

Submitter : Dr. Arif Asif
Organization : University of Miami School of Medicine
Category : End-Stage Renal Disease Facility

Date: 06/13/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1478-IFC-17-Attach-1.WPD

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May 25, 2005

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 416

re: CMS-1478-IFC Section C. Additions: Inclusion of CPT Codes 35475 and 35476 as Medicare Approved ASC Procedures

Dear Sir/Madam,

Background

- On November 26, 2004 a proposed rule was published in the Federal Register. The proposed rule made recommendations for additions and deletions to the current list of Medicare approved ambulatory surgical center (ASC) procedures. The Proposed Rule allowed for a comment period prior to the Final Rule being published.
- That list included adding angioplasty CPT codes 35475 and 35476 to the list of approved ASC procedures.
 - 35475 - transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
 - 35476 - transluminal balloon angioplasty, percutaneous; venous
- It also recommended that those two codes be placed in Payment Group 9.

- The Final Rule was published on May 4, 2005, effective July 5, 2005. There is a comment period up to that date.
- The Final Rule removed CPT codes 35475 and 35476 from the list of Medicare approved additions to the ASC procedures based on a comment received during the Proposed Rule comment period.
 - “Comment: We received many comments in support of the proposed additions to the ASC list. However, we received one comment that opposed the additions of CPT codes 37205, 37206, 35475, and 35476. The commenter stated that these procedures were not appropriate for the ASC setting and would allow for potential substandard care.”

Position:

We disagree with this comment and action. Our disagreement is based on information published in well-established, peer-reviewed journals with favorable impact factor (1-8). Consequently, in responding to this proposal we rely on documentation rather than opinion-based comments.

Much of what has been recently published regarding the above-cited procedures has resulted from ASC scenarios (1-8). A recent report by Beathard et al (8) published in one of the leading journals of nephrology (*Kidney International*) is a prime example of such documentation. In this article, the authors reported the success and safety of hemodialysis endovascular procedures. In addition, the article documents the complication rate during these interventions. Of note, all procedures were performed in an outpatient setting. Data were derived from 11 outpatient interventional facilities located in various regions of the United States. To date, this is the largest prospective series (n=14,047) reported on arteriovenous hemodialysis access interventions.

This analysis included 10,020 interventions that relate to the procedures mentioned in the background section (see above). In 5,121 PTA procedures (fistulae n=1,561; grafts n=3,560), the success rate was 97% and 98% for fistulae and grafts, respectively. The complication rate in cases of fistulae and grafts included 3.35% and 0.76% grade 1 hematoma (stable, does not affect flow), 0.4% and 0.11% grade 2 hematoma (stable, slows or stops flow) and 0.19% and 0.05% grade 3 hematoma (represents a complete vascular rupture, expands rapidly and leads to access loss), respectively (8). These results are far superior to those reported previously (1.7%-6.6%) (9-12). Amongst 4,899 thrombectomy cases (fistulae n=228; grafts n=4,671), an intervention that frequently require the above-mentioned (background section) procedures. Within this procedure there were 4,671 graft and 228 fistula cases. The complication rate in cases of fistulae and grafts included 5.7% and 3.32% grade 1 hematoma (stable, does not affect flow), 0.88% and 0.83%

grade 2 hematoma (stable, slows or stops flow) and 0.43% and 0.41% grade 3 hematoma (represents a complete vascular rupture, expands rapidly, leads to access loss), respectively (8). Peripheral artery embolism occurred in 0.38% of cases. These complication rates are lower than those reported previously (10-16%) (13-15).

In addition to the report by Beathard et al (8), we (5-7) and others (3-4) have also documented successful and safe performance of endovascular procedures highlighted in the background section (see above). Complication rates on these procedures from our center (5-7) also demonstrate a favorable profile and our results are comparable to those reported by Beathard et al (8). We believe that published data conclusively demonstrate the safety and success of these procedures when performed in an outpatient facility. In addition, this approach is convenient to the patient and improves patient care by minimizing missed dialysis sessions and hospitalization.

The magnitude of the lack of prompt availability of critical dialysis access procedures on patient care is enormous and should drive development of more practical approaches to meet this challenge. Outpatient facilities offer a practical approach to widespread availability of these procedures for end stage renal disease patients. Based on the published data, we request the codes 35476, 35475, 37205, 37206 when applied to dialysis vascular access and associated with one or more of the ICD9 codes 996.73, 585, 459.2, or 447.1 be allowed in the outpatient facilities.

References:

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A preliminary investigation of balloon angioplasty versus surgical treatment of thrombosed dialysis access grafts. *Am Surg* 69:663-667, 2003

CMS-1478-IFC-18

Submitter : Dr. Frederick Cahn
Organization : BioMedical Strategies, LLC
Category : Device Industry

Date: 06/13/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1478-IFC-18-Attach-1.RTF

June 13, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1478-IFC
PO Box 8017
Baltimore MD 21244-8017

Re: CMS-1478-IFC
CPT procedures 15342/15343 should be included in Update of Ambulatory Surgical
Center List of Covered Procedures

Dear Dr. McClellan:

We are writing this letter to comment on the Interim Final Rule for the Medicare Program, Update of Ambulatory Surgical Center List of Covered Procedures, that was published in the Federal Register, Vol. 70, No. 85 on Wednesday, May 4, 2005, and to recommend that CPT codes 15342 and 15343 be added to the list of covered ASC procedures.

We previously submitted these same comments in response to the Proposed Rule for the Medicare Program, Update of Ambulatory Surgical Center List, Covered Procedures, that was published in the Federal Register, Vol. 69, No. 227 on Friday, November 26, 2004. However, the Interim Final Rule did not address our comments at all, and thus we are resubmitting them at this time for consideration.

The list of covered ASC procedures includes most of the related codes for free skin grafts, which the American Medical Association CPT system groups in CPT codes 15000 through 15401. However, codes 15342 and 15343 are not included in the list of ASC covered procedures.

In the 2005 CPT, the AMA descriptor for these skin graft procedures is as follows:

- 15342 Application of bilaminate skin substitute/neodermis; 25 sq cm
- 15343 Application of bilaminate skin substitute/neodermis; each additional 25 sq cm (List separately in addition to code for primary procedure)

These two codes describe the procedures that are used to apply skin substitute products to excised skin wounds.

When these procedures, 15342 and 15343, are used to apply the skin substitute "collagen glycosaminoglycan bilayer matrix (CGBM)," they meet the Medicare criteria for inclusion in the List of Covered Procedures for the Ambulatory Surgical Centers, because they are safe and effective for Medicare patients when performed in ASCs and meet all the regulatory standards for coverage in ASCs, as we will explain more fully below.

Collagen glycosaminoglycan bilayer matrix is the proposed working title of a monograph that was been accepted for inclusion in the United States Pharmacopeia as a biologic. Two commercial products that can be described by that monograph are The Integra Dermal Regeneration Template (DRT) and the Integra Bilayer Matrix Wound Dressing (BMWD). While these products are physically identical, they are approved by FDA under different mechanisms and have different indications for use:

Intended Use of Bilayer Matrix Wound Dressing (From K021792)

“Bilayer Matrix Wound Dressing is indicated for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grfts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is intended for one-time use.”

Indication for Use of Dermal Regeneration Template (From P900033)

“INTEGRA Dermal Regeneration Template® is indicated for the postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. INTEGRA Dermal Regeneration Template® is also indicated for the repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiological condition of the patient.”

The indication of the Dermal Regeneration Template for repair of scar contracture is an example of use for the CGBM that may be carried out safely and effectively in an ASC. The CGBM is used as an alternative to a conventional skin autograft in the surgical repair a full-thickness skin wound created by surgical excision. As with autograft, the CGBM is cut to fit the wound bed and is fixed in place, usually by suture or staple at the margins. The wound is further protected by surgical dressings. The patient can be discharged the same day as the procedure.

Within 14 to 21 days, a dermal-like tissue (“neodermis”) that is distinct from granulation tissue is formed, at which time the second step of the skin replacement surgery is performed by removing the temporary epidermal substitute layer and applying a thin epidermal autograft to the neodermis. Epidermal tissue engraftment completes a permanent wound closure. Like autograft, the use of CGBM enables regeneration of histologically and functionally normal skin. Because the harvesting of conventional skin autograft creates a second deep skin wound at the donor site of the graft, a key advantage of using CGBM as an alternative is that it avoids the need to create such a wound. The use of these advanced dermal regeneration products avoids the need for more invasive procedures and thus can be performed appropriately in an ASC.

CMS has covered these procedures applying CGBM under the Hospital Outpatient Prospective Payment System (HOPPS) (November 15, 2004, Federal Register (Vol. 69, No. 219). Collagen-Glycosaminoglycan Bilayer Matrix was assigned code C9206 and a separate payment. Many of the same clinical features that support coverage under HOPPS support coverage in the ASC. On January 3, 2005 an application for new HCPCS codes for CGBM was submitted to CMS.

Most important, the procedures 15342/15343 meet all the criteria for inclusion in the List of Covered Procedures for the Ambulatory Surgical Center. Procedures 15342 and 15343 are very similar in operative time and clinical features to the other conventional skin graft procedures that are presently included on the list of covered ASC procedures. As with conventional skin grafts, elective surgery using CGBM will meet the specific standards in 42 C.F. R § 416.65(b) that cover ASC procedures if they do not generally exceed 90 minutes operating time and a total of 4 or less hours recovery or convalescent time, Anesthesia may be required, and if so, the anesthesia is local or regional anesthesia, or general anesthesia of not more than 90 minutes duration. Furthermore, these procedures, which can be carried out more than 20% of the time on an inpatient basis and less than 50% of the time in physician's offices [Federal Register April 21, 1987 (52 FR 13176)], are typically done safely and effectively in an ASC setting. The procedures require a dedicated operating room and

generally require a post-operative recovery room, but not overnight care. The procedures further comply with ASC criteria in that the procedures do not:

- Generally result in extensive blood loss
- Require major or prolonged invasion of body cavities
- Directly involve major blood vessels, or
- Generally involve emergency or life threatening conditions.

Not only are these procedures safe and effective in an ASC, but in many cases, the ASC may be a more cost effective alternative to hospital inpatient or outpatient procedures. Thus, we recommend that CMS add procedures 15342 and 15343 to the list of covered ASC procedures.

Sincerely yours,

Frederick Cahn, Ph.D.

Cc: Robert Cereghino (CMS)

Submitter : Dr. Mark Rassier

Date: 06/16/2005

Organization : Dr. Mark Rassier

Category : Physician

Issue Areas/Comments

Issue

Regulatory Impact Statement

PTA of hemodialysis grafts and fistula's is done safely on a daily basis in outpatient settings. This practice should be allowed to continue.

Submitter : Mr. Michael Perry
Organization : US Vascular Access Center of Dallas
Category : Ambulatory Surgical Center

Date: 06/20/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1478-IFC-20-Attach-1.WPD

**COMMENTS TO CMS ON PROPOSED 2005 FEE SCHEDULE
CMS-1478-IFC****RESPONDENT: Mike Perry**
Mike.Perry@FMC-NA.com**RE: CMS-1478-P; Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures**

We are submitting the following comments in response to the interim final rule that proposes to update the list of Medicare covered procedures that may be performed in an ambulatory surgical center (ASC) published in the April 29, 2005 Federal Register. In this publication, CMS seems to be in direct contrast to a previous proposal they released on November 26th of 2004. The contrasting opinion of concern is for Arterial and Venous Angioplasty (CPT 35475 and 35476). In the November 26th of 2004 opinion CMS intended to allow an ASC the facility fee for Angioplasty CPT codes 35475 and 35476 under Grouper 9. However, in this latest proposal, CMS seems to be reversing that recommendation due to a single, recent commenter. This commenter, who appears to be a surgeon society, raised a concern that the ASC would provide a "substandard of care" because of "major vessel" involvement.

The dichotomy of this comment and CMS's response is that more invasive procedures involving "major vessels" are currently covered in an ASC and other less regulated places of service. In an ASC, these procedures are performed safely and successfully due to the high ASC standards that are in place under the Federal regulations 42 CFR Part 416 and local department of health regulations. The issue of vessel size for ASC's was initially made due to level of complication, surgical technique, anesthesia types and delivery and blood transfusion that could be involved. Even so, Federal and State ASC guidelines allow for procedures of various patient risk and difficulty statuses. In fact, even more invasive surgery involving "open surgery technique" and access of vessel anatomy is currently allowed in an ASC due to its strict staff, equipment and environment guidelines for these procedures. An example is CPT code 36819 which is transposition of vessels to create A-V Fistulae. This procedure can be performed and is allowed for reimbursement by CMS in an ASC as are other codes representing "open surgery technique", (i.e. 36830 and 36821). Additionally, ASC guidelines have current PS (Patient Sedation) criteria as well as Patient Risk Classification that are well defined within the State and Federal regulations. A further point is that Angioplasty, codes 35475, 35476 and Vascular Stent Placement, codes 37205 and 37206 are both allowed and reimbursed in a Physician Group Practice place of service which has far less regulation than an ASC or a hospital outpatient department, (HOPD).

Even though CMS and local regulations allow for various levels of defined risk for outpatient procedures in an Ambulatory Surgical Center, it is understandable that there would be concern for intravascular angioplasty or more invasive surgery of great vessels. Certainly subclavian arteries, aorta, common femoral or even cardiac arteries in any outpatient provider setting are inherently more risky to access. With that in mind we would hope that the review panel would consider that the primarily venous angioplasty or venous stent procedures we propose to provide on an outpatient basis for end stage renal disease patients are low risk involving mostly peripheral vasculature. Central veins such as subclavian or vena cava are currently accessed with tunneled cuffed catheters and allowed in an ASC via codes 36558, 36581 or 36580 as but a few examples. At the very least we propose that the original recommendation of the panel would be approved with a modifier for ESRD vascular access.

