therapy treatment planning is not CPT 77295, 77300, 77315 and 77370, combined. In 2002, 77295 had a median cost of \$803. Therefore, the cost of G0242 was \$740 more, or 92% greater than the cost of 77295. CMS should recognize that 77295 represented 36,809 single frequency counts, which was significantly more than 243 single frequency counts that were associated with Cobalt-60 based stereotactic radiosurgery treatment planning.

CMS should also realize that even if we compared the cost of G0242 to that of CPT 77295, 77300, 77315, and 77370 combined, there would have been a \$334 cost difference, or 28% difference from the cost of the four radiation therapy services. By making this comparison, we aren't suggesting there might be a relationship between all four radiation therapy services and radiosurgery treatment planning. We are only trying to show that there are cost differences, and they are not insignificant.

The same comparisons were made using 2003 Medicare data. G0242 had 980 single frequency counts and a median cost of \$1,398. CPT 77295 had 68,546 single frequency counts and a median cost of \$843. We should mention, in calendar year 2003, CMS requested that hospitals use CPT 77295 for all linac-based radiosurgery treatment planning (and G0242 was exclusive to Cobalt-60 based radiosurgery). The cost of G0242 was \$555 greater than the cost of 77295, or 66% greater. As before, if we compare the cost of G0242 (\$1,398) to the cost of the four radiation therapy services (\$1,254), there was a \$144 difference, or 11% variation.

Similar comparisons were made using 2004 Medicare data. In CY 2004, CMS asked hospitals to use G0338 for linac based radiosurgery and hypofractionated (few fractions) radiation therapy treatment planning. G0242 had 629 single frequency counts and a median cost of \$1,244. G0338 had 1,041 single frequency counts and a median cost of \$1,026. The cost difference between these procedures was \$218, or a 21% variation. In our opinion, this is a significant cost difference and does not suggest similarities between the Cobalt-60 based radiosurgery and linac based radiosurgery/radiation therapy modalities.

We compared the 2004 Medicare cost data of Cobalt-60 based radiosurgery treatment planning (G0242) to that of radiation therapy treatment planning (CPT 77295). CPT 77295 had 70,382 single frequency counts and a median cost of \$844. Therefore, the cost of Cobalt-60 based radiosurgery treatment planning was \$400 more than the cost of radiation therapy treatment planning, a difference of 47%.



Comparing the cost of the four radiation therapy services with Cobalt 60 based radiosurgery treatment planning, there was only a \$30 cost difference, or a 2% variation. However, for reasons, which we will discuss below (see “Trends in Billing: A Review of Medicare Claims Data”), we lack confidence in these figures.

We reiterate that Cobalt-60 based stereotactic radiosurgery and linac-based radiosurgery/radiation therapy are clinically distinct and consume different resources, and therefore, they should not share the same generic treatment planning codes. Below, we examine the CMS claims data in greater detail, which reinforces our position that the different radiosurgery and radiation therapy (linac) modalities deserve different coding. We will address more trends in the data below, which hopefully, will help clarify matters for CMS.

Recommendation

CMS’ proposal to replace Cobalt-60 based stereotactic radiosurgery treatment planning (G0242) and linac based stereotactic radiosurgery/radiation therapy treatment planning (G0338) with radiation therapy coding (CPT 77295, 77300, 77315, 77370) would provide common coding for procedures that are very different. Furthermore, this proposal would be problematic for the Gamma Knife and its hospital users. It is likely that the large volumes of single frequency counts for radiation therapy would dominate the relatively small number of single frequency counts for Cobalt-60 based radiosurgery. This would make meaningful and accurate Cobalt-60 based radiosurgery claims data collection impossible and result in reduced estimated costs for this valuable procedure (see Table 2). Because the cost differences between these procedures are significant (e.g. G0242 vs. 77295 and G0242 vs. 77295, 77300, 77315 and 77370 (except 2004 data)), it would be inappropriate to combine treatment planning coding.

Table 1
Summary of Radiosurgery/R.T. Treatment Planning Median Costs

Year	2002	2003	2004
G0242	\$1,543	\$1,398	\$1,244
G0338	N.A.	N.A.	\$1,026
77295	\$803	\$843	844
77295, 77300, 77315, 77370	\$1,209	\$1,254	\$1,274

Source: 2002 – 2004 Medicare Hospital Outpatient Claims Database
 Some information provided by Cleverley and Associates



Table 2
Summary of Radiosurgery/R.T. Single Frequency Claims

Year	2002	2003	2004
G0242	243	980	629
G0338	N.A.	N.A.	1,041
77295	36,809	68,546	70,382

Source: 2002 – 2004 Medicare Hospital Outpatient Claims Database
 Some information provided by Cleverley and Associates

2.) Single Unique Code

Trends in Billing: A Review of Medicare Claims Data

Over the last few years, the percentages of total claims for data analysis of Cobalt-60 based stereotactic radiosurgery treatment planning (G0242) and treatment delivery (G0243) have been consistently low (e.g. 14% - 33%; see Table 3). These percentages are relatively small compared to the 28% - 70% of total claims that were used for linac-based radiosurgery (G0338 and G0173). These percentages have declined from 2003. To determine the potential causes of these low percentages, we analyzed the Medicare claims data from 2002 through 2004.

Table 3
Percentage of Single Frequency Claims Used for Stereotactic Radiosurgery

Procedure	Claim Year		
	2002	2003	2004
G0242	19%	33%	22%
G0243	14%	19%	17%
G0173	28%	40%	38%
G0338	N.A.	N.A.	70%

Source: Medicare 2002 – 2004 Hospital Outpatient Claims Database
 Some information provided by Cleverley and Associates

Through our own analysis, we discovered that while hospitals were billing codes G0242 and G0243 together on the same claim (as we might have thought), they were also billing other APC paid services on the same claim. Because of CMS' single coded claim methodology for determining costs, these claims/occurrences were not used for cost analysis purposes. However, we discovered that the largest group of claims/occurrences that were not used for cost analysis was those with multiple APC paid services with bundled items and/or multiple units. The G0242 claims/occurrences with bundling and/or multiple units that were not used from Medicare's 2003 and 2004 hospital outpatient database accounted for approximately 54% and 70% of the total claims/occurrences, respectively. The G0243 claims/occurrences with bundling and/or multiple units that weren't used from Medicare's 2003 and 2004 database represented 61% and 76% of the total claims/occurrences, respectively.



Since the entire Cobalt 60 based radiosurgery procedure is performed in a single day, the likelihood that hospitals will bill treatment planning (G0242) and treatment delivery (G0243) codes together on the same claim is highly probable. Elekta is concerned that as more hospital billing personnel become more knowledgeable about Cobalt-60 based radiosurgery coding, they will bill treatment planning and treatment delivery codes together on the same claim and potentially with bundled items or multiple units. If this situation continues, more claims/occurrences will be omitted by CMS, and the number of single frequency claims/occurrences available for cost analysis will continue to decline. As a result, CMS' cost data for Cobalt-60 based radiosurgery will continue to deteriorate. We believe the cost data that is currently available to CMS is inaccurate, and therefore, it's not suitable for determining payment rates. This situation will have negative consequences for Cobalt-60 based radiosurgery hospital outpatient payment.

Recommendation

To alleviate this ongoing data problem, Elekta recommends that a single unique code, possibly G0243, be used to represent the entire Cobalt-60 based radiosurgery procedure. This recommendation would be helpful for several reasons:

- 1) it should be easier for CMS to collect and track claims data;
- 2) more data would be utilized by CMS for cost analysis (with the single coding payment methodology);
- 3) a single code would more likely capture all the components of Cobalt-60 based radiosurgery, which are more than just what is currently described as treatment planning and treatment delivery;
- 4) the data which is collected would be more accurate, because the single code should represent the entire radiosurgery procedure;
- 5) more accurate claims data would lead to more accurate payment;
- 6) there would be less chances of hospital coding errors and misinterpretation of codes;
- 7) the single code would be unique to Cobalt-60 based radiosurgery and more representative of the procedure (e.g. integrated, single session);
- 8) coding should be easier for hospital billing personnel and hopefully easy for them to institute in their billing systems;
- 9) a single code would prevent the chances of conflicting revenue codes (e.g. one revenue code used for G0242 and a different revenue code used for G0243)

With a reduction of codes, there are also potential problems. Some of these include:

- 1) failure of hospitals to include all charges into one code; charge compression;
- 2) some hospitals would continue to use multiple codes;
- 3) the code could be misused by hospitals which perform only part of the procedure;
- 4) some hospitals might be attracted to codes which have higher payments, even if code descriptors are not entirely clinically accurate; misuse/abuse

However, in this situation, we feel that the advantages of a single code would far outweigh the disadvantages.



3.) Appropriate Reimbursement

Over the last few years, CMS' reimbursement of Cobalt-60 based stereotactic radiosurgery has not been consistent with Medicare's median cost of the procedure. For instance, the median costs for treatment planning (G0242) and treatment delivery (G0243) combined, from Medicare's 2003 hospital outpatient claims database, was \$8,694 (\$1,398 (plan) + \$7,296 (del)). The 2005 payment rate for this procedure is \$6,700. Therefore, there is approximately a \$2,000 underpayment. The 2004 Medicare median cost of this procedure was \$8,058 (\$1,244 (plan) + \$6,814 (del)). Based on the arguments we presented earlier in these comments (e.g. limited and unrepresentative data), we think the 2003 and 2004 median costs are low.

Recommendation

We recommend that the new code (G0243 or other) be placed in a higher paying New Technology APC than the current APCs (1516 and 1528) to account for the combined costs of G0242 and G0243 and any other codes CMS determines as appropriate for Cobalt-60 based radiosurgery hospital billing. We believe the New Technology APC placement is important for CMS to collect accurate cost data, while it also should support appropriate payments to hospitals for their services.

We recommend that Cobalt-60 based stereotactic radiosurgery remain in the New Technology APCs until CMS has sufficient cost data to move the procedure to an appropriate clinical APC. We suggest that CMS take these factors into consideration when setting the new Cobalt-60 based radiosurgery payment rate(s) for 2006.

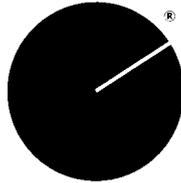
Additional Recommendation

Finally, to clarify and improve CMS' coding and payment policies toward Cobalt-60 based stereotactic radiosurgery, Elekta proposes that CMS work with a Coalition of experts in the radiosurgery field, including neurosurgeons, radiation oncologists and hospital administrators. This collaborative effort would help CMS sort through these types of coding issues. Elekta would be happy to assist in this effort.

Thank you, again, for the opportunity to comment. Should you need to contact me, please feel free to call me at (800) 535 - 7355.

Sincerely,

Soren Johansson
Vice President
Elekta



ELEKTA

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Imaging
MEG
Inf
NTAPC
Burling
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Spalten
Hostetler

Via Fed Ex

September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P. O. Box 8016
Baltimore, MD 21244-8018

Re: CMS' proposed changes for Magnetoencephalography (MEG) within the hospital outpatient prospective payment system (OPPS)

Dear Administrator:

Thank you for the opportunity to comment on the CMS-1501-P proposed rule. On behalf of Elekta, Inc., we are submitting comments concerning the coding and reimbursement of Magnetoencephalography (MEG). We specifically address the coding and reimbursement changes which are being proposed for calendar year 2006. The changes that we refer to are posted in the July 25, 2005 Federal Register, on page 42709. For reference, the HCPCS codes involved include: 95965, 95966 and 95967 (see descriptions below).

Descriptions of CPT Codes for MEG

95965: MEG recording and analysis for spontaneous brain magnetic activity. This CPT code is used for epileptic cerebral cortex localization.

95966: MEG for evoked magnetic fields, single modality. This CPT code is used for sensory, motor, language, or visual cortex localization.

95967: MEG for evoked magnetic fields, each additional modality to be listed separately in addition to code 95965 for primary procedure.

Background

The Elekta Neuromag is a dedicated, imaging device, known as magnetoencephalography (MEG). The device provides neurological mapping for both functional neurosurgery, such as the localization of epilepsy, and improved surgical outcomes in the removal of tumors. The Neuromag delivers real time, 3-D mapping of brain activity by non-invasively measuring the magnetic fields produced by the brain. The device produces functional images of brain impulse pathways that allow neuroscientists to decide where activity in the brain is being produced and how the brain functions, both normally and in disease states. MEG offers a unique combination of both fine spatial and fine temporal resolution with millimeter and sub-millisecond accuracy.



Elekta manufactures and distributes the Elekta Neuromag. Elekta leads the development of disease specific treatments with unique competencies in neurosurgery, stereotaxy, and precision radiation delivery. The history of Elekta in instrumentation and software within the MEG field spans 20 years and five system generations—from early prototypes to today's multi-channel systems covering the entire head.

Clinical Availability of MEG in the United States

By the end of 2005, there will be 20 medical institutions in the US that offer MEG in a clinical setting. About 75% of these MEGs are associated with comprehensive epilepsy programs, which assist in the diagnosis and treatment of difficult epilepsy cases.

Clinical Utility of MEG in Evaluation of the Epilepsy Procedure

MEG is useful in the evaluation of epilepsy patients, since it can be used to clarify conflicting neurophysiological data. The device can also obtain functional data prior to surgery that can help reduce the risk of surgical complications, such as reducing the number of seizures in a patient.

A clinical epilepsy case from the University of Utah, where MEG has proved to be an invaluable tool, is being submitted to CMS (see Appendix 1 – Clinical Utility of MEG). We have also provided clinical study citations involving MEG performed by several academic institutions, such as Medical College of Georgia, Massachusetts General Hospital and the University of Alabama.

MEG Benefits

MEG benefits to Medicare include increasing the chances of neurosurgical outcomes in treating epileptic patients. In addition, MEG can eliminate the need for invasive epileptic monitoring. The average savings in the study of an epilepsy patient can easily amount to \$20,000.

MEG Coding and Reimbursement History

Prior to 2003, MEG was billed by hospitals with neurology codes 95812 (EEG) and 95927 (evoked potentials, head). Effective January 1, 2002, AMA assigned three new CPT codes, 95965 (epilepsy), 95966 (tumor mapping, first evoked), and 95967 (tumor mapping, second and further). These codes were approved with both technical and professional components. Technical reimbursement in 2002 was \$150 for each of the three procedures. Also in early 2002, the American Academy of Neurology and the American Society of Neuroradiology submitted a New Technology application to CMS, and it was approved.

In 2003, these procedures were placed in the following New Technology APCs with the indicated payments:

- 95965 New Tech APC 717 with a payment of \$2,250.
- 95966 New Tech APC 714 with a payment of \$1,375.
- 95967 New Tech APC 712 with a payment of \$875.



In 2004, the three procedures were moved again to different New Tech APCs as follows:
95965 New Tech APC 1528 with a payment of \$5,250.
95966 New Tech APC 1516 with a payment of \$1,450.
95967 New Tech APC 1511 with a payment of \$950.

The three procedures currently remain (in 2005) in the New Technology APCs of 2004.

Sources: Federal Registers of November 1, 2002, vol. 67, No. 212; November 7, 2003, vol. 68 No. 216; November 15, 2004, vol. 69, No. 219 (book 2); and CMS Handout at APC Panel Meeting of August 18, 2005, MEG History, Form G-1-6.

Hospital Costs

The following costs were reported in the New Tech APC application by the American Academy of Neurology and the American Society of Neuroradiology in February 2002.

Hospital Costs for MEG Services

<u>Procedure Code</u>	<u>Hospital Cost</u>
95965	\$5,023
95966	\$4,733
95967	\$4,656

Source: American Academy of Neurology and the American Society of Neuroradiology, 2002

Analysis of Medicare Outpatient Claims Data (2002 – 2004)

(the following statistics were provided by CMS and Cleverley and Associates.)

Limited Claims Data

(refer to MEG chart provided by CMS at APC Panel meeting of August 18, 2005, G-1-6)
In 2004, only 7 single coded claims* of 95965 and 3 claims of 95966 were available for cost analysis. There were only 11 total claims submitted for these procedures. No claims were submitted for 95967.

The data available in 2003 was somewhat better. There were 19 single coded claims of 95965 and 7 single coded claims of 95966. A total of 28 claims were submitted for these two procedures. No claims were submitted for 95967.

2002 was also a lean year for MEG data. There were only 2 single coded claims submitted for 95965 and 5 claims submitted for 95966. There were only 7 total claims submitted for the entire year. Therefore, there were no claims submitted for 95967.

* Due to HIPAA regulations we are only able to report statistics that are 11 counts or greater, or statistics that have already been made public by CMS' staff.



Number of Hospitals Reporting

In 2004, there were less than or equal to 7 hospitals reporting 95965 and less than or equal to 3 hospitals reporting 95966*. Of these few hospitals, Elekta learned that one of them did not even have a MEG device. In 2003, two other hospitals reported this service, which didn't report in 2004.

* These figures were deduced from single frequency counts in CMS' Median Costs of Hospital Outpatient Services, by HCPCS code. Due to HIPPA regulations, we are restricted from reporting statistics, which are less than 11 counts, unless CMS has already publicized the information.

Reasons for Limited Data

Elekta wants to call to CMS' attention that one of the primary reasons for such low Medicare utilization is due to the average age of epilepsy patients. Most patients investigated with MEG are between the ages of 17 and 32. Because of this factor, Elekta estimates that Medicare utilization and resulting claims data will remain low, as long as epilepsy remains the primary application. Furthermore, it could be the case that in some future years no Medicare patients will be investigated on this device. However, this could change over time, as other applications are being explored and clinicians are optimistic for other uses.

Hospital Charges (2004)

The national average charge for 95965 was \$3,049, and the national average charge for 95966 was \$6,592*. No claims were reported for 95967. The discrepancy with this data is the actual cost of 95965 is greater than the cost of 95966 (see "Costs of MEG" in next section). Therefore, the charges for 95965 should have been greater than the charges for 95966.

We also wanted to compare the CMS charge information to charges obtained directly from a hospital. We contacted several hospitals, and one physician responded with his hospital's charge information (see Appendix 2 – Charges from Western US Hospital). The hospital list includes charges for both private payers and Medicare. The charges to Medicare were \$10,532 and \$10,674, well above CMS' \$3,049 and \$6,592 reported in the Medicare 2004 claims database.

* Source: Medicare Hospital Outpatient 2004 Claims Database

Costs of MEG (Medicare Claims)

(refer to MEG Chart provided by CMS at APC Panel Meeting, G-1-6, August 18, 2005)

The MEG costs reported by CMS are inconsistent. In 2004, the cost of 95965 (epilepsy) was \$688 and the cost of 95966 (tumor mapping) was \$1,435. The hospital resources and time commitment to perform an epilepsy procedure is significantly more than the cost of performing a tumor mapping procedure. The American Academy of Neurology and the American Society of Neuroradiology reported the actual MEG costs in their 2002 New Technology APC application, and CMS set the payment rates accordingly (\$5,250 for



95965 and \$1,450 for 95966, in 2004). We believe this cost discrepancy is an indication of the magnitude of the problems with this data. Also, because there were no claims for 95967, there was also no cost data for the three year period from 2002 through 2004.

In 2003, the relative cost of 95965 (\$826) was higher than that of 95966 (\$507), which was more logical than the data of 2004 in terms of proportion of resources used for both procedures. However, the cost of 95966 was extremely low in 2003. In fact, it was the lowest it had been in all three years from 2002 through 2004. We noticed that the cost of 95966 in 2002 was somewhat consistent with the cost in 2004 (\$1,435); a difference of \$514.

In 2002, the median costs were relatively similar to the figures of 2004. The cost of 95965 was \$332, and the cost of 95966 was \$1,949. Again, we have inconsistent data, where the cost of epilepsy is less than tumor mapping. As mentioned before, this is an indication of poor charging by hospitals.

Problems with Medicare MEG Claims for 2002, 2003 and 2004:

Potential Reasons for Inadequate Charging and Inconsistent Costs

1. Given the limited data in past Medicare date for the years of 2002, 2003, and 2004, there has been a "disconnect" between MEG clinicians and their hospital billing staff. MEG clinicians at various institutions have not communicated the true costs associated with operating a clinical MEG center that studies clinical epilepsy patients. The clinical department heads of MEG facilities have to assume responsibility for poor communication with their hospital billing staff during 2002, 2003 and 2004. This situation is only now (in 2005) being addressed at some hospitals.
2. There are additional reasons for why some hospital billing personnel submitted low Medicare charges on claims in 2002, 2003 and 2004. One is that MEG is a new technology and billing personnel are concerned about over charging for this new technology. Another reason is that the payment rates have changed several times over the last few years. As late as 2002, reimbursement was only set at \$150 per procedure. Frequent changes in coding and reimbursement can be confusing for hospital billing personnel and make it difficult for them to keep their billing systems current.
3. MEG may have experienced billing problems during 2002, 2003 and 2004 due to the fact that MEG is an evolving technology that has been progressing from a research tool to one of clinical utility. In 2005, MEG has become more of a clinical utility for investigating epilepsy. It is just starting to receive administrative support from hospitals that it requires to be financially sound.
4. The Medicare charge data from 2002, 2003 and 2004, as reported by CMS, are not consistent with the charge data we are obtaining directly from hospitals. It is important to note that some hospitals furnishing this information did not submit claims to CMS in 2002, 2003 and 2004.



4. (continued)

Also, the charges to third party payers are not representative of the charges CMS is reporting (see Appendix 2 - Charges from Western US Hospital).

Actual Cost of MEG

Elekta performed an Absorption Based Costing analysis of the MEG procedure. This analysis takes into account all the resources used to perform the procedure, such as personnel, equipment, building (facility), construction, supplies, operating expenses and financing. The price of the equipment is \$2,100,000 and the construction cost is \$500,000 (based on an existing facility). The analysis takes into account the depreciation of the equipment (7 years) and building facility (10 years). This information is based on the "Estimated Useful Lives of Depreciable Hospital Assets," by George S. Arges, American Hospital Association, 1998. The analysis uses an annual patient volume of 120 patients (70 epilepsy and 50 tumors), which is characteristic of one hospital. Note, we removed the research costs of this particular program and related procedures for purposes of the analysis. The total annual cost of the MEG program is \$987,760, and the procedure cost is \$8,230.

(see Appendix 3 – Absorption Based Costing Analysis (MEG))

Orphan Technology

Because of the limited number of Medicare patients who's diseases are investigated by MEG, Elekta is concerned that MEG is an 'orphan technology' and doesn't fit Medicare's methodology for determining costs of new technologies under the Hospital Outpatient Prospective Payment System. Therefore, Elekta feels this procedure, and those like it, require special consideration and other more appropriate methods of cost analysis, especially if Medicare wants these technologies to remain available to patients.

Reimbursement Concerns

1. The charge data collected by CMS is extremely limited. Elekta feels this information is not adequate for setting new payment rates.
2. There have been inconsistencies in the filings of Medicare claims by MEG institutions.
3. Revenue codes also vary by hospital (e.g. four different revenue codes in 2004 claims data).

