

CMS-1478-IFC-1 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Dr. Wayne Gradman

Date & Time: 05/07/2005

Organization : Triangle Surgery Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Codes 36475, 36476, 36478, and 36479 are suitable inclusions for the Medicare ASC list, but only if reimbursement reflects the significant costs of each procedure. Category 3 is inadequate.

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

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1478-IFC
PO Box 8017
Baltimore, MD 21244-8017

I am writing to comment on the proposed inclusion of codes 36475, 36476, 36478, and 36479 on the Medicare ASC list. I am the owner and medical director of Triangle Surgery Center, an ASC which was established for the treatment of venous disorders.

Code 36475 is endovenous ablation of the saphenous vein with a radiofrequency fiber. 36478 is the same procedure with a laser fiber. The procedures are well suited for treatment in an ASC.

My objection is directed to the Category 3 classification for each of these procedures. By way of background, these four CPT codes are new, introduced only this year (2005) into the CPT book. Prior to introduction of these codes, endovenous ablation of the saphenous vein was most commonly billed as a combination of several procedures, including 37204 (obliteration of a vein), an ultrasound supervision and interpretation code, and 36011 for catheter placement. The new codes were designed to consolidate all aspects of the endovenous ablation of the saphenous vein into a single code.

The procedures themselves require expensive disposable equipment, expensive dedicated equipment (task specific generator or laser, and a Duplex ultrasound machine), as well as an ultrasound technician, who may not be readily available to the ASC except on an as-needed basis. Medicare has properly acknowledged the expensive costs of these procedures. If a procedure is done in a doctor's office, the physician's reimbursement is approximately \$2300 if a laser is used, and \$2700 if a radiofrequency fiber is used. This reimbursement includes both the professional services and the cost of necessary surgical supplies, equipment, and nursing services. If the procedure is performed in a hospital (in- or outpatient), the physician's reimbursement is only \$400. Medicare has therefore determined that the fixed costs run about \$1900-\$2300, which is the difference between reimbursement for the physician services (\$400) and reimbursement for the supplies and services (\$2300 - \$2700).

The radiofrequency catheter alone costs \$750, which assures that no ASC can afford to do the procedure. Even though the laser fiber is less expensive (about \$150), the total cost of the fiber plus other disposables exceeds \$600. No laser procedures will be done in an ASC, either. Thus, Category 3 woefully underpays the ASC.

Another problem with Category 3 reimbursement relates to the manner in which saphenous vein and varicose procedures are usually done. Most surgeons prefer to treat both the saphenous vein problem and the varicose vein problem (CPT code 36655) in one

setting. Varicose vein removal is not a procedure that is commonly done in an office setting. An ASC would simply not allow a surgeon to combine these procedures (typically 1.5 hours) for Category 3 reimbursement. With this reimbursement, the surgeon will make every effort to do the endovenous ablation of the saphenous vein in an office setting, and then take the patient to the ASC for vein removal. This fragmentation of care is highly undesirable.

These two new procedures (CPT 36475 and 36478) are becoming quite popular alternatives to traditional saphenous vein stripping (which always requires general anesthesia). The Medicare ASC reimbursement should reflect the costs of providing for these procedures. The Category for each of these procedures should be raised much higher, namely to 8 or 9. Otherwise, this new policy will drive patients from the ASC to the doctor's office. I believe the ASC is a far superior environment to perform this procedure in the Medicare age population.

Please note that from my point of view (as an ASC owner,) it is preferable if these two codes (36475 and 36478) were left off the ASC Medicare list. As I understand current Medicare reimbursement policy, if a procedure is not on the ASC Medicare list, the surgeon's services are reimbursed as if the procedure is done in an office setting (in this case \$2300-\$2700) and the ASC receives nothing. It is then legal for the ASC to negotiate reimbursement for its equipment and services with the surgeon. In this case, both the surgeon and ASC will receive an equitable amount, and the patient will have both endovenous ablation of the saphenous vein and varicose vein removal in an appropriate facility.