In July 2003, CPT code 36870 (Thrombectomy) was added to the ASC List. This procedure sometimes requires subsequent angioplasty to be performed in addition to or as part of the Thrombectomy. This procedure, like peripheral intravascular angioplasty, has a low complication rate in an outpatient setting and is well documented by the American College of Radiology. The ASC regulations have specific Radiation Safety Standards as well as physiologic monitoring of the patient before (pre operative), during (procedure room) and after (post operative) a procedure.

The credibility of an ASC has long been established by CMS and is enforced by local State Departments of Health and national organizations such as the Accreditation Association for Ambulatory Health Care (AAAHC) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). ASC's are developed and constructed in accordance with the latest edition of the "Guidelines for Design and Construction of Hospital and Healthcare Facilities" which is required by the State and Federal regulations. These construction standards allow for the safe provision of services at the ASC.

We urge CMS to give serious consideration to our recommendation to keep venous and arterial angioplasty as well as stent placement codes (35475, 35476, 37205 and 37206) added to the ASC list under grouper 9. This is especially critical for ESRD patients who have limited access to care and end up hospitalized, creating a further burden for them and payers. CMS, State and local regulations have been very successful toward guiding and allowing the ASC to develop a less expensive but highly safe environment for patient care. Outcome data as presented by various physicians and the American Society of Diagnostic and Interventional Nephrology support this.

It has taken providers years of innovative approaches to respond to what was HCFA and their call for more credible, cost effective and accessible ESRD outpatient care to reduce hospitalizations and associated costs as outlined in detail in the 1997 US Renal Data Systems Chapter 10. As the largest provider of ESRD services, Fresenius Medical Care, through its US Vascular subsidiary has been a leader in developing the Ambulatory Surgical Center and dedicated out patient service to reduce hospitalization of its patients.

I believe once the ASC criteria and the objective to reduce hospitalization associated with ESRD vascular access complication are further investigated by the CMS Medical Staff, they will find favorable allowance of peripheral vascular angioplasty and stent placement in an ASC

Michael A. Perry, RDMS, RT, MBA
VP and General Manager
US Vascular Access Centers

Submitter : Dr. Michael Repka
Organization : American Academy of Ophthalmology
Category : Health Care Professional or Association

Date: 06/22/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1478-IFC-21-Attach-1.DOC

CMS-1478-IFC-21-Attach-2.DOC

Submitter : Mr. Bob Thompson
Organization : Medtronic CRM
Category : Device Industry

Date: 06/30/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1478-IFC-22-Attach-1.DOC

1

July 5, 2005

Submitted Via Electronic Mail

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478- IFC
PO Box 8017
7500 Security Blvd.
Baltimore, MD 21244-8017

Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule [CMS-1478-IFC]

Dear Dr. McClellan:

Medtronic, Inc. is one of the world's leading medical technology companies specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high quality products and to support innovative therapies that improve patients' health outcomes. While we acknowledge that the notice and comment period for Interim Final Rule for the Update of Ambulatory Surgical Center List of Covered Procedures (CMS-1478-IFC, Federal Register, Wednesday, May 4, 2005) has been waived, Medtronic Cardiac Rhythm Management feels compelled to comment on some of the additions to the ambulatory surgical center (ASC) list of covered services.

Issue Identifier: Analysis of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of This Interim Final Rule With Comment Period

Based on the input from one commenter, the Interim Final Rule adds three pacemaker procedures to the ASC list of covered procedures. The added procedures and corresponding ASC payment rates are as follows:

CPT	Code Description	ASC Payment Group	ASC Payment Rate
33212	Insertion or replacement of pacemaker pulse generator only; single chamber, atrial or ventricular	3	\$510
33213	Insertion or replacement of pacemaker pulse generator only; dual chamber	3	\$510
33233	Removal of permanent pacemaker pulse generator	2	\$446

CMS indicates in the Interim Final Rule that it will “try not to add procedures to the list that would be significantly underpaid in the highest ASC payment group.” However, the addition of the pacemaker procedures to the list of ASC covered services will create a situation where ASCs would be grossly underpaid.

With other implanted devices (implantable pumps, neurostimulators, etc.) provided in the ASC setting, the ASC payment rate is meant to encompass the facility's costs associated with the procedural portion of the implant, while the device is billed with a HCPCS code and is paid separately under the DMEPOS fee schedule. However, for pacemakers, currently there is no HCPCS code available to report the device in the ASC setting. Therefore, under the Interim Final Rule, the ASC would only be reimbursed \$510 for the procedural costs and the pacemaker device; a significant underpayment resulting in an unsustainable financial burden for the ASCs that provide these services.

Under CMS' Outpatient Prospective Payment System, hospitals are reimbursed \$5,159 and \$6,005¹ respectively for the same single or dual chamber pacemaker implantation procedures. Under CMS' Inpatient Prospective Payment System, the payment level increases to \$8,328². While we recognize that there are other costs related to services performed in the outpatient and inpatient hospital settings that justify the increased payment levels, we know that the majority of the cost associated with any pacemaker implant, regardless of the site of service in which it is performed, is the device itself. The most recent external data available to us regarding device acquisition costs show that the median acquisition costs of the single and dual pacemaker device are \$4,269 and \$5,149³ respectively. These costs are more than eight times the planned ASC payment rate of \$510 for CPT codes 33212 and 33213.

As stated in the Interim Final Rule, “under the current ASC facility services payment system, the ASC payment rate is a standard overhead amount established on the basis of our (CMS') estimate of a fair fee that takes into account the costs incurred by the ASCs generally in providing facility services in connection with performing a specific procedure.” Given that an ASC would lose over \$3,700 on each case in just the device costs alone, the planned \$510 payment rate cannot be considered a “fair fee”. Therefore, **we respectfully request that CMS delay the inclusion of CPT codes**

¹ November 15, 2004 Federal Register. Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Rates; Final Rule

² Payment amount for DRG 118 for FY 2005. Assumes payment for a large urban hospital with wage index and geographic adjustment of 1.000. Payment = DRG relative weight x (labor standardized amount + non-labor standardized amount + capital)

³ IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004

33212, 33213, and 33233 until CMS develops the forthcoming revised payment system for ASC facility services based on the hospital outpatient prospective payment system (OPPS) and a more equitable payment rate can be established for pacemaker services.

We appreciate the opportunity to submit these comments and trust that CMS will delay the addition of the pacemaker services in the ASC list of covered services until a fair payment rate can be established. If you have questions or require additional information regarding these comments, please contact me at 763.514.4181.

Sincerely,

Bob Thompson, MS., MA.
Director, Reimbursement, Economics and Health Policy
Medtronic Cardiac Rhythm Management

Submitter : Ms. Anne Marie Bicha
Organization : American Gastroenterological Association
Category : Health Care Provider/Association

Date: 06/30/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1478-IFC-23-Attach-1.DOC



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AGA WEB SITE

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June 30, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
PO Box 8017
Baltimore, MD 21244-8017

RE: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim final rule with comment period

Dear Dr. McClellan:

The AGA is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system.

As we indicated in our proposed rule comments, AGA is pleased that CMS has added six gastrointestinal endoscopic procedures to the ASC list:

44397 (Colonoscopy w/stent);
45327 (Proctosigmoidoscopy w/stent);
45341 (Sigmoidoscopy w/ultrasound);
45342 (Sigmoidoscopy w/us guided bx);
45345 (Sigmoidoscopy w/stent); and
45387 (Colonoscopy w/stent).

We are disappointed, however, that CMS has decided to retain all of these new procedures in payment group 1 (\$333). For the four stent procedures 44397, 45327, 45345 and 45387, the cost of the stent is in excess of \$1,400.

In comparison, payment for these stent procedures when performed in the hospital outpatient setting is \$1,543. Clearly, no physician can perform these procedures in an ASC setting if the payment is \$333. Even the base procedure of a diagnostic colonoscopy (code 45378) is placed in payment group 2.

We note that code 44379, enteroscopy beyond second portion of duodenum, including ileum with transendoscopic stent placement, is in payment group 9.

Mark McClellan, MD, PhD

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This procedure is clinically and technically similar, in terms of facility resources, equipment, sedation and staff, to the other stent procedures. Again, we request that these four stent procedures be placed in payment group 9.

CMS has commented that the intent of this rule is to update the list of procedures on the ASC list and it is beyond the scope of this rule to create payment groups that would provide payments closer to the costs of procedures. There are still several years before CMS moves to a new payment methodology for ASCs. As endoscopic stent procedures are performed primarily for patients with neoplasms, we request in the interim that CMS provide appropriate rates to maintain beneficiary choice and access to important medical procedures.

We also request that CMS reconsider the placement of codes 45341 and 45342 in payment group 1. We believe that payment group 3 is more appropriate, as these procedures utilize expensive ultrasound probes, specialized echoendoscopes, and fine needle aspiration systems.

If we may provide any additional information on our comments, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664, or abicha@gastro.org.

Sincerely,



David A. Peura, M.D.
AGA President

Submitter : John McClanahan
Organization : Cochlear Americas
Category : Device Industry

Date: 06/30/2005

Issue Areas/Comments

GENERAL

GENERAL

ASCs offer an affordable option for patients as well as payers. As a lower cost alternative to surgery, diligent efforts must be made to develop a Medicare payment system that adequately reimburses device dependent procedures. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requires CMS to implement a revised payment system for services furnished in an ASC before 1/1/08. When reviewing the results of the Congressionally mandated GAO study of the appropriateness of using OPPS as a basis for a new ASC payment system, we ask CMS to consider and address the following issues: 1) Physician choice: Any payment policy must allow a physician to choose the setting best suited for the patient's care. Payment rates should not unduly influence this choice; 2) Adequacy of OPPS rates: Some OPPS rates are not adequate to cover the costs of performing a procedure in the hospital setting. This must be corrected before using OPPS as a model/gauge for setting ASC rates; 3) Annual updates: ASC payment rates should be updated annually. There should be an explicit mechanism to calculate cost. For new devices, a new technology APC and pass-through program should be developed for the ASC setting. The same application should be used for new technology in both outpatient hospital and ASC environments; 4) Service bundles: The same bundle of services should be covered in both settings. Current ASC payments do not cover the costs of certain implantable devices (now paid under DMEPOS) thus many device dependent procedures are significantly underpaid in the ASC setting. Accordingly, the new ASC payment system should carefully account for the costs of implantable devices in the service bundle.

Submitter : Ms. Susan Walker
Organization : St. Jude Medical, Inc.
Category : Device Industry

Date: 06/30/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1478-IFC-25-Attach-1.PDF

June 30, 2005

Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

**Re: Update of Ambulatory Surgical Center List of Covered Procedures;
Interim Final Rule (CMS -1478-IFC)**

Dear Dr. McClellan:

St. Jude Medical, Inc. appreciates the opportunity to provide you with comments to the Centers for Medicare and Medicaid Services' (CMS) interim final rule that updates the list of covered procedures performed in an ambulatory surgical center (ASC).

St. Jude Medical is dedicated to the design, manufacture, and distribution of cardiovascular medical devices of the highest quality, offering physicians, patients, and payers outstanding clinical performance and demonstrated economic value. The Company's product portfolio includes cardiac resynchronization therapy (CRT) devices, implantable defibrillators (ICDs), pacemakers, specialty catheters, vascular devices, and heart valve replacement and repair products.

Our comments will address the addition of pacemaker procedure codes 33212, 33213, and 33233 to the list of procedures that are covered when furnished in an ASC.

Addition of CPT Codes 33212, 33213, 33233

We encourage CMS to withdraw pacemaker codes 33212, 33213 and 33233 from the additions to the list of Medicare approved ASC procedures addressed in the interim final rule. We believe these procedures should be retained in the hospital setting (either inpatient or outpatient) until such a time that CMS develops a revised payment system required by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).



Procedure codes 33212 (insertion or replacement of pacemaker pulse generator, single chamber) and 33213 (insertion or replacement of pacemaker pulse generator, dual chamber) are assigned to payment group 3 (\$510) and 33233 (removal of permanent pacemaker pulse generator) is assigned to group 2 (\$446). Payment group 3 is intended to cover the procedural costs associated with the pacemaker, but not the costs associated with the device itself. Under the current system, the costs of implantable devices, such as pacemakers, are paid separately through the Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) Fee Schedule. However, there is no HCPCS code available to report the device. Therefore, the ASC would only be reimbursed \$510 for the procedural costs with no reimbursement for the device.

In the hospital outpatient setting, the Ambulatory Payment Classification (APC) rate for 33212 and 33213 is \$ 5,159 and \$6,005, respectively. Given the substantial cost of the device associated with these procedures, ASCs will be unable to provide these services under the \$510 payment amount established by CMS. Until such a time as CMS develops and implements a new payment system that bundles the cost of the device into the ASC payment and establishes reimbursement that compensates adequately for the device and the procedure, CMS should withdraw these pacemaker codes from the list of covered ASC procedures.

St. Jude Medical greatly appreciates the opportunity to comment on the interim final rule updating the ASC Covered Procedure List.

Sincerely,

A handwritten signature in black ink that reads 'Susan Walker'.

Susan Walker
Director, Reimbursement

Submitter : d cra
Organization : en
Category : Device Industry

Date: 07/01/2005

Issue Areas/Comments

Background

Background

Endo is concerned about issue of low reimbursement.

Submitter : Mr. Craig Davenport
Organization : Endocare, Inc.
Category : Device Industry

Date: 07/01/2005

Issue Areas/Comments

Background

Background

Endocare is concerned about recent issuance of ASC list inclusive of cryoablation of the prostate code without sufficient reimbursement. See Attachment.

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See Attachment.

Issue

Background

See Attachment.

