Submitter : **Mr. Stephen McMillan** **Date: 10/10/2006**

Organization : **AstraZeneca Pharmaceuticals LP**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-504-Attach-1.TXT

CMS-1506-P-504-Attach-2.DOC

Attachment 1 to #504

AstraZeneca

October 10, 2006

By Electronic Delivery
Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Proposed Rule: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rules

Dear Dr. McClellan:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca") is pleased to submit comments on the Proposed Rule issued by the Centers for Medicare & Medicaid Services ("CMS") to revise payment policies under the Hospital Outpatient Prospective Payment System for 2007 (the "Proposed Rule", 71 Fed. Reg. 49,506 (Aug. 23, 2006)). We appreciate this opportunity to share our views on the proposed changes to Medicare Part B payment policies.

AstraZeneca is one of the world's leading pharmaceutical companies, with a strong commitment to developing treatment options for debilitating diseases and improving patient lives. In keeping with this commitment, AstraZeneca manufactures several drugs that are reimbursed under Hospital Outpatient Prospective Payment System ("OPPS"). We support revisions to OPPS policies that provide open access to drugs and ensure continuity of patient care. In that regard, the Final Rule should set forth clarifications in accordance with the following principles:

- **CMS should not reduce the payment rate for separately payable specified covered outpatient drugs to 105 percent of average sales price (ASP). Pricing differentials between sites of care (e.g., ASP+6% for physician offices) may lead to inappropriate steering of patients based on reimbursement rates and could adversely impact patient access to care.**

- **CMS Should Provide Separate Reimbursement for All Drugs Administered in Hospital Outpatient Departments.**

- **CMS should take steps to ensure that facilities are appropriately reimbursed for the time and resource utilization associated with drug administration. Economic factors should not impact treatment decisions and therapy selection.**

Our detailed comments on specific provisions in the Proposed Rule are set out below. We are available to provide additional information about any of these items or answer any questions you may have.

I. CMS Should Ensure That All Drugs Are Appropriately and Equally Reimbursed in Treatment Settings.

AstraZeneca appreciates the efforts that CMS has undertaken to improve the reimbursement system for hospital outpatient departments. However, we are concerned that the current proposals may endanger the ability of many hospitals to continue to provide necessary services to the patients in their communities or may result in reimbursement rates instead of patient need determining site of care. In particular, we are concerned that the proposed reduction in reimbursement rates of separately payable specified covered outpatient drugs to ASP+5% may significantly underreimburse hospitals for the costs associated with these drugs. Because of the additional financial burden, hospitals may be reluctant to stock the full spectrum of drugs which, in turn, may reduce patients' access to appropriate drug therapies.

Hospital outpatient departments are a critical part of the health care infrastructure, including sites of care for serious chronic diseases such as cancer and accordingly overhead costs are significant. These facilities often serve patients who are difficult to treat because they have complications and comorbidities or a history of infusion reactions. Since the payment for separately payable outpatient drugs is intended to reflect payment for *both* the hospital acquisition cost for the drug plus the pharmacy overhead costs and the hospital is commonly furnishing care to a more vulnerable patient base, these costs substantially increase. Moreover, outpatient departments generally have significantly higher staffing costs to address the needs of this patient base. Plus, hospitals also offer a safety net for Medicare and Medicaid patients and the uninsured. Because hospital outpatient departments frequently are involved in clinical trials, they tend to be early adopters of new drugs and biologicals and assist patients who need cutting-edge treatments. In fact, certain drug and biological treatments are only available in hospital outpatient departments because they require special equipment, preparation, storage, handling, and disposal. Hospitals also are more heavily regulated than physician offices and must meet stringent licensing and accreditation requirements. For example, because effective medication management is so important for quality health care, the Joint Commission on Accreditation of Healthcare Organizations promulgated a new set of Medication Management standards – along with a new survey process, effective July 1, 2004. Compliance with these and other state and federal health care standards have imposed additional and significant overhead and handling costs on hospital outpatient pharmacies. Finally, the physical structure of the hospital itself leads to increased costs since the pharmacy may be a significant distance from the patient treatment location.

Additionally, as CMS notes in the Proposed Rule, the Medicare Payment Advisory Commission (MedPAC) reports that hospitals include the cost of pharmacy overhead in their drug charges. However, CMS itself has historically taken the position that, for separately payable drugs, such costs were reimbursable through the drug

administration payments.[1] While AstraZeneca applauds CMS for its efforts to better determine and to further refine its methodology for determining pharmacy overhead costs, we are concerned about the possible adverse impacts on hospitals of reducing the reimbursement rate for drugs (and pharmacy overhead costs under the current methodology) without having this additional data. MedPAC itself noted that pharmacy costs are significant, ranging between 25 and 33 percent of pharmacy-related direct costs.[2] To the extent that these costs are captured in the drug reimbursement rate, reducing that rate to ASP+5% will result in inadequate reimbursement for these costs. If, in fact, the current ASP+6% does not accurately reflect pharmacy overhead costs (as many hospital groups contend), the reduction will likely produce more significant underreimbursement. Given the past confusion about what costs are reimbursed in which component of the OPPS system, AstraZeneca requests that CMS reconsider its proposal and not reduce payment in an area that is still subject to data collection and not fully understood.

Finally, although perhaps most importantly, failure to provide equal and appropriate reimbursement, as we noted above, could result in reduced access to care for critically ill patients. Specifically, if hospitals are not adequately reimbursed for the products and services they provide, they may no longer be able to continue providing such services. Some patients may have been referred to the hospital outpatient department because their physicians could not provide the care required.[3] Reimbursement rates that favor physician office treatment could lead to these patients being referred back to their physician or forced to locate another physician to obtain treatment. As a result, some patients may not be able to find another site of care and may have to delay or even forgo treatment. Consequently, any potential savings that the Medicare Program may achieve through reduced drug expenditures could result in greater overall Program costs from inadequate, delayed, or forgone early care. For all these reasons, it is critical that hospitals be reimbursed at least as much as physician offices for drugs and biopharmaceuticals and their administration. Therefore, we encourage CMS not to implement the proposed reduction in separately payable specified covered outpatient drug reimbursement rates.

II. CMS Should Provide Separate Reimbursement for All Drugs Administered in Hospital Outpatient Departments.

CMS pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status by either packaging payment with the payments for associated items and services or providing a separate payment. Currently, CMS pays separately for drugs,

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[1] See, e.g., 67 Fed. Reg. 66,718, 66,769 (Nov. 1., 2002) (stating that "[c]osts associated with administering the drug and with other pharmacy overhead are captured in pharmacy revenue cost centers and reflected in the median cost of APCs involving drug administration").

[2] See Medicare Payment Advisory Commission, Report to Congress: Issues in a Modernized Medicare Program, June 2005, at 140. Theses costs include, for example, the use of clinical pharmacists, who provide important contributions to the overall quality of patient care through monitoring polypharmacy issues and providing appropriate education to patients and physicians.

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biologicals, and radiopharmaceuticals with per-day costs that exceed a threshold amount and packages those with per day costs less than or equal to the threshold. The Proposed Rule proposes to index the packaging threshold to inflation, which result in an increase from $50 in 2006 to $55 dollars for 2007.[4] CMS recognizes that packaging risks "insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services."[5] In addition, the APC Panel recently heard testimony requesting that the packaging threshold be eliminated, and recommended that "CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes."[6] We are concerned that CMS' proposal to increase the packaging threshold is moving in the wrong direction, and urge the agency to separately pay for all drugs with HCPCS codes, which would not only help ensure adequate payments to hospitals, but would also improve the uniformity of reimbursement among sites of care (i.e., physician offices and hospital outpatient departments).

III. CMS Should Ensure that Drug Administration Services Are Appropriately Reimbursed.

AstraZeneca commends CMS for its continued efforts to improve the coding and reimbursement of drug administration services in the hospital outpatient department. We believe that setting rates based on time and resource utilization, similar to the methodology employed in physician office reimbursement, is the most appropriate means for providing facility reimbursement.