CMS' Proposed APC Changes

CPT Code	2006 Proposed APC	2006 Proposed Reimbursement	2005 APC	2005 Reimb
95965	430	\$674	1528	\$5,250
95966	430	\$674	1516	\$1,450
95967	430	\$674	1511	\$950



Summary

1. Clinical APC assignment must be supported by adequate data.
2. CMS claims data are not representative of the true charges for MEG.
3. APC Advisory Committee recommended maintaining the current New Technology APCs and reexamination of the issue with external claims data.
4. Proposed clinical APC payment levels could severely limit access to MEG for Medicare beneficiaries.

Recommendations

Elekta believes that CPT codes 95965, 95966 and 95967 should remain in New Technology APC's 1528, 1516, and 1511, respectively, at the 2005 payment rates until sufficient and accurate claims data are available for clinical APC assignment. The above was also recommended by the APC Advisory Committee that met August 18, 2005 after presentations made by the MEG specialists from University of California at San Diego, MGH and the University of Utah.

Final Comment

CMS states in the proposed rule, "We remain committed to the overarching goal of ensuring that Medicare beneficiaries have timely access to the most effective new medical treatments and technologies... We believe that our current New Technology APC assignment process helps to assure such access."

If CMS moves the MEG procedure, or any new technology for that matter, to a clinical APC using limited, unrepresentative cost data, this won't support and is not consistent with the Agency's stated goal of ensuring that Medicare beneficiaries have access to the most effective new medical treatments.

Elekta, Inc.

Enclosures:

- 1) Appendix 1 – Clinical Utility of MEG
- 2) Appendix 2 – Charges from Western US Hospital
- 3) Appendix 3 – Absorption Based Costing Analysis (MEG)

Appendix 1

Clinical Utility of MEG

INFORMATION ON MAGNETOENCEPHALOGRAPHY FOR CMS DIVISION OF OUTPATIENT CARE

CLINICAL VIEW OF MAGNETOENCEPHALOGRAPHY

INTRODUCTION

Magnetoencephalography (MEG) is a totally noninvasive technology that has proven useful in the real time functional viewing of brain activity. MEG is unlike Magnetic Resonance Imaging (MRI) or Computer Tomography (CT) that provides structural and anatomical information.

MEG measures the magnetic fields produced by the brain and offers a combination of fine temporal resolution with fine spatial resolution with millimeter as well as sub millisecond accuracy. MEG is also commonly referred to as magnetic source imaging (MSI) when it is combined with structural imaging such as MRI.

Hans Berger, a German psychiatrist, was the first to record electroencephalographs (EEG) from humans during the 1920's. In 1929, Berger published a paper in which he first named the alpha/beta waves and began to use the initials EEG for a human electroencephalograph. EEG was soon established as a noninvasive procedure used to provide functional anatomic localization when combined with sensory stimulation to generate evoked potentials. However, this procedure has limitations in spatial resolution related to the low spatial density of surface electrodes as well as the spatial distortion of EEG signals affected by various tissue layers.

MEG has been proven to be of clinical utility allowing for improved patient management in the evaluation of epilepsy as well as the presurgical mapping of visual, auditory, somatosensory, and motor cortex functional areas.

There are 20 MEG evaluation centers located in the United States at the end of 2005. Out of these 20 MEG centers, 75% of them are associated with comprehensive surgical epilepsy programs.

BACKGROUND OF MEG

The human brain produces magnetic signals both spontaneously as well as in response to sensory stimuli. These magnetic signals are created by intracellular currents of dendrites which can be measured at the scalp using MEG. A MEG signal is very small (weak femto Telsa range), minimally affected by skull/scalp.

To record the MEG, superconduction is required since the small electrical current in the magnetic field would be lost in the energy needed to overcome the impedance of the recording coil wire. A superconducting quantum device (SQUID) immersed in liquid helium eliminates the impedance problem and allows for high sensitivity. However to successfully obtain clinical MEG, a magnetically shielded room is needed to eliminate external magnetic noise generated in a hospital environment. Magnetic noise within the MEG room can be cancelled by placing gradiometers comprising two pick-up loops wound in opposition to measure the differences of the magnetic field at two nearby locations. The nearly homogenous field arising from far away sources is thus greatly reduced. Single coil MEG systems involving magnetometers are more sensitive, but have more noise.

The first magnetoencephalogram was performed by David Cohen in 1968. The original MEG's were measured using 4-24 channel magnetometers. In 1992, a 122 channel MEG whole head system was introduced. The introduction of whole head systems with large fixed arrays varying in number from 122 to 306 channels allow shorter clinical recording sessions as well as the inclusion of simultaneously recorded EEG, increasing the yield of both MEG and EEG data during an evaluation. The advantage of MEG over EEG is that scalp and skull, each of which affects the electrical potential distributions, do not affect the magnetic signals and the MEG is able to view cortical events directly through the scalp and skull. MEG is also less influenced by the different conductivity in various brain tissues than is the electrical field, and does not require a reference as does EEG.

A mathematical algorithm called least squares technique allowing for comparison of a measured field pattern with a computer simulated forward solution derived from dipole source is used for localization in MEG. Using this technique, it is possible to localize the brain neurons that produce the recorded signal. A sound model for the neural current distribution consists of one or more point sources, current dipoles. The best fit current dipole called the equivalent current dipole can be found reliably by using the standard non-linear least squares optimization methods.

The growing sophistication of tools for analysing MEG data such as spatiotemporal analysis, evaluation of propagation features, and multiple source investigation has improved the clinical relevance of the technology in both epilepsy and presurgical mapping.

MEG devices are classified by the FDA as Class II devices that do not require Premarket Application Approval (PMA), but do require 510K clearance. MEG devices have been manufactured by a number of different companies and several models from those

respective groups have received 510K clearance from the FDA for both hardware and software.

MEG waves are recordable both at rest and after sensory stimulation using auditory, visual, and somatosensory inputs such as evoked potentials. MEG can localize sensory cortical areas with a great degree of structural accuracy. MEG generates a functional map of cortical organization. MEG is well suited for investigation of brain areas within cortical sulci. These cortical areas produce an extracranial magnetic field which can be detected by MEG. It is important to note that MEG signals are evident without resulting to complicated statistical analysis apart from signal averaging. This trait allows a clinician/researcher to evaluate signal quality during data acquisition and provides for a useful and timely MEG study.

It is possible to derive brain maps of sub-centimeter spatial resolution and millisecond temporal resolution that can be easily integrated with the patient's MRI. The Magnetic Source Imaging (MSI) procedure consists of several steps that culminate in the positioning of functional information on high resolution anatomic images provided by MRI. Once the best fit magnetic dipoles have been identified, they are coregistered on a set of sagittal, coronal, and axial MRI brain slices. This becomes the basis for clinical utility of MEG involving two patient indications.

CLINICAL UTILITY OF MEG

MEG AND EPILEPSY EVALUATION

Current estimates indicate that 20-30% of patients with epilepsy are refractory to all forms of medical therapy. These medically intractable patients are candidates for surgical treatment in an attempt to achieve better seizure control. The goal of surgical epilepsy treatment is to identify an abnormal area of cortex from which seizures originate and remove it without causing any significant functional impairment. The primary components of the presurgical evaluation for a number of years have included a detailed clinical history and primary examination, video EEG monitoring, advanced neuroimaging, and neuropsychological testing. The surgical evaluation is meant to answer whether the seizures are focal or generalized and if they are focal, are they temporal or extratemporal in origin; is there a lesion associated with the seizures; and if surgery is undertaken what functional deficits, if any, might be anticipated. MEG can play and has played a very large part in answering many of the above, delineated questions.

MEG AND EPILEPSY: CLINICAL BACKGROUND

Researchers have sought to confirm the accuracy of MEG using both direct and indirect approaches.

According to Robert Knowlton of the University of Alabama at Birmingham writing in *Epilepsia*, MEG can detect spikes that EEG does not and vice versa. In addition, Knowlton cites that given “ the classic estimate of 6cm cubic required for EEG to detect spikes, MEG may be more sensitive for convexity neocortical sources. Finally, MEG is intrinsically better at recording and detecting signals from sources that are primarily oriented tangentially to the convexity, such as intrasylvian cortex”. (1)

Direct methods of MEG accuracy in epilepsy localization mainly reflect work done with special intracranial electrodes and simultaneous intracranial/MEG recordings. Data from DF Rose published in *Epilepsia* from implanted dipoles with the intracranial electrodes in lateral, basal, and mesial regions of the temporal lobe indicated that MEG predicted localizations were respectively within 4, 2, and 1 mm of the actual locations.(2)

Knake of the Martinos/MGH/MIT/HMS Bioimaging Center presented during the Biomag 2004 meeting a study meant to evaluate the clinical impact of a combined 306 channel MEG and a 70 channel EEG recording array on the presurgical evaluation of epilepsy patients. The conclusion of the study was that MEG and simultaneously acquired EEG are complementary in the presurgical evaluation of the patient. The combined evaluation improved the selection of candidates for epilepsy surgery. (3) In addition, there was a suggestion that simultaneous MEG/EEG investigation could induce a change in the clinical management of the epilepsy patient.

In addition to using MEG as a noninvasive tool for spike localization, there is a general feeling that MEG could also be used to aid in the placement of intracranial electrodes for surgical epilepsy evaluations. It is hoped that MEG spikes would correlate well with intracranial electrodes. Sutherling in a study published in the journal *Neurology* looked at how well MEG predicted, in neocortical epilepsy, localization of discharges when compared with subdural grids used in presurgical epilepsy evaluation. (4)

In all of the patients evaluated by Sutherling, MEG localization estimates were in the same lobe as the epileptic focus determined by invasive methods and EEG.

MEG has great clinical utility in temporal lobe epilepsy (TLE) when one compares the distribution of spikes and surgical outcome related with anterior medial temporal lobectomy. Iwasaki in the *Journal of Clinical Neuroscience* compared anterior MEG spike localization with non anterior temporal spike localization, showing that patients with anterior localization became seizure free following anterior temporal lobectomy. (5) In addition, Iwasaki suggested that preoperative MEG detected additional epileptogenic foci outside a surgically resected region in patients who were not seizure free post epilepsy surgery.

During the Biomag 2004 meeting, Ossenblok presented a study from the Netherlands aimed at demonstrating that advanced source analysis of interictal MEG yields an

additional tool for preoperative localization in frontal lobe epilepsy (FLE) when compared to EEG alone. (6)

EPILEPSY CLINICAL CASE

Clinical History

The patient is a 38 year old female with a history of epileptic seizures occurring at a frequency of 3 to 4 per week. The patient also has a history of multiple head traumas. Prior ambulatory EEG monitoring and EEG video monitoring showed electrographic seizures discharges over the right fronto-temporal areas, but no discrete localization was seen. Many of the observed clinical attacks were not associated with any electrographic seizure. Interictal transients were seen over the right temporal area. One video EEG session indicated right fronto-temporal activity associated with some clinical events, but precise localization was not clear.

Imaging Studies

Prior MRI at another institution excluded mesial temporal sclerosis.

MRI was performed using a 1.5 T MRI with the following pulse sequences:

- Sagittal and axial 3D RF-Fast whole brain images
- Axial FSE proton density and T2-weighted images
- Axial and coronal FLAIR images
- Axial EXPRESS images

MRI Results:

There is an area of thickening and irregularity of the gray matter mantle involving the right perisylvian cortex which extends around the posterior margin of the sylvian fissure. This is an area of cortical dysplasia. In addition, there is diffuse cortical atrophy, more pronounced in the left hemisphere.

The MRI Impression: Right perisylvian cortical dysplasia and diffuse cortical atrophy

MEG

Magnetic Source Imaging (MSI) evaluation consisting of MEG and MRI was performed.

MEG Protocol:

Data were acquired with a whole head MEG instrument. 70 minutes of continuous data were recorded during which the patient reported that she had a seizure. Following sedation with oral Chloralhydrate, approximately 50 minutes of continuous data were recorded while the patient slept. All data were analyzed off-line for epileptiform transients. Somatosensory functioning was assessed using electrical stimulation of right and left index fingers. Fingers were used due to the fact that the patient indicated prior wrist surgery bilaterally with no thumb twitch being achieved with stimulation above the median nerve.

MEG Results:

Stimulation of the left index finger elicited a cortical response with age appropriate latency and distribution over the right hemisphere. The source of the 20 millisecond component (which has been shown in normal subjects to localize to the primary somatosensory cortex) localized to an appropriate region of the post central gyrus. Stimulation of the right index finger elicited only a very weak left hemisphere cortical response and source localization was not possible.

The spontaneous data were abnormal, showing right fronto-temporal slowing and frequent bursts of sharp transients over the right hemisphere. These bursts appear epileptiform and are likely to reflect spike trains. The epileptiform activity occurred with only one distribution. The burst discharges were over the right perisylvian region and occurred at an overall rate of 2-3 per minute, but sometimes there were bursts every 3-4 seconds. Source modeling showed this activity to originate from the right inferior parietal/frontal junction, just above the sylvian plane, but with rapid spread and reciprocal to the right superior and middle temporal gyri. The implicated superior peri-sylvian region is the region identified as dysplastic on the MRI.

There was no clear evidence for interhemispheric propagation.

At least one electrographic seizure was recorded. This seizure was characterized by an extended 25 second long burst of sharp transients. Like the interictal bursts, sources for these localized above the sylvian plane at the inferior aspect of the central frontal region.

Summary:

An abnormal MSI exam showing right hemisphere slowing and epileptiform activity appearing as bursts of sharp transients. Sources for these localized just above the sylvian plane at the inferior parietal frontal region with propagation to the superior and middle temporal gyri. Epileptic activity originates from the area of dysplasia and from the adjacent peri-rolandic cortex.

An overall conclusion of this clinical case of the MEG used to evaluate an epilepsy patient is one of an abnormal cranial MSI with epileptiform activity involving the right perisylvian region corresponding to an area of cortical dysplasia and the adjacent cortex.

The author is a neurophysiological and MEG consultant to Elekta Inc.

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1. Knowlton, R, Shih, J Magnetoencephalography in Epilepsy. Epilepsy 2004 Volume 45 Supplement 4 61-71.
2. Rose DF, Sato S Magnetoencephalographic localization of subdural dipoles in a patient with temporal lobe epilepsy. Epilepsia 1991; 32 635-41.
3. Knake S, Stufflebeam, S. et al. Whole Head MEG and EEG in the Presurgical Evaluation on Epilepsy Patient: A Prospective Study. Biomag 2004
4. Sutherling WW, Crandall PH, Cahan LD et al. The magnetic field of epileptic spikes agrees with intracranial localizations in complex partial epilepsy. Neurology 1988; 38 778-86.
5. Iwasaki M, Nakasato N, Shamoto H et al. Surgical implications by neuromagnetic spike localization in temporal lobe epilepsy Epilepsia 2002 43: 415-24.
6. Ossenblok P, de Munck, et al. MSI yields an additional tool for successful presurgical evaluation of frontal lobe epilepsy Biomag 2004.

APPENDIX

CPT CODES AND REIMBURSEMENTS IN UNITED STATES

The result of the review by the American Medical Association (AMA) was to grant MEG a Current Procedural Terminology (CPT) I code. A Category I CPT code describes a procedure or service identified with a five-digit code and descriptor nomenclature. In developing new Category I CPT codes, the Advisory Committee of the AMA requires: (1) that the service receive approval from the FDA for the specific use of the device; (2) that the procedure is performed across the country in multiple locations; (3) that many physicians perform the service/procedure; and (4) that the clinical efficacy of the service/procedure has been well established and documented.

The three CPT I codes of the MEG technology are:

95965; MEG recording and analysis for spontaneous brain magnetic activity. This CPT code is used for epileptic cerebral cortex localization.

95966; MEG for evoked magnetic fields, single modality. This CPT code is used for sensory, motor, language, or visual cortex localization.

95967; MEG for evoked magnetic fields, each additional modality (ie. Sensory, motor, language, or visual cortex localization)- to be listed separately in addition to code 95966 for primary procedure.

Thus the above CPT codes, cover three MEG procedures: pre-surgical functional mapping prior to tumor resection, assessment of brain trauma, and epilepsy localization.

Standard of Care

TriCare has established a medical policy stating that MEG is the standard of care in the treatment of epilepsy.

S. Sato of the Epilepsy Service at NIH reports that NIH has refused a multicenter study protocol because it randomized the patients. According to NIH, MEG is the standard of care and randomization would be unethical.

MEG compared with Confirmatory Testing in Epilepsy Patients

1. Knowlton et. al. 1997 University of California at San Francisco

Prospective study of 22 clinical patients to evaluate MEG for identification of epileptogenic zone.

Results:

16/22 patients had interictal spike discharges on EEG while recording MEG
11/12 patients with nonlocalizing MRI has spike sources localized with MEG

2. Lin et al. 2003 Taipei, Taiwan

Prospective study in 46 patients to compare MEG with scalp EEG to detect interictal spikes in TLE to aid in localization of epileptogenic foci.

Results:

36/46 patients had interictal spikes during MEG.

Compared with EEG, MEG gave better spike yield in patients with lateral TLE.

Combination with EEG may enhance spike detection and therefore aid in localization of epileptogenic regions.

3. Smith et al 2003 Medical College of Georgia

Retrospective study in 94 patients evaluating accuracy of MEG/MRI for localizing of epileptogenic foci.

Results:

MEG dipoles were identified in 80/94 patients. 60 patients underwent resective surgery. MSI made of MRI and MEG may have a complementary role in identifying epileptiform foci.

4. Patarraia et al 2004 University of Texas Health Science Center

Prospective study in 113 patients to compare MEG with EEG as a diagnostic tool in epilepsy surgery.

Results:

MEG and EEG results were equivalent in 32.3% of patients. MEG provided additional localization data in 40% of patients.

Several clinical trials of MEG/MSI are currently either enrolling patients or in the planning stages. One study, sponsored by the National Institute of Neurological Disorders and Stroke (NINDS), will evaluate MEG alone and together with EEG in noninvasive presurgical evaluation for patients with medically refractory epilepsy. (Clinical Trials.gov 2004)

Submitted by:

James R. Petite Ph.D.

Neurophysiologist and MEG Consultant to Elekta

September 14, 2003

Appendix 2

Charges from Western US Hospital (MEG)

Charges from Western US Hospital (MEG)

<u>INSURANCE</u>	<u>DATE of SCAN</u>	<u>Billed on</u>	<u>Amount Billed</u>	<u>Amt Reimbursed</u>	<u>Comments</u>
0 ALTIUS	January 5, 2005	3/23/05	\$10,531.80	\$6,161.10	
0 ALTIUS	January 12, 2005	3/25/05	\$10,531.80	\$6,845.67	
0 MEDICARE	February 2, 2005	4/12/05	\$10,531.80	\$4,200.66	
0 MEDICARE	February 9, 2005	4/5/05	\$10,531.80	\$4,200.66	
0 MEDICARE	February 23, 2005	4/18/05	\$10,673.60	\$4,285.51	
0 MEDICARE	March 2, 2005	4/11/05	\$10,531.80	\$5,112.66	
0 MEDICARE/BENESIGHT	March 30, 2005	4/12/05	\$10,531.80	\$6,930.66	
8 HEALTHY X	April 20, 2005	No Charges	\$0.00	\$0.00	bill re-submitted
9 ALTIUS	April 27, 2005	No Charges	\$0.00	\$0.00	bill re-submitted
0 MEDICARE/MEDICAID	April 27, 2005	7/13/05	\$10,531.80	\$4,200.66	
0 HEALTH XXXX	June 8, 2005	7/8/05	\$10,531.80	\$6,740.35	
12 MEDICAID	June 8, 2005	7/11/05	\$10,531.80	\$0.00	- Noncovered is fixed
0 IDAHO MEDICAID	June 15, 2005	7/12/05	\$10,531.80	\$3,369.92	
0 IHC CARE PLUS	July 13, 2005	8/8/05	\$10,673.65	Processing	
0 IHC CARE PLUS	July 27, 2005	8/8/05	\$10,673.65	Processing	
0 IHC CARE PLUS	July 27, 2005	8/8/05	\$10,673.65	Processing	
0 IHC CARE PLUS	August 10, 2005	8/19/05	\$10,648.00	Processing	
0 IHC SELECT/MEDICAID	August 10, 2005	8/19/05	\$10,648.00	Processing	
0 IHC CARE PLUS	August 17, 2005	Not Yet			
		Total	\$169,308.55	\$52,047.85	
		Average	\$9,406.03	\$4,337.32	

Appendix 3

Absorption Based Costing Analysis (MEG)

Absorption Based Costing
Direct and Indirect Costs
Neuromag Imaging

	Full Time Equivalents	Amortized (Yrs.) ^A	Cost (\$)	Benefits ^D	Total Annual Cost (\$)	Cost per procedure (\$) ^F	Cost Type (Direct/Indirect)
<u>Personnel</u>							
nurse	0.42	n.a.	50,000	16,667	28,000	233.33	indirect
scheduler	1.00	n.a.	25,000	8,333	33,333	277.78	direct
secretary	0.12	n.a.	25,000	8,333	4,000	33.33	indirect
admitting/registration personnel	0.05	n.a.	25,000	8,333	1,667	13.89	indirect
clerk	0.05	n.a.	25,000	8,333	1,667	13.89	indirect
transcriptionist	1.00	n.a.	35,000	11,667	46,667	388.89	direct
lab technician	0.25	n.a.	25,000	8,333	8,333	69.44	indirect
EEG technician	0.42	n.a.	35,000	11,667	19,600	163.33	indirect
neuroscientist	0.59	n.a.	112,500	37,500	88,500	737.50	indirect
				sub-total	231,767	1,931	
<u>Equipment</u>							
Neuromag System ^P	1.00	7	2,100,000	n.a.	300,000	2,500.00	direct
Couch and chair ^V	1.00	7	n.a.	n.a.	n.a.	n.a.	direct
Other room equipment ^W	1.00	5	50,000	n.a.	10,000	83.33	direct
stethoscope	0.20	5	150	n.a.	6	0.05	indirect
wheelchair	0.10	5	300	n.a.	6	0.05	indirect
Furniture -							
Office/waiting area furniture	0.12	15	10,000	n.a.	80	0.67	indirect
Computers -							
Planning Software ^H	1	3	n.a.	n.a.	n.a.	n.a.	direct
Hardware ^H	1	5	n.a.	n.a.	n.a.	n.a.	direct
internet / ethernet (scanner) connect.	0.12	5	n.a.	n.a.	n.a.	n.a.	indirect
Printer (b & w) ^H	0.12	5	n.a.	n.a.	n.a.	n.a.	indirect
Scanner ^H	0.12	5	n.a.	n.a.	n.a.	n.a.	indirect
Upgrade cost (reserve)	1	5	8,000	n.a.	1,600	13.33	direct