Provisions of this interim final rule with comment period

See Attachment.

Regulatory Impact Statement

See Attachment.

CMS-1478-IFC-27-Attach-1.DOC



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July 1, 2005

VIA ELECTRONIC MAIL AND U.S. MAIL

Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
Room 314G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on: *Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures (CMS -1478-IFC)*

Dear Dr. McClellan:

On behalf of Endocare, Inc., I respectfully offer the following comments on the correction to the Interim Final Rule updating the Medicare Ambulatory Surgical Center (ASC) list of covered procedures. The Interim Final Rule with comment was published in the *Federal Register* on May 4, 2005, and the correction was published in the *Federal Register* on June 24, 2005. The correction notice added CPT Code 55873, *Cryosurgical ablation of the prostate*, to the list of ASC-covered procedures.

Endocare is a medical device company focused on the development and commercialization of minimally invasive technologies for tissue and tumor ablation. Our primary area of focus has been urology (prostate cancer, in particular), and our objective is to improve men's health and quality of life. Endocare manufactures a total system required to perform cryosurgery, as well as the CryoProbes used in the prostate cryosurgery procedure.

Background on Prostate Cryosurgery

In 1999, the procedure, *cryoablation of the prostate*, was assigned a CPT Code, 55873. That same year, Medicare issued a National Coverage Determination to cover prostate cryosurgery for primary treatment. Two years later, in 2001, this surgery was covered for salvage treatment.

Prostate cryosurgery is a cancer treatment that involves the placement of cryosurgical probes transperineally into the prostate. Typically, at least six (6) (and sometimes up to eight [8]) probes are used. These probes conduct argon and helium gases in a controlled freeze process that is targeted at the cancer cells in the prostate. Other cryosurgical supplies used in this procedure include temperature probes used in tandem with the CryoProbes, and a urethral warmer.



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Honorable Mark McClellan, M.D., Ph.D.
July 1, 2005
Page 2 of 3

These supplies — CryoProbes, temperature probes, and urethral warmer—are typically purchased by healthcare providers in “kits” which range in price from \$4,500 to \$5,000. Facilities performing this procedure must have available a technician to operate the cryosurgery equipment. Beyond this, facilities incur costs associated with operating room time, recovery room and nurse/licensed practical nurse staffing, and basic surgical supplies and medications. In our experience, the cost of performing prostate cryosurgery procedures in outpatient facilities, like hospital outpatient departments and ASCs (some private payers cover this procedure in ASCs) is approximately \$9,400 per case.

For the past several years, we have collected information on hospital outpatient facility costs associated with this procedure, and we have shared it with CMS for consideration under the hospital outpatient prospective payment system. We are also willing to share this data with you as you consider an ASC payment rate for prostate cryosurgery procedures. As we mentioned earlier, our experience is that ASC have costs quite similar to hospital outpatient departments.

Payment Considerations

If prostate cryosurgery is incorporated into Medicare's ASC payment system, where other less-invasive prostate cancer treatments are offered (e.g., prostate brachytherapy), it should receive a payment amount that approximates the costs associated with performing the procedure. We note, however, that while the procedure is assigned to the highest paying category for ASC procedures (payment group 9 that has a payment rate of \$1,339), this amount clearly does not come close to covering an ASC facility's costs. Given this, we are seriously concerned that this payment rate will be misconstrued by government and private payers as appropriate for this procedure.

We understand that currently there are no other, higher-paying categories in which prostate cryosurgery can be placed. Nevertheless, we believe that, if prostate cryosurgery is added to the Medicare ASC payment system without adding higher-paying categories, CMS can take other short-term steps to alleviate the shortfall in ASC reimbursement that would result from an ASC performing this procedure.

Recommendation

We suggest that physicians be permitted to bill Medicare separately for the cryosurgical supplies used in this procedure (i.e., the CryoProbes, temperature probes, and urethral warmer) while the procedure continues to be assigned to payment group 9. We also suggest that CMS review our data on hospital outpatient facility costs associated with this procedure and use it to construct a new payment group that more-accurately reflects ASC costs.

The payment approach we suggest is similar to that taken by CMS with respect to another less-invasive prostate procedure, prostate brachytherapy. In this payment approach, brachytherapy “seeds” are billed and paid under the Medicare physician fee schedule. Failure to take a similar



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

July 1, 2005

Page 3 of 3

payment for prostate cryosurgery would create serious incentives for providers to perform one procedure instead of another, based on the size of the payment—not the best medical interests of the patient.

Thank you, Dr. McClellan, for giving us the opportunity to comment on this proposed rule. Please do not hesitate to contact me if you have questions or require additional information.

Sincerely,

Craig T. Davenport
Chief Executive Officer
Chairman of the Board

c: Herb Kuhn, Director
Centers for Medicaid Management

Submitter : Ms. Jane Hyatt Thorpe

Date: 07/01/2005

Organization : AdvaMed

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Thank you.

CMS-1478-IFC-28-Attach-1.DOC

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Tel: 202 783 8700
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July 1, 2005

Via Electronic Mail and U.S. Mail

Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Room 314G
Washington, DC 20201

**Re: Update of Ambulatory Surgical Center List of Covered Procedures;
Interim Final Rule (CMS-1478-IFC)**

Dear Dr. McClellan:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to provide you with comments to the Centers for Medicare and Medicaid Services’ (“CMS”) interim final rule that updates the list of covered procedures performed in an ambulatory surgical center (“ASC”).

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed’s more than 1,300 members and subsidiaries manufacture nearly 90 percent of the \$75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have less than \$30 million in sales annually.

In our comments set forth below, we will address (I) procedures involving medical devices and other technologies for which the costs are not captured by the payment group rate and (II) reform of the ASC payment system.

I. Procedures Involving Medical Devices and Other Technologies for which the Costs Are Not Captured by the Payment Group Rate

The ASC covered procedure list includes procedures that involve the utilization or implantation of medical devices or other technologies for which the cost significantly exceeds the payment group rate. Where the cost of the device or other technologies exceeds the available ASC payment group rate, ASCs will be discouraged from making these procedures available. This not only impedes the transition of procedures associated with devices or other technologies to the ASC setting, but also limits patient access to these procedures. Although AdvaMed recommends that CMS develop a consistent and permanent solution to this issue in the forthcoming revised ASC payment system (discussed in further detail under Section II, ASC Payment Reform), until the system is revised AdvaMed recommends (A) Reclassification of procedures to higher payment groups, (B) Separate payment for medical devices or other technologies, or (C) Delayed inclusion of certain CPT codes on the covered procedure list.

A. Reclassification of Procedures to Higher Payment Group

In some cases, the discrepancy between the total cost of the procedure (including the device) may be addressed by reclassifying the procedure to a higher payment group. We understand that many interested parties have submitted and/or will be submitting formal comments urging CMS to reclassify certain procedures to more appropriate payment groups in conjunction with the 2003 update and this update. Below are just two of many examples where the costs of procedures involving medical devices or other technologies are not adequately reflected by the ASC payment group.

CPT 46947 was placed in payment group 3 (\$510) because the resource utilization for CPT 46947 was viewed as similar to other codes included in this group. However, in addition to the similar resources used for other procedures in this group, this procedure, Stapled Hemorrhoidopexy, involves the use of the Hemorrhoidal Circular Stapler which costs \$389 or 76% of the proposed ASC payment rate. As such, AdvaMed recommends reassigning this code to a higher payment group (7 or higher).

Likewise, CPT 57288 was placed in payment group 5 (\$717). Under the hospital outpatient prospective payment system ("OPPS"), CPT 57288 is assigned to APC 202 with a payment of \$2,260. In the ASC setting, payment group 5 does not cover the device costs associated with this procedure, repair bladder defect, or the facility costs. As such, AdvaMed recommends reassigning this code to payment group 9 (\$1339).

B. Separate Payment for Medical Devices or Other Technologies

In other cases, allowing the medical devices or other technologies to be reimbursed separately may address the issue. For example, the interim final rule includes HCPCS 55873, cryosurgery of prostate, in payment group 9 (\$1339). Based on recent external data submitted to CMS this rate is \$7,500 less than the actual procedural costs of

hospitals when the procedure is conducted in an outpatient setting and over \$5,000 less than the current OPSS payment to hospitals for the same procedure. The supplies alone – cryoprobes, temperature probes, and urethral warmer – are typically purchased by healthcare providers in “kits” which range in price from \$4,500 to \$5,000. Including this HCPCS code in the list of covered procedures without the appropriate reimbursement relays an inaccurate message to governmental and private payers that this amount may be appropriate reimbursement when it has been clearly demonstrated that a payment rate this low it is not sufficient to meet the basic expenses of the procedure. As such, CMS should indicate that prostate cryosurgery in an ASC should be treated comparably with prostate brachytherapy – the cryoprobes should be paid for separately from the procedure, as are brachytherapy seeds.

Another example involves CPT 19298. Under OPSS this code is assigned to APC 1524 with a payment of \$3,250. Per the interim final rule, this code has been assigned to payment group 1 (\$333). This rate does not cover the facility costs of this procedure and creates a large disparity of payment for HDR brachytherapy performed in the ASC setting from services provided in the hospital outpatient setting. As such, CMS should reassign CPT 19298 to payment group 9 (\$1,339). In addition, this procedure typically requires 30 button-end implant catheters that cost \$18.50 each for a total supply cost of \$555. These added costs are not covered by the highest paying ASC group. Therefore, we recommend separate payment for these items.

Similarly, AdvaMed recommends that CMS clarify that brachytherapy catheter(s) are paid separately as are other supplies utilized in brachytherapy procedures. The breast brachytherapy catheter(s) range in cost from \$2,500 to \$3,500 per patient, and even the highest ASC payment group is insufficient to cover the costs of the catheter(s).

C. Delayed Inclusion of CPT Codes on the Covered Procedure List

CMS has added two pacemaker implantation procedures to the ASC list of covered procedures. However, for pacemakers, there is currently no HCPCS code available to report the device in the ASC setting. Therefore, the ASC would only be reimbursed \$510 for the procedural costs and the pacemaker device. Given the inadequacy of the pacemaker payment rate, AdvaMed recommends that CMS delay the inclusion of CPT codes 33212, 33213, and 33233 until a new ASC payment system is developed.

Similarly, endovenous radiofrequency ablation of venous reflux procedure (“RFA”), which was assigned new CPT codes (36475 & 36476) effective January 2005, has been included on the covered procedure list and assigned to payment group 3 (\$510). RFA has a \$725 disposable catheter cost plus the costs of additional supplies and capital equipment required to perform the procedure. Thus, payment group 3 does not even closely approximate the total cost for RFA which is approximately \$4,800. Because these codes are new there is no cost data to support assignment of these codes to payment

group 3. As such, AdvaMed recommends that CMS delay the inclusion of CPT codes 36475 and 36476 until a new ASC payment system is developed.

II. ASC Payment Reform

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“MMA”) requires CMS to implement a revised payment system for services furnished in an ASC before January 1, 2008. As noted throughout the interim final rule, this will be the last list of covered ASC procedures issued before the implementation of the revised payment system. It is our understanding that before CMS revises the payment system, it will review the results of an ongoing MMA mandated General Accountability Office (“GAO”) study of the appropriateness of using the hospital OPPS as a basis for an ASC payment system. In reviewing the results of the GAO’s study and devising a revised ASC payment system, AdvaMed urges CMS to address and incorporate the issues set forth below.

A. Clinician Choice

Payment policies should allow a clinician to choose the setting most appropriate for the patient's care. This choice should not be unduly influenced by the payment rates the facility will receive.

B. Service Bundles

The current base payment rates for OPPS and ASCs cover different bundles of services in each setting. We believe that the bundle should be the same. Those items covered as part of the OPPS APC payment rate should be included in the ASC bundled rate. Items not included in the APC rate should likewise be excluded from the ASC rate. For example, current ASC payments do not cover the costs of certain implantable devices (which are paid separately through the DMEPOS fee schedule), corneal tissue, or new technology IOLs. This creates a situation where device related procedures are significantly underpaid in the ASC setting. As such, the new ASC payment system should adequately account for the costs of medical devices and other technologies in the service bundle.

C. Non-Covered CPT Codes

Some APCs include CPT codes that are not covered in the ASC setting. When calculating the ASC weight for a particular APC group, the median costs of the procedures represented by non-covered CPT codes should be excluded from the determination of the ASC relative weights.

D. Brachytherapy

Brachytherapy sources should not be included in the bundle for the ASC rate, since it is not included in the OPPS APC rate, per the Medicare Modernization Act.

E. Adequacy of OPPS Rates

Some OPPS rates are not adequate to cover the costs of performing the procedure in the hospital, and should be corrected before being used as a gauge for setting ASC rates. For example, many device-related procedures are significantly underpaid by OPPS.

F. Budget Neutrality

The budget neutrality requirements for the ASC payment system changes under the MMA may be problematic and should be clarified. Specifically, in establishing budget neutrality, all Part B costs associated with the covered ASC procedure should be taken into account, not just the published ASC payment rate for the procedure. We are concerned that historical budget restrictions applied to the OPPS setting, as well as possible future reductions, could negatively impact the development of appropriate payment levels in the ASC setting.

G. Annual Updates

ASC payment rates should be updated annually, and have an explicit mechanism to take into account the cost of new technology. A new technology APC and/or pass-through program for new devices should be developed for the ASC setting. Applicants should be able to use the same application to apply for new technology categories or designation in both hospital outpatient and ASC settings.

AdvaMed greatly appreciates this opportunity to comment on the interim final rule updating the ASC covered procedure list. We urge CMS to consider these comments and incorporate them into an update to the list of covered procedures and the revision of the ASC payment system. We also urge CMS to refer to comments from our members and others who will be providing detailed recommendations, data and information for guidance on appropriate additions, deletions, and assignment or reassignment of procedure codes.