AstraZeneca understands that certain drugs, particularly those provided in chemotherapy and other complex diseases treatment regimens, may require hours and significant expenditure of hospital resources for administration and monitoring of side effects. We believe these expenses should receive appropriate reimbursement and support CMS' efforts to collect data reflecting this utilization. However, we do not believe that differentials in reimbursement should become a basis for treatment selection. As new or modified (e.g., more concentrated) formulations of existing therapies become available, the time required for administration may be reduced, and the potential for patient discomfort or side effects may be reduced. Hospitals should not be discouraged from using such therapies because the reimbursement schedule for either the older therapies or those with longer administration times is inappropriately higher. Therefore, AstraZeneca urges CMS to carefully analyze the data it collects on administrative services so that any future reimbursement rates for longer, more resource intensive administration services are based on the actual time and resource usage and do not create economic incentives for selecting a particular therapeutic regimen.

* * * * *

Again, AstraZeneca appreciates the opportunity to share our views on these proposed Medicare program policies. We look forward to working together with CMS to

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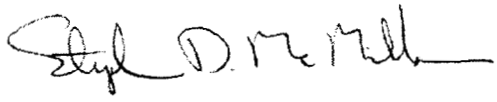
promote high-quality care for Medicare beneficiaries while improving the administration of the Medicare program. Please do not hesitate to contact me at 202.350.5577 or by electronic mail at Stephen.S.D.McMillan@AstraZeneca.com if you have any questions or need further information about these comments.

Sincerely,



Stephen D. McMillan
Director, Government Reimbursement

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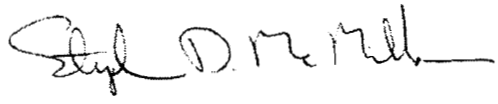

Stephen D. McMillan
Director, Government Reimbursement

Submitter : **Date: 10/10/2006**

Organization : **Carmel Pharma, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Ms. Michele Rainville **Date:** 10/10/2006

Organization : Hungerford Emergency

Category : Nurse

Issue Areas/Comments

Visits

Visits

See Comments

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

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

Submitter : **Ms. Brette McClellan** **Date: 10/10/2006**

Organization : **Alcon**

Category : **Device Industry**

Issue Areas/Comments

NTIOL

NTIOL

See attachment

CMS-1506-P-507-Attach-1.DOC

#507

October 10, 2006

Alcon

ALCON LABORATORIES, INC.
6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 293-0450

Via Electronic Mail

Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, Maryland 21244

Re: NTIOL: CY 2007 Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses (NTIOLs) (CMS-1506-P)

Dear Dr. McClellan:

Alcon welcomes the opportunity to comment on the proposals of the Centers for Medicare and Medicaid Services (CMS) to modify the current ASC process for adjusting payment for NTIOLs (*Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, pages 49631-49635). Alcon is the world's leading manufacturer of ophthalmic surgical supplies and devices that are used in procedures to treat cataracts, glaucoma, vitreoretinal diseases, corneal diseases, and other ocular disorders.

Our comments are organized into the following sections:

1. Factors CMS considers when determining whether an adjustment of payment for insertion of a new class of NTIOL is appropriate, including
    a. CMS' examples of superior outcomes that would be considered clinically meaningful,
    b. practical and meaningful approaches to elaborating on the phrase "currently available lenses" when considering requests for new NTIOL classes
    c. appropriate choice of comparator IOL in clinical studies that are submitted as a part of a request to fall into an active NTIOL class
    d. requiring FDA to approve claims of specific clinical benefit in labeling and advertising,
    e. placing greater consideration for the submission of published, peer-reviewed literature,
2. How a NTIOL payment adjustment amount is determined,
3. How a NTIOL would be paid after expiration of the payment adjustment,
4. Frequency of notices of CMS determinations regarding NTIOL requests, and
5. Posting the information required for an NTIOL request on the CMS web site.

1. Factors CMS considers when determining whether an adjustment of payment for insertion of a new class of NTIOL is appropriate

a. Examples of superior outcomes that would be considered clinically meaningful.

In the proposed rule, CMS states "*. . superior outcomes that would be considered include the following . . . Reduced dependence on other eyewear (for example, spectacles, contact lenses, and reading glasses)*" [page 49633].

We recommend removing this example from the list.

There should not be an NTIOL class for which the class-defining clinical advantage does not fall into a benefit category. Except for one pair subsequent to cataract surgery with IOL insertion, spectacles and contact lenses that are worn to correct refractive errors are excluded from coverage by Medicare. Thus, when the added benefit of a new IOL technology is to reduce the need for spectacles or contact lenses that are worn to correct refractive errors, that added benefit is not covered. This policy was established in 2005 with CMS Ruling 05-01 for presbyopia-correcting IOLs.

b. Practical and meaningful approaches to elaborating on the phrase "currently available lenses"

In the proposed rule, CMS states,

"*. . . we are seeking public comments on the desirability of further interpreting the phrase 'currently available lenses' for purposes of comparison and specific approaches to providing such clarifications . . . we also believe that any clarifications should incorporate our expectations for technological progression of the baseline comparison lenses over time as we make future annual determinations regarding the establishment of new NTIOL classes*" [page 49634].

and,

"*[t]he IOL [for which a request has been made to establish a new NTIOL class] is not described by an active or expired NTIOL class, that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcomes with designated members of an active or expired NTIOL class*" [page 49633].

Our comments below consider the interaction of the above two passages from the proposed rule.

We believe that the definition of "currently available IOLs", and thus the appropriate comparator IOL in clinical studies submitted as part of a request for an IOL to fall into a new NTIOL class, should in many cases take into account the most recent preceding level of technological advancement and corresponding patient benefit that has been or is rapidly becoming accepted by the ophthalmic medical community. *Situations will arise, however, in which this will not be the most appropriate way to define "currently available IOLs."*

- ***In general*, but with some exceptions, the next IOL technological advancement should build upon latest, preceding technological advancement.**
- **To identify the current technological baseline, CMS could consider market shares and growth of various types of IOLs. CMS should also consider**

whether the class-defining characteristic of IOLs in an active or expired NTIOL class has become baseline technology.

- **There may be situations in which the added benefit of a candidate for a new NTIOL class is so overwhelmingly important to patients that it trumps the benefit of the preceding technological development.**
- **It may be appropriate for a candidate for a new NTIOL class to not offer the characteristics of an active or expired class when the class-defining technology associated with the active or expired class has not been accepted as a standard of care.**
- **Unless CMS changes or clarifies the NTIOL eligibility criterion cited above, requestors will face a perverse incentive to omit the class-defining characteristic of an existing or active NTIOL class into its next technology.**

Following are our explanations for these comments.

In general, but with some exceptions, the next IOL technological advancement should build upon the then-current state of technology. For example, IOLs that reduce spherical aberration (RSA) are becoming the technology of choice for most cataract surgeons because of the greater quality of vision they provide. In addition, CMS has recognized the clinical advantages of these lenses by establishing a new NTIOL class for them. When CMS evaluates a future IOL technology as a candidate to establish a new class, then, in many cases, both the candidate IOL and the comparator IOL should offer the clinical advantages of the latest, preceding technology (RSA in this example). CMS should be reluctant to establish a new NTIOL class for a future candidate IOL that does not reduce spherical aberrations; however, situations may arise in which an exception is warranted.