Sincerely,

Wayne S. Gradman, MD
Triangle Surgery Center
450 North Roxbury Drive #250
Beverly Hills, CA 90210
Phone: (310) 550-9200
Fax: (310) 278-2877
Email: wayne@gradman.com or wayne.gradman@cshs.org

Submitter : Dr. Richard Rosenfield
Organization : Pearl Surgicenter
Category : Ambulatory Surgical Center

Date: 05/09/2005

Issue Areas/Comments

Background

Background

There are very few "Gynecology only" Ambulatory Surgical Facilities in the US. As a physician owner of a new ASC, I have recently gone through the process of negotiating for reimbursements with the payors in Oregon, who base all reimbursements on the CMS ASC tiers. The majority of Gyn ASC cases fall into the levels 3 and 4, and result in a net loss scenario (financials).

GENERAL

GENERAL

Some Gyn procedures, at their current ASC tiers, are virtually impossible to perform in an ASC setting due the high cost of the procedures and low reimbursements as set by the CMS ASC tiers. These procedures, such as endometrial ablation and operative laparoscopy, warrant Level 9 placement as CMS describes the category assignments based on cost per procedure. Endometrial ablation technology yields a > 90% patient satisfaction, with a low adverse outcome rate, and is an alternative to traditional hysterectomy. Hysterectomy is one of the most common procedures performed in the US on women, and the cost savings of endometrial ablation is ~ 1/7 of the cost of hysterectomy. The CPT code for this procedure in the office yields a steep reimbursement, but most physicians prefer the ASC setting, which allows for a safer environment for the patient. The ASC tier yields a much lower reimbursement, and the cost of the device cannot be covered in this setting.

The procedures can be easily performed in an ASC, but the technology utilizes high priced disposable instruments which have per unit prices in excess of \$700. Operative laparoscopy, also safely performed in an ASC, is reimbursed at a low level- new, safer techniques for peritoneal access and decreased thermal injury have increased costs for these operations. We strongly desire for CMS to evaluate the true costs of these types of surgery. I would be more than happy to share our cost analyses and experiences with you.

Richard Rosenfield MD
Director, Pearl Surgicenter
Portland OR 97209
503-771-1883

Issue

Background

Modern medicine brings new technology. This new technology creates safe and efficient alternatives to older procedures, but not without some economic impact. Although Gynecology procedures such as endometrial ablation (with or without hysteroscopy), and operative laparoscopy drastically reduce cost when compared to traditional hysterectomy and laparotomy, the ASC reimbursements at the current levels yields a net operating loss for the ASC due to cost of the instruments used in surgery.

Submitter : Dr. Lee Hindin
Organization : Creative Intervention fro MH & CD, P.C.
Category : Physician

Date: 05/11/2005

Issue Areas/Comments

Background

Background

Medicare should cover the institutional fee for electroconvulsive therapy in appropriate outpatient settings. A JCAH accredited ambulatory care center that is part of a general hospital is a perfect venue. Several years ago my hospital forced me to stop providing 'Outpatient ECT' because, although my physician fee was paid, the hospital's fee was not, because the service was not provided in the hospital. (Apparently, when Medicare first began there was no other setting than a hospital for ECT and so after considerable investigation senior hospital administration informed me that it would, literally, take an act of Congress to change the Medicare rule for ECT coverage.)The benefits for patients as well as cost effectiveness are obvious.

CMS-1478-IFC-4 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Dr. Donald Schon

Date & Time: 05/22/2005

Organization : AKDHC-ASC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issue

Background

Proposal to add CPT codes 37205, 37206, 35475, 35476 to the list of ASC approved procedures

Provisions of this interim final rule with comment period

Proposal to add CPT codes 37205, 37206, 35475, 35476 to the list of ASC approved procedures

CMS-1478-IFC-4-Attach-1.DOC

CMS-1478-IFC-4-Attach-2.DOC

CMS-1478-IFC-4-Attach-1.DOC

CMS-1478-IFC-4-Attach-2.DOC

CMS-1478-IFC-4-Attach-1.DOC

CMS-1478-IFC-4-Attach-2.DOC

Donald Schon, MD
Rick Mishler, MD
Co-Medical Directors
Jeff Packer, DO
Pete Leopold, DO
AKDHC ASC
3320 N. 2ND ST.
Phoenix, Arizona 85012

June 6, 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 or 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.