Honorable Mark McClellan, M.D., Ph.D.
Page 6 of 6

We would be pleased to answer any questions regarding these comments. Please contact Jane Hyatt Thorpe, Associate Vice President, Payment and Policy, at 202/434-7218, if we can be of further assistance.

Sincerely,

 /s/
David Nexon
Senior Executive Vice President

cc: Don Thompson
Joan Sanow

Submitter : Mr. Michael Mabry
Organization : Society of Interventional Radiology
Category : Health Care Professional or Association

Date: 07/01/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1478-IFC-29-Attach-1.PDF

CMS-1478-IFC-29-Attach-2.PDF



SOCIETY OF
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July 1, 2005

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

**Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures
[CMS-1478-IFC]**

Dear Administrator McClellan:

The Society of Interventional Radiology (SIR) is a national specialty association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States, along with other physicians and allied health professionals interested in interventional radiology.

SIR appreciates the opportunity to comment upon the Interim Final Rule, Medicare Program; Update of Ambulatory Surgical Center List of Covered Services as published in the May 4, 2005 *Federal Register*. SIR's comments are directed to the proposed additions to the ASC list, specifically:

- ❖ Angioplasty and stenting,
- ❖ Vertebroplasty,
- ❖ Endovenous ablation, and
- ❖ Catheterizations.

Additions to the ASC List – Angioplasty and Stenting (Pages 23698, 23705)

SIR recommends that percutaneous angioplasty (CPT codes 35470 through 35476) and percutaneous non-coronary stent placement (CPT codes 37205 and 37206) be included in the ASC list of covered services. Additionally, SIR strongly takes issue with the comment that these services, when performed outside of the hospital setting, would result in "substandard care" or that they should be limited to the hospital outpatient and inpatient settings.

A major trend in health care is the migration of services from hospitals to non-hospital settings (e.g., ambulatory surgical centers, offices). This trend is true for interventional radiology procedures. The very nature of interventional radiology services – the fact they are less invasive, have fewer complications, and require less follow up care than analogous surgical procedures – makes them well suited to be performed in non-hospital settings.

SIR was taken aback by the commenter who stated (page 23698), “that these procedures [angioplasty and stenting] were not appropriate for the ASC setting and would allow for potential *substandard* (emphasis added) care.” We also question why CMS sided with this lone commenter when the agency acknowledged in the rule that, “we received many comments in support of the proposed additions to the ASC list.” Furthermore, SIR is troubled by CMS’ own statement (page 23705) that, “we have determined that they [angioplasty codes] are more appropriately limited to the hospital outpatient and inpatient settings at this time.” Both statements could not be farther from current clinical practice in angioplasty and stent placement. Advances in pain and drug management, catheter and guidewire technology, and delivery devices have improved the safety and effectiveness of percutaneous angioplasty and stenting. The relatively recent advent of percutaneous closure devices has reduced post-procedure observation time significantly (from 4-6 hours to 1-2 hours) while decreasing the risk of post-catheterization bleeding complications.

CMS cites the lack of utilization in the office or ASC settings as part of its justification not to add angioplasty and stenting to the ASC list (page 23705). This is a “catch-22”. Until this year, Medicare did not cover angioplasties in the office setting. Angioplasties are not covered in ASCs. However, despite the lack of Medicare payment, the non-hospital setting (office and ASC) accounted for 26 percent of brachiocephalic angioplasty (code 35475) and 17 percent of venous angioplasty (code 35476); offices account for most of the volume, however.

Procedures involving major blood vessels require great care and precision. Furthermore, we agree with CMS that not all procedures are appropriate in the non-hospital setting. In the case of angioplasty and stent placement, the procedures are performed typically through a small incision (nick) in an artery or vein to gain access. The techniques to gain safe vascular access were developed in the early 1960s and have been refined since. Since the therapy is conducted endovascularly, the trauma to the vessel is much less than that associated with surgery. We would expect that non-hospital settings would be equipped appropriately and have processes in place in case of an emergency.

Additions to the ASC List – Vertebroplasty (Page 23702)

SIR recommends that percutaneous vertebroplasty (CPT codes 22520, 22521, and 22522) be added to the ASC list of services.

CMS, in its decision not to add vertebroplasty to the ASC list, cites: (1) “there is often an overnight stay required” and (2) “the recovery period usually is longer than 4 hours.” These points might have been accurate of the early experience of vertebroplasty when first introduced in the United States in the mid-1990s -- not now. Since then, the technique and materials associated with vertebroplasty have changed considerably. Also, interventional radiologists have emphasized providing their own pre- and post-procedure follow-up care. As a result, in the major studies of vertebroplasty consisting of a large number of patients (for example -- Evans¹, McGraw², and Zoarski³), the typical observation/recovery period is between one and three hours followed by hospital discharge. It is unusual for compression fracture symptoms to worsen. Overnight hospital stays are atypical, unless severe co-morbidities are present. SIR, having addressed CMS’ major objections for not adding vertebroplasty to the ASC list, recommends that CMS add vertebroplasty to the ASC list.

1. Evans AJ, Jensen ME, Kip KE, et al. Vertebral compression fractures: pain reduction and improvement in functional mobility after percutaneous polymethylmethacrylate vertebroplasty retrospective report of 245 cases. *Radiology* 226:366-72, 2003.

2. McGraw JK, Lippert JA, Minkus KD, Rami PM, Davis TM, Budzik RF. Prospective evaluation of pain relief in 100 patients undergoing percutaneous vertebroplasty: results and follow-up. *J Vasc Interv Radiol* 13(9 Pt 1):883-6, 2002.

3. Zoarski GI, Snow P, Olan WJ, Stallmeyer MJ, Dick BW, Hebel JR, De Deyne M. Percutaneous vertebroplasty for osteoporotic compression fractures: quantitative prospective evaluation of long-term outcomes. *J Vasc Interv Radiol* 13(2 Pt 1):139-48, 2002.

Additions to the ASC List – Endovenous Ablation (Page 27305)

SIR agrees with CMS' decision to add endovenous ablation (CPT codes 36475, 36476, 36478, and 36479) to the list of ASC covered services. However, the proposed ASC assignment (ASC Group 3) results in an ASC payment (\$510) that is too low relative to the costs of the procedure. SIR recommends that endovenous ablation be assigned to ASC Payment Group 9.

SIR believes that endovenous ablation will be provided in hospital and non-hospital settings, with the office being the predominate non-hospital setting in our estimation. ASCs do play a role as an endovenous ablation facility particularly for those Medicare patients requiring conscious sedation, more careful hemodynamic evaluation, and/or have more extensive venous disease (e.g., ulcers, higher-class signs and symptoms).

We can appreciate CMS' rationale for assigning endovenous ablation to ASC Group 3 based on clinical comparability. However, such an approach fails to take into account the costs related to endovenous ablation. As a result, the proposed ASC payment is inadequate to cover the costs of the procedure.

ASC Group 3 includes surgical codes (37720-37780) for the ligation and stripping of veins in the leg. This involves making multiple incisions along the vein to be treated, followed by removal of the targeted vein. Basic surgical expenses are incurred. In endovenous ablation, the target vein is accessed with a catheter, through which an ablation device (either laser or radiofrequency) is introduced under ultrasound guidance. Energy is applied to the device as it is withdrawn along the length of the vein (typically the greater saphenous vein in the thigh), "sealing" the vein shut. Endovenous ablation entails the use of a disposable catheter costing in the range of \$700 (depending on laser or radiofrequency), a generator in the range of approximately \$20,000 (radiofrequency) to \$40,000 (laser), and a treatment room/suite equipped with ultrasound. Endovenous ablation carries significantly less morbidity for the patient than surgical vein stripping. Its inherent costs are, however, higher than vein stripping due to the equipment needed. Payment Group 9 includes other imaging guided interventions as dialysis dec clotting (code 36870) and biliary drainage (code 47511).

Additions to the ASC List – Catheterizations (Page 27305)

ASC payments need to reflect the costs associated with catheterizations, either as part of the payment for the primary procedure or through separate payment.

Catheterizations procedures (CPT codes 36010-36248) are essential to interventional diagnosis and treatment. In the case of angiography and venography, a catheterization code(s) and the associated radiology code(s) (75XXX) would be the only services reported and would not be part of a primary procedure. A diagnostic study could lead to subsequent therapy.

SIR wants to make sure that the costs associated with catheterizations are appropriately reflected in Medicare's payment methodologies. Catheterization services require the use of various guidewires and catheters. It is currently unclear to us whether or not the ASC rates sufficiently cover these costs. SIR, previously, has expressed similar concerns with respect to the hospital outpatient prospective payment system (HOPPS).

Thank you, again, for the opportunity to comment on the interim final rule for the ASC list of covered services. If you have questions or require additional information, please contact Michael R. Mabry, SIR's Assistant Executive Director for Policy, at (703) 691-1805, ext. 201 or mabry@sirweb.org.

Sincerely,

A handwritten signature in black ink that reads "Michael E. Edwards, MD". The signature is written in a cursive style with a large, stylized "M" at the beginning.

Michael E. Edwards, MD
SIR Councilor for Health Policy & Economics

cc: Dana Burley, CMS
Curtis A. Lewis, MD, MBA, SIR
Peter B. Lauer, SIR
Michael R. Mabry, SIR

Submitter : Mr. Michael Mabry
Organization : Society of Interventional Radiology
Category : Health Care Professional or Association

Date: 07/01/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1478-IFC-30-Attach-1.PDF



SOCIETY OF
INTERVENTIONAL
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July 1, 2005

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

Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures [CMS-1478-IFC]

Dear Administrator McClellan:

The Society of Interventional Radiology (SIR) is a national specialty association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States, along with other physicians and allied health professionals interested in interventional radiology.

SIR appreciates the opportunity to comment upon the Interim Final Rule, Medicare Program; Update of Ambulatory Surgical Center List of Covered Services as published in the May 4, 2005 *Federal Register*. SIR's comments are directed to the proposed additions to the ASC list, specifically:

- ❖ Angioplasty and stenting,
- ❖ Vertebroplasty,
- ❖ Endovenous ablation, and
- ❖ Catheterizations.

Additions to the ASC List – Angioplasty and Stenting (Pages 23698, 23705)

SIR recommends that percutaneous angioplasty (CPT codes 35470 through 35476) and percutaneous non-coronary stent placement (CPT codes 37205 and 37206) be included in the ASC list of covered services. Additionally, SIR strongly takes issue with the comment that these services, when performed outside of the hospital setting, would result in "substandard care" or that they should be limited to the hospital outpatient and inpatient settings.

A major trend in health care is the migration of services from hospitals to non-hospital settings (e.g., ambulatory surgical centers, offices). This trend is true for interventional radiology procedures. The very nature of interventional radiology services – the fact they are less invasive, have fewer complications, and require less follow up care than analogous surgical procedures – makes them well suited to be performed in non-hospital settings.

SIR was taken aback by the commenter who stated (page 23698), “that these procedures [angioplasty and stenting] were not appropriate for the ASC setting and would allow for potential *substandard* (emphasis added) care.” We also question why CMS sided with this lone commenter when the agency acknowledged in the rule that, “we received many comments in support of the proposed additions to the ASC list.” Furthermore, SIR is troubled by CMS’ own statement (page 23705) that, “we have determined that they [angioplasty codes] are more appropriately limited to the hospital outpatient and inpatient settings at this time.” Both statements could not be farther from current clinical practice in angioplasty and stent placement. Advances in pain and drug management, catheter and guidewire technology, and delivery devices have improved the safety and effectiveness of percutaneous angioplasty and stenting. The relatively recent advent of percutaneous closure devices has reduced post-procedure observation time significantly (from 4-6 hours to 1-2 hours) while decreasing the risk of post-catheterization bleeding complications.

CMS cites the lack of utilization in the office or ASC settings as part of its justification not to add angioplasty and stenting to the ASC list (page 23705). This is a “catch-22”. Until this year, Medicare did not cover angioplasties in the office setting. Angioplasties are not covered in ASCs. However, despite the lack of Medicare payment, the non-hospital setting (office and ASC) accounted for 26 percent of brachiocephalic angioplasty (code 35475) and 17 percent of venous angioplasty (code 35476); offices account for most of the volume, however.

Procedures involving major blood vessels require great care and precision. Furthermore, we agree with CMS that not all procedures are appropriate in the non-hospital setting. In the case of angioplasty and stent placement, the procedures are performed typically through a small incision (nick) in an artery or vein to gain access. The techniques to gain safe vascular access were developed in the early 1960s and have been refined since. Since the therapy is conducted endovascularly, the trauma to the vessel is much less than that associated with surgery. We would expect that non-hospital settings would be equipped appropriately and have processes in place in case of an emergency.

Additions to the ASC List – Vertebroplasty (Page 23702)

SIR recommends that percutaneous vertebroplasty (CPT codes 22520, 22521, and 22522) be added to the ASC list of services.

CMS, in its decision not to add vertebroplasty to the ASC list, cites: (1) “there is often an overnight stay required” and (2) “the recovery period usually is longer than 4 hours.” These points might have been accurate of the early experience of vertebroplasty when first introduced in the United States in the mid-1990s -- not now. Since then, the technique and materials associated with vertebroplasty have changed considerably. Also, interventional radiologists have emphasized providing their own pre- and post-procedure follow-up care. As a result, in the major studies of vertebroplasty consisting of a large number of patients (for example -- Evans¹, McGraw², and Zoarski³), the typical observation/recovery period is between one and three hours followed by hospital discharge. It is unusual for compression fracture symptoms to worsen. Overnight hospital stays are atypical, unless severe co-morbidities are present. SIR, having addressed CMS’ major objections for not adding vertebroplasty to the ASC list, recommends that CMS add vertebroplasty to the ASC list.