To determine what is the latest, preceding technological advancement, CMS could consider

- market shares and/or growth rates of various classes of currently-available IOLs, regardless of whether they fall into an active or expired NTIOL class
    - high market share and/or market share growth rate for a particular class may be an indicator that it represents the latest state of technology
    - the latest level of technological advance may not have been used to establish an NTIOL class *(e.g.*, IOLs that are foldable, IOLs that filer blue light),
- comments from members of the ophthalmic medical community and IOL industry received during the 30-day comment period following CMS' notice of requests to establish new NTIOL classes,
- whether the class-defining characteristic of IOLs in an active or expired NTIOL class has become a medically-accepted baseline technology upon which future technologies will be added, and
- other credible information that helps CMS determine the appropriate baseline IOL benefits that new NTIOL classes should build upon.

There may be special situations in which the new benefit of a candidate for a new NTIOL class is so overwhelmingly important to patients that it trumps the benefit of the preceding technological development. In the event of such a situation, we believe that CMS should be allowed to use its discretion in defining "currently available" IOLs and thus the appropriate choice of comparator lens in clinical studies. For example, if a special IOL is introduced without the RSA benefit, but it has the ability to effectively treat

or cure a serious, sight-threatening comorbidity, then CMS may determine that, for a subset of patients with the comorbid condition, the benefits of the candidate for a new NTIOL class outweigh the benefits of IOLs in the active or expired NTIOL RSA class. CMS may determine that the clinical study to demonstrate the superiority of this lens would not have to use RSA IOLs as the comparator. This would enable a new class to be created for this special IOL, while the RSA class would continue to exist until expiration. The special IOL would fall into the newly created class but not into the RSA class, thereby preventing "double-dipping" into payment adjustments.

If a NTIOL class is requested for a new IOL technology, but the manufacturer of the new IOL did not offer the characteristics and benefits of an active or expired class, it may be because the class-defining technology associated with an active or expired class has not been widely adopted or accepted as the standard of care. It would have been inappropriate, for example, for CMS to view the ARRAY[1] multifocal IOL and the Staar[2] toric IOL as the current standard of care when it considered appropriate comparator IOLs for evaluation of aspheric optic technology to create the RSA NTIOL class, because the former technologies experienced very low acceptance in the medical community.

There is another potential reason why a new NTIOL class may be requested for a new IOL technology, but the new IOL does not offer the same characteristics and benefits of an active or expired class. Specifically, a requestor may have responded to the following NTIOL criterion in a way that was not intended by CMS:

> *"t]he IOL is not described by an active or expired NTIOL class, that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcomes with designated members of an active or expired NTIOL class"* [page 49633].

By purposefully <u>not</u> incorporating the class-defining characteristic of an existing or active NTIOL class, a manufacturer can meet the above criterion that would otherwise have rendered the IOL ineligible. Using the currently active RSA class as an example, a new IOL technology that <u>could</u> be designed with an aspheric optic to reduce spherical aberration could intentionally be designed without aspheric optics so that it would not be described by the currently active RSA category. This would eliminate one reason for CMS to reject the request for a new class. The motive for wanting the new lens to establish a new class rather than being added to the existing RSA class would be to enable the candidate IOL to have five full years of NTIOL adjustment instead of a shorter length of time remaining in the RSA class. This situation could also arise after the RSA category expires, because of the phrase *"active **or expired** NTIOL class."* [page 49633, emphasis added].

- Consider the hypothetical example of an important new IOL technology that is introduced to the market in early 2010. Because the new IOL has an aspheric optic and reduces spherical aberrations, it would qualify for the active RSA class which is active through February 11, 2011. However, the IOL also features a new characteristic—distinguishable from RSA—that offers a different and substantial clinical benefit to cataract patients. The manufacturer has evidence that meets CMS'

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[1] *Array* is a registered trademark of Advanced Medical Optics, Inc.
[2] *Staar* is a registered trademark of Staar Surgical, Inc.

criteria for establishing a new class based on the new, different characteristic. The manufacturer does not wish for the IOL to be assigned to the existing RSA class because it will expire in only one year.

- The manufacturer did the right thing for patients by adding the new technology onto an aspheric optic platform, and that should not prevent it from seeking a new, five-year NTIOL class based upon the new characteristic that is clearly distinguishable from the class-defining characteristic of the RSA NTIOL class.
- Similarly, if this lens were introduced after the RSA class expires, it should not be permanently precluded from NTIOL eligibility because of its RSA characteristic.

Manufacturers should not have to omit an NTIOL-class-defining characteristic from future IOL technologies in order for the future technologies to be eligible to establish a new NTIOL class.

To avoid this perverse incentive, and to foster the introduction of outcome-improving new technologies more often than every five years, we ask that CMS clarify its policy that applies when a requestor seeks to establish a new NTIOL category for a candidate IOL that bears the class-defining characteristic of an existing or expired NTIOL category but also offers an **additional, new** technological characteristic for which a new category is being sought. If a new IOL has the class-defining characteristic of an active or expired class, **but also features a new, outcome-improving characteristic that is distinguishable from the class-defining characteristic of an active or expired class**, then the fact that it provides the clinical benefit linked to an expired or active class should not eliminate it from consideration for a new class **as long as the characteristic and associated benefit of the active or expired class is not the basis of the request for a new class**.

c. Appropriate choice of comparator IOL in clinical studies that are submitted as a part of a request to fall into an **active** NTIOL class

The clinical study submitted to demonstrate the same or greater level of clinical advantage should not be required to prove that the next entrant into the active NTIOL class is superior to the IOL that established the class.

When reviewing a request for an IOL to be eligible for the payment adjustment of an active NTIOL class, CMS' process requires that the evidence submitted by the requestor "supports the claim of achievement of the same or greater subset-specific quantitative and qualitative clinical benefit as the NTIOL that established the subset" [http://www.cms.hhs.gov/CoverageGenInfo/downloads/AppforcurrentNTIOLsubset.pdf]. Demonstrating that a subsequent IOL offers the same or greater level of clinical benefit does not require a head-to-head study of the subsequent IOL versus the first IOL. Therefore, in studies that are submitted as part of a request for an IOL to fall into an active NTIOL class, the IOL that established the active class should not be the required comparator.

A clinical study submitted as part of a request for an IOL to fall into an active NTIOL class may use the same comparator IOL that was used in the study of the IOL that established the class, but that should not be a requirement. The lens model to be used as the control in a clinical study is determined well before a study starts. By the time the

study starts, newer technologies may have been introduced, but whether they will be embraced by the medical community is unknown. Manufacturers make conservative choices in lens models to be used as controls due to the relative inexperience with newer lens features. By the time the data are available, however, another lens feature could have been launched and be gaining wide acceptance.

There are other reasons why CMS should not require that the evidence for an IOL that is a candidate for an active class must be based upon the same control lens in the evidence for the IOL that established the class. Consider these possible scenarios:

- The first IOL to establish a new class is made of hydrophobic acrylic and was compared to another hydrophobic acrylic control lens. Choosing the same material for both the study lens and control lens was done to control for confounding variables associated with different IOL materials. The second IOL to seek entrance into the established class is made of a different material (*e.g.*, silicone or hydrophilic acrylic). If the control lens in the study of the first IOL (acrylic) was also used as the control lens in the study of the second IOL (silicone or hydrophilic acrylic), then confounding variables related to different IOL materials may make the study results difficult to interpret.
- The clinical study that a manufacturer conducts for purposes of seeking NTIOL status is started around the same time as a comparable study from another manufacturer of the same lens technology. One of these studies is submitted to CMS before the other, and both demonstrate a significant clinical advantage, but the two studies use different controls. CMS should not define the appropriate choice of control lens solely on the basis of which manufacturer's request is received first.

To summarize our comments on the appropriate policy guiding the choice of comparator IOLs, we believe that, in general, the next IOL technological advancement worthy of NTIOL status should build upon the then-current state of technology. As described above, however, there are myriad different and often unpredictable scenarios that may present themselves, many of which would justify exceptions to this policy. Therefore, CMS should exhibit reasonable flexibility and consider each request individually.