Other -	Full Time		Amortized (Yrs.) ^A	Cost (\$)	Benefits ^D	Total Annual Cost (\$)	Cost per procedure (\$) ^F	Cost Type (Direct/Indirect)
	Equivalents							
Telephone system	0.12		10	8,000	n.a.	96	0.80	indirect
Stereo	0.12		5	300	n.a.	7	0.06	indirect
Refrigerator	0.12		10	300	n.a.	4	0.03	indirect
Television	0.12		5	300	n.a.	7	0.06	indirect
<u>Building</u>						311,806	2,598	
Neuromag imaging room ^I	0.00		10	n.a.	n.a.	n.a.	n.a.	direct
Neuromag planning room ^I	0.00		10	n.a.	n.a.	n.a.	n.a.	direct
Patient waiting area ^I	0.00		10	n.a.	n.a.	n.a.	n.a.	direct
Elevator ^O	0.04		15	60,000	n.a.	160	1.33	indirect
Reception area	0.12		10	n.a.	n.a.	n.a.	n.a.	indirect
Nurse office	0.12		15	n.a.	n.a.	n.a.	n.a.	indirect
Administrative offices	0.12		15	n.a.	n.a.	n.a.	n.a.	indirect
HVAC (main hospital) ^J	0.000		15	1,500,000	n.a.	0	0.00	indirect
Parking (main hospital) ^J	0.000		25	5,000,000	n.a.	0	0.00	indirect
<u>Supplies</u>						160	1	
I. V.	n.a.		n.a.	3.00	n.a.	118.80	0.99	direct
catheter	n.a.		n.a.	16.62	n.a.	132.96	1.11	direct
syringes	n.a.		n.a.	5.26	n.a.	21.04	0.18	direct
bandages	n.a.		n.a.	3.33	n.a.	133.2	1.11	direct
dressings	n.a.		n.a.	2.56	n.a.	10.24	0.09	direct
applicators, cotton	n.a.		n.a.	2.64	n.a.	10.56	0.09	direct
electrodes	n.a.		n.a.	4.43	n.a.	106.32	0.89	direct
alcohol	n.a.		n.a.	0.43	n.a.	13.76	0.11	direct
scrubs ^X	0.12		1	80.00	n.a.	9.60	0.08	indirect
sheets/pillows ^X	0.12		1	80.00	n.a.	9.60	0.08	indirect
gloves (disposable)	n.a.		n.a.	5.90	n.a.	88.08	0.73	direct
washcloths	n.a.		n.a.	2.19	n.a.	8.76	0.07	direct
cups	n.a.		n.a.	0.24	n.a.	1.92	0.02	direct
urinals	n.a.		n.a.	0.26	n.a.	5.2	0.04	direct
sub-total						670	6	

Full Time Equivalents	Amortized (Yrs.) ^A	Cost (\$)	Benefits ^D	Total Annual Cost (\$)	Cost per procedure (\$) ^F	Cost Type (Direct/Indirect)
				0	0	direct
				0	0	direct

Medications

Full Time Equivalents	Area (s.f.)	Cost (\$)	Cost per s.f. (\$)	Annual Cost (\$)	Cost per procedure (\$)	Cost Type (Direct/Indirect)
1.00	n.a.	500,000	278	50,000	416.67	direct
0.00	1,000	45,000	45	0	0.00	direct
0.00	800	224,000	280	0	0.00	direct
0.00	n.a.	60,000	33	0	0.00	direct
		sub-total		50,000	417	

Construction

construction (hard and soft costs & structural work)^U
 office (waiting area, office, planning room, etc.)^B
 shielded imaging room (based on pre-existing structure)^C
 architectural fees (12% of hard and soft costs)

Operating Expenses^E

maintenance contract (Neuromag) ^C						
helium						
marketing ^Z						
utilities ^Z						
insurance ^Z						
real estate taxes ^Z						
1.00	n.a.	120,000	n.a.	120,000	1,000.00	direct
1.00	n.a.	30,000	n.a.	30,000	250.00	direct
0.12	n.a.	50,000	n.a.	6,000	50.00	direct
0.12	2,500	8,000	3.2	960	8.00	indirect
0.12	2,500	15,000	6	1,800	15.00	indirect
0.12	2,500	5,000	2	600	5.00	indirect
		sub-total		159,360	1,328	

Financing

1.00	n.a.	234,000	n.a.	234,000	1,950	direct
		sub-total		234,000	1,950	

Total cost per procedure:

120 pat. scans \$987,763

\$8,231

Direct cost: \$6,936
 Indirect cost: \$1,296

84.00%
 16.00%

Notes:

- A. Arges, George S. "Estimated Useful Lives of Depreciable Hospital Assets," revised 1998, American Hospital Association, American Hospital Publishing, Inc., 1998.
- B. Office construction is typically \$50 - \$60 per square foot.
- C. The shielded imaging room costs more to construct with an existing structure than if it was new construction.
- D. Personnel benefits are 33% of total compensation. Benefits include: vacation, seminars/conferences, and travel.
- E. The 2,500 s.f. area used to expense utilities, insurance and taxes takes into consideration the common areas.
- F. Patient volume at Neuromag center is 120 patients/year.
- G. Software upgrades included with annual maintenance contract.
- H. Software and hardware included in price of system.
- I. Cost to build Neuromag suite, planning area, offices and waiting room are included in \$500,000 construction cost (allocated under "Construction").
- J. Hospital operates at 75% capacity.
- O. Elevator throughput equals 3,000 patients per year.
- P. Case mix - of the 120 patients scanned per year, 70 are Epilepsy and 50 are tumor patients.
- Q. Annual service contract is \$120,000 beginning in the second year of operation. Assumes life of Neuromag is 7 years.
- R. Cost of annual maintenance contract equals approx. 6% of the equipment cost. The procedure cost is based on the annual volume of 120 patients per year.
- S. Interest is calculated at 9% per year.
- T. Cost model based on program at Massachusetts General Hospital, Boston, MA.
(capital equipment and construction costs are representative of new sites)
- U. This line item includes those construction line items listed below.
- V. Included in price of system
- W. Includes patient monitoring devices; oxygen; other patient support systems
- X. Sheets, pillows and scrubs shared w/ main hospital. FTE is percentage of use.
- Y. Sub-total figures are rounded to the nearest whole number.
- Z. Marketing, utilities, insurance, and real estate taxes shared w/ main hospital.



RECEIVED - CMS

September 9, 2005

2005 SEP 16 A 11: 53

Imaging / MEG
APC / on

Burley

Marc McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.
Washington, DC 20201

Reference: CMS 1501-P

Dear Dr. McClellan,

Thank you for this opportunity to submit comments on the proposed APC assignment of the three magnetoencephalography (MEG) CPT codes 95965, 95966 and 95967. VSM MedTech Ltd. manufactures and markets medical devices for the diagnosis and treatment of neurological disorders and cardiovascular diseases, and is one of the leading suppliers of MEG systems for noninvasive imaging of brain function.

VSM MedTech is very concerned with the proposed assignment of the three MEG CPT codes to APC 0430, Nerve and Muscle Tests Level IV. The proposed APC payment level of \$676.75 is entirely inadequate and will not cover the acquisition and operating costs of providing MEG services. In addition, VSM is concerned that under the proposed changes the status indicator for each of the codes would be changed from "S" to "T" resulting in a 50% reduction in payment when one of the procedures is performed in combination with another procedure.

The MEG codes are currently assigned to three New Technology APCs. Code 95965 is in APC 1528 with a payment level of \$5,250, code 95966 is in APC 1516 with a payment level of \$1,450 and code 95967 is in APC 1511 with a payment level of \$950. The New Technology APC assignments are reflective of the costs of providing MEG services and recognize the differential in costs between the three services.

Several providers of MEG services presented this issue at the APC Advisory Committee meeting held on August 18, 2005. Following its discussion, the APC Advisory Committee voted to recommend that CMS retain the current New Technology APC assignments for the MEG codes for 2006. We strongly endorse this recommendation. The Committee also discussed the need to collect more accurate data that could be used in helping CMS determine a permanent APC assignment for MEG services. We agree with this need and commit to

working with MEG providers and CMS to collect hospital cost and charge data. We would also urge CMS to apply a status indicator of "S" for these codes since the current payment rates reflect appropriate differentials in the costs of performing these services and any economy of scale for add-on procedures.

Magnetoencephalography (MEG) is a revolutionary medical imaging technology that provides unprecedented insight into the workings of the human brain through the measurement of electromagnetic activity. MEG identifies brain activity associated with various human functions in real time, with millimeter spatial accuracy. This non-invasive approach is used to evaluate neurological disorders and plan surgical treatments. There are three CPT codes that describe MEG procedures. Under CPT code 95965, MEG is used as part of the noninvasive presurgical evaluation of epilepsy patients to determine if epileptic activity is concentrated in one or a few focal regions and whether those regions are candidates for surgical resection. Under CPT codes 95966 and 95967, MEG is used prior to surgery to identify functional areas of the brain, including visual, language, auditory and somatosensory cortex, and to minimize the risk of neurological damage to these areas during surgery. It is not unusual for an individual patient to receive two or more of these diagnostic tests in succession.

MEG is a highly specialized service used to evaluate patients with intractable epilepsy and other patients considering neurosurgery near areas of eloquent cortex. Most patients who receive MEG services are relatively young, and therefore the volume of Medicare services is low (the majority of Medicare claims are for individuals that qualify for Medicare due to their disability). While we do not believe that the volume of Medicare claims will increase significantly, it is extremely important to provide adequate reimbursement due to private payers' use of Medicare's hospital outpatient payment system in setting their own payment rates.

The proposed payment rate of \$676.75 for all three codes would not cover the costs of providing MEG services. In reviewing the claims data made available by CMS, there were a total of ten single claims for MEG services in 2004, seven for 95965 and 3 for 95966. There were no claims for 95967. We question whether ten claims is a sufficient number for CMS to make an estimate of hospital median costs. We are also concerned about the quality of the data. For 95965, the calculated median cost was \$688.16 and for 95966 the median cost was \$1,498.11. In addition to the absolute level of payment being inadequate, there is an anomaly in the hospital charge data. Code 96565 is much more costly to perform than code 96566, however CMS' median cost data based on the hospitals' submitted charges shows the opposite relationship.

A total of five hospitals submitted one or more claims for outpatient MEG services. Our sense is that hospitals incorrectly coding (one of the hospitals that submitted a claim does not even provide MEG services) and/or submitting charge data reflecting less expensive imaging

services likely led to the inaccuracy of the estimated median costs. We ask that CMS not base a reassignment of the MEG codes on this small number of claims with such obvious errors.

In conclusion, VSM MedTech requests that the MEG codes remain in their current New Technology APC categories and that the codes' current status indicator of "S" be maintained in 2006. In addition, VSM will work with those hospitals providing MEG services to collect cost data that can be used to determine a more appropriate APC payment level for these services.

Thank you for your consideration of these comments. Please contact me if you have any questions related to the information provided.

Sincerely,

A handwritten signature in black ink, appearing to read "Jack E. Price". The signature is fluid and cursive, with a prominent initial "J" and a long horizontal stroke at the end.

Jack E. Price
President and Chief Executive Officer
VSM MedTech Ltd.



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NATIONAL HEMOPHILIA FOUNDATION

for all bleeding disorders

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2005 SEP 16 A 11: 54

CCPIS Ritten
BBP Hunter

September 16, 2005

Mark McClellan, M.D., Ph.D.

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

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Alan J. Kinniburgh, PhD
Chief Executive Officer
New York, NY
ex officio

RE: CMS 1501-P: Prospective Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

I am writing in response to the July 25, 2005 proposed rule for 2006. The National Hemophilia Foundation (NHF) is the largest health care advocacy organization serving the needs of individuals with bleeding and clotting disorders. These comments are focused on persons with hemophilia, von Willebrand disease, and other bleeding disorders who require blood clotting factors.

The National Hemophilia Foundation recommends that, similar to the Part B drug reimbursement policy and the proposed inpatient administration fee, an additional payment of \$0.14 a unit of clotting factor (which will be updated in the Medicare Part B / Physician Fee Schedule final rule for 2006) be provided for patients receiving clotting factor under the Medicare hospital outpatient PPS. NHF is concerned that the proposed additional payment of 2% of ASP does not fully cover hospital costs of procuring, storing and furnishing clotting factor to patients with hemophilia.

BACKGROUND

Hemophilia and other bleeding disorders occur when any one of several essential proteins necessary for clotting is missing. Without treatment, individuals with a bleeding disorder may bleed internally, which can be fatal or can severely damage joints. Although there is no cure, there is effective treatment. Clotting factor, derived either from human plasma or manufactured through recombinant technology, is infused to compensate for the missing protein. Persons with bleeding disorders generally are taught to self-infuse clotting factor and manage bleeds at home, in order to treat the bleed as soon as it occurs and minimize complications.

116 West 32nd Street • 11th Floor
New York, NY 10001

(800) 42-HANDI • (212) 328-3700 • fax (212) 328-3777

www.hemophilia.org • info@hemophilia.org

Most Medicare beneficiaries with a bleeding disorder are eligible for the program due to their disability caused by the severity of the disease and its complications. These complications include joint damage from a history of frequent bleeds, as well as HIV/AIDS and hepatitis B and C, which were transmitted through contaminated blood products in the 1970s and 1980s. Approximately 1,100 individuals with a bleeding disorder receive Medicare benefits.

MEDICARE PAYMENT FOR CLOTTING FACTOR

Clotting factor is covered under Parts A and B of the Medicare program. Like most other Part B Medicare covered drugs, payment for clotting factor transitioned to a new formula, beginning January 1, 2005, as a result of provisions in the Medicare Modernization Act (MMA). The new formula is average sales price (ASP) plus six percent. Under the new formula, providers of clotting factor also are paid an additional administrative fee to cover the costs of providing the product to Medicare beneficiaries. This fee was set at \$0.14 per unit of clotting factor prescribed for 2005 and is required to be updated annually.

In the hospital inpatient setting, an add-on payment is made to hospitals for clotting factor provided to patients above and beyond the diagnosis related group (DRG) payment. This payment rate currently is 95 percent of average wholesale price (AWP). For 2006, CMS has proposed setting the reimbursement rate and the administration fee for clotting factor used in the hospital inpatient at the same rate as for drugs provided under Part B.

PAYMENT IN THE HOSPITAL OUTPATIENT SETTING

In the hospital outpatient setting, clotting factor is reimbursed as a non-pass-through biological under the prospective payment system for drugs and biologics. MMA requires CMS to utilize hospital acquisition survey data to develop a revised prospective payment system for outpatient drugs and biologics. Using cost data furnished by the U.S. General Accounting Office, CMS is proposing to base hospital outpatient drug payment for 2006 on ASP plus six percent plus an additional two percent fee to cover handling costs. This proposed change is intended to bring Medicare drug payment in the hospital outpatient setting in line with payment in other settings, while also recognizing the costs incurred by hospitals in procuring, storing, and furnishing drugs.

The National Hemophilia Foundation strongly supports the concept of recognizing the additional administrative costs incurred by providers in furnishing drugs and biologics. The Foundation supports the administration fee currently paid to providers of clotting factor under the Part B drug payment system and proposed by CMS for hospital inpatient payment for clotting factor beginning in 2006 and believes that the hospital outpatient administration fee should not be treated differently. The costs of inventory, specialized refrigeration, assay management and formulation of clotting factor are

similar for all providers of these drugs and certainly do not vary between the hospital inpatient and outpatient setting. The National Hemophilia Foundation is concerned that the proposed two percent of ASP does not fully cover the additional costs of furnishing clotting factor to Medicare beneficiaries in the hospital outpatient setting. The National Hemophilia Foundation urges CMS to apply the Part B administration fee (\$0.14/unit as updated for 2006), as it has proposed in the hospital inpatient setting, to the hospital outpatient setting as well.

Within the context of outpatient care, the volume of clotting factor is low. Individuals with hemophilia are likely to receive infusions of clotting factor in the hospital outpatient setting as result of an emergency or trauma situation, a severe bleed that can not be controlled, or a scheduled outpatient procedure. A small number of Medicare-eligible individuals also rely upon hospital outpatient services for regular infusions to treat their bleeds.

I appreciate your attention to this matter of great importance to persons with hemophilia and other bleeding disorders who are dependent upon these life-sustaining products. Please contact Glenn Mones, NHF's Vice President for Public Policy, at 212-328-3755 if you have any questions regarding this request, or need any additional information.

Sincerely,

Alan J. Kinniburgh, Ph.D.

Alan J. Kinniburgh, Ph.D.
Chief Executive Officer



4-D | NEUROIMAGING

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September 6, 2005

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2005 SEP 15 A 11: 54

Marc McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.
Washington, DC 20201

*Inquiry
MEG
APC*

Burley

9727 Pacific Heights Blvd.

San Diego, CA

92121-3719

Reference: CMS 1501-P

Dear Dr. McClellan,

On behalf of 4D-Neuroimaging, a manufacturer of Magnetoencephalography (MEG) instrumentation based in San Diego, CA, I wish to comment on the proposed assignment of the three MEG Codes 95965-95967 to APC 0430, Level IV Nerve and Muscle Tests. This proposed APC assignment and payment rate of \$676.75 is grossly inadequate and would not cover the costs of providing MEG services. For this reason, 4-D Neuroimaging supports the APC Advisory Committee's recommendation that CMS retain the current new technology APC assignments for the MEG codes. In addition, we recommend that CMS maintain the "S" status indicator for each of the codes.

Phone

858.453.6300

Fax

858.458.5698

MEG is a non-invasive procedure that essentially superimposes the precise location of the source of seizure activity or evoked sensory activity onto MRI images of the brain. It is principally used for determining the appropriateness of surgery in epilepsy patients whose seizures cannot be well controlled by drug therapy. In addition, for all patients undergoing a neurosurgical procedure of the brain, MEG is used to locate the precise regions of the brain responsible for sensation, movement, vision and hearing relative to the surgical target. This enables the neurosurgeon to avoid inadvertently injuring the parts of the brain critical to these functions.

www.4dneuroimaging.com

Because of the highly specialized nature of the MEG technology, it is used at a very limited number of sites, primarily teaching facilities and specialized epilepsy centers. Currently, there are approximately 10 hospitals in the United States where MEG services are provided. We believe that this number will not substantially change in the next few years.[FYI I agree with this because most near term installations will be outside hospitals. OK?] It should also be noted that MEG is rarely provided to Medicare beneficiaries over the age of 65. A limited number of candidates for epilepsy surgery qualify for Medicare due to their disability, but the vast majority of patients that receive MEG services are privately insured.

The MEG codes are currently assigned to three New Technology APCs. Code 95965 is assigned to APC 1528 with a payment rate of \$5,250. Code 95966 is assigned to APC 1516 with a payment rate of \$1,450. And, Code 95967 is assigned to APC 1511 with a payment rate of \$950. Under the proposed rule, all three codes would be assigned to APC 0430, Level IV Nerve and Muscle Tests, with a payment of \$676.75. In addition, under the proposed rule, the status indicator would be changed from "S" to "T", so that when one of the procedures is performed in combination with another procedure, payment would be reduced by 50 percent.

The assignment of the MEG services to an APC paying \$676.75 is grossly inadequate and would not remotely cover the costs of providing these valuable services. The MEG equipment has a price of approximately \$2.3 million with an annual maintenance cost of \$120,000. The other large fixed cost item is \$22,000 per year for helium, which is used to cool the equipment regardless of the number of services provided. Labor costs for these services are also significant as both Registered EEG Technologists and Ph.D. Neurophysiologists prepare and provide the patient the service[OK as edited]

In analyzing the data used by CMS to assign MEG to APC 0430, there were a total of 7 single claims for Code 95965 with a calculated median cost of \$688.16, 3 single claims for Code 95966 with a median cost of \$1,498.11 and zero claims for Code 95967. We do not think that this is an adequate number of claims to make a reasonable estimate of hospital median costs. The cost data derived from the hospital charge data also is illogical in terms of the relative costs of the procedures. That is, Code 95965 is much more costly to perform than Code 95966 (which is reflected in the current APC assignments) while CMS's median cost data showed the opposite relationship.

Further analysis indicated that these claims came from five different hospitals, each submitting one or two claims. These hospitals' charging practices led to estimated median costs that do not reflect the actual costs of providing MEG services. We suspect that some hospitals misunderstood the code and/or set their charges in relationship to some other imaging service, such as MRI, which is much less costly. In any case, it is clear that CMS should not be basing a national payment rate (and potentially influencing the rates of private payers) on this handful of claims with obvious erroneous charges.

We are also concerned that the MEG codes were placed in an APC for nerve and muscle tests. As stated above MEG is a neurophysiological technique that measures the magnetic fields generated by neuronal activity of the brain. It provides information about both the structure and function of the brain. It clearly should not be considered to be in the family of nerve and muscle tests.

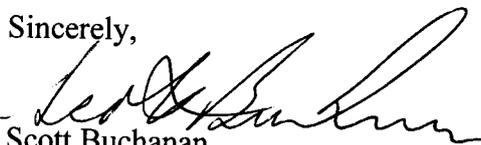
At its August 18 meeting, the APC Advisory Committee heard testimony from three clinicians that provide MEG services. As a result of these presentations, the Committee voted to recommend that CMS retain the current New Technology APC levels for the MEG Codes for 2006. 4D Neuroimaging strongly endorses this recommendation. Consistent with the advice of

the APC Advisory Committee, we certainly agree that there is a need for the manufacturers and providers of MEG technology to work with CMS in gathering cost and charge data from hospitals for all MEG patients to assist CMS in determining an appropriate APC rate for MEG in future years.

We would also urge CMS to maintain the status indicator of "S" for these codes since the current APC payment rates reflect appropriate differentials in the costs of performing these services and any economy of scale for add-on procedures.

Thank you for the opportunity to offer these comments. If I can answer any questions regarding these comments please contact me directly at (858) 458-5657 or by e-mail: scott@4dneuroimaging.com

Sincerely,

A handwritten signature in black ink, appearing to read "Scott Buchanan", written over a horizontal line.

Scott Buchanan
President and CEO

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APC

Burley
Heppner

September 15, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

The Society of Gynecologic Oncologists wishes to provide comments on the "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" published in the Federal Register on July 25, 2005 as a proposed rule with the comment period ending on September 16, 2005.

The Society of Gynecologic Oncologists (SGO) is a national medical specialty society of physicians who are trained in the comprehensive management of women with malignancies of the reproductive tract. Its purpose is to improve the care of women with gynecologic cancer by encouraging research, disseminating knowledge, which will raise the standards of practice in the prevention and treatment of gynecologic malignancies, and cooperating with other organizations interested in women's health care, oncology and related fields.

SGO's members make it the leading organization of gynecologic oncologists in the United States. As gynecologic oncologists, our members are women's cancer specialists who have received an additional 3-4 years of intensive medical training in the study and treatment of malignancies arising in the female reproductive tract

Our comments will address CMS' proposal to move CPT code 57155 from APC 193 to APC 192.