1. Evans AJ, Jensen ME, Kip KE, et al. Vertebral compression fractures: pain reduction and improvement in functional mobility after percutaneous polymethylmethacrylate vertebroplasty retrospective report of 245 cases. *Radiology* 226:366-72, 2003.

2. McGraw JK, Lippert JA, Minkus KD, Rami PM, Davis TM, Budzik RF. Prospective evaluation of pain relief in 100 patients undergoing percutaneous vertebroplasty: results and follow-up. *J Vasc Interv Radiol* 13(9 Pt 1):883-6, 2002.

3. Zoarski GI, Snow P, Olan WJ, Stallmeyer MJ, Dick BW, Hebel JR, De Deyne M. Percutaneous vertebroplasty for osteoporotic compression fractures: quantitative prospective evaluation of long-term outcomes. *J Vasc Interv Radiol* 13(2 Pt 1):139-48, 2002.

Additions to the ASC List – Endovenous Ablation (Page 27305)

SIR agrees with CMS' decision to add endovenous ablation (CPT codes 36475, 36476, 36478, and 36479) to the list of ASC covered services. However, the proposed ASC assignment (ASC Group 3) results in an ASC payment (\$510) that is too low relative to the costs of the procedure. SIR recommends that endovenous ablation be assigned to ASC Payment Group 9.

SIR believes that endovenous ablation will be provided in hospital and non-hospital settings, with the office being the predominate non-hospital setting in our estimation. ASCs do play a role as an endovenous ablation facility particularly for those Medicare patients requiring conscious sedation, more careful hemodynamic evaluation, and/or have more extensive venous disease (e.g., ulcers, higher-class signs and symptoms).

We can appreciate CMS' rationale for assigning endovenous ablation to ASC Group 3 based on clinical comparability. However, such an approach fails to take into account the costs related to endovenous ablation. As a result, the proposed ASC payment is inadequate to cover the costs of the procedure.

ASC Group 3 includes surgical codes (37720-37780) for the ligation and stripping of veins in the leg. This involves making multiple incisions along the vein to be treated, followed by removal of the targeted vein. Basic surgical expenses are incurred. In endovenous ablation, the target vein is accessed with a catheter, through which an ablation device (either laser or radiofrequency) is introduced under ultrasound guidance. Energy is applied to the device as it is withdrawn along the length of the vein (typically the greater saphenous vein in the thigh), "sealing" the vein shut. Endovenous ablation entails the use of a disposable catheter costing in the range of \$700 (depending on laser or radiofrequency), a generator in the range of approximately \$20,000 (radiofrequency) to \$40,000 (laser), and a treatment room/suite equipped with ultrasound. Endovenous ablation carries significantly less morbidity for the patient than surgical vein stripping. Its inherent costs are, however, higher than vein stripping due to the equipment needed. Payment Group 9 includes other imaging guided interventions as dialysis dec clotting (code 36870) and biliary drainage (code 47511).

Additions to the ASC List – Catheterizations (Page 27305)

ASC payments need to reflect the costs associated with catheterizations, either as part of the payment for the primary procedure or through separate payment.

Catheterizations procedures (CPT codes 36010-36248) are essential to interventional diagnosis and treatment. In the case of angiography and venography, a catheterization code(s) and the associated radiology code(s) (75XXX) would be the only services reported and would not be part of a primary procedure. A diagnostic study could lead to subsequent therapy.

SIR wants to make sure that the costs associated with catheterizations are appropriately reflected in Medicare's payment methodologies. Catheterization services require the use of various guidewires and catheters. It is currently unclear to us whether or not the ASC rates sufficiently cover these costs. SIR, previously, has expressed similar concerns with respect to the hospital outpatient prospective payment system (HOPPS).

Thank you, again, for the opportunity to comment on the interim final rule for the ASC list of covered services. If you have questions or require additional information, please contact Michael R. Mabry, SIR's Assistant Executive Director for Policy, at (703) 691-1805, ext. 201 or mabry@sirweb.org.

Sincerely,



Michael E. Edwards, MD
SIR Councilor for Health Policy & Economics

cc: Dana Burley, CMS
Curtis A. Lewis, MD, MBA, SIR
Peter B. Lauer, SIR
Michael R. Mabry, SIR

Submitter : Ms. Ann Gosier
Organization : Guidant Corporation
Category : Device Industry

Date: 07/01/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1478-IFC-31-Attach-1.DOC

GUIDANT

July 5, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule (CMS-1478-IFC)

Section II D. ANALYSIS OF AND RESPONSES TO PUBLIC COMMENTS RECEIVED ON THE NOVEMBER 26, 2004 PROPOSED RULE AND PROVISIONS OF THIS INTERIM FINAL RULE WITH COMMENT PERIOD.

Dear Administrator McClellan:

Guidant Corporation welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed interim final rule that updates Ambulatory Surgical Center List of Covered Procedures.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research and development facilities in the states of Minnesota, California and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leading designer and manufacturer of medical technologies used primarily to treat cardiovascular and vascular illnesses. Guidant's products save and enhance lives.

SUMMARY OF GUIDANT RECOMMENDATIONS

Guidant recommends that CMS defer the inclusion of permanent pacemaker CPT codes 33212 and 33213 in the ASC procedure list until the scheduled overhaul of the ASC payment system.

DETAILED RECOMMENDATIONS

The interim final rule recommends including CPT codes 33212 (insertion or replacement of single chamber pacemaker pulse generator only) and 33213 (insertion or replacement of single chamber pacemaker pulse generator only) on the ASC list of eligible procedures. Guidant recommends that CMS defer the inclusion of these CPT codes until the revised payment system for ASC facility services required by section 626(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is implemented.

A HCPCS code is currently not available to bill separately for the device used in connection with these pacemaker procedures. This results in a drastic underpayment for these procedures. Specifically, under Group 3 of the ASC payment rates, these procedures will be paid at \$510. Currently, through the Outpatient Prospective Payment System, the insertion or replacement of single chamber pacemaker pulse generator only (APC 0090) has a base payment of \$5,159 and the insertion or replacement of dual chamber pacemaker pulse generator only (APC 0654) has a base payment of \$6,005. The inadequacy of payment in the ASC system will discourage the availability of such procedures in this setting. Guidant Corporation recommends that CMS delay inclusion of CPT codes 33212 and 33213 pending revisions to the ASC payment system.

ASC payment rates should include device costs. As noted in the interim final rule, the payment system addresses "the cost of items and services furnished by the facility where the procedure is performed"¹. The devices required for CPT codes 33212 and 33213 are items provided by the facility, but their costs are currently not covered through a HCPCS code or the ASC payment rates. A restructuring of the payment system is needed to address the cost of these items.

In January 2003, the OIG issued the study *Payments for Procedures in Outpatient Departments and Ambulatory Surgical Centers* that stated, "there should be greater parity of payments for services performed in an outpatient setting and those performed on ASCs"². This recommendation is consistent with the Medicare Payment Advisory Commission's *June 1998 Report to Congress* which stated, "all else being equal, Medicare should pay for ambulatory care based on the service, not the setting"³. The services provided in the insertion or

¹ 42 CFR Part 416; Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures (CMS-1478-IFC); pg 6.

² *Payments for Procedures in Outpatient Departments and Ambulatory Surgical Centers Office of Inspector General, January 2003, OEI-05-00-00340; pg 10.*

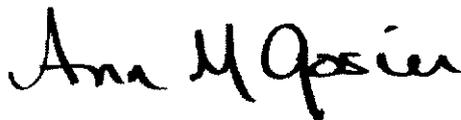
³ Report to Congress, Context for a Changing Medicare Program, Medicare Payment Advisory Commission, June 1998. pg. 72.

replacement of single or dual pacemakers are similar, whether performed in the outpatient setting or in an ambulatory surgical center. Based on comments from the OIG and MedPAC, the ASC payment should be aligned with the OPPS payment and should be based on the service being performed. In this instance, the Group 3 ASC payment rate of \$510 is neither aligned with the \$5,159 - \$6,005 OPPS base payments nor is the \$510 payment rate based on the service being performed by the facility, which includes the purchase of a permanent pacemaker.

CONCLUSION

Guidant Corporation recommends that CMS defer the inclusion of permanent pacemaker CPT codes 33212 and 33213 in the ASC list of eligible procedures until the revised ASC payment system is implemented.

Sincerely,

A handwritten signature in black ink that reads "Ann Gosier". The signature is written in a cursive, flowing style.

Ann Gosier
Vice President, Government Affairs

Submitter : Dr. Robert Zwolak
Organization : Society for Vascular Surgery
Category : Health Care Professional or Association

Date: 07/04/2005

Issue Areas/Comments

Issue

Provisions of this interim final rule with comment period

The Society for Vascular Surgery (SVS) respectfully requests that CPT codes 36475, 36476, 36478, and 36479 be removed from the roster of approved ASC services. This request supersedes our comment dated Jan 25, 2005, in which we originally asked that they be added to the list. SVS is making the current request because assignment of the four services to payment group 3 will block their performance in what we believe to be an appropriate clinical setting.

The four new procedures involve minimally invasive means to ablate incompetent saphenous veins, either by use of radiofrequency energy (36475 & 36476) or laser energy (36478 & 36479). SVS requested that they be added to the ASC list based primarily on clinical grounds. We believe the services meet all established ASC clinical requirements, and we are confident they may be performed safely in that setting. We realized that the highest ASC payment level, \$1,339, would be substantially lower than facility and non-facility MFS PE payments (e.g. \$1947 MFS non-facility PE payment for CPT 36475), but with economy of scale we felt there might be some opportunity for this technology to diffuse to the ASC. More importantly, at that time we were completely unaware of Transmittal B-01-43, a Medicare Carrier Program Memorandum, dated July 18, 2001, that allows physicians and qualified non-physician practitioners to bill for procedure not on the Medicare-approved ASC list at the MFS non-facility Practice Expense rate.

CMS assigned 36475, 36476, 36478 and 36479 to payment group 3 with an indicated reimbursement of \$510. We suspect the assignment was made on clinical grounds because there is no established facility cost data available for these new procedures. In reality, each requires a single-use disposable catheter that costs in excess of \$700, plus a substantial number of other disposables and significant depreciable equipment. Thus, assignment to group 3 will exclude performance in the ASC because true costs will substantially exceed ASC payments.

We realize that a major revision to the ASC payment system will be implemented in January 2008, and we understand and apologize for the additional work required of CMS to add and then remove these four procedures from the approved list at this time. Nevertheless, we still believe on clinical grounds that these services should be offered in the ASC. In the absence of extant data to assign a payment level based on facility costs it seems that removing them from the approved list is the best option, thereby allowing providers to employ the payment algorithm provided in PM B-01-43. SVS appreciates CMS' attention to this important matter.

Submitter : Dr. Keith Brandt
Organization : American Society of Plastic Surgeons
Category : Health Care Provider/Association

Date: 07/05/2005

Issue Areas/Comments

Issue

Provisions of this interim final rule with comment period
See Attachment

CMS-1478-IFC-33-Attach-1.PDF

CMS-1478-IFC-33-Attach-2.PDF



July , 2005

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-IFC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

**Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures;
Interim Final Rule**

Dear Dr. McClellan:

The American Society of Plastic Surgeons (ASPS) is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports the education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Centers for Medicare and Medicaid Services (CMS) Interim Final Rule with comment period for "Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures" that was published in the May 4, 2005 *Federal Register*. As requested in the Rule, the relevant "issue identifier" is used below to assist the Agency in reviewing these comments.

Analysis of and Responses to Public Comments Received on the November 26, 2004 Proposed Rule and Provisions of This Interim Final Rule with Comment Period; Proposed Deletions

On page 23697 of the Interim Proposed Rule is the statement: "Therefore, we will delete only the five codes [from the ASC covered services list] about which we received no comments." CPT 21440 (*Closed treatment of mandibular or maxillary alveolar ridge fracture (separate procedure)*) is included among the five procedures to be deleted from the ASC list. The rationale offered by CMS for deleting this code is that the procedure is performed in a physician's office more than 50 percent of the time according to Medicare claims data. However, in the May 4 Rule, Agency officials acknowledge that there are clinical concerns which must be considered along with claims

data when deciding whether or not to delete procedures from the list. Furthermore, the Agency did receive comments opposing the proposal to delete this code from the list.

ASPS and the American Society of Maxillofacial Surgeons (ASMS) submitted a joint letter to CMS on January 21, 2005, which specifically included a request not to delete code 21440 (and 34 other reconstructive codes) from the list. As stated in that letter, our rationale for retaining code 21440 on the list is that "this procedure is not always safe in the office. It may require conscious sedation or general anesthesia. Airway compromise from swelling from surgery is a concern." In addition, if there is significant bleeding, this can also cause difficulty managing the airway.

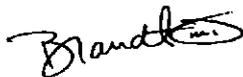
We also have concerns about the effects that deleting code 21440 will have in the private insurance sector. Many private insurers follow Medicare national policies when drafting their own coverage and payment policies, therefore, this regulation could have unintended consequences for other patient populations in addition to Medicare beneficiaries. For example, a child or adolescent with an alveolar ridge fracture will consistently require general anesthesia in order to be able to accomplish the fracture reduction, fabrication of a splint, and securing of the splint to the adjacent dentition. Not all physician offices are equipped to provide this level of care, particularly conscious sedation or general anesthesia. Thus, patients with special needs will have to be treated in the more costly hospital outpatient department if they cannot have this procedure done in an ASC.

We do not dispute that the repair of an alveolar ridge fracture can sometimes be performed safely in an office, but it is unrealistic and questionable patient care to expect that every patient will have a good surgical outcome if the procedure is always performed in the office regardless of individual needs. The decision of where to perform a procedure should be made by the physician and the patient and should not be dictated by payment policy. Thus, we hope that CMS will reconsider this decision and will keep this code on the covered list.