CMS should agree to meet with a prospective requestor prior to the time that the requestor initiates a clinical study of its IOL. The purpose of the meeting would be to discuss study design and agree upon the appropriate control lens for the study. CMS has been very willing to talk to requestors in advance of NTIOL submissions, and that cooperative approach is essential to avoiding unwanted surprises when CMS reviews NTIOL requests.

d. Requiring claims of clinical benefit to be approved by FDA for use in labeling and advertising

In the proposed rule, CMS states, *"The IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by FDA for us in labeling and advertising"* [page 49633].

If the IOL's label includes a claim of superiority, then CMS should take that into account, but having the claim in FDA-approved labeling must not be a requirement.

We agree that the FDA-approved labeling should refer to the physical characteristic of the IOL that is associated with its purported clinical benefit. We disagree that FDA-approved labeling must include a statement of specific clinical benefits that will be the basis of an NTIOL request.

- FDA's role is to determine safety and efficacy of new drugs and devices. It is not FDA's role to make determinations of comparative clinical superiority over other IOLs. CMS is accountable for those decisions; FDA is not.
- FDA has expressed to Alcon that it is not responsible for and has no desire to determine the superiority of one manufacturer's lens over another manufacturer's lens.
- FDA does not require a control lens in studies submitted to gain FDA approval for IOLs
- Device manufacturers are not obligated to get CDRH's (FDA's) approval of advertising claims. CDRH's (FDA's) jurisdiction over device advertising encompasses claims that would misbrand the device (*i.e.*, false or misleading in any particular, 21USC502(a)).

e. Placing greater weight on evidence that is published in peer-reviewed literature

In the proposed rule, CMS states, *"We strongly encourage and may give greater consideration for the submission of published, peer-reviewed literature and other materials that demonstrate substantial clinical improvement with the use of the candidate IOL over use of currently available IOLs."*

The mere fact that scientific evidence has been published in a peer-reviewed journal should not impact whether CMS determines that the evidence is credible.

In a request for an NTIOL payment adjustment, requestors should submit any of the following types of evidence, if they exist:

- published, peer-reviewed evidence of the superiority of the candidate IOL as compared to currently available IOLs,
- evidence that has been accepted for publication but not yet published,
- evidence that has been submitted but not yet accepted, and
- any relevant evidence from well designed studies, regardless of peer-review publication status.

A study that has been accepted or published in a peer-reviewed journal should not be given greater weight simply because it has been published. There are numerous reasons why excellent science does not get published in peer-reviewed journals—reasons that have nothing to do with the quality of its evidence. Even if a study is destined for publication in peer-reviewed literature, the lag time between study completion and publication is often very, very long. Therefore, the politics and bureaucracy that influence whether and when a study is published should not have an impact on whether CMS determines that the evidence for a candidate IOL is persuasive.

2. How a NTIOL payment adjustment amount is determined

In the proposed rule, CMS states, *"The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50. We are not proposing to revise this payment adjustment for CY 2007."*

CMS should reconsider the appropriateness of the $50 payment amount on a class-by-class basis rather than waiting to decide that an across-the-board change in the adjustment amount for all NTIOL classes is warranted.

Section 141(b)(1) of the Social Security Act Amendments of 1994 requires CMS to review the appropriateness of the payment amount for insertion of an IOL and to ensure that the facility fee for the procedure includes payment that is reasonable and related to the cost of acquiring a lens that belongs to a class of NTIOLs. CMS' current regulations establish $50 as the payment adjustment amount that is added to the ASC facility fee for insertion of a lens that CMS determines is a NTIOL. After July 16, 2002, CMS has the option of changing the $50 adjustment amount through proposed and final rulemaking in connection with ASC services.

To streamline the NTIOL process, CMS should allow a requestor of a new NTIOL class to concurrently request a payment amount that is greater than $50. The request for a different payment amount for a new technology IOL should be reviewed by CMS during the time period that CMS reviews the information and evidence that is submitted as part of the request to establish a new class for that IOL. As is already the case in requests for transitional pass-through categories under the OPPS, the requestor of a new NTIOL class should provide CMS with information on the average cost of the IOL in its request to establish a new NTIOL class.

It has been several years since CMS last considered what the payment adjustment for NTIOLs should be. The decision to set the adjustment at $50 was based upon a review of the costs of IOLs that were on the market prior to 1999. It is reasonable to expect that new IOL technologies introduced several years after that time will bear a reasonable cost that is measurably higher than $50.

If CMS determines that a $50 adjustment is insufficient to enable access to an IOL technology that it has determined will be approved to establish a new NTIOL class, then the different payment adjustment should be specific to that class rather than a blanket adjustment amount that applies to all classes of NTIOLs. It is reasonable to expect that different technologies in different NTIOL classes will not be equal in cost.

3. How a NTIOL would be paid after expiration of the payment adjustment

In the proposed rule, CMS states, *"For CY 2007, we are proposing to revise how . . . the IOL payment adjustment would be made and how a NTIOL would be paid after expiration of the payment adjustment."*

After expiration of an NTIOL class, the payment for cataract surgery should continue to reflect the costs of the technology. Otherwise, providers will revert to less-expensive, older-technology IOLs that do not offer the same clinical advantages of IOLs in the expired NTIOL class.

In the OPPS transitional pass-through program, CMS has a method for folding the additional cost of new technology into the associated procedure payment after expiration of the pass-through category. Were it not for the fact that the costs are folded into the associated APC payment, the pressure from hospitals would result in reversion to older technology. This is what will happen in ASCs if NTIOL payments completely cease upon expiration of the NTIOL class.

- Proposal #1: Automatically establish a corresponding OPPS pass-through category effective on the same date that a new NTIOL class becomes effective in the ASC payment system.

- Rationale for proposal #1:

    - The additional cost of devices that are eligible for pass-through payments will eventually be reflected in the APC payment amount for the procedures in which they are used. When CMS' proposal for a revised ASC prospective payment system (ASCPPS) is implemented in 2008, changes in relative weights in the OPPS will result in equivalent changes in weights under the ASCPPS.
    - If all NTIOLs were also eligible for pass-through payment in the OPPS, then the added costs of the NTIOLs would be reflected in the OPPS relative weights for the procedures in which they are used and, in turn, would result in higher weights used in the calculation of ASC payments for those procedures.
    - Currently, it is possible for a new IOL technology to be eligible for NTIOL payment in the ASC setting but not be eligible for pass-through payment in the HOPD setting. While the criteria for establishing a pass-through category include a requirement that the cost of the device be at least 25% of the payment for the procedure in which it is used, there is no such requirement in the NTIOL program for ASCs (for example, a NTIOL costing $275 could potentially qualify for NTIOL status but be ineligible for transitional pass-through status due solely to its cost). Therefore, under the current system, a manufacturer that establishes a new NTIOL class in the ASC system may not be able to establish a corresponding new pass-through category in the OPPS, even though the evidence demonstrating that the use of the IOL results in substantial clinical improvement is sufficient to meet the requirements of both programs.
    - Addressing payment for a NTIOL after expiration of the NTIOL class by automatically establishing a corresponding pass-through category in the OPPS would require waiving the requirement that the cost of the IOL be at least 25% of the procedure payment for cataract surgery with IOL insertion. CMS has the authority to do this.
    - By the time the NTIOL class expired in the ASCPPS, the OPPS relative weight for cataract surgery (and thus the ASCPPS relative weight for cataract surgery) will reflect 3-4 years of adoption in the HOPD setting.
    - If adopted, this proposal will also eliminate site-of-service differential in access to NTIOLs.

- Proposal #2: After expiration of an NTIOL class, increase the ASCPPS payment for cataract surgery by an amount based on the percentage of utilization of the NTIOL in the 12 months prior to expiration of its NTIOL class.