Proposal to Move CPT 57155 from APC 193 to APC 192

CMS proposes to move CPT 57155 Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy from APC 193 Level V Female Reproductive Procedures to APC 192 Level IV Female Reproductive Procedures. The current payment for CPT

57155 is \$758.17 and decreases by 66.4% in 2006 with assignment in APC 192 with a 2006 proposed payment of \$255.66. We note that some CPT codes were moved to different APCs without a discussion in the preamble providing the rationale for the changes. For example, there was no discussion in the proposed rule regarding the proposed assignment of CPT 57155 to APC 192 and we are concerned that a reduction of 66% could have a negative impact on Medicare beneficiaries' access to this important treatment for vaginal and/or uterine cancer. In addition, nothing has changed in the technology or provision of these services that would justify a reduction in reimbursement for this procedure. The typical patient who requires this procedure has a locally advanced cancer of the lower genital tract, often with compromise of adjacent pelvic organs (bladder and/or rectum). These factors significantly complicate the placement of the brachytherapy equipment, increase the time to complete the procedure, and often require use of additional equipment beyond the standard tandem and ovoid set-up.

- The SGO recommends that CMS maintain CPT 57155 in APC 193 Level V Female Reproductive Procedures. Further, we request that all changes to APC assignments be listed in the preamble for future proposed and final rulemaking.

The SGO appreciates the opportunity to provide comments on this proposed rule. If the Society can provide CMS with additional information regarding this matter, please do not hesitate to contact Jill Rathbun, SGO Director of Government Relations at 703-486-4200.

Sincerely,

Gary S. Leiserowitz, MD
Chair, Coding and Reimbursement Ctme.

Carol L. Brown, MD
Chair, Government Relations Ctme.



162

Joint Council of Allergy, Asthma and Immunology

50 N. Brockway Street Suite 3-3 Palatine, IL 60067 Voice: 847-934-1918 FAX: 847-934-1820 E-Mail: info@jcaai.org

September 16, 2005

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By Courier

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

Re: Proposed Rule on Hospital Outpatient Payments for 2006

Dear Dr. McClellan:

The Joint Council of Allergy, Asthma and Immunology is pleased to submit comments on the proposed rule on hospital outpatient prospective payment rule (HOPPS) for 2006 as published in the July 25, 2005 Federal Register. JCAAI is an organization sponsored by the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. It represents the interests of over 4,500 physicians board-certified in allergy and immunology.

Payment for IVIG

We are very concerned about the effect of the drastic reduction in payment for intravenous immunoglobulin (IVIG) on our patients with primary immune deficiency disease. Currently, the payment rate for IVIG in the hospital outpatient setting is \$80.68 per gram. The proposed 2006 OPPS payment rate for liquid IVIG is \$56.71 and \$39.46 for lyophilized. This represents reductions of 30% and 51% respectively. Hospitals may decide that they are unable to absorb these reductions in reimbursement, especially where payment is below hospital acquisition cost. In some communities, hospitals have become the provider of last resort for IVIG due to the payment

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reductions imposed on physician offices and infusion centers already in effect. The reduced payment amount will likely result in many hospital clinics deciding not to acquire, stock and administer IVIG therapy. This will create serious access problems for Medicare beneficiaries who rely on IVIG and may well lead to adverse health consequences among this vulnerable population.

One solution to this is for CMS to adopt a dampening provision that will limit the reduction in payment rate for IVIG to 15% during the first year of the new payment methodology. This would give hospitals time to adjust to the lower reimbursement rate and implement cost efficiencies in their clinics. At the same time, it would have a less severe impact on patient care.

Payment for Administration of IVIG

Administering IVIG to patients with primary immune deficiency disease is a complex undertaking which typically takes between three to eight hours, and requiring careful monitoring by a trained infusion nurse.

In primary immune deficiencies and in other indications, IVIG modifies aberrant immune response to protect, maintain and restore normal physiology to prevent disease. As is commonplace with this type of therapy, adverse events (AE) occur frequently, and the risk of severe adverse effects (AEs) is real. For example the FDA licensing studies of IVIG for patients with primary immune deficiency disease include an occurrence of AEs as high as in 72% of patients. There are also severe AEs, many of which are acute, including thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress syndrome, and transfusion associated lung injury. All IVIG products also include a black box warning regarding acute renal failure. The proper diagnosis of acute AEs in the context of IVIG infusions requires expert supervision and skilled intervention. This is necessary to minimize the impact of the AEs to the patient receiving treatment and in some cases can be life-saving.

Given the gravity and acuity of risks in administering IVIG, special precautions are required. These include careful monitoring of the entire infusion process which can be as short as three to four hours, but as long as eight hours. Expert nursing care by registered nurses skilled in the administration and risks of IVIG is essential. Nurse to patient ratios of 1:1 and never less than 1:2 are essential to allow frequent clinical assessment (including neurological checks), measurement of vital signs every 15 minutes (including temperature, respirations, heart rate and blood pressure) and comprehensive documentation. Physician and nurse assessment of a patient to determine suitability for the infusion is also necessary as certain comorbidities of the primary diagnoses can preclude, or alter the administration of IVIG. The immediate availability of the physician to evaluate the patient at any point during the infusion for assessment of potential

complications is also critical. Finally, preparedness for a number of interventions to manage common infusion-related complications, including adjustment of the infusion rate, supplementation with physiological fluids, and provision of analgesics, non-steroidal anti-inflammatories, bronchodilators, antihistamines, steroidal anti-inflammatories, or occasionally systemic sympathomimetics is also required. Clearly, the safe and effective prescription and administration of IVIG requires a highly skilled and coordinated effort from both nurse and physician.

For these reasons, we believe CMS should issue specific instructions stating that IVIG administration should be billed using the higher complexity HCPCS code that applies to administration of chemotherapy and other complex infusions. This will allow for more appropriate APC assignment and more equitable reimbursement.

APC Assignment of Allergy Immunotherapy Codes:

The seven codes which describe allergy immunotherapy (CPT codes 95144-95165) are mapped to three different APCs (APC 0353, 0359 and 0352). The cost of providing these services is similar and we believe they should continue to be mapped to the same APC. Currently, all of the immunotherapy codes are paid under APC 0371 at a rate of \$24.56. We see no reason to change this APC assignment.

Moreover, the proposed rule contains several rank order anomalies. CPT Codes 95145 – 95149 describe venom immunotherapy used to treat patients with allergies to stinging insects. CPT code 95145 describes immunotherapy for one stinging insect venom; 95164 describes immunotherapy for two stinging insect venoms, and so on up to 95149 which describes immunotherapy with five venoms. Generally, the more venoms used in providing the immunotherapy the greater the cost. However, the proposed rule would assign 95149 – the most costly of the venom immunotherapy codes to the lowest paying of the APCs - APC 352 - with a payment of \$8.32 while 95146 and 95147 which describe treatment with two and three venoms, respectively are assigned to APC 0359 with a payment of \$49.11. The single venom and four venom codes (95145 and 95148) are assigned to APC 0353 with a payment of \$23.36. These APC mappings are illogical and do not reflect the costs involved in providing the service. To the extent that these APC assignments come from hospital charge data, we suspect that hospitals have not known how to properly code for these services as these are services that are most typically provided in the physician office setting and not in the HOPD.

We recommend that the current APC (0371) be maintained. Alternatively, we recommend that CPT Codes 95144, 95145, 95146, 95147 and 95165 be mapped to APC 0353 and that CPT Codes 95148 and 95149 which are the two most costly, be mapped to APC 0359. This would establish a rational relationship between cost and payment. We

Mark McClellan, M.D.
September 16, 2005
Page 4

believe the RVU assignments established under the Medicare physician fee schedule provides a useful model in this regard.

APC Assignment for Allergy Testing

We agree with CMS' proposal to rationalize the payment amounts and APC assignments for the allergy testing codes (CPT Codes 95004, 95010, 95015, 95024, 95027, 95028 and 95065) by placing them in a single APC solely for these codes. Currently there is significantly confusion as to how to bill for these services with payment amounts varying significantly for what are essentially similar services. Therefore, we support the assignment of these codes to the new APC 0381.

If you have any questions concerning these comments, please contact JCAAI's Washington counsel, Rebecca Burke, at 202-466-6550.

Sincerely,



Stanley Fineman, M.D.
President

163



American College of Radiation Oncology

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(301) 718-6515 • FAX (301) 656-0989 • EMAIL acro@paimgmt.com

September 15, 2005

CCRs
DA
APC/D-D

Ritter
Kane
Heygster

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Rule Hospital Outpatient Prospective Payment System for 2006 CMS-1501-P

Dear Dr. McClellan:

The American College of Radiation Oncology (ACRO) wishes to offer comments to the Centers for Medicare and Medicaid Services about the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule posted in the *Federal Register* on July 25, 2005.

We are very concerned about the reduced payment proposed for brachytherapy APC 312, 313, and 651. We understand that only a small percentage of services were sampled due to the rules for single claims analysis. Brachytherapy typically involves multiple services so single claims are not representative and it is apparent that the pseudo single claim approach and the exclusion list did not effectively mitigate the problem. The proposed reimbursement is dramatically reduced for the foundation CPT codes for prostate and other complex interstitial brachytherapy (CPT 77778) and intracavitary gynecological brachytherapy (CPT 57155). In addition, the proposed changes in the Medicare Physician Fee schedule for certain brachytherapy codes including 57155 (see separate communication to follow) by reducing office practice expense by minus 100% would effectively eliminate a venue for gynecological brachytherapy. It appears that non-representative and erroneous claims are having disproportionate impact on the reimbursement rates for these codes that CMS, as proposed in the recent notice. We believe that payment for this service is already at or below cost and further reductions will be severely detrimental to patient care.

CMS has used only 3 percent of all claims for APC 0651 and that does not seem representative to us. Study has shown that claims that had both the brachytherapy procedure and a brachytherapy source "C" code had median costs that were significantly higher than the average all single-procedure claims for the APC. We believe that a thorough analysis of brachytherapy would show that it is a complex process that requires resources in excess of the proposed reimbursement.

We realize that the agency has attempted to include multiple procedure claims data to calculate relative payment weights by using the "same date of service" and an expanded list of "bypass"

codes to provide more “pseudo” single claims. We believe, however, that changes in the current methodology must be used to gather accurate, complete, and representative cost data. A “device-dependent” APCs or some other solution may be necessary to ensure more appropriate and accurate payment rates for brachytherapy APCs. Furthermore that a study of the both the process and resources would show that the cost of providing this traditionally effective treatment to cancer patients in the hospital outpatient setting exceeds the proposed reimbursement. In our opinion the restrictive nature of the dataset and the incomplete listing of resources has resulted in significant reductions in payment. We recommend the following for your consideration:

1. Use only “correctly coded” claims for brachytherapy APCs 312, 313 and 651.
2. Apply a “dampening” adjustment to all device-related APCs to limit the reduction in payment from 2005 to 2006 rates, including APCs 312, 313 and 651.
3. Require mandatory hospital coding of appropriate brachytherapy source “C” codes for brachytherapy procedure APCs 312, 313 and 651.
4. Educate hospitals on the importance of accurate coding of devices, including brachytherapy sources.
5. Develop alternative methodologies to utilize single and multiple-procedure claims for determining median costs and setting HOPPS payment rates, including the use of the best external data available in constructing APC rates, including proprietary or confidential data, to determine median cost calculations.
6. Maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures*. Further, we request that all changes to APC assignments be listed in the preamble of future proposed and final rulemaking.
7. CMS work with the American College of Radiation Oncology (and other specialties as appropriate) to study the breadth of services and resources needed to provide brachytherapy

Methodology

We noticed that all other radiation oncology codes have increased with the exception brachytherapy codes in APCs 312, 313 and 651. We are concerned that the reductions are based in part upon inaccurate hospital coding of brachytherapy source device “C” codes, elimination of multiple-procedure claims used to determine relative weights, and utilization of “incorrectly” coded brachytherapy claims to determine payment rates. There is across the board reduction in payment rates for the calendar 2006 compared to 2005: (312) –6.6%, (313) – 3.5%, and (651) – 42.3%. We believe the single claims and that the pseudo single claims data do not accurately reflect the cost of providing the service because they are both atypical and too few in number to be representative. They represent 2.8% for code 651 (total 11,963 claims) and 41.2% for code 312 (total 882 claims only). *The typical brachytherapy service is a multiple claims process.* There are often associated codes in the 777xx and other code series such as 55859, 31543, 43241, 57155, 58346 and others. In addition the equipment, supplies, and personnel required for

brachytherapy often cross medical specialties and departments within the hospital system. We also believe that correct coding is both more complex and less likely to be complete and consistent, especially with the regular changes from year to year.

We urge that CMS modify the data analysis method for brachytherapy to take into account that it is fundamentally a multiple procedure and often multi-disciplinary process.

We also recommend that external data such as proprietary or confidential data should be used determine median cost calculations if payment rates are based upon a small percentage of claims reviewed. The criteria for such submissions should be such that meaningful data can be included.

Various analyses have shown that correctly coded claims tend to result in median costs that are significantly higher than the CMS calculations based upon limited data. We believe it is the intention of the agency to correctly match cost and reimbursement for each type of service. Since brachytherapy is applicable to a broad range of cancer types it would most reasonably be coded with many categories and be site specific much like surgery and other procedure type services. Lumping all brachytherapy into few categories reflects a limited understanding of the diversity of the service and the resources necessary for its delivery. The concern is that the complexity is so variable that a "one size fits all" approach does not adequately address the cost of providing the service. Unlike some other services there is a particularly great variability between facilities in the type of brachytherapy services offered. Using a typical or average case approach therefore undermines the financial viability of centers that provide particularly complex brachytherapy.

Given these complexities and the frequent change in the system in recent years it is not surprising that hospitals find it hard to correctly code claims and that the agency is having difficulty in finding a balanced and stable means of providing reimbursement to the facilities. Within the confines of the current system we would suggest the following:

1. Claims have both the brachytherapy procedure and a brachytherapy source "C" code
2. A coding screen, similar to the screens CMS applied to "device-dependent" APCs be used to ensure more appropriate and accurate payment rates for brachytherapy APCs.
3. CMS use only "correctly coded" claims to determine brachytherapy payment rates and that multiple claims be analyzed.
4. If data is insufficient then external cost information should be applied.

The following table correlates the type of radioactive material to the existing APCs for brachytherapy.

APC	CPT Codes	Brachytherapy Device "C" Codes
312 Radioelement Applications	77761, 77762, 77763, 77776, or 77777	C1716, C1718, C1719, C1720, C2616, C2632, or C 2633
313 Brachytherapy	77781, 77782, 77783, 77784, or 77779	C1717 only
651 Complex Interstitial Radiation Source Application	77778	C1716, C1718, C1719, C1720, C2616, C2632, or C 2633

We suggest that CMS review the 2004 claims data used to package appropriate costs into Brachytherapy APCs 312, 313 and 651 to ensure that the reasonable cost of the brachytherapy source(s) was included on each hospital claim. We request that CMS select the claims that accurately reflect the source and device costs and delete the claims that do not, and revise the final payment rate for 2006 to reflect the appropriate cost of the brachytherapy procedure(s).

CMS should issue a Medicare Program Transmittal instructing providers to report the cost of the brachytherapy source(s) on all brachytherapy procedure claims. We request that CMS also instruct providers to report all brachytherapy procedures by date of service.

CPT 77778 Interstitial Radiation Source Application

APC 651 includes one CPT code 77778 *Interstitial Radiation Source Application; Complex*. This interstitial brachytherapy procedure is used to code most often but not exclusively for prostate brachytherapy. The reduction in payment to the facility for this service is dramatic. We believe it brings reimbursement to levels below the median cost of providing the service.

There are some practical limits on changes in cost per year for a service and these should be reflected in the HOPPS. It is not conceivable that costs for complex interstitial brachytherapy would change in one year by 42% (minus). For some reason, CMS did not apply its policy of stabilizing all device-related APC rates by protecting against such large cuts to APCs. For the last several years, CMS established a “dampening” adjustment to virtually all APCs (except “New Technology” APCs). These adjustments were created to limit the impact of payment reductions from year to year. A dramatic payment reduction of more 42.3% for APC 651 will cause hospitals to negatively consider their ability to provide this service. Further considerable payment instability makes it impossible to plan and develop quality brachytherapy programs.

We recommend therefore that CMS apply the “dampening” adjustment to all device-related APCs, including APC 651, and limit the reduction in payment from 2005 to 2006 rates.

In 2004, there were 11,963 claims that contained CPT code 77778; however, CMS based the 2006 proposed payment on just 342 claims or approximately only 2.8% of outpatient claims. If CMS had used claims that contained CPT 77778 and at least one brachytherapy device “C” code, the median cost increases by approximately 18% to \$864.54. In past years, CMS has used only “correctly coded” claims to determine payment rates. A claim for brachytherapy without a C-code would imply that brachytherapy was not delivered or that it was incorrectly coded.

We request that CMS review the 2004 claims data for APC 651 *Complex Interstitial Radiation Source Application* to ensure that the reasonable costs of brachytherapy sources are included on each hospital claim that contains CPT procedure code 77778.

If the 2006 median for APC 651 results in a 15% or greater reduction than the current 2005 payment, we request that CMS apply the “device-dependent” or similar adjustment factor to limit the decrease to 85 percent of the CY 2005 median.

CPT 57155 Insertion of Uterine Tandems and/or Vaginal Ovoids for Brachytherapy

CMS proposes to move CPT 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* from APC 193 *Level V Female Reproductive Procedures* to APC 192 *Level IV Female Reproductive Procedures*. The current payment for CPT 57155 is \$758.17 and decreases by 66.4% in 2006 with assignment in APC 192 with a 2006 proposed payment of \$255.66. We are very concerned about this level of reduction. This code is relatively new and unfamiliar to hospitals. We are also aware that many of our members did not understand how to use the code properly and that the billing departments were confused. There are at least two circumstances where code 57155 may be applied in the hospital outpatient setting: 1) operating room with anesthesia or 2) brachytherapy suite with conscious sedation and local anesthesia. In both cases considerable resources of personnel, supplies, and equipment are required. The most common approach involves placement of an intrauterine brachytherapy device (cost \$55) that must be sutured to the cervix. The purpose of the device is to permit safe and correct placement of the tandem (commonly in a series of brachytherapy sessions.) Surgical equipment for vaginal surgery, scrub technologist, circulating nurse, bladder catheter, intravenous tubing and fluids, gauze pads, vaginal packing, suction, cervical markers, and various means to achieve hemostasis are required. The tandem and ovoid or similar applicator used for brachytherapy must also then be inserted under anesthesia or conscious sedation. The tandem and ovoids may be reusable (costs in the range of \$15,000) or disposable (costs.) It is apparent to us that the proposed payment rate does not cover the cost of providing the service and the data used in the calculation are suspect.

We recommends that CMS maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures*. Further study of the costs of this procedure are required to set accurate reimbursement and we would be interested in working with CMS to that end.

Summary

The major changes to brachytherapy reimbursement are of concern to the American College of Radiation Oncology. The diversity of brachytherapy services and the differences in the type and complexity of procedures performed within and between facilities is noteworthy. The advanced technology of permanent seeds and high dose rate mean that much of brachytherapy can now be done on an outpatient basis. While inpatient service may decrease there will necessarily be some compensatory increase in costs in the outpatient setting. We believe that the decrease in reimbursement across the board for brachytherapy related APCs (312,313,651) are not well correlated with the true cost of providing the service and that such reductions will negatively impact brachytherapy health care deliver.

Further one of the foundation codes 57155 (APC 193) for gynecological brachytherapy applicator placement has been drastically reduced (by transfer to a lower APC category). These brachytherapy services are intrinsically linked in the step-by-step process (from applicator placement, to imaging, to dose calculation, and finally to radiation source delivery.) A change in

Dr. Mark McClellan
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Page 6

one impacts the entire service series, making single claim analysis inadequate and misleading. We also recognize the difficulties of calculating correct payment rates for such a complex process and hope that some solution to the methodology can be found.

We appreciate the opportunity to bring our views to the attention of the agency, and we would like to offer our assistance the agency in the study of the costs associated with of providing brachytherapy services.

Respectfully submitted,



D. Jeffrey Demanes, MD, FACRO
President



Michael R. Kuettel, MD, PhD, FACRO
Chair, ACRO Economics Committee



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September 15, 2005

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RE: Comments on the Proposed Rule for Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P

Dear Dr. McClellan:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the proposed rule for the changes to the Hospital Outpatient Prospective Payment System (HOPPS), which was published in the *Federal Register* on July 25, 2005. ASH represents approximately 10,000 hematologists in the United States who are committed to the treatment of blood and blood-related diseases. These diseases include malignant disorders such as leukemia, lymphoma, and myeloma as well as non-malignant conditions such as anemia, thrombosis, and bleeding disorders. ASH members include hematologist/oncologists who frequently render services to Medicare beneficiaries utilizing the HOPPS and we ask the Centers for Medicare and Medicaid Services (CMS) to consider our comments on the following three issues:

- APC 0112, Apheresis and Photopheresis;
- Code 38230, Bone Marrow Harvesting for Transplantation; and
- Equitable Adjustment.

APC 0112, Apheresis and Photopheresis

We would first like to express our appreciation to CMS for accepting our recommendation to move Code 36515, Therapeutic Apheresis with Extracorporeal Immunoabsorption and Plasma Reinfusion, from Ambulatory Payment Classification (APC) 0111 back to 0112 where it had previously been located. This is a very costly procedure and APC 0112 is a much better fit both clinically and in terms of resource requirements. However, the proposed decrease in payment level for the overall APC would result in grossly inadequate reimbursement, a circumstance that could have a devastating impact on the ability of hospitals to provide these services.

There are three procedure codes assigned to APC 0112: Code 36515, Therapeutic Apheresis with Extracorporeal Immunoabsorption and Plasma Reinfusion, which is used to treat patients with immune thrombocytopenic purpura (287.3) refractory to conventional steroid therapy and advanced rheumatoid arthritis (714.0) unresponsive to at least two conventional disease-modifying anti-rheumatic drugs. Code 36516, Therapeutic Apheresis with Extracorporeal Selective Adsorption or Selective Filtration and Plasma Reinfusion, is used to treat patients with hypercholesterolemia (272.x) who are not successfully managed with diet or maximum lipid-lowering drug therapy and who are at high risk for adverse cardiovascular events. Code 36522, Photopheresis, Extracorporeal, is used to treat patients with cutaneous T-cell lymphoma of various types (202.1, 202.2) and increasingly to treat graft versus host disease in bone marrow transplant patients and to prevent solid organ transplant rejection. All of these procedures are performed using sophisticated and costly technology.

The proposed reduction in payment for these services, from \$2,127 to \$1,583, is greater than 25 percent. This level of payment will not cover the costs of performing these services. For example, just the disposable supplies for Code 36516 cost more than \$1,485, close to the total APC payment. This does not include the clinical labor, equipment and overhead associated with a procedure that can take five hours to perform. Similar supply cost issues exist with respect to Code 36515.