- o 35475 - transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
- o 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.

- o "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 the proposed deletion of codes 37205, 37206, 35475 and 35476 and the associated supervision and interpretation codes from being authorized for reimbursement in the setting of an ambulatory surgical center (ASC). In responding to this proposal we wish to rely on documentation rather than simply opinion.

In a recent publication, Beathard et al, *Kidney Int.* 2004, 66: 1622-32, reported their success rate and complication rate performing interventional nephrology procedures for dialysis vascular access. All procedures were performed in an outpatient setting. Within this publication he reported on 1561 angioplasties [35476] on A-V fistulas. Success rate was 97 percent and the major complication rate was at the 0.2 percent. 3560 procedures were on AV grafts for dialysis. The success rate was 98 percent and the major complication rate was 0.1 percent. An additional 228 cases on A-V fistulas and 4671 cases on A-V grafts involved thrombectomy procedures in concert with angioplasties. The success rate was 93 percent for grafts and 78 percent for fistulas and the major complication rates were 0.6 percent for grafts and 0.4 percent for fistulas respectively. In this study procedures in the artery, the access body and the drainage were not separated out.

We will now relate data from our own outpatient Access Center. Our center is devoted to doing procedures only on dialysis access. In calendar year 2004, 1697 procedures were performed on dialysis fistulas or grafts involving the code [35476]. These procedures included simple angioplasties as well as angioplasties with thrombectomy procedures. In addition, 434 procedures were on native arteries contiguous with the arterial anastomosis of a dialysis access and involved billing code [35475]. The incidence of major complications associated with these procedure codes 35475 and 35476 was 6 or 0.3 %.

In addition, from 1998 to 2005 the physicians of our center have placed 51 stents in central vessels or the cephalic arch. There were no major complications. These procedures were all performed on outpatients either in an outpatient vascular center or a outpatient hospital setting determined only by provider restrictions.

It is clear that the use of these codes with one or more of the ICD9 codes 996.73, 585, 459.2, or 447.1 involving dialysis vascular access is routinely and safely done as an outpatient. In addition, we feel that they meet the other key criteria listed in your selection process. They are performed under conscious sedation and only on very rare occasions require general anesthesia. The vast majority of procedures require less than 90 minutes as documented by Beathard, et al (ibid). Therefore, it is hard to understand how performance of these procedures in an ASC facility could lead to substandard care. We respectfully 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 ASC setting.

CMS-1478-IFC-5 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Dr. Kevin Martin

Date & Time: 05/24/2005

Organization : Saint Louis University

Category : Physician

Issue Areas/Comments

Background

Background

Re: Additions to ASC procedures

Nov 26th, 2004 -It was proposed to add 37205,37206,35475,35476 to the list of approved procedures.

May 4, 2005, these additions were deleted from the final rule

GENERAL

GENERAL

In my opinion, and based upon considerable with these procedures, 37205,37206,35475,35476 these should be allowed in the ASC setting. To allow these codes will be a valuable addition to the care of vascularaccess in patients with ESRD.

Published peer-reviewed literature should be considered as more valuable and more relevant to a single anecdotal comment.

Issue

Background

The deletions of 37205,37206,35475,35476 were based on ONE COMMENT stating that these procedures were not appropriate for an ASC!

However, there is extensive published peer reviewed literature to support the safety of these procedures.

In my opinion, and based upon considerable with these procedures, 37205,37206,35475,35476 these should be allowed in the ASC setting. To allow these codes will be a valuable addition to the care of vascular access in patients with ESRD.