Overall, we are very pleased that CMS considered the concerns we raised in our January letter about the other 34 reconstructive procedures we felt should not be deleted from the list. Likewise, we agree with the Agency's decision to add many procedures to the covered list. Agency officials should be commended for putting the needs of Medicare beneficiaries in front of other factors in their decision-making process.

As always, we appreciate your consideration of these comments. Please contact us if we may answer any questions about this issue. In the meantime, we will continue to carefully monitor future correspondence on these and other relevant health care issues.

Sincerely,



Keith E. Brandt, MD
Chair, ASPS Payment Policy Committee

CC Robert J. Havlik, MD, Chair, ASMS Task Force on Reimbursement

Submitter : Ms. Deborah Neymark

Date: 07/05/2005

Organization : Vascular Solutions

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1478-IFC-34-Attach-1.DOC



June 22, 2005

VIA: Electronic Submission

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule with Comment Period. File Code CMS-1478-IFC, Issue Identifier: Additions and ASC Group Assignment of Procedures that were not Proposed for Addition in the November 26, 2004, Rule.

Dear Administrator McClellan:

These comments are submitted on behalf of Vascular Solutions, Inc., a leading manufacturer of state-of-the-art medical products and systems that employ novel surgical laser technologies to treat diseases of the vascular system. Our products include the Vari-Lase® Endovenous Laser System, which offers a highly effective and less invasive treatment for symptomatic venous insufficiency.

We appreciate the opportunity to comment on the interim final rule (IFR) with comment period published by the Centers for Medicare & Medicaid Services (CMS) on May 4, 2005, which provides an update of the ambulatory surgical center list of covered procedures. See Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Interim Final Rule, 70 Fed. Reg. 23690 (May 4, 2005).

In this comment letter, we contend that the assignment of **CPT 36478** (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein) and **add-on code CPT 36479** (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites) to payment group 3 is an error that CMS should be corrected in the final rule by removing CPT 36478 and 36479 from the ASC list.

CMS assigned CPT 36478 and 36479 to group 3 based on clinical similarity of these codes with procedures currently assigned to group 3. But CMS correctly states in the

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background section of the IFR that there is no clinical consistency among the procedures in a payment group and group assignment is based solely on estimated facility costs. The assignment of 36478 and 36479 to group 3 based on clinical similarity without consideration of facility costs is at odds with CMS's stated methodology for ASC payment group assignment. Because CMS currently lacks facility cost data for these codes, it should not add these codes to the ASC list at this time.

We set forth more details below.

I. PROPOSED ADDITION OF CPT 36478 AND CPT 36479 TO THE ASC LIST AND ASSIGNMENT OF THESE CODES TO PAYMENT GROUP 3

In response to a comment on the proposed rule, CMS is now proposing to add CPT 36478 and CPT 36479 to the ASC list. We agree with CMS's statement in the IFR that: "these codes are appropriate for the ASC setting . . ." However, we disagree with the assignment of these codes to payment group 3. CMS's reason for the assignment of these codes to payment group 3 is explained in the following statement from the IFR: "We will assign the codes to payment group 3 consistent with other procedures with similar clinical indications." (emphasis added). See 70 Fed. Reg. 23690, 23705. But this approach is incorrect, because basing an ASC payment group assignment on similar clinical indications to other procedures is contradictory to CMS's stated methodology for ASC payment group assignments.

CMS explicitly states in the IFR in section I E (Current ASC Payment Rates) that: "There is no clinical consistency among the procedures in a payment group. Rather, assignment to a payment group is based solely on an estimate of facility costs associated with performing the procedures." (emphasis added). See 70 Fed. Reg. 23690, 23692. Furthermore, CMS states in the IFR: "The payment group for each addition to the ASC list in this interim final rule is based on the payment group to which procedures currently on the list, which our medical advisors judged to be similar in time and resource inputs, are assigned. *Id.* Therefore, the assignment of CPT 36478 and CPT 36479 to an ASC payment group should be based on the facility costs of performing the procedure in an ASC, and placed in a group with procedures that have similar time and resource inputs.

II. PAYMENT GROUP 3 GROSSLY UNDERPAYS ASC FACILITY COSTS FOR CPT 36478 AND 36479

The \$510 Group 3 ASC payment only covers a fraction of the estimated facility costs associated with endovenous laser therapy performed with the Vari-Lase Endovenous Laser System. The laser probe kit alone has a price of \$315. By comparison, the national average nonfacility physician fee schedule payment for CPT 36478 = \$2041.16. When the facility physician fee schedule payment of \$364.57 is subtracted, the additional practice expenses associated with performing this procedure in the office = \$1676.59. This value was created by the PEAC, agreed upon by the RUC, and ratified by CMS. Also by comparison, for the

hospital outpatient setting, CPT 36478 is assigned to APC 92, which pays a national average of \$1538.27. Therefore, the ASC group 3 payment of \$510 is only 30% of the Medicare payment for the practice expenses associated with doing the procedure in the physician's office, and it is only 33% of the APC payment in the hospital outpatient setting.

An ASC payment at the ASC group 3 level is woefully insufficient for endovenous laser therapy and does not make sense in light of the current Medicare reimbursement in either the physician office setting or the hospital outpatient setting. If endovenous laser therapy is relegated to ASC group 3, the result will be an artificial site of service selection for either the physician office or the hospital outpatient setting, regardless of which setting would best serve the individual patient. Essentially, it would amount to the death of endovenous laser therapy in ASCs for Medicare beneficiaries.

III. CONCLUSION

Ideally, endovenous laser therapy would be assigned to a payment group that accurately reflects its facility costs. But because the procedure is new, actual ASC facility cost data is currently unavailable. Therefore, we recommend that CPT 36478 and CPT 36479 not be added to the ASC list at this time. Vascular Solutions appreciates the opportunity to comment on the IFR and we are eager to provide CMS with any additional information that would enable the agency to properly evaluate this matter. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me at (763) 656-4349.

Sincerely,

Deborah L. Neymark
Vice President, Regulatory Affairs, Clinical
Research and Quality Systems

Submitter : Mr. Thomas Weinberg
Organization : DaVita Inc.
Category : Health Care Provider/Association

Date: 07/05/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1478-IFC-35-Attach-1.DOC

June 30, 2005

Via Electronic Filing

Mark 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: File Code CMS-1478-IFC

Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures, 70 Fed. Reg. 23,690 (May 4, 2005).

ANALYSIS OF AND RESPONSES TO PUBLIC COMMENTS
RECEIVED ON THE NOVEMBER 26, 2004 PROPOSED RULE AND
PROVISIONS OF THIS INTERIM FINAL RULE WITH COMMENT
PERIOD

Dear Dr. McClellan,

The Centers for Medicare & Medicaid Services should permit a full range of vascular access-related procedures to be performed in an ambulatory surgery center (“ASC”) setting by adding two CPT codes to list of services eligible for payment in the ASC setting. CMS proposed adding these codes in a Proposed Rule, but removed them from its Final Rule on ASC payments.

The Importance of Reform of Vascular Access Payment

CMS proposed the “Fistula First” initiative in 2004 to encourage greater use of arterio-venous (AV) fistulae as the vascular access of choice for end-stage renal disease (“ESRD”) patients. The Fistula First initiative aims at having fistulae placed in at least half of new dialysis patients with a long-range goal of maintaining fistulae in 40 percent of eligible patients who remain on dialysis. As CMS knows, currently only about 30 percent of Medicare beneficiaries dialyze with a fistula.

How can Medicare build on the early successes of Fistula First and realize savings to the program through the increased prevalence of fistulae? First, it can reform the professional surgical reimbursement rates for grafts and fistulae.¹ Second, it should

¹ Under current surgical reimbursement rates, Medicare reimburses surgeons at a greater rate for the installation of a graft, even though the procedure is less time-intensive than placement of a fistula.

permit a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent setting in a hospital.

Unfortunately, the optimal continuum of care and communication does not currently exist in ASCs, because the current coding rules exclude two important angioplasty codes from ASC reimbursement—CPT codes 35475 and 35476.² These codes should be on the list of approved Medicare list of ASC procedures. If they were, then the full range of vascular access procedures may be performed in an ASC setting, providing greater access to the full range of vascular access procedures at lower costs for the ESRD population.

CMS Rulemaking for ASC Codes

CMS published a Proposed Rule on November 26, 2004 . *Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures*, 69 Fed. Reg. 69,178, 69,181 (November 26, 2004). At that time, CMS included CPT codes 35475 and 35476, and concluded:

After careful review by our medical staff to determine whether these procedures are consistent with our criteria (see section I.C.2 of this proposed notice), we agree with commenters that [these procedures] are appropriate and safely performed in an ASC setting.

Id.

The Final Rule was published on May 4, 2005, effective July 5, 2005. *Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures*, 70 Fed. Reg. 23,690, 23,698 (May 4, 2005). There is a comment period up to that date.

In the Final Rule, CMS removed CPT codes 35475 and 35476 from the list of Medicare approved additions to the ASC procedures in response to one comment claiming these procedures are not safely performed in an ASC. Final Rule, 70 Fed. Reg. at 69,181. CMS did not elaborate on the comment nor did it cite safety data to back the claim. CMS's reversal was not necessary or appropriate given the ample clinical evidence available that indicates these procedures can be safely performed in freestanding, ambulatory settings.

² 35475 - transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel.
35476 - transluminal balloon angioplasty, percutaneous; venous.

Angioplasty—to correct local narrowing in a fistula—is sometimes needed during the life of a fistula. While a good fistula can last for years, creation and maintenance of reliable accesses for dialysis is an ongoing process.

Mark McClellan, M.D.

June 30, 2005

Page 3

CMS Should Restore Coverage of CPT Codes 35475 and 35476 in the ASC Setting

In our view, the referenced codes are safe and appropriate for the ASC setting. First, initial placements are already permitted in an ASC, so it seems illogical to exclude maintenance procedures. Second, data show that these procedures are safely performed in settings like an ASC setting. Lifeline, a subsidiary of DaVita, provides management services to physician outpatient offices that provide vascular access procedures. Angioplasty data from Lifeline-managed physician outpatient offices from October 1, 2002 to May 5, 2005 show an exemplary success rate. Of 16,319 patients who had angioplasty procedures performed, there were only 353 complications (2.2 % of the procedures). A total complication rate of 2.2 % is well below the established threshold of 5% for safe practice established by the reporting standards of the Society for Interventional Radiology.

This large compilation of data clearly demonstrates that both venous and arterial angioplasty can be safely and effectively performed in the outpatient setting.

Conclusion

Medicare can reduce the cost of, and promote quality outcomes for, ESRD patients through more thoughtful reimbursement and regulation of vascular access procedures. CMS should permit a full range of access-related procedures to be performed in an ASC setting by restoring CPT codes 35475 and 35476 to its payment rules, codes that were proposed by CMS in its Proposed Rule but removed from a Final Rule on ASC payments.

Sincerely,
DAVITA INC.

/S/
Thomas L. Weinberg
Vice President
LeAnne Zumwalt
Vice President

cc: Barry Straube, M.D.

* * * * *

Literature and References

Below is listed some of the publications that have appeared in peer reviewed journals supporting the safety of these procedures:

1. Beathard GA: Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. *Kidney Int* 42:1390-1397, 1992
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3. Beathard GA, Settle SM, Shields MW: Salvage of the nonfunctioning arteriovenous fistula. *Am J Kidney Dis* 33:910-916, 1999
4. Khan FA, Vesely TM. Arterial problems associated with dysfunctional hemodialysis grafts: evaluation of patients at high risk for arterial disease. *J Vasc Interv Radiol* 13:1109-1114, 2002
5. Vesely TM. Endovascular intervention for the failing vascular access. *Adv Ren Replace Ther* 9:99-108, 2002
6. Beathard GA: Angioplasty for arteriovenous grafts and fistulae. *Semin Neph* 22:202-210, 2002
7. Beathard GA, Arnold P, Jackson J, Litchfield T: Aggressive treatment of early fistula failure. *Kidney Int* 64:1487-1494, 2003
8. Beathard GA: Management of complications of endovascular dialysis access procedures. *Semin Dial* 16:309-313, 2003
9. Asif A, Merrill D, Briones P, Roth D, Beathard GA. Hemodialysis vascular access: percutaneous interventions by nephrologists. *Semin Dial.* 17:528-534, 2004
10. Beathard GA, Litchfield T, Physician Operators Forum of RMS Lifeline, Inc: Effectiveness and Safety of Dialysis Vascular Access Procedures Performed by Interventional Nephrologists. *Kidney Int* 66:1622-1632, 2004
11. Surowiec SM, Fegley AJ, Tanski WJ, Sivamurthy N, Illig KA, Lee DE, Waldman DL, Green RM, Davies MG. Endovascular management of central venous stenoses in the hemodialysis patient: results of percutaneous therapy. *Vasc Endovascular Surg* 38:349-354, 2004
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* * * * *

Further Vascular Access References

High-Cost Medicare Beneficiaries , Congressional Budget Office, May 2005

Fistula First Press Release, www.cms.hhs.gov/esrd/3.asp., April 2004

Fistula First Web Site, www.ihf.org/IHI/Topics/ESRD/VascularAccess/

Eggers P, Milan R. Trends in vascular access procedures and expenditures in Medicare's ESRD program. In: Mitchell L Henry. Vascular Access for Hemodialysis - VII. Chicago, Illinois: WL Gore & Precept Press;2001.

Fistula First Texas Progress Report, www.esrdnetwork.org.