While we recognize that the proposed rate is derived from estimated median costs converted from hospital charges attributed to this APC, we suspect that there may be significant sources of inaccuracy in the data. Some hospitals obviously did not fully reflect the costs of the expensive disposables such as the ProSORBA® column or the lipid apheresis disposables in their charges for the procedure. This might well be a reflection of the so-called "charge compression" phenomenon that has been noted for other costly procedures. We also think hospitals which charge separately for the disposables are apt to charge more accurately for the procedure than hospitals which bundle the entire costs of the disposable supplies in their charge for the procedure. In fact, we understand that if the rates were derived only from claims which included separate charges for supplies with the claim for the procedure, the average charges would be substantially higher. We therefore urge CMS to consider basing the rate only on claims where separate charges for supplies have been identified.

We also ask CMS to reexamine the calculation of the median costs. We do not know if an error was made; however, the data certainly look peculiar. Code 36522 represents almost 85 percent of the single claims used in calculating the APC rate. This code has an indicated median cost of \$2,095. Thus, 42.5 percent of the claims had a cost in excess of \$2,095. One would logically expect that if there was a remotely normal distribution of the 42.5 percent of claims for Code 36522 with costs less than \$2,095, the resultant median costs of the overall APC would be in excess of the \$1,620 figure used in determining the APC rate.

We are particularly concerned about the payment level for this APC, not just because it will make it difficult for hospitals to provide these procedures but also because of the

adverse impact it could have on new applications of the apheresis technology that may soon be available. New apheresis treatments are of particular significance to Medicare beneficiaries. Areas that include dry age-related macular degeneration and congestive heart failure are showing great promise in pivotal trial phase or have already been approved. Unless corrected, the proposed payment level of APC 0112 could have a severe chilling effect on the potential availability of these valuable technologies to Medicare beneficiaries who need them the most. This clearly cannot be the goal of the HOPPS.

We would very much appreciate the opportunity to work with CMS going forward to develop more reliable data to help establish the actual costs of providing these services in the hospital outpatient setting. ASH would willingly embark (in collaboration with other interested societies) on an educational program geared toward hospitals that provide these specialized services to improve the accuracy of claims submitted for these services. We suggest that CMS consider requiring the separate reporting of the very costly disposable supplies for this APC as it has already done for the "device dependent" APC's.

However, for 2006, we ask CMS to (1) reexamine the calculation of the median costs of this APC as discussed above and/or (2) consider basing the rate only on claims that have separate charges for supplies. If these approaches are impractical or do not resolve the current problem of median costs, we would then urge CMS to freeze the current APC rate or, at a minimum, provide a floor on a reduction similar to the proposal for device dependent APC's.

Code 38230, Bone Marrow Harvesting for Transplantation

Code 38230, Bone Marrow Harvesting for Transplantation, is assigned to APC 0111 (Blood Product Exchange) with a payment level of \$732. There were only 9 claims used for this code. The median cost of this service is \$1,209 and the data shows a range of \$140 to \$66,770 and a mean cost of \$10,740. This procedure is an extremely costly procedure with actual cost probably five to ten times the median cost indicated. Many of these services are performed for much younger patients and/or in cancer exempt hospitals so it is not surprising that the number of claims used is so low.

We want to clarify the steps of a bone marrow harvest procedure, of which the great majority are allogeneic transplant procedures. The bone marrow harvest patient goes to the operating room for a procedure to be performed under general anesthesia. To collect an average of 1000 cc of bone marrow (range is 500 cc to 1500cc depending on the size of the recipient) requires 200-400 needle aspirations of bone marrow from the posterior iliac crest through two to six skin holes. The average time for the surgeon to collect this volume is about one hour. Anesthesia time usually is about 45 minutes longer. The total operating room (OR) time is about two hours. One to two units of pre-collected blood are usually transfused in the recovery room after the procedure. We think if CMS compared this procedure to other procedures involving two hours of OR time and general anesthesia, the degree to which the proposed APC rate is inadequate will be obvious.

We would like the opportunity to work with CMS to determine what cost data would be useful to establish a reasonable rate for this service. However, we recognize that these data could not be obtained and provided in time to influence the 2006 HOPPS rate. As a temporary measure, we would strongly urge CMS to move this code from the current APC to APC 0123, Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant, which has a proposed payment rate of \$1,364. This rate would be more reflective of the costs of the service and would also result in an APC grouping which would be more clinically homogenous. In fact, the very title of APC 0123 would seem to apply specifically to this procedure code which makes us suspect that there seems to have been an inadvertent error made in the APC assignment.

Equitable Adjustment

CMS proposes moving from applying an equitable adjustment to determine payment rates for darbepoetin alfa to establishing the payment rate using the Average Sales Price (ASP) methodology. ASH agrees that the ASP methodology is appropriate for establishing the payment rates for this therapy and recommends that CMS implement this change in the final rule.

In summary, ASH appreciates this opportunity to comment on the proposed changes to the HOPPS. We agree with the proposed changes listed below and support implementation in the final rule:

- Move Code 36515, Therapeutic Apheresis with Extracorporeal Immunoabsorption and Plasma Reinfusion, from APC 0111 to 0112; and
- Replacing the equitable adjustment methodology for darbepoetin alfa with ASP methodology

Additionally, ASH urges CMS to:

- Delay implementing proposed changes regarding the reduction of the payment rate for APC 0112 pending further evaluation of cost data; and
- Temporarily move Code 38230 from APC 0111 to APC 0123 while reviewing correct permanent placement for this code.

ASH is willing to work with CMS to identify appropriate data sets and cost information regarding APC 0112 and Code 38230. Placement into the appropriate APCs with adequate reimbursement is essential for ensuring beneficiaries access to these important therapies. If you have questions or would like additional information, please contact Pamela Ferraro, ASH Practice Advocacy Manager at 202-776-0544 or pferraro@hematology.org.

Sincerely,



James N. George, MD
President



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September 16, 2005

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APC/AM
MEG
Bunley

Reference: CMS 1501-P

Dear Dr. McClellan,

The National Association of Epilepsy Centers (NAEC) joins the American Academy of Neurology in asking that CMS maintain the current New Technology APC assignments for the Magnetoencephalography (MEG) CPT Codes 95965 – 95967 in 2006. Under the proposed rule, MEG services would be assigned to APC 0430, which has a payment rate of \$676.75. This payment level will not adequately cover the costs of providing these specialized services.

In addition, the APC Advisory Committee recommended that the existing APC assignments for MEG services be extended in 2006 and asked that providers of MEG services work with CMS to collect hospital cost and charge data in order to determine an appropriate APC for the technology in future years. NAEC concurs and supports the Committee's recommendation.

MEG is a non-invasive procedure that can be provided as part of an epilepsy surgical evaluation to patients whose seizures are not well controlled with drug therapy. Most patients considering epilepsy surgery are under 65 years of age. Therefore, the number of Medicare claims for MEG services, as with most of the highly specialized services provided by comprehensive epilepsy centers, are small. Currently, there are approximately 10 hospitals in the United States where MEG services are provided and this number is not expected to substantially change in the next few years. It remains critically important for CMS to adequately cover the costs of MEG services provided in hospital outpatient departments as private insurers often model their reimbursement policies on Medicare's payment systems.

Established in 1988, NAEC represents over eighty specialized epilepsy centers in the United States. On behalf of its member centers, the Association actively advocates for high quality, accessible comprehensive epilepsy services.

If you have any questions regarding these comments please contact Ellen Riker, NAEC's Washington Representative at 202-833-0007 or Ellen@marcassoc.com. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Robert J. Gummit, MD". The signature is written in a cursive style with a large, prominent initial "R".

Robert J. Gummit, MD
President

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September 16, 2005

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RE: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Administrator McClellan:

Biogen Idec appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule implementing portions of the Medicare Modernization, Prescription Drug and Improvement Act of 2003 (MMA), and revising payment rates and policies under the Hospital Outpatient Prospective Payment System (HOPPS). Biogen Idec is a global leader in biotechnology headquartered in Cambridge, Massachusetts. Our products and development programs have addressed key medical needs in the areas of oncology, neurology, dermatology and rheumatology.

Biogen Idec's pipeline and existing products are infused or injected in a variety of settings, including hospital outpatient departments. Biogen Idec supports CMS' continuing efforts to address concerns expressed by patients, providers, and industry regarding Medicare beneficiary access to quality hospital outpatient care. As detailed below, Biogen Idec:

- Generally supports Medicare hospital outpatient department payment for radiopharmaceuticals based upon hospital charges converted to cost provided that:
 - CMS and its contractors utilize each hospital's overall cost-to-charge ratios (rather than department-specific CCRs); and
 - The agency operationalizes its stated intent in utilizing hospital charge data of preventing significant decreases in payment by implementing product-specific payment floors set at the level

identified by the GAO in its recent study or, if GAO data is not available for a product, at no lower than 95% of the 2005 HOPPS payment rate for that product;

- Urges CMS to continue working with hospitals and manufacturers, including manufacturers of therapeutic products within the radiopharmaceutical classification, to develop a long-term payment methodology for radiopharmaceuticals that complies with the MMA and considers the complex manufacturing, distribution, handling, and use procedures associated with these products;
- Supports continued pass-through status for Natalizumab under APC 9126 in 2006;
- Supports CMS' proposal to utilize the new Current Procedural Terminology (CPT) codes for drug administration services under HOPPS, and urges CMS to:
 - Provide guidance to hospitals on the use of these codes, particularly for monoclonal antibodies and other biological response modifiers that are appropriately billed under the chemotherapy administration codes; and
 - Monitor access to drugs and biological therapies and adjust payment rates as necessary to facilitate continued patient access; and
- Encourages CMS to ensure that the HOPPS Final Rule incorporates any changes in the HCPCS codes effective for 2006 so that coding for products such as Zevalin is consistent between the hospital outpatient and physician office settings.

Payment for Radiopharmaceuticals

Biogen Idec acknowledges that the MMA provisions regarding hospital outpatient payment for radiopharmaceuticals in years beyond 2005 create unique challenges for CMS. Under the HOPPS, radiopharmaceuticals are generally treated as drugs and biologicals with Medicare payment based upon hospital actual acquisition cost. The MMA provides that in the absence of actual acquisition cost data, payment rates for drugs and biologicals administered in the hospital outpatient setting may be based upon the methodologies utilized in the physician office setting, yet it exempts radiopharmaceuticals from the primary physician office setting payment methodology – ASP. While CMS received hospital acquisition cost data from the Government Accounting Office (GAO) for nine (9) radiopharmaceuticals, it noted that use of that data in setting Medicare rates would significantly reduce payment for many products and rejected the GAO data as a basis for HOPPS radiopharmaceutical payment. Given the lack of ASP data, CMS proposed to utilize hospital charges converted to cost for 2006 as

a proxy for actual acquisition cost, and stated its intention to require ASP reporting for radiopharmaceuticals beginning in 2006.

Biogen Idec appreciates CMS' recognition that precipitous drops in Medicare payment rates can constrict beneficiary access to medical care. While we generally support CMS in its efforts to derive actual acquisition cost data from hospital charges, our review of hospital charge data provided by The Moran Group to the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) reveals that the methodology may trigger the drastic payment drops it was intended to avoid. For example, the Zevalin therapeutic regimen was utilized for 325 Medicare beneficiaries in 186 different hospitals during 2004. Even if CMS uses hospital-specific overall cost-to-charge ratios (CCRs), only 26% of hospitals will be able to recover the cost of the imaging dose of Zevalin (C1082) while only 18% of hospitals will recover the therapeutic dose of the regimen (C1083). Biogen Idec urges CMS to consider the following refinements to its methodology for 2006:

- Implement the CCR methodology utilizing hospital-specific overall, rather than departmental, CCRs;
- Ensure that the resultant payment for each product in 2006 does not fall below the level identified in the GAO data, or if GAO data is unavailable, that the payment not be less than 95% of the 2005 HOPPS payment rate;
- Provide hospital outpatient departments with clear guidance on the 2006 payment methodology so that data gathered in 2006 accurately reflects hospital acquisition cost for each radiopharmaceutical product.

Biogen Idec agrees with CMS in its selection of the cost-to-charge methodology as the most appropriate means of gathering actual acquisition cost data so long as hospitals are given clear guidance and the opportunity to ensure that their reported charges reflect the cost of providing radiopharmaceuticals. We believe that adoption of the refinements identified above will facilitate continued Medicare beneficiary access to essential therapeutic and diagnostic products while CMS gathers and ensures the integrity of data to support future HOPPS payment levels. Biogen Idec views buffering tools such as the proposed payment floor as temporary measures to further CMS' objective of protecting beneficiary access to medical care in the hospital outpatient setting.

Given CMS' identification of the CCR methodology as an appropriate proxy for hospital actual acquisition cost, and the fact that 2006 data will be available to CMS as it sets 2007 HOPPS payment rates, CMS will not face the unavailability of data to trigger application of other Part B payment methodologies. Biogen Idec also urges CMS to recognize the operational and statutory impediments to ASP reporting for radiopharmaceuticals and the inherent difficulties in establishing HOPPS payment for these products based upon any ASP methodology. Biogen Idec contends that when Congress exempted radiopharmaceuticals from the MMA provisions modifying Part B payment for drugs and biologicals in the physician office setting (including ASP), it did

so because of the unique nature and complexities associated with radiopharmaceuticals rather than the unique nature of the physician office setting. It is unlikely that Congress intended for CMS to collect average sales price data for radiopharmaceuticals that the agency would be precluded from utilizing as a Part B radiopharmaceutical payment methodology. In its Proposed Rule, CMS has acknowledged, the variability in distribution, manufacturing, and use of radiopharmaceuticals from product to product and even from hospital to hospital. This variability, and the complexities associated with these products, makes uniform application of ASP processes to radiopharmaceuticals a virtual impossibility for CMS.

We urge CMS to continue working with hospitals and manufacturers, including manufacturers of therapeutic products within the radiopharmaceutical classification, to ensure that both short and long-term payment methodologies for radiopharmaceuticals sufficiently reimburse providers for medically necessary therapies and generate valid and reliable data to support future payment rates.

Pass-through Status for Tysabri (natalizumab)

Biogen Idec supports continued pass-through status for Tysabri (natalizumab) under APC 9126 in 2006. Tysabri was approved by the FDA on November 23, 2004 for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. On February 24, 2005, Biogen Idec and Elan announced a voluntary suspension of the marketing of Tysabri due to safety concerns. We anticipate making submissions to regulatory authorities in early fall of 2005. Biogen Idec was pleased by the expeditious manner in which CMS granted pass-through status and a product-specific code to Tysabri, and urges the agency to retain this code to facilitate future beneficiary access to this promising therapy. We do, however, remain concerned that continuation of the 1-mg unit descriptor will present confusion to providers and inject the potential of erroneously denied or underpaid claims. Tysabri is infused in a uniform 300 mg dose, and we urge CMS to amend the coding descriptor to reflect its clinical use.

Administration Services for Drugs and Biologicals

Biogen Idec supports CMS' proposal to utilize the new Current Procedural Terminology (CPT) codes for drug administration services under HOPPS. We understand that while CMS will set initial rates for these new codes based upon two-year old data that does not reflect the granularity of the new codes, charge data will enable the agency to set more appropriate rates for these services in future years. We urge CMS to monitor beneficiary access to drugs and biological therapies in the hospital outpatient setting and to adjust rates as necessary to facilitate continued access.

Biogen Idec also recommends that CMS provide clear guidance to hospitals on adoption of the new codes, both through the Final Rule and in the form of transmittals and MedLearn Matters articles on the CMS website. Specifically, we suggest that CMS clearly convey to hospitals that the administration of substances such as monoclonal

antibody agents and other biological response modifiers are properly billed as chemotherapy administration services.

Incorporating 2006 HCPCS Coding Changes

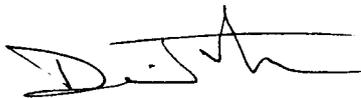
In the 2004 hospital outpatient final rule CMS assigned a temporary code for 90Yttrium Zevalin, C1083, *Supply of radiopharmaceutical therapeutic imaging agent, yttrium-90 ibritumomab tiuxetan, per dose*. This code was assigned to alleviate confusion and billing errors encountered by facilities billing multiple units of the per mCi code A9523 for 90yttrium Zevalin. CMS indicated that the HCPCS review and update process did not permit simultaneous modification of the A9523 description, and advised Biogen Idec to submit an application for the revision.

Biogen Idec submitted a HCPCS application for the 2006 update and suggests that if the HCPCS Committee determines to modify the HCPCS descriptor to reflect a per dose unit, the HOPPS Final Rule should reflect use of the A9523 code, rather than C1083, to describe the imaging agent in the Zevalin therapeutic regimen.

Conclusion

Biogen Idec appreciates the significant efforts that CMS has made in incorporating consideration of patient access issues into payment policies in the hospital outpatient setting. If you have any questions regarding our comments, or need any additional information, please contact me at (202) 383-1444.

Sincerely,



David V. Foster
Vice President, Government Relations

Enclosure: Moran Company data analysis for Zevalin

167

Joaquin Duato
President

◆
ORTHO BIOTECH

Ortho Biotech Products, L.P.
430 Route 22 East
Bridgewater, NJ 08807-0914
(908) 541-4822 Phone

BBP
APC
HWA
BWA

September 16, 2005

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room 445-G, HHS Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule July 25, 2005 (CMS-1501-P)

Dear Dr. McClellan,

On behalf of Ortho Biotech Products, L.P., I am pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2005 (CMS-1501-P, Federal Register, Vol. 70, No. 141, Monday, July 25, 2005, p. 42674). Ortho Biotech Products, L.P. markets PROCRIT (epoetin alfa), a manufactured form of a naturally occurring hormone (erythropoietin) that is given by injection to stimulate the bone marrow's production of red blood cells. Clinical studies and over 15 years of clinical practice have demonstrated that epoetin alfa effectively treats anemia by increasing hemoglobin, reducing red blood cell transfusion utilization, and reducing anemia-related symptoms, particularly fatigue.

Ortho Biotech appreciates the considerable effort you and your staff have put into the development of the outpatient prospective payment system (OPPS) and to your commitment to ensure patient access to the full range of drugs and other treatments, with fair and equitable payment to hospitals. Our comments will focus on CMS payment policy for PROCRIT (epoetin alfa) and ARANESP (darbepoetin alfa).

PAYMENT POLICY FOR PROCRIT (EPOETIN ALFA) AND ARANESP (DARBEPOETIN ALFA)

PROCRIT (epoetin alfa) and ARANESP (darbepoetin alfa) are used for the treatment of chemotherapy-induced anemia and for the treatment of anemia associated with chronic kidney disease. Despite a small difference in molecular structures, both agents stimulate red blood cell production by the same mechanism of action as endogenous erythropoietin. In previous proposed and final rules since the CY 2003 Final Rule, published November 1, 2002, CMS has concluded that the products are almost identical and has relied on its authority in section 1833(t)(2)(E) of the Social Security Act to make adjustments "necessary to ensure equitable payments". The history of previous CMS decisions is provided below:

- For the 2003 OPPS, CMS established a conversion ratio for purposes of payment of 260 International Units of epoetin alfa to one microgram of darbepoetin alfa (260:1).
- For the 2004 OPPS, CMS concluded that the appropriate conversion ratio should be 330 International Units of epoetin alfa to one microgram of darbepoetin alfa (330:1) for the purpose of treating chemotherapy-induced anemia and the anemia associated with chronic kidney disease. While we disagreed with the new conversion ratio, we strongly supported the agency's decision to continue to link the payment for ARANESP to the payment for PROCRIT.
- After considering the nature of the MMA payment changes pertaining to this policy, CMS concluded in the January 6, 2004 interim final rule that it was still appropriate to rely on this authority to ensure equitable payments between PROCRIT and ARANESP.
- For the 2005 OPPS, CMS announced that it continued to believe the conversion ratio of 330:1 used for CY 2004 was appropriate for purposes of establishing equitable payment under the OPPS for both PROCRIT and ARANESP.

In the proposed rule for CY 2006, CMS proposes to abandon its equitable adjustment policy and to establish the payment rate for darbepoetin alfa using the ASP methodology because "...this method will permit market forces to determine the appropriate payment for this biological". Ortho Biotech disagrees with this proposal and strongly believes that PROCRIT and ARANESP should continue to be paid equitably as CMS has concluded in the past.

Our comments on this issue will address the clinical justification for continuing an equitable payment policy, including the appropriate conversion ratio and its budgetary effect, as well as the financial impact on beneficiaries responsible for coinsurance payments.

We recommend that CMS continue the equitable payment and the linkage of these two products. The results of multiple new and previously reported clinical studies, which are outlined in this comment letter and fully discussed in the attached clinical paper, clearly confirm that an equitable payment adjustment continues to be necessary and that the appropriate conversion ratio for making this adjustment is less than or equal to 260:1.

I. Background

While not structurally identical, PROCrit and ARANESP use the same biological mechanism of action to produce a similar clinical effect. When dosed to achieve a comparable effect with PROCrit, the cost of treatment with ARANESP is greater for both the Medicare program and its patients, through the coinsurance they must pay. Based on these facts, CMS has concluded since November 2002 that the two products should be paid equitably *based on authority in section 1833 (t)(2)(E) of the Social Security Act to make an adjustment we (CMS) determine "necessary to ensure equitable payments". (Federal Register/Vol. 67, No. 212 Friday November 1, 2002 / Rules and Regulations)*

Ortho Biotech agrees with CMS' application of an equitable payment policy to PROCrit and ARANESP and we urge you to continue this policy in CY 2006. We also note that Amgen has supported the linkage of erythropoietin and ARANESP, so that ARANESP can be used interchangeably with EPOGEN (epoetin alfa) and be reimbursed for use in the ESRD patient population as well as for other indications.¹

II. Clinical Justification and Rationale for an Equitable Payment Policy in CY 2005; Establishing Conversion Ratio

CMS' identification of a conversion ratio between the dosages of the two products was solely for the purpose of establishing an equitable and appropriate Medicare payment policy; it did not suggest treatment for individual patients in clinical practice. Although, in the past, CMS determined the conversion ratio using the best information available, the agency did not have available head-to-head comparisons of the products because such studies did not yet exist. CMS acknowledged that the gold standard for scientific comparison between these two products was the conduct of a well-designed randomized head-to-head clinical trial. In response to this request, over the last two years, Ortho Biotech sponsored a well-designed, randomized, controlled, comparative clinical trial, as well as several other studies, to fill this knowledge gap and respond to the

¹ See document entitled "Medicare Coverage and Payment Issues for Aranesp™" 11/19/01 correspondence from A. Vickery to T. Hoyer that quotes, "Although Aranesp™ is a different and distinct erythropoietic protein, it functions the same as erythropoietin in stimulating the production of red blood cells, and should be so considered under statute". "We do believe that Aranesp™ fits within the erythropoietin sections of the statute" sections 1861 (s)(2)(O) and 1881 (b)(11)(B) of the Social Security Act (reference to ESRD).

agency's clear call for better evidence. The results of these studies are described in a clinical paper attached to these comments.

The clinical paper provides new and updated clinical data from seven different studies involving thousands of patients, which support a conversion ratio of $\leq 260:1$ (Units PROCrit: mcg ARANESP). The randomized head-to-head clinical trial in patients with chemotherapy-related anemia confirms a dose conversion ratio of 199:1. This study is superior to other available studies because it is designed to evaluate the relative efficacy of the agents over the entire treatment course, randomized to limit the effects of bias, and designed and statistically sized specifically to answer the question of whether commonly used dosing regimens for both treatments produce the same hemoglobin effect.