Published peer-reviewed literature should be considered as more valuable and more relevant than a single anecdotal comment.

CMS-1478-IFC-6 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Dr. Jeffrey Packer

Date & Time: 05/25/2005

Organization : AKDHC, LLC

Category : Physician

Issue Areas/Comments

Background

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.

GENERAL

GENERAL

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 as published removed CPT codes 37205, 37206, 35475, 35476 from the list of Medicare approved additions to the ASC procedures based on a comment received during the Proposed Rule comment period.

I strongly disagree with the proposed deletion of codes 37205, 37206, 35475 and 35476 and the associated supervision and interpretation codes from being authorized for reimbursement in the setting of an ambulatory surgical center (ASC). Our experience is that these procedures can be routinely and safely performed in this setting. Also, this has been documented in the medical literature.

In a recent publication, Beathard et al, *Kidney Int.* 2004, 66: 1622-32, reported their success rate and complication rate performing interventional nephrology procedures for dialysis vascular access. All procedures were performed in an outpatient setting. Within this publication he reported on 1561 angioplasties [35476] on A-V fistulas. Success rate was 97 percent and the major complication rate was 0.2 percent. In addition, this author reported on 3560 procedures on AV grafts for dialysis. The success rate was 98 percent and the major complication rate was 0.1 percent. Additionally, 228 cases on A-V fistulas and 4671 cases on A-V grafts involved concomitant thrombectomy procedures in concert with angioplasties. The success rate was 93 percent for grafts and 78 percent for fistulas and the major complication rates were 0.6 percent for grafts and 0.4 percent for fistulas respectively. In Beathard's study, there was no delineation of procedures as to whether they were in the artery, or the access body and its drainage.

Our practice provides services in an outpatient Access Center. Our center solely devoted to procedures involving dialysis access. In calendar year 2004, 1697 procedures were performed on dialysis fistulas or grafts involving the code [35476]. These procedures included simple angioplasties as well as angioplasties with thrombectomy procedures. In addition, 434 procedures were performed on native arteries contiguous with the arterial anastomosis of a dialysis access and involved billing code [35475]. The incidence of major complications associated with these procedure codes 35475 and 35476 was 6 out of the total or 0.3 %.

Intravascular stents are part of our outpatient and ambulatory approach to dialysis access issues. From 1998 to 2005 the physicians of our center placed 51 stents in central vessels or the cephalic arch. There were no major complications. These procedures were all performed on outpatients either in an outpatient vascular center or in an outpatient hospital setting determined only by provider restrictions. None of these patients required inpatient care for these procedures. Procedures on the vascular access for dialysis involving one or more of the ICD9 codes 996.73, 585, 459.2, or 447.1 is routinely and safely done as an outpatient. This has been clearly demonstrated in our experience and in the medical literature. These procedures are usually performed using conscious sedation. The vast majority of procedures require less than 90 minutes as documented by Beathard, et al (ibid). Therefore, it is hard to understand how performance of these procedures in an ASC facility could lead to substandard care. We respectfully 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 ASC setting.

Submitter : Ms. JANICE HOLMGREN
Organization : SURGERY CENTER PLUS
Category : Nurse

Date: 05/25/2005

Issue Areas/Comments

Background

Background

Nursing Supervisor with Surgery Center Plus

GENERAL

GENERAL

"See Attachment"

CMS-1478-IFC-7-Attach-1.DOC

Department of Health and Human Services
CMS-1478-IFC
P.O. Box 8017
Baltimore, MD 21244-8017

**Re: New Code's group assignment is wrong
CPT 46957 Hemorrhoidopexy by Stapling
Payment Group 3, \$505
Effective date of July 1, 2005**

Dear Medicare:

Our facility is writing to request you change the Group assignment for the new CPT code 46957 for Ambulatory Centers from 3 to 8.