Submitter : Dr. Harvey Neiman
Organization : American College of Radiology
Category : Association

Date: 07/05/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1478-IFC-36-Attach-1.DOC

July 5, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1478-IFC
PO Box 8017
Baltimore, MD 21244-8017.

Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, writes to provide comments on the "Update of Ambulatory Surgical Center List of Covered Procedures" published in the Federal Register as an interim final rule with comment period on May 4, 2005.

Our comments will address coding and billing guidelines for brachytherapy services performed in an ASC setting, the inadequacy of payment rates for selected surgical procedures associated with the delivery of brachytherapy, the inappropriate payment policy for "add-on" procedures and the development of a revised ASC payment system as required by the Medicare Modernization Act (MMA).

Coding and Billing Guidelines for Brachytherapy Services

In our comments on the proposed rule, we requested clarification of the manner in which brachytherapy and other radiation therapy codes should be billed and reimbursed when they are provided in conjunction with a related surgical procedure that is on the ASC list, such as 55859 (*Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy*). We made this request because there is much uncertainty (and variation among Medicare carriers) surrounding prostate brachytherapy in an ASC setting. The need for clarification has been increased by the addition of surgical procedures associated with brachytherapy for cancer of the breast and uterus to the ASC list in the interim final rule (19296, 19298, 57155 and 58346).

In the interim final rule, CMS indicates that the agency is "currently trying to resolve a number of payment options related to the performance of prostate brachytherapy and the extent to which those services could be paid for when furnished in an ASC under existing regulations related both to ASCs and other payment systems such as the Medicare physician fee schedule." In our comments on the proposed rule, we expressed our support for guidance that was included in the preamble of the 1998 proposed rule on

ASCs.¹ CMS acknowledged that code 55859 represents only the surgical component to prostate brachytherapy treatment and stated:

“The other procedures and services performed to furnish this treatment fall within the radiology range (70,000-79,999) of CPT®. Since radiology procedures are not included on the ASC list, there is no basis for Medicare to make payment to an ASC for brachytherapy service. However, if the facility were to obtain supplier numbers from its carrier indicating that the carrier recognizes the facility both as a non-physician supplier of radiology services and as a freestanding radiation therapy center, the facility should be able to bill for and be paid the technical component for brachytherapy services within the radiology range under the Medicare physicians’ fee schedule. Similarly, if a Medicare approved ASC were to furnish diagnostic X-ray and other diagnostic test in connection with performing a procedure on the ASC list, such as visualizing the preoperative placement of needle localization wires, and if payment for those services is not otherwise included in the ASC facility fee as signified by an ASC payment policy indicator “2”, the facility could be paid the technical component provided for those services under the Medicare physicians’ fee schedule as long as it meets the requirements for independent diagnostic testing facilities (IDTFs).”

We continue to believe this CMS statement of policy is reasonable and appropriate and urge CMS to consider this a starting point for discussions with the ACR and other stakeholders involved in the provision of brachytherapy services in an ASC setting. The representatives of ACR’s Radiation Oncology CAC Network have been active in working with Medicare’s Carrier Medical Directors on local guidelines on how to pay for all elements of prostate brachytherapy in the ASC setting. The ACR requests that CMS review the guidelines when considering developments of national policy for these procedures.

Coding and billing guidelines for brachytherapy services also should include clarification of CMS payment policies regarding payment for imaging and guidance services that are performed in conjunction with surgical procedures and brachytherapy services. In this regard, CMS’s June 12, 2003 clarification of CMS payment policies regarding ASCs and Independent Diagnostic Testing Facilities (IDTF) conducting business from the same location (Ref: S&C-03-22) was a helpful resource.

Finally, the ACR suggests that these important clarifications also reiterate that ASC arrangements are subject to applicable Federal Self Referral Regulations and Antitrust guidelines. Additionally, any use of radioactive material requires full compliance with Nuclear Regulatory Commission (NRC) guidelines.

Inadequate Payment Rates for Selected Surgical Procedures Associated with the Delivery of Brachytherapy

¹ Federal Register. Vol. 63, No. 113. June 12, 1998. page 32314.

Based on comments received on this year's proposed rule, CMS added the following surgical procedures associated with brachytherapy for cancer of the breast, cervix, vagina and uterus to the list of covered ASC procedures:

19296	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy
19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance
57155	Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy
58346	Insertion of Heyman capsules for clinical brachytherapy

ACR supports these additions. Unfortunately, the payment rates will be inadequate to cover the costs of providing the services. For example, code 19296 was assigned to the highest paying group (Group 9 at \$1339). However, the cost of the balloon catheter alone exceeds \$2500. Clearly, this procedure will never be performed in an ASC if the total payment will be only \$1339.

The ASC payment rates for these four procedures are inconsistent with their payment rates in hospital outpatient departments. For example, code 19296 is assigned to APC 1524 New Technology - Level XIV with a payment rate of \$3250 under the outpatient prospective payment system (OPPS) for calendar year 2005. Large discrepancies in payments will create significant financial disincentives for performing these procedures in ASCs and will restrict access to care in the ASC setting. We urge CMS to examine the costs of these procedures and to issue instructions that will permit separate payment for the expensive supplies and devices that are used during these procedures. We would be pleased to assist you in the collection of accurate cost information.

Inappropriate Payment Policy for "Add-On" Procedures

CMS received comments asking that the following radiology related procedures be added to the list of covered ASC procedures:

Code	Long Description
19295	Image guided placement, metallic localization clip, percutaneous, during breast biopsy (List separately in addition to code for primary procedure)
19297	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)

CMS rejected the recommendations to include these codes on the ASC list because they are “add-on” procedures that are included in another procedure and not typically performed on its own. CMS stated in the interim final rule:

We do not typically approve this type of procedure for addition to the ASC list as the facility costs for the additional work included in the procedure is not usually significant. That is, the resources required to perform a procedure with or without also performing an ‘add-on’ procedure are not significantly different. Time in the operating suite, supplies, and other resources that Medicare pays for in the ASC, are not significantly increased by performance of the additional procedure. Therefore, under the current rate-setting method, we cannot accurately identify a separate price for ‘add-on’ procedures.

We strongly disagree with this characterization of “add-on” procedures. While there may be some “add-on” procedures for which the facility costs associated with the procedures may not be significant, this is simply not the case with codes 19295 and 19297 which involve supplies that are not covered by the payment for the basic procedure. For code 19295, the cost of the clip is \$75 and for code 19297 the cost of the balloon catheter exceeds \$2,500. Excluding codes 19295 and 19297 from the ASC list will reduce access to these procedures in the ASC setting for those women being evaluated or treated for breast cancer.

We also note that the decision to exclude these codes because they are “add-on” codes is inconsistent with the decision to add the following vascular surgery “ad-on” codes to the list:

36476 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

36479 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

We ask that CMS reconsider its decision and add codes 19295 and 19297 to the list of covered ASC procedures. In the future, decisions about including or excluding “add-on” procedures should be made on a case-by-case basis, taking into account the actual resources required to perform the procedures.

Revised ASC Payment System

Section 626(b) of MMA requires CMS to implement a revised payment system between January 1, 2006 and January 1, 2008, that takes into account recommendations in the

report to the Congress that was to be submitted by January 1, 2005 by the GAO. In developing this revised payment system, ACR recommends that CMS consider the following principles:

- Physicians must be free to choose the setting most appropriate for the patient's care. This choice should not be unduly influenced by marked variations in payment rates between ASCs, hospital outpatient departments and physicians' offices.
- Caution must be exercised if a decision is made to pay ASCs at a discounted percentage of the hospital APC payment because the total costs of certain procedures are primarily attributable to expensive supplies and devices that may not be available to ASCs at a discounted rate. As a result, a uniform reduction in payment across all APCs could limit access to these procedures if the ASC payment does not cover the cost of the supplies or devices.
- There must be clear instructions regarding the coding and billing for imaging and radiation therapy services that are commonly associated with certain surgical procedures.
- Items not included in the basic OPPS payment rate also should be excluded from the ASC rate. For example, brachytherapy seeds are separately paid under the OPPS system and should be separately paid under the ASC payment system. If seeds are folded into the ASC payment rate, it will be difficult to establish a fair payment rate because of the wide variation in the number of seeds required to appropriately treat a given patient.
- If the OPPS APC rates are to be the basis of payment for the ASCs, it is essential that the rates for some APCs be corrected before implementation to be more consistent with actual relative costs.
- ASC payment rates should be updated annually
- There must be a mechanism to recognize the cost of new technology.

Conclusion

Thank you for this opportunity to comment on this proposed rule. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Carisia Switala at the ACR offices. Carisia may be reached at 1-800-227-5463 ext. 4587 or via email at carisias@acr.org.

Respectfully Submitted,
[Endorsed copy to follow]

Harvey L. Neiman, M.D., FACR
Executive Director

cc: Herb Kuhn, CMS
Ken Simon, MD, CMS
Bob Cereghino, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
Pamela J. Kassing, ACR

Submitter : Mike Romansky
Organization : OOSS and ASCRS
Category : Health Care Professional or Association

Date: 07/05/2005

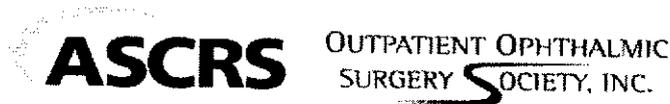
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1478-IFC-37-Attach-1.DOC



**AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY**

July 5, 2005

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

Re: Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures, Interim Final Rule with Comment Period; CMS-1478-IFC.

Dear Administrator McClellan:

On behalf of the Outpatient Ophthalmic Surgery Society and the American Society of Cataract and Refractive Surgery, please accept these comments concerning the Centers for Medicare and Medicaid Services' ("CMS") interim final rule, published May 4, 2005, governing additions to and deletions from Medicare's list of procedures approved for performance in ambulatory surgery centers ("ASC List").

The Outpatient Ophthalmic Surgery Society ("OOSS") is an organization comprised of approximately 900 ophthalmologists dedicated to providing high-quality and cost-effective ophthalmic surgical care in various outpatient settings. Most of our members either own or perform surgery in Medicare-certified ambulatory surgery centers ("ASC").

The American Society of Cataract and Refractive Surgery ("ASCRS") represents over 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures done annually in the United States.

As such, our memberships are critically concerned with changes in Medicare's payment and coverage policies with respect to ASCs and believe that we are uniquely qualified to comment on the Agency's proposal to update the ASC List. OOSS and ASCRS are pleased that CMS has complied with the statutory mandate that the ASC List be updated on a biennial basis. Too often in the past, deadlines for these updates have passed with the Agency failing to implement appropriate adjustments to the List, thereby depriving Medicare beneficiaries of access to high-quality, cost-effective, patient-friendly care in the ASC environment. We appreciate our ongoing dialogue with CMS through which we are hopeful the Agency is coming to the understanding that virtually all ophthalmic surgical services can be safely and effectively performed in the ASC environment. It is in this spirit that we offer these comments and hope that they will be seriously considered prior to the publication of the final rule.

General Comments

We are delighted that the Agency has restored to the ASC List all of the ophthalmic surgical procedures which had been proposed for deletion in the November 26, 2004 Notice of Proposed Rulemaking. As a result, Medicare beneficiaries will continue to have access to the following services within the ASC setting: 11444, 11446, 11644, 13131, 13132, 13150, 13152, 14000, 14040, 14041, 14060, 14061, 68340, and 68810. Your action reflects the reality that ASCs have an unblemished record with respect to delivering the highest quality care to Medicare patients, that our surgical outcomes are exceptional, and that beneficiaries are enthusiastic about their surgical experiences.

Our comments on both the NPRM and the IFR are premised on the notion that the physician, in consultation with his patient, should determine the appropriate site of surgery. The vast majority of the proposed deletions would have been effectuated by the application of a CMS' policy that pre-supposes that procedures which are performed more than a majority of the time in the "physician's office" are inappropriate for conduct in the ASC setting. We understand that the intent of this criterion is to prevent the inappropriate migration of procedures from the less intensive and less costly office setting to the more intensive and more expensive ASC environment. However, as we emphasized in our comments to the proposed rule, although a procedure may be more commonly performed in a physician's office, it is rare that it is furnished exclusively in the office. There are many good reasons for the physician to conclude that the ASC environment is preferable to the office operatory, including the patient's age, size, comorbidities, or personal preferences. Second, CPT codes, which are designed to define physician (not facility) services, are often sufficiently broad as to encompass surgical services which might be appropriate for the office setting under some circumstances but not in others. Third, the decision as to the appropriate surgical environment may also be based upon the training, skills, and experience of the surgeon, and, perhaps, by the scope of his professional and facility malpractice insurance coverage. Finally, state regulation (like certificate-of-need and licensure) may define a facility as an office or an ASC without regard to the physical structure, equipment, or staffing of the facility.

The interim final rule is, in many instances, unclear as to the rationale used by the Agency to restore each of the aforementioned services to the ASC List. Nonetheless, we applaud the Agency for its willingness to reconsider its prior methodology and modify the NPRM to better enable the beneficiary, in consultation with his physician, to determine whether a surgical procedure should be performed in the office or ASC.

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Failure of CMS to Make Appropriate Additions to the ASC List

Our comments to the NPRM incorporate a multitude of specific and detailed recommendations regarding procedures which are entirely appropriate for performance in an ASC and which should be added to the ASC List. Virtually none of our recommendations have been adopted, nor, in most instances, has the Agency provided any explanation, much less a credible justification, for its refusal to add these services to the List. It is all the more frustrating that many of these recommendations have been made by our two Societies and by other reputable medical organizations multiple times in formal comments respecting prior ASC List Update rulemakings over the course of the past decade. CMS' failure to meaningfully expand the List contravenes the intent of Congress and it needlessly deprives beneficiaries of receiving their care in the ASC environment. Moreover, it makes little policy or economic sense, since the Medicare program reaps savings virtually every time a surgical case is performed in the ASC instead of the HOPD.