As we have noted in the past, studies comparing doses with differing patient outcomes require consideration of both dose and overall hematologic effect (assessed by Hb area under the curve). Comparisons based on dose-only data, without regard to outcomes, do not consider the totality of hemoglobin effect and patient benefit, and are, therefore, inadequate for determining an appropriate conversion ratio. With this caveat, the attached paper also presents six different studies in patients with chemotherapy-related anemia or pre-dialysis chronic kidney disease demonstrating a dose-only ratio of $\leq 278:1$. Even when dose utilization is considered alone, without any consideration of clinical comparability, a conversion ratio of 330:1 is not supported by the most current evidence.

Before summarizing the results of the new studies, which are discussed more fully in the attached paper, we want to emphasize the importance to the patient of two clinical outcomes: early hemoglobin improvement and cumulative hemoglobin improvement (as measured by Hb area under the curve).

- Early hemoglobin improvement (≥ 1 g/dL Hb rise at week 4) in weekly PROCrit trials is associated with a lower proportion of patients requiring transfusion, lower average weekly PROCrit dose over treatment period, and improved quality of life scores compared to non-early responders.² The head-to-head trial results reported below confirm previous results that a comparable early hemoglobin rise is not achieved with ARANESP when dosed sub-optimally at 200mcg every two weeks.
- Area under the hemoglobin (Hb) curve (AUC) is a well-established metric used to evaluate hematologic outcomes over an entire treatment course and has been used by multiple manufacturers of erythropoietic agents, including Amgen (Egrie 2003), to evaluate response.³ The clinical benefits of higher Hb AUC (e.g. lower proportion of patients requiring red

² Rosberg J et al. Benefits of early hemoglobin response to epoetin alfa in elderly patients with chemotherapy-related anemia. Poster presented at: 46th annual American Society of Hematology Meeting, San Diego CA, December 4-7, 2004.

³ Egrie JC, Dwyer E, Browne JK et al Exp Hem (2003) 31:290:299

blood cell transfusion, lower drug utilization) have been described in published scientific literature.^{4,5} The head-to-head trial results also confirm PROCRT QW superiority over ARANESP Q2W in this important clinical outcome.

The attached clinical paper is summarized in the points under “a” to “e” below:

a. Results from head-to-head comparison in randomized clinical trial (dose conversion ratio of 199:1)⁶

- Waltzman et al. (2005) reported final results of a 16-week, prospective, Phase III, randomized, multicenter, open-label trial directly comparing hemoglobin (Hb) response and transfusion requirements of PROCRT and ARANESP in 358 anemic cancer patients with solid tumors receiving chemotherapy. Patients were randomized 1:1 to receive either PROCRT 40,000 units (U) once weekly (QW) or ARANESP 200 micrograms (mcg) every other week (Q2W). The primary efficacy endpoint was the percent of patients with a Hb increase of ≥ 1 g/dL by Week 5 (i.e. within four weeks of treatment).
- Results demonstrate that a significantly greater proportion of patients achieved the primary efficacy endpoint (% of patients achieving a Hb rise ≥ 1 g/dL within 5 weeks) in the PROCRT group compared to the ARANESP group. Additionally, a greater proportion of patients achieved a Hb increase ≥ 2 g/dL at Weeks 9 and 17 in the PROCRT group compared to the ARANESP group. Although the study was not powered for comparison of red cell transfusion utilization, a lower proportion of patients required red blood cell transfusion in the PROCRT group compared to the ARANESP group. The total number of red blood cell units transfused was also lower in the PROCRT group.
- A significantly greater increase in Hb at all measurement intervals was observed from Week 3 to end of study in the PROCRT-treated patients compared to ARANESP-treated patients ($p \leq 0.023$). Additionally, there was significantly greater cumulative hematologic effect, assessed by area under the Hb change curve (or Hb AUC), in the PROCRT-treated patients compared to the ARANESP-treated patients ($p < 0.001$).

⁴ Duh MS, Lefebvre P, Fastenau J, et al: Assessing the Clinical Benefits of Erythropoietic Agents Using Area Under the Hemoglobin Change Curve. *The Oncologist* 2005; 10:438-448

⁵ Lefebvre P et al. Greater area under the hemoglobin change curve during epoetin alfa treatment is associated with improved patient outcomes. Poster presented at International Pharmacoeconomics and Outcomes Research Meeting, May 16-19, 2004, Arlington VA

⁶ Waltzman R et al. Poster presented at the 2005 ASCO Annual Meeting. May 13-17, 2005, Orlando, FL

- The authors concluded that in chemotherapy-treated anemic patients with solid tumors, PROCRT 40,000 U QW resulted in a significantly greater hemoglobin response (Hb increase of ≥ 1 g/dL by Week 5) compared to ARANESP 200 mcg Q2W.
- The randomized head-to-head trial confirms a dose conversion ratio of 199:1, based on dose utilization and differing hematologic outcomes.

b. Results from two comparative studies of PROCRT 40,000 units QW vs. ARANESP 200 mcg Q2W

- Glaspy et al. (2005) reported final results of a randomized, Phase III, open-label, multicenter study to compare the efficacy and safety of ARANESP with PROCRT in anemic (Hb ≤ 11 g/dL) patients with non-myeloid malignancies receiving chemotherapy.⁷ One thousand two hundred and twenty-two patients were randomized to receive either ARANESP 200 mcg Q2W or PROCRT 40,000 U QW for 16 weeks. Dose titration (following protocol amendment) occurred at the physician's discretion. The primary efficacy endpoint was measured by the incidence of transfusions from Day 29 (Week 5) to the end of treatment period (EOTP). The authors did not report weekly hemoglobin change over baseline, which prevents understanding of hematologic outcomes prior to study Week 9 in this study. Additionally, the mean cumulative dose for each treatment was not reported, precluding any calculation of a dose conversion ratio.

However, based on a pre-specified margin of 11.5% selected by the sponsor and investigator, the incidence of transfusions from Week 5 to EOTP demonstrated non-inferiority of ARANESP. This 11.5% margin would suggest that the investigator could conclude non-inferiority despite 1 in 9 more patients requiring red blood cell transfusions in the ARANESP arm. Additionally, post hoc analysis by Ortho Biotech statisticians testing for differences in the proportion of patients transfused found the PROCRT group had a significantly lower proportion of patients transfused compared to the ARANESP group ($p < 0.05$). Using Kaplan-Meier (K-M) estimates, a higher percentage of patients achieved a target Hb earlier in the PROCRT group compared to the ARANESP group.

- Case (2005) reported a retrospective chart review of gynecologic oncology patients with chemotherapy-induced anemia who were receiving

⁷ Glaspy J et al. Final results of a Phase 3, randomized, open-label study of Aranesp 200 mcg every 2 weeks (Q2W) versus PROCRT 40,000 U weekly (QW) in patients with chemotherapy-induced anemia. Poster presented at the 41st Annual Meeting of the American Society of Clinical Oncology; May 13 – 17, 2005; Orlando, Florida.

PROCRIT or ARANESP.⁸ One hundred and twenty-three patients were identified with similar age, tumor type, and baseline hemoglobin. Eighty-six percent of PROCRIT patients received PROCRIT 40,000 Units weekly, and 93% of ARANESP patients received ARANESP 200 mcg Q2W. A significantly lower proportion of patients required red blood cell transfusions in the PROCRIT group compared to the ARANESP group (PROCRIT 19%, ARANESP 35%, $p=0.05$). This difference was maintained when controlling for age, chemotherapy courses, types of chemotherapy given, number of cycles of chemotherapy, tumor site, and baseline hemoglobin. Additionally, fewer total units of blood were transfused in the PROCRIT group compared to the ARANESP group (PROCRIT 32 units, ARANESP 62 units).

c. Results from a practical clinical trial (dose conversion ratio of 215:1)⁹

- To understand PROCRIT and ARANESP dosing patterns and hematologic outcomes, a prospective, observational study is underway at multiple U.S. sites. A total of 464 patients from 25 sites were enrolled between January 2004 and April 2005 in the Dosing and Outcomes Study of Erythropoiesis Stimulating Therapies (D.O.S.E. Registry). Inclusion criteria included age ≥ 18 , diagnosis of non-myeloid malignancy, receiving PROCRIT or ARANESP for chemotherapy-related anemia, no erythropoietic agents for at least 90 days prior to study entry, and signed informed consent. Exclusion criteria included active participation in a PROCRIT or ARANESP clinical trial (which might dictate protocol-mandated dosing), dialysis for end-stage renal disease, planned stem cell transplant, or a diagnosis of myelodysplasia.

The median dose for PROCRIT was 40,000 Units (range 16,000-90,000) and the median dose for ARANESP was 200 mcg (range 100-500). Weekly, every 2-week, and every 3-week dosing was reported in both groups. Treatment duration was similar in both groups (PROCRIT 7.8 weeks, ARANESP 8.1 weeks).

- Significant differences were observed in the Hb change over baseline at the week 12 timepoint ($p=0.02$). To understand the relative effectiveness of these agents, consideration of both cumulative dosing and hematologic effectiveness over the study period was employed. A dose conversion ratio of 215:1 was calculated based on cumulative dose and hematologic effect (Hb AUC).

⁸ Case AS et al. Comparison of transfusion rates between erythropoietic stimulating agents in gynecologic oncology patients with chemotherapy-induced anemia. Poster presented at the 41st Annual Meeting of the American Society of Clinical Oncology; May 13 – 17, 2005; Orlando, Florida.

⁹ Data on file, Ortho Biotech Clinical Affairs, LLC

d. Results from utilization studies (dose only ratio of 234:1-278:1)

This section includes brief summaries of several dose only studies. We wish to make it clear that, while we believe these and other dose only studies provide useful information, they are clearly inferior to a head-to-head trial since they do not provide any information about the patients' responses to therapy.

Also, while specific doses (e.g., PROCRIT 40,000 Units, ARANESP 200 mcg) may represent the most common administered dose, understanding utilization patterns requires consideration of dose, dosing frequency, and dose alterations during treatment. Multiple observational studies have reported that both PROCRIT and ARANESP are administered at weekly, every 2-week, and every 3-week frequencies.^{10,11} Therefore, weekly PROCRIT and every 2-week ARANESP should not be considered the respective universal dosing frequency.

A study was conducted to understand utilization trends of PROCRIT and ARANESP in community oncology practices and estimate a dose only ratio between these two agents in approximately 11,000 patients/month.¹² This cross-sectional analysis provided data describing the most recent weekly dosing trends from May 2003 through May 2005. An average of 5,424 PROCRIT patients and 5,935 ARANESP patients contributed data monthly. Mean weekly doses (May 2003 versus May 2005) increased 1.5% (35,735 to 36,280 Units) for PROCRIT and increased 12.2% for ARANESP (122 to 137 mcg) resulting in an overall decline in the PROCRIT: ARANESP dose only ratio from 294:1 to 266:1. The weighted dose only ratio, based on patient number by month and dose only ratio, was 278:1.

Reporting of the cumulative PROCRIT or ARANESP dose provides comparative information as it considers the patient-specific sum of all doses (considering dose, frequency, and dose alterations during treatment). To provide meaningful comparisons, we believe claims studies should meet the following criteria:

- Longitudinal in nature
- Concurrent study periods of PROCRIT and ARANESP
- Provide date(s) of service to establish dosing frequency and duration of treatment
- Patient age \geq 18 years of age

¹⁰ Lefebvre P et al. Treatment patterns and frequency of outpatient visits in adults with cancer receiving erythropoietic agents in a managed care setting. Poster presented at the Academy of Managed Care Pharmacy, 17th Annual Meeting and Showcase, April 20-23, 2005, Denver CO

¹¹ Mark TL et al. Retrospective Observational Study of Patients with Chemotherapy-Related Anemia Receiving Erythropoietic Agents *Curr Med Res Opin.* 2005;21:1347-1354.

¹² Coletti T et al. Dosing trends of epoetin alfa and darbepoetin alfa in adult patients with cancer receiving chemotherapy in community practice settings. *JMCP.*2005; 11:267-268 (abstr). Ortho Biotech Clinical Affairs, LLC data on file.

- ≥ 2 treatment claims for either PROCRIT or ARANESP (to establish dosing frequency)
- ≥ 1 cancer diagnosis claim within three months of initiating the erythropoietic therapy
- To eliminate the potential confounding effect from patients switched from one agent to another, or on maintenance treatment, the newly initiated population (defined as those patients with a 3-month washout period prior to the first PROCRIT or ARANESP claim) should be investigated.

The results of studies which meet these criteria are presented in the following:

- An analysis of medical claims was conducted to investigate the dose only ratio between PROCRIT and ARANESP in patients with cancer.¹³ The analysis was conducted in a similar format to the medical claims study reported in the October 2004 Ortho Biotech white paper submitted to CMS, however the data reported here were updated to include January-December 2004. From the database, a total of 8,022 patients consisting of 5,796 PROCRIT and 2,226 ARANESP patients were identified. Treatment duration was similar between groups, and cumulative PROCRIT and ARANESP doses over the course of treatment resulted in a dose only ratio of 234:1.
- A pooled analysis of dose only ratios of three medical claims studies with > 18,000 patients reported a dose only ratio of 256:1 (Units PROCRIT: mcg ARANESP).¹⁴ Combining the results of the three studies allowed consideration of recent PROCRIT and ARANESP dosing data from over 18,000 patients. The weighted average of dose only ratios, based on the relative sample sizes of these three studies, resulted in a dose only ratio of 256:1 (Units PROCRIT: mcg ARANESP).

e. Results from medical claims study of patients with predialysis chronic kidney disease (dose only ratio of 271:1)¹⁵

A medical claims study was conducted to understand relative PROCRIT and ARANESP dosing patterns in patients with predialysis chronic kidney disease. Because patients with predialysis chronic kidney disease have longer treatment duration (relative to oncology patients), and variability of dosing patterns in the early initiation phase vs. maintenance phase, comparison of the weighted average weekly dose was reported for both groups. Comparison of the weighted average weekly dose results in a dose only ratio of 271:1 (Units PROCRIT: mcg ARANESP).

¹³ Lefebvre P, et al. Poster presented at the 17th Academy of Managed Care Pharmacy (AMCP) Mtg; April 20 -23, 2005; Denver, CO; Data on file, Ortho Biotech Clinical Affairs, LLC

¹⁴ Data on file, Ortho Biotech Clinical Affairs, LLC.

¹⁵ Data on file, Ortho Biotech Clinical Affairs, LLC.

Summary of new and updated clinical data

New clinical data continue to support the initially established dose conversion ratio of $\leq 260:1$ (Units PROCRT: mcg ARANESP). A large randomized controlled trial designed to evaluate the hematologic and dosing outcomes of PROCRT and ARANESP in oncology patients reported a dose conversion ratio of 199:1, which aligns with the dose conversion ratio of 200:1 described in the published literature of ARANESP registration trials. A practical clinical trial of real world PROCRT and ARANESP dosing practices and outcomes reported a dose conversion ratio of 215:1. A large observational study demonstrated a steady increase in the average weekly ARANESP dose. The average weekly dose of ARANESP in May 2003 was 122 mcg, but by May 2005 there had been a 12% increase in the average weekly dose, bringing it to 137 mcg. This could have been anticipated since the mean weekly dose recommended in the FDA approved package insert for ARANESP is 157.5 mcg¹⁶, and with experience health care professionals may now be dosing ARANESP to achieve hematologic outcomes previously observed with PROCRT. Multiple observational studies support a dose only ratio of $\leq 278:1$ in oncology and chronic kidney disease. Based on the new and previously summarized clinical data, the preponderance of evidence from a variety of study designs and data types over the past three years supports the true conversion ratio to be $\leq 260:1$ (Units PROCRT: mcg ARANESP), as was initially described by CMS in its 2003 Final Rule.

III. Budgetary Effect and Beneficiary Coinsurance

The CMS decision concerning whether to continue to apply the equitable payments policy to PROCRT and ARANESP, and what conversion ratio to use, will affect both Part B program payments and the amount of beneficiary coinsurance payments. Ortho Biotech strongly believes that the appropriate conversion ratio for PROCRT and ARANESP is $\leq 260:1$. If an equitable adjustment is not made, CMS and its beneficiaries will spend more than is necessary to achieve a comparable therapeutic effect. If an equitable adjustment is made, CMS could use the savings from a revised conversion ratio on other OPSS services.

The table on page 11 shows projected product growth between 2004 (the year for which utilization data is available) and 2006. In developing these projections, the following assumptions were made: 1) ARANESP unit sales in the hospital setting will grow approximately 50% per year under current policies, and 2) PROCRT unit sales in the hospital setting will remain relatively stable over the same period.

¹⁶ FDA-approved ARANESP starting dose – 2.25 mcg/kg QW * 70kg (mean weight) = 157.5 mcg QW

HCPCS	Title	OPPS 2004 Claims (Estimated CY 2004 Totals), Frequency Paid	2006 Projection Assuming Product Specific Growth Rate
Q0136	Injection, epoetin alpha (for non ESRD use), per 1000 units	20,116,918	19,706,855
J0880	Injection, darbepoetin alfa, 5 mcg	39,118	87,542
Q0137	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)	30,444,222	68,131,125
C1774	Injection, darbepoetin alfa (for non ESRD use), per 1 mcg	1,692,477	3,787,594

Using this projected growth, we calculated the projected Medicare spending under the proposed payment rates for 2006 (without an equitable adjustment) and with an equitable adjustment at two different conversion ratios: 260:1 and 200:1. The results are shown in the following table:

<u>Proposed 2006 OPPS Rates</u>		<u>Projected 2006 Medicare Spending</u>
PROCRIT	\$9.99/1000 Units	\$196,871,481
ARANESP	\$3.28/mcg	\$237,329,087
<u>260:1 Ratio</u>		
ARANESP	\$2.60/mcg	\$188,126,715
TOTAL 2006 OPPS SAVINGS AVAILABLE FOR OTHER SERVICES		\$49,202,372
<u>200:1 Ratio</u>		
ARANESP	\$2.00/mcg	\$144,712,858
TOTAL 2006 OPPS SAVINGS AVAILABLE FOR OTHER SERVICES		\$92,616,229

Beneficiary coinsurance payments will also be higher unless CMS maintains its equitable adjustment policy and re-establishes a conversion ratio \leq 260:1. At a conversion ratio of 260:1, beneficiary coinsurance payments would be reduced by \$9.8 million. At a conversion ratio of 200:1, the reduction would be \$18.5 million.

Conclusions regarding PROCRIT and ARANESP

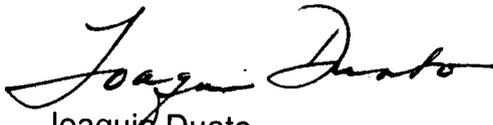
The same circumstances that led CMS to pay equivalent rates for PROCRIT and ARANESP in 2003, 2004, and 2005 argue for application of a comparable policy in 2006.

- PROCRIT and ARANESP have the same mechanism of action, and they can produce the same desired clinical effect depending on dosing.
- The original OPSS legislation provides the Secretary with the authority to make payment adjustments to ensure equitable payments, and the MMA confirms that authority, especially for PROCRIT and ARANESP.
- Ensuring equitable payments lowers the beneficiary coinsurance and generates savings that could be used for other OPSS services. It also minimizes the role of financial incentives in the choice of drug.

In addition, setting an appropriate conversion factor for PROCRIT and ARANESP can be based on the results of a scientifically rigorous head-to-head trial for the first time. This is consistent with the provision of the MMA that encourages studies of comparative effectiveness.

Thank you for your consideration of our comments and recommendations. If you have any questions, please contact Cathleen Dooley at 202-589-1008 (cdooley@obius.jnj.com).

Sincerely,



Joaquin Duato
President, Ortho Biotech Products, L.P.

- Attachment: White Paper – September 2005

Clinical White Paper Developed for CMS – September 2005

Executive Summary

Clinical White Paper Developed for CMS – September 2005

Executive Summary

This document summarizes new PROCRT (epoetin alfa) and ARANESP (darbepoetin alfa) clinical data, and supplements previous clinical white papers Ortho Biotech has submitted to CMS, regarding the PROCRT: ARANESP conversion ratio.

Since PROCRT is dosed in Units and ARANESP is dosed in micrograms (mcg), it is important to determine the conversion ratio that enables the crosswalk between the two agents. The conversion ratio informs policy makers at which doses the agents have comparable efficacy, thus providing guidance for equitable reimbursement decisions. There are two approaches to determining a conversion ratio (Units PROCRT: mcg ARANESP), -- the “dose only ratio” and the “dose conversion ratio”. The dose only ratio (dose only ratio = $\text{Dose}_{\text{PROCRT}}:\text{Dose}_{\text{ARANESP}}$) considers only PROCRT and ARANESP dose utilization and is useful when dose utilization data without corresponding hematologic outcomes data (e.g. claims data) are available. The dose conversion ratio (dose conversion ratio = $\text{Dose}_{\text{PROCRT}}/\text{Hb effect}_{\text{PROCRT}}:\text{Dose}_{\text{ARANESP}}/\text{Hb effect}_{\text{ARANESP}}$) considers the relative efficacy of the agents and is useful when data on dose utilization as well as hematologic effects over time are available for both agents (e.g. clinical trial data). When hematologic effects over time are the same for both drugs, either ratio approach yields the same results. When hematologic effects over time differ between the two agents, the dose conversion ratio is appropriate. For purposes of determining the dose conversion ratio of these two erythropoietic agents, a head to head study was designed and powered to compare hematologic outcomes with cumulative drug utilization. This study represents the gold standard, the highest level of evidence possible to address the conversion ratio issue, and fulfills the request initially made by CMS in its November 2002 Final Rule for OPSS (Federal Register 2002).

Analyses of these and other new data continue to uphold a dose conversion ratio of $\leq 260:1$ (Units PROCRT: mcg ARANESP). The Ortho Biotech-sponsored head to head study reported a dose conversion ratio of 199:1 (Units PROCRT: mcg ARANESP). Data updates from a practical clinical trial and drug utilization studies support a dose conversion ratio of 215:1 and a dose only ratio of $\leq 278:1$ in patients with chemotherapy-related anemia. Another study of chronic kidney disease patients support a dose only ratio of 271:1. These findings align with multiple studies that have previously been presented to CMS and are summarized in the table that follows.

New data and analyses

Chemotherapy-related anemia

Randomized head to head clinical trial designed to evaluate hematologic outcomes reported significantly better hematologic outcomes and lower red blood cell utilization in PROCRT-treated group compared to ARANESP-treated group (Waltzman 2005). The dose conversion ratio of 199:1 (Units PROCRT: mcg ARANESP) is consistent with published ARANESP registration trials, which describe a conversion ratio of 200:1 (Locatelli 2001, Vansteenkiste 2002, Vanrenterghem 2002).