- Rationale for proposal #2:

  - This proposal assumes that proposal #1 is not adopted. Proposal #2 is consistent with the net result of how the costs of a pass-through device are folded into the associated procedure payment by the time its pass-through category expires. APC weights are driven by median procedure costs across all HOPDs. The amount by which the additional costs of a pass-through device increase the relative weight for its associated procedure is directly and positively correlated with the degree of utilization of the device. If the device is used in a small fraction of procedures, then the amount folded into the procedure payment will be a small fraction of the average additional cost of the device. Conversely, if the device is used in a very large percentage of procedures, then the amount folded into the procedure payment will be higher and come closer to the actual average cost of the device.
  - ASCs' claims for cataract surgery with IOL insertion include codes that make it possible for CMS to calculate the utilization percentage of IOLs that fall into an expiring NTIOL class. CMS can measure the utilization of a class of NTIOLs in the twelve months preceding the expiration of the class by dividing the total number of claims that include the HCPCS code for that NTIOL by the total number of ASC claims for cataract surgery with IOL insertion.
  - The utilization percentage should then be applied to the average additional cost of NTIOLs in the expiring class. This is not possible, however, because CMS does not have data to determine the average additional cost of the NTIOLs, because there are no cost reports from ASCs and there are no CCRs for ASCs. The NTIOL payment adjustment amount (for example, $50) can be used as a surrogate for the average cost of the NTIOLs in the expiring class. The payment for cataract surgery with IOL insertion would be increased by an amount equal to the utilization percentage times the NTIOL payment adjustment amount. For purposes of budget neutrality, this increase in payments for cataract surgery can be treated in the same way as CMS' set-aside for estimated total pass-through payments in the coming year.

4. Frequency of notices of CMS determinations regarding NTIOL requests

In the proposed rule, CMS states, *"The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement. The date of implementation of a payment adjustment in the case of approval of a lens as a member of an active NTIOL class would be set prospectively as of the publication date of the ASC payment update final rule."*

We urge CMS to make the NTIOL program more consistent with the OPPS transitional pass-through program by enabling NTIOL announcements once per quarter.

We appreciate the intent to implement payment adjustment for IOLs falling into an active class more quickly than implementation of payment adjustment for IOLs that establish a new class. When an IOL offers the same characteristics and documented clinical

benefits as another IOL that established a new NTIOL class, the higher payment for the latter creates an artificial and substantial competitive disadvantage for the former. This disadvantage is not the natural result of disparities in the IOLs' performance but, rather, is a byproduct of a system that interferes with what would otherwise have been a level of demand based on price elasticity created by free market forces.

For these reasons, we are concerned with CMS' proposal to announce NTIOL approvals for new and active classes only once per year. If an IOL meets the criteria for inclusion in a new or active NTIOL class but is approved by FDA just a few days, weeks, or months after publication of the annual ASC final rule, then access to that IOL will be unfairly blocked for up to one year. Blocking access for as little as six months can foment competitive advantage for an artificially long period of time. This results in permanent revenue loss to a manufacturer that introduces an equivalent-technology IOL shortly after the establishment of a new NTIOL class that describes it. We urge CMS to make the NTIOL program more consistent with the OPPS transitional pass-through program by enabling NTIOL announcements once per quarter.

5. Posting the information required for an NTIOL request on the CMS web site

In the proposed rule, CMS states: *". . . we are not proposing to incorporate the list of proposed information required with each request in the regulations, but are proposing to post it on the CMS Web site to ensure that such information is updated in a timely manner and relevant to advancing IOL technologies. We are proposing . . . that the content of each request for an IOL review must include all information as specified on the CMS Web for the request to be considered complete."*

There must be enough stability in the requirements that a manufacturer does not invest several months or years in conducting a comparative clinical study, only to learn when it is ready to submit an NTIOL request that the criteria have changed.

We support the idea of making CMS' latest list of required information available on its web site. We are concerned, however, that an applicant may be unfairly trapped in between web site updates at the time it is designing and conducting clinical studies that will be included in a subsequent request for NTIOL designation. There must be enough stability in the requirements that a manufacturer does not invest several months or years in conducting a comparative clinical study, only to learn when it is ready to submit an NTIOL request that the criteria have changed. We suggest that the manufacturer have the option to meet with CMS before designing its study and reach agreement with CMS as to the information that will be required for that particular NTIOL request to be considered complete. CMS should then commit to the requestor that, once the request is actually submitted, the previously agreed-upon list of information will be honored even if new or different required information is later posted on the CMS web site.

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Alcon appreciates the considerable time, effort, and quality of thinking that CMS has put into its proposed revisions to the NTIOL process. Thank you for welcoming and encouraging comments on the proposal.

Sincerely,

Brette McClellan
Director, Health Policy Government Relations
Alcon Laboratories, Inc.

c: Leslie Norwalk, CMS

Submitter : Mr. Michael Parini **Date:** 10/10/2006

Organization : Pfizer Inc

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-508-Attach-1.PDF

#508

Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

October 10, 2006

BY ELECTRONIC DELIVERY

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1506-P; Medicare Program, Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates

Dear Administrator McClellan:

I am writing on behalf of Pfizer Inc, a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life for people around the world. We appreciate the opportunity to comment on the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates Proposed Rule,[1] and look forward to working with the Centers for Medicare & Medicaid Services to ensure that the final rule protects patient access to needed medicines, promotes high quality healthcare, and improves health outcomes.

I. General Comments

The Proposed Rule presents changes to several important aspects of the outpatient prospective payment system (OPPS). Pfizer generally applauds CMS' proposal to implement a new tiered Ambulatory Payment Classification (APC) payment structure and to incorporate quality measures and health information technology (HIT) into the OPPS. However, as described below, we have some reservations regarding certain aspects of these proposals. Specifically, with regard to reimbursement for separately payable drugs, Pfizer is concerned with the effects of reduced payments on Medicare beneficiaries' access to drugs and urges CMS to reconsider its proposal. Below, we provide more detailed comments on these and other issues presented in the Proposed Rule.

II. Payment for Separately Payable Covered Outpatient Drugs

CMS has proposed to reduce reimbursement for separately payable covered outpatient drugs and biologicals from average sales price (ASP) plus 6% to ASP plus 5% for CY 2007.[2] While such a reduction may not seem significant, it could have a severe impact on small hospitals and rural hospitals that are already operating on very thin margins. These hospitals do not have the purchasing power to obtain the volume discounts that are available to large urban

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[1] 71 Fed. Reg. 49,506 (Aug. 23, 2006).

[2] Id. at 49,584.

institutions, yet they are still burdened with patients who have poor insurance coverage and little or no means to handle copayment responsibilities. Because many of these hospitals may actually pay more than ASP for these drugs, the proposed ASP + 5% payment rate could mean they will lose money each time the drugs are administered to a Medicare beneficiary. Moreover, hospitals are often called upon to treat patients with few or no therapeutic alternatives using drugs for which there is little or no buying efficiency because of low volume. Thus, even a one-percent reduction in reimbursement rates could be devastating to some hospitals that are already struggling under the current rates and, as a result, could reduce Medicare beneficiaries' access to life-saving and other important drugs.

Importantly, this proposed change would also reduce hospitals' reimbursement for these drugs below that for physician offices, which are paid on the basis of ASP + 6%. Because ASP is set nationally across all purchasers of drugs rather than in a particular segment or class of trade, we believe reimbursement rates should also be uniform.

For the foregoing reasons, we urge CMS not to reduce the reimbursement rate for separately payable outpatient drugs below the current rate of ASP + 6%.

III. Drug Administration

CMS is proposing a six-level drug administration APC payment system that assigns drug administration codes to APCs based on their clinical and projected resource utilization

characteristics.[3] As part of this new system, CMS is proposing a separate administration payment for additional hours of infusion.[4] If adopted, this proposal would represent substantial progress in achieving alignment between reimbursement and the actual resources expended in providing drugs to patients. We urge CMS to finalize this proposal.