We reiterate our prior recommendations and hope that the Agency will expand the ASC List, as follows:

OOSS and ASCRS strongly recommend that the following ophthalmic laser procedures be added to the ASC List: 65855 (Trabeculoplasty by laser surgery), 66761 (Iridotomy/iridectomy by laser surgery), 67105 (Repair retinal detached, photocoagulation), 67145 (Phophylaxis of retinal detachment, photocoagulation), 67210 (Destruction of retinal lesions, photocoagulation), 67221 (Destruction of retinal lesions, photodynamic therapy), and 67228 (Destruction of extensive or progressive retinopathy, photocoagulation). There is no basis under the Agency's criteria for failing to include these procedures on the ASC List; as discussed above, CMS has ignored for almost a decade our requests for inclusion of these procedures, never even providing a rationale for their exclusion. These services are vital to the treatment of the most common forms of vision loss and blindness in elderly Americans, including diabetic retinopathy and macular degeneration. They meet the Agency's clinical procedures addition criteria in that they involve only 15-20 minutes of intra-operative time and 40-60 minutes of physician-supervised recovery. No major blood vessels are encountered with these procedures. Topical drops or local blocks are typically used to manage pain. And, anesthesia is rarely required, unless the patient is uncooperative or incapable of remaining still.

CMS also should add procedure 67028 (Intravitreal injection of a pharmacologic agent) to the ASC List. This code describes a procedure used to treat severe eye infections with antibiotics and retinal swelling in diabetics with steroid injections. Additionally, a new treatment for wet macular degeneration called Macugen will be released in early 2005 which will require intravitreal injections of a new drug. This procedure also satisfies CMS' clinical

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procedure addition criteria, involving 15 to 20 minutes of intra-operative time, 30 to 40 minutes of physician-supervised recovery prior to release and no encounter with major blood vessels. Local blocks are most often used to manage pain and general anesthesia is rarely required, unless the patient is uncooperative or incapable of remaining still. While this procedure can be furnished in the office setting with most patients, there are times when the ASC is most appropriate, e.g., the surgeon is injecting material directly into the eye and the patient either already suffers from an infection or is prone to infection, making a sterile OR environment preferable. Additionally, if the patient is having surgery in the ASC and an intravitreal injection is required as an adjunct, it would be performed in the operating room at the time of surgery; the facility should be reimbursed in those instances.

CMS also should add procedure code 67110 (Repair detached retina) to the ASC List. This procedure satisfies CMS's clinical procedure addition criteria, involving about 45 minutes of intra-operative time. While this procedure can be safely performed in the physician's office in certain circumstances, oftentimes, the sterile environment of the ASC is warranted because the procedure involves placing a needle into the eye. By adding this procedure to the ASC List, CMS would give physicians and beneficiaries an additional site of service option. Additionally, Medicare and beneficiaries would save money. If CMS added this procedure to payment group 8, it would be paying substantially less than the \$1,200 Medicare pays hospital outpatient departments for these procedures.

Future Updates to the ASC List

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that, by 2008, CMS establish a new prospective payment system for ASCs. In light of the anticipated overhaul of the methodology for identifying which procedures should be covered when performed in an ASC and at what payment rates, it makes little public policy sense to embark upon any future ASC List updates which contemplate the deletion of any codes for services which have been safely and effectively performed in ASCs in the past. The concept of a government-promulgated list of services which can be performed within an ASC is flawed in many respects. An inclusionary list is an artifact of another era, reflecting the concern of policy-makers a quarter-century ago that ASCs, which numbered only a hundred or so at the time the enabling rules were promulgated, should not perform services which require the intensity of resources of a hospital. Today, the Medicare program has certified over 4,000 surgery centers, all of which must comply with patient health and safety, structural, governance, supervision, management, and utilization review and quality assurance standards which parallel those applicable to hospitals.

Indeed, the Medicare Payment Advisory Commission ("MedPAC") recommended in its 2004 Report that the ASC List be abolished and replaced instead by a list of services

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which, for patient health and safety reasons, are not appropriate for performance in an ASC. The MedPAC policy recommendation contemplates that those procedures which can be safely and effectively performed in an ASC should be covered and reimbursed in the ASC, notwithstanding the fact that they might also be appropriate for conduct in the office setting. While we recognize that legislation may be required to establish an exclusionary rather than inclusionary ASC List, CMS should not undertake to delete procedures from the List and disrupt the delivery of services which have heretofore been provided to beneficiaries for two decades. The Agency and Congress should take every step to effectuate MedPAC's recommendation, thereby establishing a rational and coherent policy which promotes, rather than impedes, the conduct of surgery in high quality, lower cost, and patient-friendly ASCs.

Thank you for providing us with the opportunity to comment on this important regulation.

Should you have any questions regarding these comments, please contact Michael A Romansky, Counsel, OOSS, at 202-626-6872 or Emily Graham, Manager of Regulatory Affairs, ASCRS, at 703-591-2220.

Sincerely,



Roger Steinert, MD
President, ASCRS

William Fishkind, MD
President, OOSS

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Submitter : Dr. John Duggan

Date: 07/05/2005

Organization : AAASC

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1478-IFC-38-Attach-1.DOC

American Association of



Ambulatory Surgery Centers

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July 5, 2005

VIA HAND DELIVERY

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **Re: Medicare Program; Update of Ambulatory Surgical Center
List of Covered Procedures, Interim Final Rule with Comment
Period; CMS-1478-P.**

Dear Sir or Madam:

On behalf of the American Association of Ambulatory Surgery Centers ("AAASC"), please accept these comments concerning the Centers for Medicare and Medicaid Services' ("CMS") interim final rule with comment period, published November 4, 2005, regarding additions and deletions of Medicare approved ambulatory surgical center ("ASC") procedures. These comments supplement and incorporate our comments submitted on January 24, 2005 regarding the Agency's ASC Procedures List NPRM, published on November 26, 2004.

AAASC is a professional medical association of physicians, nurses, and administrators who specialize in providing surgical procedures in cost-effective outpatient environments, primarily in Medicare-certified ASCs. Most AAASC members own or operate in Medicare-certified ASCs, and so have considerable experience with and interest in the criteria utilized to determine whether a procedure is appropriate for performance within an ASC.

Restoration of Proposed Deletions

AAASC commends CMS for adhering to a biennial update schedule in its publication of the 2005 update, as mandated by the Social Security Act. Biennial reviews help to ensure that the list of covered ASC procedures (the "ASC List") keeps pace with technological advancement, and that the ASC setting is available to Medicare beneficiaries in all appropriate instances. Moreover, we are delighted that the Agency has restored to the ASC List ninety-five of the 100 surgical services which had been slated within the NPRM for deletion from the List. This reversal in CMS' position will ensure that Medicare beneficiaries continue to enjoy access to services in ASCs without unnecessary interruption. Your action reflects the reality that ASCs have an unblemished record with respect to delivering the highest quality care to Medicare patients, that our surgical outcomes are exceptional, and that beneficiaries are enthusiastic about their ASC experiences.

Our organization believes that the physician, in consultation with his patient, should determine whether an ASC, an office, or an HOPD is the appropriate site for a patient's surgery. The NPRM, in proposing the deletion of so many codes, would have violated this premise with no corresponding health policy or patient health benefit. The vast majority of the proposed deletions would have been effectuated by the application of a site-of-service policy that, in attempting to forestall the migration of services from the office to the higher intensity ASC environment, presupposes that procedures which are performed more than 50 percent of the time in the physician's office are inappropriate for conduct in the ASC setting. The arbitrary application of this policy abnegates the fact that there are many appropriate reasons for the physician to conclude that the ASC environment is preferable to the office environment:

- The patient's age, size, comorbidities, or personal preferences may dictate that a service be performed in the ASC rather than the office.
- CPT codes, which are designed to define physician (not facility) services, are often sufficiently broad as to encompass surgical services which might be appropriate for the office setting under some circumstances but not in others.
- The decision as to the appropriate surgical environment may also be based upon the training, skills, and experience of the surgeon, and, perhaps, by the scope of his professional and facility malpractice insurance coverage.
- State regulation (e.g., certificate-of-need and licensure) may define a facility as an office or an ASC without regard to the physical structure, equipment, or staffing of the facility.

The interim final rule is not specific as to the rationale used by the Agency to restore each of the services to the ASC List. Nonetheless, we are delighted that CMS was willing to reconsider its prior methodology and modify the NPRM to better enable the beneficiary, in consultation with his physician, to determine whether his surgical procedure should be performed in the office or ASC.

The preamble includes a statement regarding the economic impact of the regulation on Medicare program expenditures, specifically, the costs of an estimated twenty-five (25) percent migration of services from the physician's office to the ASC environment. As surgeons and ASC-owners, it seems inconceivable that the addition of services contemplated in the regulation could result in that order of magnitude of change in site of service. If the agency or its actuaries believe that such a windfall for ASCs is likely to occur, it would be most appreciated if the analysis were provided to the public when the rule is published in final.

Additions to the ASC List

Notwithstanding the Agency's decision to restore 95 surgical services to the ASC List, this update falls short in several other respects. CMS continues to leave unresolved the potential inclusion within the ASC List of many procedures that CMS proposed to add in the June 1998 proposed update (*See, 63 Fed. Reg. 32,290 et seq. (June 12, 1998)*), as well as many procedures that interested organizations, like AAASC, have since urged CMS to add. Moreover, CMS continues to utilize the same unreliable site-of-service statistics discussed for purposes of determining whether a procedure should or should not be added to the list. What is particularly frustrating is the Agency's unwillingness to offer any meaningful policy basis or procedure-specific explanation for its failure to incorporate within the ASC List a plethora of services which our organization and

others have recommended be included.

Therefore, we again recommend that CMS add the following CPT codes to the ASC List (our detailed justification for inclusion of each of these services within the list may be found in our January 24 comments to the NPRM):

- 11423 and 11433 (Excision of benign lesion)
- 11603 (Excision, malignant lesion)
- 13102, 13122 and 13133 (Repair, complex)
- 17106, 17107 and 17108 (Destruction of benign or pre-malignant lesions)
- 17304, 17305, 17306, 17307 and 17310 (Chemosurgery)
- 21030, 21031 and 21032 (head and facial excisions)
- 22520, 22521 and 22522 (Percutaneous vertebroplasty)
- 27096 (Injection of sacroiliac joint)
- 27412 (autologous chondrosite implantation in the knee) and 27415 (Osteochondral allograft in the knee)
- 29866 ((Osteochondral autograft in the knee), 29867 (Osteochondral allograft in the knee) and 29868 (Mensical transplantation)
- 31040 (Pterygomaxillary fossa surgery)
- 43761 (Reposition gastrostomy tube)
- 45300 and 45303 (Proctosigmoidoscopy)
- 45330 (Sigmoidoscopy, diagnostic)
- 46604 and 46614 (Anoscopy)
- 46900 and 46910 (Destruction, anal lesion(s))
- 46916 (Cryosurgery, anal lesion(s)).
- 46221, 46946 and 46947 (Ligation of hemorrhoids)
- 47562, 47563 and 47564 (Laparoscopic cholecystectomy).
- 52301 (Cystourethroscopy)
- 62290 and 62291 (Injection procedures)
- 62367 and 62368 (Analyze spine infusion pump)
- 63030 (Low back disk surgery)
- 65855 (Trabeculoplasty by laser surgery)
- 66711 (Ciliary body destruction, cyclophotocoagulation)
- 66761 (Iridotomy/iridectomy by laser surgery)
- 67028 (Intravitreal injection of a pharmacologic agent)
- 67105 (Repair retinal detached, photocoagulation)
- 67110 (Repair detached retina)
- 67145 (Prophylaxis of retinal detachment, photocoagulation)
- 67210 (Destruction of retinal lesions, photocoagulation)
- 67221 (Destruction of retinal lesions, photodynamic therapy)
- 67228 (Destruction of extensive or progressive retinopathy, photocoagulation)
- 67912 (Correction of lagophthalmos with implantation of upper eyelid gold weight load)
- G0289 (Arthro, loose body + chondro)

Future Updates to the ASC List

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that, by 2008, CMS establish a new prospective payment system for ASCs. In developing this system, it is imperative that the Agency develop a coherent and administratively practicable process for determining what services should be eligible for facility payment when furnished within the ASC. Our organization strongly believes that the use of an inclusionary list is antiquated and irrational, the vestige of a quarter-century ago when there were few ASCs in existence and public policy-makers were uncertain about what standards should be applied to determine whether a procedure was appropriate for an ASC. Today, the Medicare program has certified over 4,000 surgery centers, all of which must comply with patient health and safety, structural, governance, supervision, management, and utilization review and quality assurance standards which parallel those applicable to hospitals.

AAASC strongly believes that CMS should adopt, or urge Congress to legislate, the Medicare Payment Advisory Commission's ("MedPAC") recommendation in its 2004 Report that the ASC List be abolished and replaced instead by a list of services which, for patient health and safety reasons, are not appropriate for performance in an ASC. The MedPAC policy recommendation contemplates that those procedures which can be safely and effectively performed in an ASC should be covered and reimbursed in the ASC, notwithstanding the fact that they might also be appropriate for conduct in the office setting. While we recognize that legislation may be required to establish an exclusionary rather than inclusionary ASC List, CMS should not undertake to delete procedures from the List and disrupt the delivery of services which have heretofore been provided to beneficiaries for two decades.

Thank you for providing us with the opportunity to comment on this important regulation.

If you have any questions concerning these comments, please contact me or our Washington Counsel, Michael Romansky, Strategic Health Care, at (202) 626-6872.

Very truly yours,



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President, AAASC

cc: Craig Jeffries, Executive Director
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