Two additional studies reported more favorable clinical outcomes in patients treated with PROCRT QW compared to ARANESP Q2W:

- Glaspy (2005) conducted a randomized clinical trial showing a lower proportion of patients transfused and significantly higher proportion of patients achieving target hemoglobin in the PROCRT group compared to the ARANESP group; and
- Case (2005) reported a retrospective chart review showing a significantly lower proportion of patients requiring blood transfusions and lower overall red blood cell utilization in the PROCRT-treated patients compared to ARANESP-treated patients.

Updated results of a practical clinical trial of erythropoietic agents in cancer patients support a dose conversion ratio of 215:1 (Units PROCRT: mcg ARANESP).

Updated monthly PROCRT and ARANESP drug utilization trends demonstrated a steady increase in weekly ARANESP dose over time resulting in a corresponding decrease in the dose only ratio (May 2003: dose only ratio 294:1, May 2005: dose only ratio 266:1).

Updated data from a medical claims analysis of patients with cancer receiving erythropoietic agents (N=8,022) demonstrated a dose only ratio of 234:1 (Units PROCRT: mcg ARANESP).

A pooled analysis of dose only ratios from three medical claims studies with > 18,000 patients reported a dose only ratio of 256:1 (Units PROCRT: mcg ARANESP).

Predialysis chronic kidney disease

A medical claims study of patients with predialysis chronic kidney disease reported a dose only ratio of 271:1 (Units PROCRT: mcg ARANESP).

Summary of reports

As summarized in the table on page 3, a conversion ratio of $\leq 260:1$ is strongly supported by the accumulated clinical evidence over the past three years.

Summary of Studies: Estimating a PROCRIT: ARANESP Conversion Ratio

Position paper ¹	Study	Number of patients ²	Dose only ratio	Dose conversion ratio
September 2005	OBI Head to Head clinical trial (Final hematologic and dosing results)	178/180		199:1
	Practical clinical trial (updated results)	199/265		215:1
	Updated medical claims dosing study	8,022	234:1	
	Pooled analysis of medical claims studies	18,781	256:1	
	Utilization study (updated results)	~280,000	278:1	
	New retrospective study – CKD patients	1,350	271:1	
January 2005	OBI Head to Head clinical trial (Final Hb results)	352		187:1
	Practical clinical trial (updated results)	266		269:1
	New medical claims dosing study #1	6,354	281:1	
	New medical claims dosing study #2	6,784	263:1	
	Utilization study (updated results)	~150,000	277:1	
	Comparison of single agent trials: PROCRIT QW v. ARANESP QW ³	166/367		276:1
	New retrospective study – CKD patients	400	270:1	
	Elderly subset of VA CKD chart review (age ≥ 65)	344	265:1	
September 2004	OBI Head to Head clinical trial – Preliminary results	339		204:1
	Practical clinical trial	167		260:1
	Medical Claims Analysis	3,971	248:1	
	Medical Record Review (age ≥ 65)	465	268:1	187:1
	Utilization study	149,541	274:1	
	Patient Preference Study	500	289:1	
	VA CKD Chart Review	800	259:1	
	Nephrology Clinic Review	1,790	243:1	
September 2003	VISN 22	2,159	276:1	173:1
	Western Growers Insurance	1,152	239:1	129:1
	Medical Record Review	1,005	241:1	172:1
	Electronic Medical Record	3,136	272:1	275:1
	Comparison of published single agent trials: PROCRIT QW v. ARANESP Q2W ⁴	2,964/1,103	333:1	258:1
	PROCRIT QW v. ARANESP Q2W ⁵	442/1,103	329:1	257:1
	PROCRIT QW v. ARANESP Front-loading ⁶	2,934/122	235:1	239:1
	Vanrenterghem (2002) (CKD - dialysis)	522		252:1
	Mann (2003) (CKD dialysis)	1,502		225:1
	Carrera (2003) (CKD dialysis)	4,792		205-232:1
September 2002	Single agent trials: PROCRIT QW v. ARANESP QW ⁷	764/156		254:1
	Nissenson (2002) (CKD dialysis)	504		260:1
	Locatelli (2001) (CKD predialysis)	166		222:1

Background

PROCRIT and ARANESP are two erythropoietic agents that differ structurally but have the same mechanism of action (i.e., both products stimulate red blood cell production). The contrasting structures are outlined on page 4.

¹ Date of Ortho Biotech position paper submitted to CMS

² Patient numbers separated by a slash indicate PROCRIT/ARANESP patient numbers in respective clinical trials

³ Witzig (2004), Kotasek (2004)

⁴ Gabrilove (2001), Vadhan-Raj (2003)

⁵ Shasha (2003), Vadhan-Raj (2003)

⁶ Gabrilove (2001), Hesketh (2003)

⁷ Vansteenkiste (2003), Gabrilove (lung cancer subset)

PROCRIT	ARANESP
<p>Identical to Natural EPO</p> <p>165 amino acids</p> <p>3 N-linked carbohydrate chains</p> <p>≤14 sialic acid residues</p>	<p>Different from Natural EPO</p> <p>165 amino acids (5 different)</p> <p>5 N-linked carbohydrate chains</p> <p>≤22 sialic acid residues</p>
<p>Similar Molecular Weight to Natural Erythropoietin</p> <p>30,400 daltons</p>	<p>Heavier in Molecular Weight than Natural Erythropoietin</p> <p>38,500 daltons</p>

The structural modifications of ARANESP, with increased sialic acid-containing carbohydrates, led to an increase in the serum half-life of the protein and a decrease in the binding affinity for the erythropoietin receptor. The clinical relevancy, if any, of these modifications is not well established. It is also worth noting that the current PROCRT package insert lists an average half-life of 40 hours in patients with cancer (range 16-67 hours), which is comparable to the ARANESP half-life ranging from 32.6 to 49.7 hours (Glaspy 2000; Tseng 2000; Heatherington 2001).

PROCRT and ARANESP have the same mechanism of action (stimulation of red blood cell production) by binding to the same erythropoietin receptor. This stimulates the proliferation and differentiation of these cells into mature red blood cells by the same series of changes, despite the chemical and pharmacokinetic differences between the two molecules.

Chemotherapy-related anemia

A randomized head to head clinical trial designed to evaluate hematologic outcomes reported significantly better hematologic outcomes and lower red blood cell utilization in PROCRT-treated group compared to ARANESP-treated group (Waltzman 2005). The dose conversion ratio of 199:1 (Units PROCRT: mcg ARANESP) is consistent with published ARANESP registration trials, which describe a conversion ratio of 200:1 (Locatelli 2001, Vansteenkiste 2002, Vanrenterghem 2002).

Waltzman et al. (2005) reported final results of a 16-week, prospective, Phase III, randomized, multicenter, open-label trial directly comparing hemoglobin (Hb) response and transfusion requirements of PROCRT and ARANESP in 358 anemic cancer patients with solid tumors receiving chemotherapy. Patients were randomized 1:1 to receive either PROCRT 40,000 units (U) once weekly (QW) or ARANESP 200 micrograms (mcg) every other week (Q2W). In accordance with the National Comprehensive Cancer Network (NCCN) guidelines, if the Hb response was < 1 g/dL, the dose of PROCRT and ARANESP was increased to 60,000 U SC QW at four weeks and 300 mcg SC Q2W at six weeks, respectively.

The primary efficacy endpoint was the percent of patients with a Hb increase of ≥ 1 g/dL by Week 5 (i.e. within four weeks of treatment). This endpoint was based on previous research which demonstrated clinical benefits (eg. lower proportion of patients requiring red blood cell transfusion, lower drug utilization) in patients achieving ≥ 1 g/dL Hb increase by Week 5. (Reed

2005, Campos 2005). The importance of early hemoglobin response is highlighted by observational studies, which reported mean treatment duration for erythropoietic agents of 7-10 weeks (Mark 2005, Lefevbre 2005). Secondary endpoints included red blood cell (RBC) transfusion requirements, the change in Hb from baseline at weekly intervals, and area under the Hb change curve, or Hb AUC. Hb AUC assesses the hematologic effect over an entire treatment course rather than at fixed time points. Hb AUC₁₆ is calculated based on the weekly mean change in Hb and is a clinically meaningful measure that is useful in quantifying clinical benefits in patients receiving erythropoietic agents (Duh 2005, Lefevbre 2004).

Eligibility criteria included adult patients with solid tumors scheduled to receive chemotherapy for at least 12 weeks with a baseline Hb \leq 11 g/dL. Patients were excluded if they were treated with any erythropoietic agent within three months of enrollment or had a RBC transfusion within 28 days prior to randomization. Patients were withdrawn from the study if they did not complete a minimum of 12 weeks of chemotherapy.

The modified intent-to-treat (MITT) population included patients who received at least one dose of study drug and had at least one post-baseline Hb value or transfusion. Hb values within 28 days of transfusion were not imputed (assumed missing). Last Hb value carried forward (LVCF) was used to analyze all Hb data post transfusion and any missing Hb data.

Baseline characteristics were similar between treatment groups with regard to age, gender, weight, tumor type, type of chemotherapy, and functional status (as assessed by Eastern Cooperative Oncology Group performance status).

Table 1. Similar baseline patient characteristics were observed in the PROCRIT QW and ARANESP Q2W groups

CHARACTERISTIC	PROCRIT QW (n=178)	ARANESP Q2W (n=180)
Age, years (SD)	62.1 (11.8)	63.4 (11.8)
Gender, % Female	61%	66%
Weight, kg (SD)	72.8 (18.2)	74.8 (19.6)
Hemoglobin, g/dL (SD)	10.14 (0.75)	10.02 (0.84)
Major tumor types (%)		
Lung cancer	26%	26%
Breast cancer	21%	28%
Colorectal cancer	16%	10%
Chemotherapy type (%)		
Platinum-based	39%	42%
Non platinum-based	61%	58%
Eastern Cooperative Oncology Group Performance Status (%)		
0	32%	34%
1	53%	49%
2	15%	17%

As shown in Table 2, a significantly greater proportion of patients achieved the primary efficacy endpoint (% of patients achieving a Hb rise \geq 1 g/dL within 5 weeks) in the PROCRIT group compared to the ARANESP group. Additionally, a greater proportion of patients achieved an Hb increase \geq 2 g/dL at Weeks 9 and 17 in the PROCRIT group compared to the ARANESP group. Although the study was not powered for comparison of red cell transfusion utilization, a lower proportion of patients required red blood cell transfusion in the PROCRIT group compared to the ARANESP group. The total number of units transfused was also lower in the PROCRIT group. This was driven by the lower proportion of patients transfused and a lower number of units transfused in those patients needing red cell transfusion.

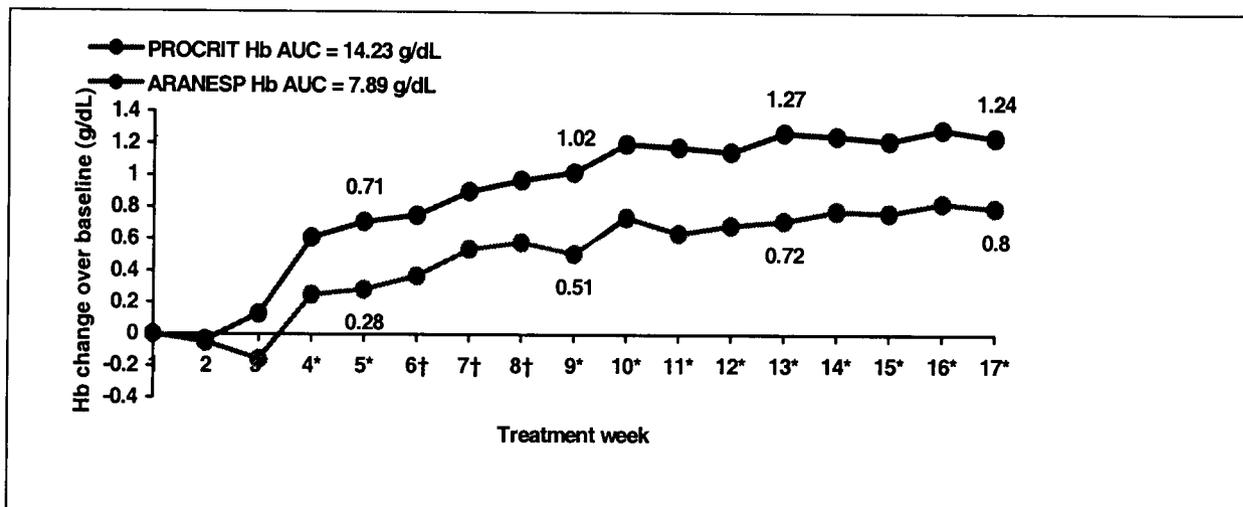
A similar proportion of patients required dose escalation in both treatment groups (PROCRIT 33%, ARANESP 34%).

Table 2. Results of randomized, controlled head to head study demonstrated significantly better hematologic outcomes and lower red blood cell utilization in patients receiving PROCRIT QW compared to ARANESP Q2W

	PROCRIT (n=178)	ARANESP (n=180)	P value
Hematologic response rates			
Number of Hb responders [Hb \geq 1 g/dL by Week 5] (%)	47% (n = 151)	32.5% (n = 154)	N = 305* P = 0.0078
Number of patients who achieved an Hb increase \geq 2 g/dL by Week 9 (%)	78 (44.6%)	48 (27.1%)	<0.001
Number of patients who achieved an Hb increase \geq 2 g/dL by Week 17 (%)	101 (57.7%)	74 (41.8%)	0.004
Transfusion Requirements			
Number of patients receiving a transfusion from Day 29 to end of study (%)	20/155 (12.9%)	29/163 (17.8%)	0.2936
Mean number of PRBC units received per transfused patients from Day 29 to end of study (number of patients transfused)	2.5 units (n = 20)	3.9 units (n = 29)	0.0334
Total number of PRBC units transfused during the study	81 units	156 units	----

*Six patients completed Week 5 on the same

Figure 1. Significantly greater hemoglobin change over baseline in PROCRIT QW group compared to ARANESP Q2W group (Week 3-17, * $p \leq 0.009$, + $p \leq 0.023$)



MEASURE	PROCRIT	ARANESP
Mean cumulative dose	427,497 Units	1,193 mcg
Hb AUC ₁₆ ⁸	14.23 g/dL	7.89 g/dL
Dose conversion ratio	199:1 (U PROCRIT: mcg ARANESP)	

A significantly greater increase in Hb at all measurement intervals was observed from Week 3 to end of study in the PROCRIT-treated patients compared to ARANESP-treated patients ($p \leq 0.023$). Additionally, there was significantly greater cumulative hematologic effect, assessed by area under the Hb change curve (or Hb AUC) in the PROCRIT-treated patients compared to the ARANESP-treated patients. The authors concluded that, in chemotherapy-treated anemic patients with solid tumors, PROCRIT 40,000 U QW resulted in a significantly greater hemoglobin response (Hb increase of ≥ 1 g/dL by Week 5) compared to ARANESP 200 mcg Q2W. The authors stated that this difference in hemoglobin response between the two groups was apparent prior to dose increases. PROCRIT-treated patients were also transfused fewer packed RBC units compared to ARANESP-treated patients.

Randomized, controlled clinical trials designed to compare hematologic outcomes represent the gold standard for understanding the relative efficacy, or dose conversion ratio, of the erythropoietic agents. This head to head clinical trial reported the overall hematologic outcomes and cumulative drug dose, which allows determination of the dose conversion ratio. The dose conversion ratio of 199:1 (Units PROCRIT: mcg ARANESP) from this randomized, controlled trial aligns with the published ARANESP registration studies, which describe a ratio of 200:1 (Vansteenkiste 2002, Locatelli 2001, Vanrenterghem 2002).

Two additional studies reported more favorable clinical outcomes in patients treated with PROCRIT QW compared to ARANESP Q2W:

- Glaspy (2005) conducted a randomized clinical trial showing a lower proportion of patients transfused and significantly higher proportion of patients achieving target hemoglobin in the PROCRIT group compared to the ARANESP group.
- Case (2005) reported a retrospective chart review showing a significantly lower proportion of patients requiring blood transfusions and lower red blood cell

⁸Dose conversion ratio: calculated as cumulative dose_{PROCRIT} divided by Hb AUC₁₆_{PROCRIT}: cumulative dose_{ARANESP} divided by Hb AUC₁₆_{ARANESP}

utilization in the PROCRT-treated patients compared to ARANESP-treated patients.

Glaspay et al. (2005) reported final results of a randomized, Phase III, open-label, multicenter study to compare the efficacy and safety of ARANESP with PROCRT in anemic (Hb \leq 11 g/dL) patients with non-myeloid malignancies receiving chemotherapy. One thousand two hundred and twenty-two patients were randomized to receive either ARANESP 200 mcg Q2W or PROCRT 40,000 U QW for 16 weeks. Dose titration (following protocol amendment) occurred at the physician's discretion. The primary efficacy endpoint was measured by the incidence of transfusions from Day 29 (Week 5) to the end of treatment period (EOTP).

Baseline characteristics were comparable between groups. The mean baseline Hb level for ARANESP and PROCRT was 10.18 g/dL and 10.21 g/dL, respectively. The primary transfusion analysis set consisted of patients who received at least one dose of study drug and remained on study until Day 29 (Week 5).

Based on a pre-specified margin of 11.5%, the incidence of transfusions from Week 5 to EOTP demonstrated non-inferiority of ARANESP. This 11.5% margin would suggest that the investigator could conclude non-inferiority despite 1 in 9 more patients requiring red blood cell transfusions in the ARANESP arm. Additionally, post hoc analysis by Ortho Biotech statisticians testing for differences in the proportion of patients transfused found the PROCRT group had a significantly lower proportion of patients transfused compared to the ARANESP group ($p < 0.05$). Using Kaplan-Meier (K-M) estimates, a higher percentage of patients achieved a target Hb earlier in the PROCRT group compared to the ARANESP group.

Table 3. Results demonstrated lower proportion of patients transfused and significantly higher proportion of patients achieved target hemoglobin in the PROCRT QW group compared with the ARANESP Q2W group

MEASURE	PROCRT (n=571)	ARANESP (n=582)
Transfusion Incidence		
K-M percentage of patients receiving RBC transfusions (Week 5 to end of treatment)	16%	21%
Hematologic endpoints		
K-M proportion of patients achieving target Hb \geq 11 g/dL (95% confidence interval)	95.5% (93.6 to 97.4%)	90.3% (87.6 to 93.1%)
K-M median time to target Hb (unadjusted)	5 weeks	6 weeks

Glaspay (2005) did not report weekly hemoglobin change over baseline, which prevents understanding of hematologic outcomes prior to study week 9 in this study. Additionally, the mean cumulative dose for each treatment was not reported, precluding any calculation of a dose conversion ratio.

Key differences of the two head-to-head clinical trials

The Waltzman (2005) and Glaspay (2005) trials described similar patient populations and initial dosing of erythropoietic agents; however, key differences exist in the protocols and study execution. To obtain a complete understanding of hemoglobin improvement in cancer patients receiving chemotherapy, the Waltzman trial required active chemotherapy for at least 12 weeks, while the Glaspay trial only required patients to have planned chemotherapy for eight weeks. Additionally, amendments during the Glaspay trial allowed dose escalation at physician discretion rather than at a recommended trigger, changed the study duration period from 12 to 16 weeks, and substantially increased the number of patients enrolled.

The following table contrasts the two comparative clinical trials using PROCRIT and ARANESP in patients with chemotherapy-induced anemia.

FEATURE	Waltzman 2005	Gaspy 2005
Study design	Superiority	Non-Inferiority
Eligibility Criteria	Required ≥ 12 weeks of chemotherapy	Planned ≥ 8 weeks of chemotherapy
No Prior EPO use	For 3 Months	For 4 Weeks
Primary endpoint	Hb response rate (% of patients with Hb $\uparrow \geq 1$ g/dL by Week 5)	Proportion of patients transfused Week 5 to end of study
Major Protocol Amendments	None	Protocol amended to extend dosing period from 12 to 16 weeks, allow dose titration by MD discretion, increase in total n to approximately 1200 patients
Reporting of Results	Complete reporting of Hb change at all treatment weeks; Reported mean cumulative dose; Number of PRBC units transfused	Hb level reported only at Weeks 9 and 17; Mean cumulative dose not reported; Number of PRBC units transfused not reported

Case (2005) reported a retrospective chart review of gynecologic oncology patients with chemotherapy-induced anemia who were receiving PROCRIT or ARANESP. One hundred and twenty-three patients were identified with similar age, tumor type, and baseline hemoglobin. Eighty-six percent of PROCRIT patients received PROCRIT 40,000 Units weekly, and 93% of ARANESP patients received ARANESP 200 mcg Q2W. A significantly lower proportion of patients required red blood cell transfusions in the PROCRIT group compared to the ARANESP group (PROCRIT 19%, ARANESP 35%, $p=0.05$). This difference was maintained when controlling for age, chemotherapy courses, types of chemotherapy given, number of cycles of chemotherapy, tumor site, and baseline hemoglobin. Additionally, fewer total units of blood were transfused in the PROCRIT group compared to the ARANESP group (PROCRIT 32 units, ARANESP 62 units).

Table 4. Lower red blood cell utilization and significantly lower proportion of patients requiring red blood cell transfusion in PROCRIT group compared to ARANESP group

MEASURE	PROCRIT (n=63)	ARANESP (n=60)
Proportion of patients requiring red blood cell transfusion	19%	35%*
Number of units transfused to entire group	32 units	62 units

*Significantly lower proportion of patients requiring transfusion in the PROCRIT group v. ARANESP group ($p=0.05$)

Updated results of a practical clinical trial of erythropoietic agents in cancer patients supported a dose conversion ratio of 215:1 (Units PROCRIT: mcg ARANESP)

To understand PROCRIT and ARANESP dosing patterns and hematologic outcomes, a prospective, observational study is underway at multiple U.S. sites. A total of 464 patients from 25 sites were enrolled between January 2004 and April 2005 in the Dosing and Outcomes Study of Erythropoiesis Stimulating Therapies (D.O.S.E. Registry). Sites were geographically dispersed with participation by oncology clinics in Alabama, Arkansas, California, Colorado, Connecticut, Hawaii, Iowa, Illinois, Louisiana, Massachusetts, Maryland, Minnesota, New Mexico, New York, Ohio, Pennsylvania, Rhode Island, Texas, Virginia, and West Virginia. Inclusion criteria included age ≥ 18 , diagnosis of non-myeloid malignancy, receiving PROCRIT or ARANESP for chemotherapy-related anemia, no erythropoietic agents for at least 90 days prior to study entry,

and signed informed consent. Exclusion criteria included active participation in a PROCRIT or ARANESP clinical trial (which might dictate protocol-mandated dosing), dialysis for end-stage renal disease, planned stem cell transplant, or a diagnosis of myelodysplasia.

As shown in Table 5, baseline demographic and clinical characteristics were similar between treatment groups regarding age, gender, weight, and baseline hemoglobin.