IV. Hospital Quality Data

CMS has proposed to develop and implement a performance measurement and reporting program for the OPPS. Under CMS' proposal, failure to provide these performance measurement data could result in a reduction to the conversion factor that determines OPPS payments.[5] While Pfizer strongly supports the development of quality measures for Medicare services, we have some concerns regarding the program proposed by CMS.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) specifically directed the creation of the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program for the inpatient prospective payment system (IPPS), whereas there is no equivalent statutory mandate under the OPPS. In the Proposed Rule, CMS cites as the legal authority to apply these quality measures to outpatient services its general authority

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[3] 71 Fed. Reg. at 49,602.

[4] Id. at 49,604.

[5] Id.

under the Social Security Act to "establish in a budget neutral manner...adjustments as determined to be necessary to ensure equitable payments."[6] We are concerned that this general "equitable payment" authority is a questionable basis for expanding the application of these measures.

Regardless of whether specific statutory authority exists for this proposal, we are also concerned that CMS is proposing to adapt the RHQDAPU program for the OPPS, using inpatient quality measures as a proxy for the outpatient setting.[7] As a general matter, we strongly support aligning incentives between the IPPS and the OPPS. However, because a reduction in the OPPS conversion factor has a severe financial impact for hospitals that fail to meet the requirements, CMS should use appropriate and relevant measures to implement any OPPS quality program. In particular, if CMS intends to implement a quality program such as the one proposed, it should not do so until it has developed appropriate quality measures specifically applicable to the outpatient setting. On their face, it is apparent that several of the RHQDAPU measures have little or no application to outpatient services. For example, five of the measures relate to best practices for treating heart attacks, which are generally not treated on an outpatient basis.[8] Thus, in order to best achieve the laudable goal of aligning quality outcomes and Medicare payments,

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[6] 42 U.S.C. § 1395l(t)(2)(E).

[7] Id. at 49,666-669.

[8] Id. at 49,667.

Pfizer recommends that CMS take the time to develop setting-specific benchmarks that will truly reward the provision of quality care to Medicare outpatients.

Toward the same end, we urge CMS to focus on developing quality measures that are based on actual patient outcomes rather than process requirements (e.g., mandating particular protocols), to ensure that high quality scores correlate with positive outcomes. Many of the RHQDAPU measures are process-oriented (e.g., was aspirin given to a patient upon arrival at the hospital?). It is critically important to validate quality measures by demonstrating that these measures bear a direct relationship to good outcomes. Absent such validation, quality measurement will not realize its potential for providing significant benefits to Medicare beneficiaries.

V. Health Information Technology

CMS has undertaken several activities to advance the Administration's goal of promoting the adoption and effective use of health information technology (HIT), and is now considering the role of interoperable HIT systems in increasing the quality of hospital services while avoiding unnecessary costs. To that end, CMS is seeking comments on its statutory authority to

encourage adoption and use of HIT and on the appropriate role of HIT in value-based purchasing.[9]

With regard to CMS' statutory authority, pursuant to the MMA, CMS is clearly authorized to use the rule-making process to promote HIT.[10] That provision specifically authorized the setting of standards for electronic prescribing (eRx). CMS has since promulgated regulations regarding such eRx standards. CMS also relied on this statutory authority to promulgate exceptions under the Physician Self-Referral (Stark) Law for donations of HIT to physicians.[11] We are uncertain as to what statutory authority CMS would have to expand this charge and promote the adoption and use of HIT beyond the bounds of these specific mandates.

Regarding the appropriate role of HIT in any value-based purchasing program, we strongly favor the incorporation of HIT in such programs provided that an adequate technology infrastructure is already in place to support the program. We, of course, recognize the pivotal role that HIT plays in any effort to improve healthcare delivery. Pfizer has been a strong proponent of HIT and has incorporated it in all aspects of its operations, including in its research facilities to make the drug development process more rigorous and quantifiable. In a program called Green Ribbon Health, in which a Pfizer subsidiary, Pfizer Health Solutions, has partnered

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[9] Id. at 49,670.

[10] See MMA, P.L. 108-173 § 101.

[11] 42 U.S.C. § 1395(b)(4).

with Humana to gather and deliver integrated data to case managers to assist them in delivering high quality healthcare to Medicare beneficiaries, HIT is an integral component.[12]

Before HIT can reasonably be expected to function as a process improvement tool, the HIT infrastructure must first be in place and used for a period of time. In other words, it is important to measure processes and outcomes for a period of time to establish baselines and benchmarks that serve as a baseline for process-improvement techniques. This means that the initial "value added" in supporting HIT adoption may be very low because incentives must first be provided to promote adoption and utilization. CMS appears to be considering bypassing incentives for the adoption of technology or reporting of outcomes and moving directly to incentives for improving the quality of care. While this is a commendable goal, we believe that CMS should first provide incentives for the electronic reporting of outcomes in standardized ways – to establish baselines and benchmarks – and later provide incentives based upon quality improvements.

With regard to the promotion of HIT through hospital conditions of participation (COP), based on our knowledge and experience with the standards development environment, we believe that forcing adoption of HIT as a requirement of participation is a reasonable objective for the future, but again, the infrastructure is not yet ready for current implementation. The set of

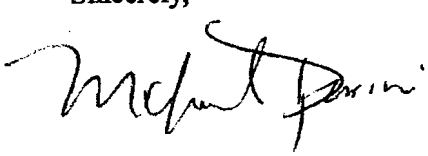
[12] Green Ribbon Health is one of eight regional pilot programs established by CMS to improve healthcare for fee-for-service Medicare patients with certain chronic conditions.

standards and criteria that are applied and required as COPs would need to be carefully considered and have not yet been fully developed. As an alternative, if the Secretary first requires standardized reporting – something that is achievable using current HIT systems – CMS could begin the process of setting benchmarks and identifying specific metrics for demonstrating improvements in quality, paving the way for mandatory usage in the future. This would provide a valuable first step on the path to integration of HIT as a condition of participation.

VI. Conclusion

We appreciate the opportunity to comment on the important issues raised by the Proposed Rule, and urge you to address these concerns in a manner that fully protects patient access to necessary medications and promotes high quality healthcare. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,



Michael J. Parini
Senior Corporate Counsel

Submitter : **Ms. Dawn Hopkins** **Date: 10/10/2006**

Organization : ***Society of Interventional Radiology***

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-509-Attach-1.PDF

#509

SOCIETY OF INTERVENTIONAL RADIOLOGY
Enhanced care through advanced technology™

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October 10, 2006

Mark McClellan, MD, PhD
Administrator
Leslie Norwalk
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
75000 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via CMS Web site with endorsed copy mailed this day

RE: "The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Payment System [CMS-1506-P; CMS-4125-P]"

Dear Administrator McClellan/Norwalk:

The Society of Interventional Radiology (SIR) is a physician association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States.

SIR respectfully requests CMS' consideration in the APC assignment/reassignment for uterine fibroid therapies performed by interventional radiologists. Additionally, SIR opposes addition of peripheral stent placement services to the ASC setting; finding the proposed reimbursement rate woefully inadequate, not even covering the cost of the typical device used for these services. And, while SIR supports CMS' decision to exclude vascular embolization services, we do not support the rationale presented for this decision. SIR proposes a mechanism to rectify the shortcoming of the ASC payment system that currently would render the performance of peripheral stent and embolization services not economically feasible in the ASC setting. SIR offers the following general and specific comments:

APC Assignment for Uterine Fibroid Therapies

Uterine fibroids (leiomyomas) are common noncancerous (benign) tumors of the uterus. Uterine fibroids may cause heavy bleeding, pelvic discomfort and pain and create pressure on other organs in addition to infertility, and urinary complications. In the United States, 30% of all women between the ages of 25 and 50 suffer from symptomatic uterine fibroids and 400,000 will undergo a surgical procedure to relieve the symptoms of uterine fibroids, each year.