Table 5. Similar baseline characteristics in PROCRIT and ARANESP group in practical clinical trial

CHARACTERISTIC	PROCRIT (n=199)	ARANESP (n=265)	p value
Age, years (SD)	62.5 (12.1)	62.3 (12.9)	0.86
% Female	64%	65%	0.87
Weight, kg (SD)	75.1 (19.6)	74.3 (19.1)	0.66
Baseline Hb, g/dL (SD)	10.4 (0.9)	10.4 (1.0)	0.99
Major Tumor Types (%)			
Breast	25%	27%	0.13
Lung	25%	26%	
Gastrointestinal	22%	14%	

The median dose for PROCRIT was 40,000 Units (range 16,000-90,000) and the median dose for ARANESP was 200 mcg (range 100-500). Weekly, every 2-week, and every 3-week dosing was reported in both groups. Treatment duration was similar in both groups (PROCRIT 7.8 weeks, ARANESP 8.1 weeks).

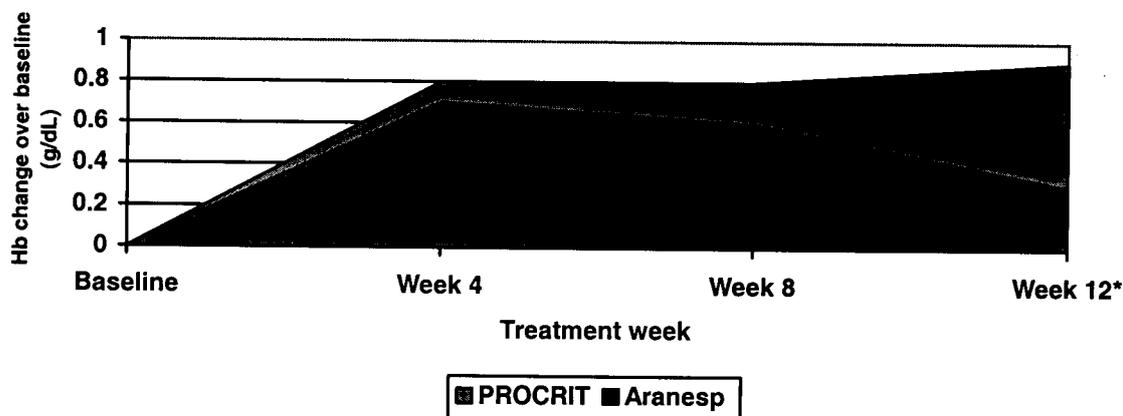
Characteristics of overall erythropoietic treatment and hematologic outcomes are summarized in Table 6 and Figure 2. The mean cumulative administered dose was 354,694 Units for PROCRIT and 1,167 mcg for ARANESP. Significant differences were observed in the Hb change over baseline at the week 12 timepoint (p=0.02) (Figure 2). To understand the relative effectiveness of these agents, consideration of both cumulative dosing and hematologic effectiveness over the study period was employed. The dose conversion ratio (215:1) was calculated based on cumulative dose and hematologic effect (Hb AUC).

Table 6. Treatment characteristics and hematologic outcomes of practical clinical trial

MEASURE	PROCRIT (n=199)	ARANESP (n=265)
Cumulative Dose	354,694 Units	1,167 mcg
Cumulative hematologic effect (12-week Hb AUC)	8.2 g/dL	5.8 g/dl
Dose conversion ratio ⁹	215:1 (Units PROCRIT: mcg ARANESP)	

⁹ Dose conversion ratio = $\text{Dose}_{\text{PROCRIT}} / \text{Hb AUC}_{\text{PROCRIT}} : \text{Dose}_{\text{ARANESP}} : \text{Hb AUC}_{\text{ARANESP}}$

Figure 2. Hb change over baseline at week 4, 8, and 12 (*p=0.02 at week 12 comparing Hb change over baseline for PROCRIT v. ARANESP group)



Number of patients by timepoint	Baseline	Week 4	Week 8	Week 12
PROCRIT	199	124	74	56
ARANESP	265	191	117	71

PROCRIT/ARANESP Utilization study (Updated results)

Updated monthly PROCRIT and ARANESP drug utilization trends demonstrated steady increases in weekly ARANESP dose over time, corresponding to a decreasing dose only ratio (May 2003: dose only ratio 294:1, May 2005: dose only ratio 266:1).

A study was conducted to understand utilization trends of PROCRIT and ARANESP in community oncology practices and estimate a dose only ratio between these two agents in approximately 11,000 patients/month. This project was described in detail in the October 2004 Ortho Biotech clinical white paper.

This cross-sectional analysis provided data describing the most recent weekly dosing trends from May 2003 through May 2005. An average of 5,424 PROCRIT patients and 5,935 ARANESP patients contributed data monthly. Mean weekly doses (May 2003 versus May 2005) increased 1.5% (35,735 to 36,280 Units) for PROCRIT and increased 12.2% for ARANESP (122 to 137 mcg) resulting in an overall decline in the PROCRIT: ARANESP dose only ratio from 294:1 to 266:1. The mean weighted dose only ratio over the course of the study was 278:1 (Units PROCRIT: mcg ARANESP). Mean weekly PROCRIT and ARANESP dosing from May 2003 through May 2005 and resulting dose only ratio are described in the figures on page 11.

Figure 3. Mean weekly PROCIT dose increased by 1.5% from May 2003 through May 2005

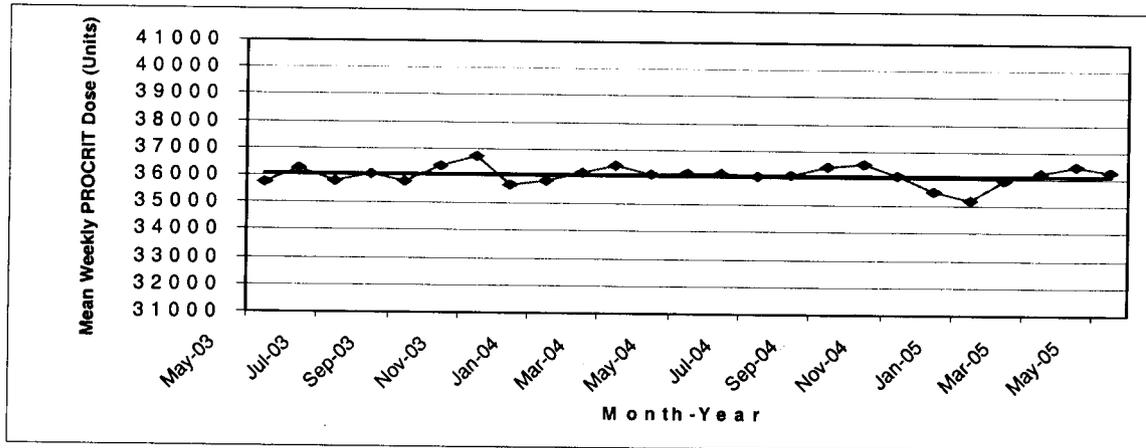


Figure 4. Mean weekly ARANESP dose increased by 12.2% from May 2003 through May 2005

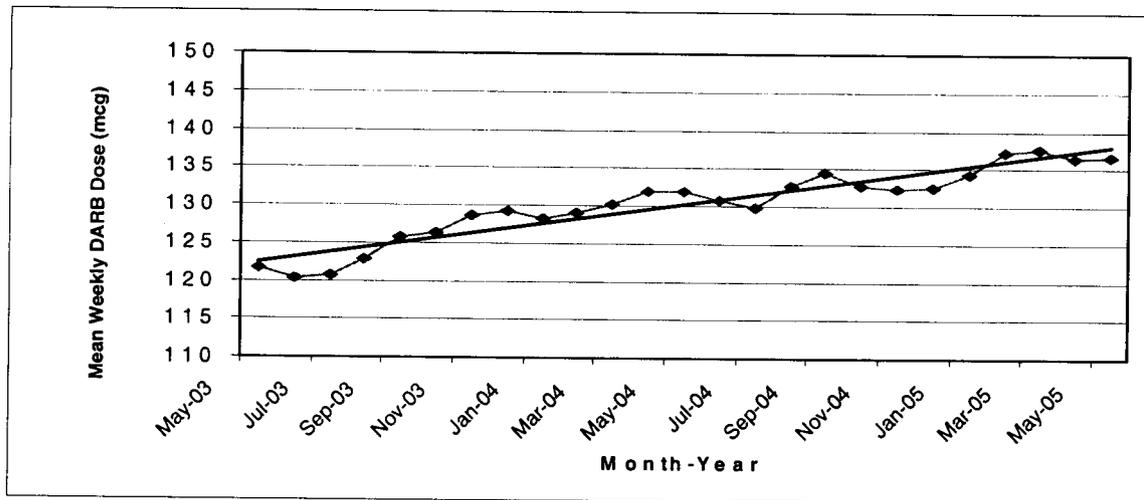
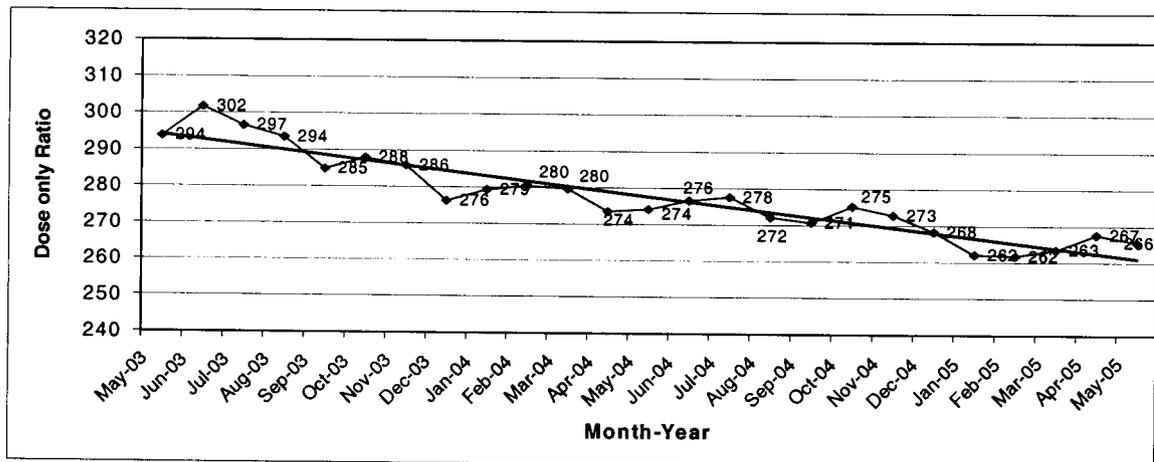


Figure 5. The dose only ratio decreased from 294:1 in May 2003 to 266:1 in May 2005



Updated data from a medical claims analysis of patients with cancer receiving erythropoietic agents (N=8,022) demonstrated a dose only ratio of 234:1 (Units PROCRIT: mcg ARANESP).

An analysis of medical claims was conducted to investigate the dose only ratio between PROCRIT and ARANESP in patients with cancer. The described analysis was conducted in a similar format to the medical claims study reported in the October 2004 Ortho Biotech white paper submitted to CMS; however, the data were updated to include January-December 2004.

A number of potential data sources were explored. It was decided *a priori* that the data source must contain a sufficient number of patients in each group, be longitudinal in nature, and provide date(s) of service to establish dosing frequency and duration of treatment. Claims data were obtained from the Integrated Healthcare Information Solutions' (IHGIS) National Benchmark Database. This database contains complete medical and outpatient prescription drug dispensing claims from approximately 35 health care plans, enrolling approximately 30 million covered lives throughout the US. To be included in the analysis, patients were required to be ≥ 18 years of age, have at least two treatment claims for either PROCRIT or ARANESP from October 1, 2002 through December 31, 2004, and have at least one cancer diagnosis claim within three months of initiating the erythropoietic therapy. To eliminate the potential confounding effect from patients switched from one agent to another, or on maintenance treatment, the newly initiated population (defined as those patients with a 3-month washout period prior to the first PROCRIT or ARANESP claim) was investigated. For evaluation of treatment courses, patients were required to have at least two doses of erythropoietic agents. If two consecutive claims of erythropoietic agents were more than 35 days apart, the second claim marked a new treatment episode. If a patient had more than one treatment episode, the most recent treatment episode was used for the analysis.

From the database, a total of 8,022 patients (consisting of 5,796 PROCRIT and 2,226 ARANESP patients) were identified. Patient baseline characteristics were comparable with respect to mean age and gender distributions (Age: PROCRIT 59 years; ARANESP 58 years; % female: PROCRIT 62%; ARANESP 67%). Treatment duration was similar between groups and cumulative PROCRIT and ARANESP doses over the course of treatment resulted in a dose only ratio of 234:1.

MEASURE	PROCRIT (N=5,796)	ARANESP (N=2,226)	P value	Dose only ratio (PROCRIT:ARANESP)
Treatment duration	58 days	59 days	0.34	
Cumulative dose	269,811 Units	1,154 mcg	NA	234 :1

A pooled analysis of dose only ratios of three medical claims studies with > 18,000 patients reported a dose only ratio of 256:1 (Units PROCRIT: mcg ARANESP).

In the January 2005 Ortho Biotech clinical white paper, two large medical claims projects were described and are summarized in the table below. Both studies reported similar age, gender distribution, and treatment duration between PROCRIT and ARANESP groups.

Study	Cumulative PROCRIT dose	Cumulative ARANESP dose	Dose only ratio (PROCRIT: ARANESP)
Medical claims study #1 (n=6,354)	280,588 Units	1,000 mcg	281:1
Medical claims study #2 (n=4,405)	357,836 Units	1,366 mcg	262:1

Combining the results of the three recent studies allowed consideration of recent PROCRT and ARANESP dosing data from over 18,000 patients. The weighted average of dose only ratios, based on the relative sample sizes of these three studies, resulted in a dose only ratio of 256:1 (Units PROCRT: mcg ARANESP) as described in the table below.

Study	N	Dose only ratio	Weighted dose only ratio
Updated IHCIS study described above	8,022	234:1	256:1 (Units PROCRT: mcg ARANESP)
Medical claims study #1	6,354	281:1	
Medical claims study #2	4,405	262:1	

Predialysis Chronic Kidney Disease

Medical claims study of patients with predialysis chronic kidney disease reported a dose only ratio of 271:1 (Units PROCRT: mcg ARANESP).

Using the ICHIS database (as described in the above oncology section), a medical claims study was conducted to understand relative PROCRT and ARANESP dosing patterns in patients with predialysis chronic kidney disease. Baseline patient demographics reported higher mean age of the PROCRT group (Age: PROCRT 64.2, ARANESP 61.9, p=0.0032) with similar gender distribution. Because patients with predialysis chronic kidney disease have longer treatment duration (relative to oncology patients) and variability of dosing patterns in the early initiation phase v. maintenance phase, comparison of the weighted average weekly dose was reported for both groups. Comparison of the weighted average weekly dose results in a dose only ratio of 271:1 (Units PROCRT: mcg ARANESP).

MEASURE	PROCRT (N=954)	ARANESP (N=396)	P value	Dose only ratio (PROCRT: ARANESP)
Treatment duration	85 days	76 days	0.09	
Weighted average weekly dose	14,759 Units	54.4 mcg	NA	271:1

Conclusion

New clinical data continue to support the initially established dose conversion ratio of $\leq 260:1$ (Units PROCRT: mcg ARANESP). A large, randomized, controlled trial designed to evaluate the hematologic and dosing outcomes of PROCRT and ARANESP in oncology patients reported a dose conversion ratio of 199:1, which aligns with the dose conversion ratio of 200:1 described in the published literature of ARANESP registration trials. A practical clinical trial of real world PROCRT and ARANESP dosing practices and outcomes reported a dose conversion ratio of 215:1. A large observational study demonstrated a steady increase in the average weekly ARANESP dose. The average weekly dose of ARANESP in May 2003 was 122 mcg, but by May 2005 there had been a 12% increase in the average weekly dose, bringing it to 137 mcg. This could have been anticipated, since the mean weekly dose recommended in the FDA approved package insert for ARANESP is 157.5 mcg¹⁰; with experience, health care professionals may now be dosing ARANESP to achieve hematologic outcomes previously observed with PROCRT. Multiple observational studies support a dose only ratio of $\leq 278:1$ in oncology and chronic kidney disease. Based on the new and previously summarized clinical data, the preponderance of evidence from a variety of study designs and data types over the past three years supports the true conversion ratio to be $\leq 260:1$ (Units PROCRT: mcg ARANESP), as was initially described by CMS in its 2003 Final Rule.

¹⁰ FDA-approved ARANESP starting dose – 2.25 mcg/kg QW * 70kg (mean weight) = 157.5 mcg QW

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September 16, 2005

By Hand Delivery

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RECEIVED - CMS
2005 SEP 16 P 3:15

**Re: CMS-1501-P
Medicare Program; Proposed Changes to the HOPPS and
Calendar Year 2006 Payment Rates, 70 Fed. Reg. 42,674 (July
25, 2005).**

Dear Dr. McClellan:

MGI PHARMA ("MGI") respectfully submits the following comments pertaining to the Proposed Rule issued by the Centers for Medicare and Medicaid Services ("CMS") on the Medicare outpatient prospective payment system for drugs. (See Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 Fed. Reg. 42,674 (July 25, 2005).) MGI is an oncology and acute care focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients. MGI markets Aloxi® (palonosetron hydrochloride) injection, Kadian® (sustained release morphine sulfate) capsules, Salagen® Tablets (pilocarpine hydrochloride) and Hexalen® (altretamine) capsules in the United States.

In brief our comments are as follows:

- MGI supports CMS's proposal to reimburse separately-payable specified covered outpatient drugs, including Aloxi, a 5HT₃ receptor antagonist, at ASP+6%.
- MGI requests that CMS consider whether, in the future, further adjustments to the pass-through payment methodology are necessary to achieve the intent of pass-through status (i.e., to recognize and cover the cost of innovative new drugs and orphan drugs).

- MGI recommends that CMS provide further guidance in the HOPPS Final Rule on coding for drug administration in the hospital outpatient setting using the new CPT codes and evaluate the adequacy of payment rates under the new codes.
- MGI encourages CMS to reevaluate the proposed payment methodology for pharmacy handling costs and postpone the implementation of the corresponding C-codes until January 1, 2007.

I. Discussion and Recommendations

A. MGI supports CMS's proposal to reimburse separately-payable specified covered outpatient drugs, including Aloxi, at ASP+6%.

MGI supports CMS's proposal to reimburse separately payable specified covered outpatient drugs ("SCODs") at ASP+6% during calendar year 2006. We believe that using ASP as the SCOD reimbursement methodology is reasonable and will be an appropriate proxy for hospital acquisition cost for calendar year 2006. In particular, we support basing payment for Aloxi on ASP+6% and applying the same reimbursement methodology to it as will be applied to all other 5HT₃ anti-emetics.

B. MGI requests that CMS consider whether further adjustments to pass-through payment amounts are necessary.

MGI requests that CMS continue to evaluate whether its reimbursement methodology for pass-through drugs appropriately recognizes and covers the "additional costs of innovative medical devices, drugs, and biologicals." See Section 1833(t)(6)(D)(i) of the Social Security Act. We believe that applying the same reimbursement methodology to pass-through drugs and SCODs (i.e., ASP+6%) may not appropriately recognize and reimburse hospitals for the additional costs that are often associated with new technologies that are given pass-through status. We request that CMS consider making the pass through payment methodology consistent with the methodology applied to new drugs in the physician office setting (i.e., wholesale acquisition cost ("WAC") or the applicable payment methodology in effect on November 1, 2003) to distinguish and provide sufficient reimbursement for the class of pass-through drugs in future years.

- C. MGI recommends that CMS provide further guidance in the HOPPS Final Rule on coding for drug administration in the hospital outpatient setting using the new CPT codes and evaluate the adequacy of payment rates under the new codes.**

MGI requests that CMS provide further guidance in the HOPPS Final Rule on the use of the new CPT codes for drug administration. We believe such guidance will reduce confusion and promote more accurate coding for hospital outpatient services during calendar year 2006. In particular, we are concerned about the new coding guidelines for multiple infusions and the reporting of infusions that are of a subsequent or concurrent nature. The guidelines provide that a subsequent or concurrent code should be reported if an injection or infusion is of a subsequent or concurrent nature, even if it is the first service within a group of services. See American Medical Association, CPT 2006, available at <http://www.ama-assn.org>. We believe this guidance, if applied in the hospital outpatient setting, could result in under-reimbursement of certain therapies because hospitals are not reimbursed under HOPPS for additional hours of drug administration. This could cause hospitals to restrict patient access to important life improving medications, including anti-emetic therapies that typically are infused in conjunction with chemotherapy. Such a result would be inconsistent with CMS's stated goal elsewhere in the HOPPS Proposed Rule of ensuring access to anti-emetic drugs. See 70 Fed. Reg. at 42733. In the Final Rule, CMS should instruct hospital outpatient departments to continue to bill multiple "initial" codes for infusions, consistent with their past practices. We also request that CMS provide guidance on the use of the new codes similar to the type of guidance CMS provided when the codes were introduced in the physician office setting (e.g., through transmittals, Medlearn Matters articles, and the CMS website).

MGI further requests that CMS evaluate the adequacy of payment rates under the new codes. In the Proposed Rule, CMS indicates that the payment rates are dependent on calendar year 2004 data containing per-visit charges for HCPCS codes Q0081, Q0083, and Q0084. MGI is concerned that, because this data is two years old, exclusive reliance on it may result in inadequate payment rates for drug administration. We recommend that CMS supplement the 2004 data with external source information, including charge data collected using the new CPT codes, and adjust rates as needed to protect access to care.

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D. MGI encourages CMS to reevaluate the adequacy of the proposed payment methodology for pharmacy handling costs.

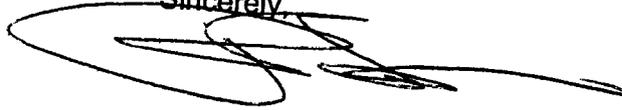
MGI encourages CMS to reevaluate the proposed payment methodology for pharmacy handling costs in the Proposed Rule. While MGI applauds CMS's recognition that additional payments are needed to cover the handling costs associated with furnishing some drug therapies in the hospital outpatient setting, we question the adequacy of the proposed rates. Specifically, a payment methodology based on 2% of ASP for a particular drug may not cover its associated handling costs. We recommend that CMS consider monitoring the payment amounts for pharmacy handling costs until such time as CMS collects enough hospital charge data to make a reassessment.

We also believe that CMS may have difficulties in collecting data on pharmacy handling services while hospitals transition to reporting charges using the applicable new C-codes if the use of the new codes is not tied to reimbursement. Therefore, we support the recommendation of the APC Advisory Panel that CMS delay the implementation of the C-codes until January 1, 2007 to allow sufficient time for CMS to refine the codes and develop instructions for their use.

* * * * *

MGI appreciates this opportunity to present these comments to CMS. Please do not hesitate to contact us if you have any questions.

Sincerely,



Eric Loukas

Senior Vice President, General Counsel
and Secretary

cc: Joan Sanow
Sabrina Ahmed
Jim Hart