While the vast majority of women suffering from uterine fibroids are not Medicare beneficiaries, Medicare payment is used as a benchmark for private insurers and thus, CMS' actions are critical to helping establish appropriate access for women with uterine fibroids.

APC Assignment for CPT 37XXX, Uterine Artery Embolization

A new Category I code to report uterine fibroid embolization (UFE) is anticipated to be presented in the Final Rule for the 2007 Medicare Physician Fee Schedule. UFE is a percutaneous, catheter-based intervention performed under fluoroscopic guidance. The procedure typically involves bilateral selective catheterization services from femoral access through which embolic material is injected to occlude the blood flow to the fibroid(s); resulting in infarction and shrinkage of the fibroids. Intra-procedureal angiography is used to map the procedure, guide the intervention, and confirmation of occlusion.

Unlike the vast majority of other interventional radiology services, the anticipated new code for UFE is a single all-inclusive code which specifically includes catheterization and radiological supervision and interpretation services. An APC classification that appropriately captures the array of resources used for both the procedural and imaging aspects of UFE is warranted. SIR finds that the UFE is most clinically similar to, and uses comparable resources to, the percutaneous insertion/revision of transvenous intraheptic portosystemic shunt(s) (TIPS/ TIPS revision, codes 37182 and 37283, respectively) which is assigned to APC 0229, Transcatheter Placement of Intravascular Shunts. It is imperative that the APC for the UFE code include procedures that are similar to UAE both clinically and in terms of resource utilization. Like the new all inclusive UFE code the services represented by the TIPS and TIPS revision codes are all-inclusive including the use of resources for both the procedural and imaging aspects of the service being provided. APC 0229 is the most logical choice for assignment of the new UFE code.

APC Assignment for CPT 0071T and 0072T, MRgFUS

An alternative treatment for uterine fibroids is Magnetic Resonance Guided Focused Ultrasound (MRgFUS), which integrates magnetic resonance imaging (MRI) with focused ultrasound energy to create a non-invasive technology that ablates tumors without cutting the skin (similar to stereotactic radiosurgery). MRgFUS for uterine fibroids is performed under conscious sedation and the treatment takes 3-5 hours. MR guidance adds two key facets to the treatment: (1) Continuous MR imaging of the fibroid/tumor/lesion, plus imaging of all the other vital structures such as the bowel, bladder, and sacral nerves; and (2) It allows physicians to monitor the temperature of every treatment point so they can adjust the temperature/power if necessary to optimize effective tissue coagulation.

After reviewing the proposed rule regarding changes to the Hospital Outpatient Prospective Payment System payment rates for calendar year 2007 and the current APC assignment for the MRgFUS procedure, we are requesting that CMS reconsider the APC

assignment of HCPCS 0071T and 0072T from APCs 0195 and 0202 respectively to a more clinically and resource appropriate APC for 2007. Current average hospital costs for the MRgFUS procedure are significantly higher than the payment rates for APCs 0195 and 0202. We request that CMS consider assigning 0071T and 0072T to APC 0127 due to the clinical and cost similarities of the Sterotactic Radiosurgery (SRS) procedure that also requires treatment planning, continuous monitoring during treatment, use of imaging technology and also involves a significant amount of time to perform the procedure.

Exclusion of Vascular Embolization Services from ASC Setting (37204)

While SIR supports the exclusion of vascular embolization services from the Ambulatory Surgical Center (ASC) fee schedule, SIR vehemently opposes CMS' conclusion that these services routinely necessitate an overnight stay. Rather, SIR finds that the ASC maximum reimbursement level would be woefully inadequate in covering the technical resources used in providing these services, with embolic material alone commonly costing in excess of the proposed ASC payment rate. Additionally, the ASC payment system would bundle in the inherent real-time, imaging required to perform these services, but affords no mechanism to capture reimbursement for the resources used.

Oppose the Addition of Peripheral Stent Placement Services to the ASC Setting (37205, 37206)

SIR finds that the ASC maximum reimbursement level would be woefully inadequate in covering the technical resources used in providing peripheral stent services. SIR finds that the most typical peripheral stent service is treatment of the iliac vessel, with the most common iliac stent costing in excess of $1600.00. Additionally, the ASC payment system bundles in the inherent real-time, imaging required to perform these services, but affords no mechanism to capture reimbursement for the resources used.

Additionally, CMS' intent regarding whether the each additional stent code, 37206 should be added to the list of approved services or excluded is unclear, as code 37206 appears on both these lists in the proposed rule. An ASC payment 9 payment group is inadequate to cover the technical costs of providing stent placement services. While there is believed to be economy for physician work for additional stent placement, there is not believed to be any economy for the technical inputs.

Pass-Thru for Device Intensive Services in the ASC Setting and Billing for Imaging

SIR would be very interested in discussing with CMS possible alternative solutions addressing the short comings of the ASC payment system including the consideration of allowing pass-thru payment for interventional radiology devices and the ability of ASCs to bill the technical component reimbursement rate established for real-time radiological/imaging supervision and intrepretion services that are provided in support of an interventional procedure and which are never provided in isolation. Such reimbursement arrangements would address the inadequacies of the ASC payment system

that make providing interventional radiology services in these settings prohibitive. Pass-through payment for interventional radiology devices and the separate reporting of the technical component for imaging services for the ASC setting are found to be relatively common place amongst non-Medicare commercial carriers payment systems. Until such time as these issues are addressed, SIR supports the continued exclusion of stent placement services in the ASC setting.

If SIR can be of any assistance as CMS continues to consider and review this issue, please do not hesitate to contact Dawn Hopkins, director of reimbursement and health policy at (800) 488-7284, ext. 588, Hopkins@SIRweb.org,

Sincerely,

[Endorsed copy mailed this day]

Gary P. Siskin, MD
Co-chair, Economics Committee

[Endorsed copy mailed this day]

Sean M. Tutton, MD
Co-chair, Economics Committee

CC: Ken Simon, MD, CMS
Edith Hambrick, MD, CMS
Carolyn Mullen, CMS
Pamela West, CMS
Katharine L. Krol, MD, SIR
Michael E. Edwards, MD, SIR
Richard A. Baum, MD, SIR
Harvey Neiman, MD, ACR
Maurine Spillman-Dennis, ACR
Angela Choe, ACR
Sherry Smith, AMA
Todd Klemp, AMA
Jennifer Gajewski, SIR
Dawn R. Hopkins, SIR

Submitter : **Marsha Flaa** **Date: 10/10/2006**

Organization : **Avera McKennan Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

Submitted electronically: http: www.cms.hhs.gov/eRulemaking.

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

This letter is to request reconsideration for the proposed changes to the CY 2007 Proposed Rules. I appreciate the opportunity to submit these comments to CMS for consideration.

OPPS: Drug Administration

For CY 2007 OPPS, CMS is proposing to continue the CY 2006 drug administration coding structure, requesting hospitals to report a combination of CPT and HCPCS codes. This has caused significant problems to OPPS facilities in 2006 as it presents difficult operational and administrative challenges due to inconsistent coding concepts. Currently the definitions do not match for CPT and HCPCS which has created difficulty in reporting the correct codes for the services rendered, increasing the chance of non-compliance. For example, code 90767(sequential infusion) does not have a specific time requirement while the corresponding HCPCS codes (C8950 or C8951) do have specific time requirements. This examples, as well as others like it, have created many problems to OPPS facilities in submitting correct claims and capturing correct data for cost reporting. Due to the above, most OPPS facilities had a difficult time implementing the CY 2006 CPT updates.

With the many coding changes in the CY 2006 CPT updates, we have had a difficult time getting clarification for the proper use of the CPT and HCPCS codes implemented in January 2006. Further clarification and more timely responses to our questions are needed for the drug administration codes for CY 2007.

I recommend that CMS change the current drug administration structure and assign one set of coding logic for OPPS facilities to follow in order to provide a clear and consistent code assignment.

Visits:

The CY 2007 Proposed rules regarding Critical Care Services clarifies that if the critical care service is less than 30 minutes in duration, the critical care codes are not reportable and facilities should be reporting either the clinic visit or an emergency visit CPT code.

I would like to recommend that facilities should be able to report the CPT codes for critical care and receive the APC payment associated with the critical care codes regardless of the time documented for critical care. The resources utilized in a facility setting for critical care are extensive and should not necessarily be dependent on the time the patient was receiving care.

Thank you again for your time and consideration of my comments.

Marsha K. Flaa, RHIT
Hospital Chargemaster Coordinator
Avera McKennan Hospital
Sioux Falls, SD

Submitter :

Date: 10/10/2006

Organization :

Category : Health Care Provider/Association

Issue Areas/Comments

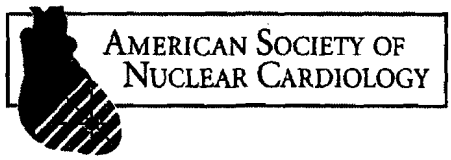
Policy and Payment Recommendations

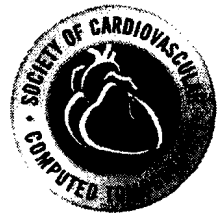
Policy and Payment Recommendations

See Attachment

CMS-1506-P-511-Attach-1.PDF

#511





October 10, 2006

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

Administrator Leslie Norwalk
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

ATTN: FILE CODE CMS-1506-P

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

Dear Administrator Norwalk:

The American College of Cardiology (ACC), American Society of Nuclear Cardiology (ASNC), Society for Cardiovascular Computed Tomography (SCCT), and Society for Cardiovascular Angiography and Interventions (SCAI) wish to express our appreciation for the opportunity to comment on the proposed rule on Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2007 Payment Rates. (71, Federal Register, 49548; No. 163, August 23, 2006).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose purpose is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

ASNC is a nearly 5,000-member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiac computed tomography angiography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

SCCT is a professional medical membership organization with more than 3,000 members since its creation in March 2005 that addresses all issues pertaining to the field of cardiovascular computed tomography. SCCT works to foster optimal clinical effectiveness of cardiovascular CT through professional education, establishment of standards for quality assurance and professional training, and development of evidence-based guidelines for its use to enhance patient care and improve the quality of cardiovascular medical practice

The SCAI is a professional association representing 3,500 invasive and interventional cardiologists. SCAI promotes excellence in cardiac catheterization, angiography, and interventional cardiology through physician education and representation, clinical guidelines and quality assurance to enhance patient care.

Our comments focus on CMS' assigned APC rates for the Category III CPT codes for cardiac computed tomographic angiography (CCTA (0144T-0151T)). The HOPPS proposed rule cross-walks 0144T-0151T to nuclear medicine Ambulatory Payment Classification (APC) codes 0376, 0377, 0398, and 0282. We appreciate CMS's recognition, by virtue of its placement in the nuclear cardiology APCs, that the category III codes for CCTA are appropriately viewed by the agency as cardiac imaging. *However, at this time, we believe that the CCTA codes should be moved to appropriate new technology APCs so that adequate hospital claims data can be gathered.* Once this level of robust data is achieved, this pricing information can be used to separate and incorporate the various CTA category III codes into routine APCs for the different levels of CCTA.

In January 2006, the AMA's designation of the proposed CCTA codes as Category III reflected the limited scope of data. Only a handful of peer-reviewed publications existed during the presentation to the CPT Panel for review and discussion. The cardiovascular community recognizes and embraces the significant potential for this technology, especially in light of its rapidly changing capabilities, and is actively gathering data that would assist in making a proper valuation. We believe these activities justify its placement as an emerging technology at this time.

As the category III CPT codes were only implemented in January 2006 and because hospitals typically do not update their charge master more than once a year, hospital claims data from the last nine months of 2005 – the period cited by CMS as its evidentiary basis for the proposed rule – do not reflect **any** true cost data for providing cardiac CTA.

As well, placement of a non-nuclear medicine technology procedure codes in any nuclear medicine APC, breaks the clinical and resource homogeneity of the APC, something that CMS has worked to develop since the inception of the HOPPS.

In addition, the rates for the APCs in which these codes have proposed are far below the true costs of providing CCTAs and fail to recognize the unique clinical benefits of CCTA. These APCs would seriously underpay hospitals and would risk limiting beneficiary access to this service.

The resources required to perform cardiac CT to perform a thorough anatomical review of the heart and coronary arteries are substantial and substantively different from either myocardial perfusion

imaging or traditional chest CT imaging with and without contrast administration for the evaluation of the pathology in the thorax.

CCTA is fundamentally different from traditional chest CT imaging in several aspects.

1) Patient preparation time is lengthy, necessitating intravenous beta blockade to slow the heart rate in an attempt to "freeze" heart motion. In addition, sublingual nitroglycerin is administered prior to the scan to enlarge the coronary arteries. This preparation time includes vital signs and often telemetry monitoring for 30-120 minutes prior to the scan itself as incremental doses of beta blockade are administered by the cardiac trained registered nurse acting under physician supervision. This is performed either in a separate holding room requiring space for the patient and the RN or in the CT scanner room itself. Patient preparation is included within the category III CCTA CPT codes and is not separately reimbursable.

2) To perform the scan itself for CCTA CPT codes 0145T-0151T an advanced CT scanner at substantively greater acquisition and maintenance costs is required. Gating is also required to synchronize with the ECG necessitating further equipment and additional software. Thirty to ninety minutes is often required for the technical staff and the interpreting physician to reconstruct the different phases of the cardiac cycle in which the coronary arteries and rest of the cardiac structures can be viewed. This length of time necessitates a separate workstation and second software application set to allow for study interpretation. The technical staff time required for post-processing consumes considerable staff time, which is taken away from other tasks. The data storage and archiving equipment needed is extremely costly due to the voluminous amount of image data generated. As many as 3000-4000 images per study may be generated. In sum, staff involved in a CCTA exam includes the physician performing and interpreting the exam, the RN to administer intravenous beta blockers and nitrates prior to a CCTA, when necessary, and a credentialed radiologic technologist to operate the CT machine who has been specifically trained in this new technique.

3) RN- managed recovery time is also required given the medications received prior to the CCTA.

We thus request that the cardiac CTA codes be placed in the New Technology APCs at rates as follows:

CPT Codes	0144T	0145T	0146T	0147T	0148T	0149T	0150T	0151T
APC Code	APC 1504	APC 1507	APC 1508	APC 1508	APC 1508	APC 1508	APC 1508	APC 1503
APC New Technology Range	$200-$300	$500-$600	$500-$600	$600 -$700	$600 - $700	$600- $700	$600 - $700	$100-$200

CCCT scanning continues to evolve with rapidly changing CT equipment, software and protocols. As the technique stabilizes, costs should become more predictable and will allow the collection of financial data to provide us sufficient, usable cost data to properly evaluate the technical competent of CCTA. The recommendation to reclassify the Category III CPT Codes for CCTA (0141T-0151T) under the New Technology APC would better reflect the inconsistency within the technology as it emerges into practice both in the hospital and physician office setting.

Again, ACC, ASNC, SCCT, and SCAI wish to express our appreciation to CMS for the opportunity to share our views with you. We are committed to working with you to enhance the delivery of quality health care to Medicare patients.

If you have any questions, please feel free to contact Denise Garris, American College of Cardiology, Regulatory and Legal Affairs, ACC (202) 375-6398.

Sincerely,

Steven E. Nissen, M.D., FACC
President
American College of Cardiology

Myron C. Gerson, M.D.
President
American Society of Nuclear Cardiology

Gregory J, Dehmer, M.D., FSCAI
President
Society of Cardiovascular Angiography and Interventions

Stephan Achenbach, MD, FACC
President
Society of Cardiac Computed Tomography