Hemorrhoidopexy by stapling is a new procedure for 2005. When it was added to the CPT book, it was approved with a facility payment level of \$1321 when performed at a hospital. Recently Medicare has approved for ASC's but allowed it only as a Group 3. This allowance does not actualize the cost of the equipment.

Our medical staff and we believe that this procedure is of a complexity substantially similar to procedure for "hemorrhoidectomy, internal and external, with fissurectomy" payer under Group 3. However, CPT 46957, requires a stapler that cost the ASC \$389 plus additional supplies of \$150. In addition, our clinical staff cost for the procedure is approximately \$150. As you are aware, as an ASC we are paid globally and are not able to bill separately for supplies. Therefore, our cost, before we start the procedure is already higher than your proposed allowed amount.

There are two primary elements in the cost of performing a surgical procedure. These costs are the cost of the physician's professional services in performing the procedure and the cost of items and services furnished by the facility where the procedure is performed, such as surgical supplies and equipment, and nursing services. It does not appear that the costs for these procedures were calculated.

Taking the above into consideration one concludes that CPT 46957 should be paid under Group 7,8 or 9, and not under Group 3. Failure to make this correction basically negates the presence of the new code on the ASC approved listing. Please reconsider it's group.

Sincerely,

Jan Holmgren, RN Nursing Supervisor

Pat Jager, RN Director of Nursing

CMS-1478-IFC-8 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Dr. Florin Gadalean

Date & Time: 05/26/2005

Organization : Nephrology Associates of Central Florida

Category : Physician

Issue Areas/Comments

Background

Background

On November 26, 2004 a proposed rule was published in the Federal Register. That list included the following CPT codes: 35475 and 35476 within the payment group 9.

The Final Rule published on May 4, 2005, effective July 5, 2005 with its comment period still present.

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 due to negative comments. These comments had in common concerns about potential substandard care.

GENERAL

GENERAL

I profoundly disagree with these comments and especially disappointed with CMS action. While concerns can be raised regarding safety and effectiveness for any given procedure, there are NO PUBLISHED DATA supporting these concerns. Moreover, there is plenty of published data in peer reviewed journals supporting the safety and effectiveness of performing these procedures in ASC (1-8). There are really 2 questions to be answered. First, if endovascular method is better than surgical and Second, if it is safe to be performed in an outpatient basis. The article written by Beathard et al (8) published in Kidney International analyzed 10,020 interventions. This is not an opinion based article but a solid evidence for safety and effectiveness of these procedures in outpatient/ASC setting which can not be refuted or simply ignored. 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). No surgical literature article showed better results on such case series volume. Other authors using the same endovascular method have documented successful and safe performance of endovascular procedures on arterio-venous dialysis accesses. Since the negative comments were all made by surgeons, the question asked is whether endovascular procedures are safer and more effective than the open surgical technique? To cite all articles showing this would take a long time. The world, in the meantime, has long time ago moved forward from surgical techniques toward minimal invasive endovascular techniques.

The safety and effectiveness of performing endovascular procedures on arterio-venous dialysis accesses in outpatient centers has been proven not only by solid publications in reputed journals but it also stood the test of time. There is no evidence to the contrary.

Outpatient centers cater for their patients at a lower cost both for the patient and insurance companies, while patient satisfaction, time effectiveness and outcome are better.

There is no doubt that if careful and impartial review of the evidence available is performed, 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 will be allowed in the outpatient facilities.

CMS-1478-IFC-8-Attach-1.PDF

CMS-1478-IFC-8-Attach-1.PDF

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. That list included the following CPT codes: 35475 and 35476 within the payment group 9.

The Final Rule published on May 4, 2005, effective July 5, 2005 with its comment period still present.

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 due to negative comments. These comments had in common concerns about potential substandard care.

Position:

I profoundly disagree with these comments and especially disappointed with CMS' action.

While concerns can be raised regarding safety and effectiveness for any given procedure, there are NO PUBLISHED DATA supporting these concerns.

Moreover, there is plenty of published data in peer reviewed journals supporting the safety and effectiveness of performing these procedures in ASC (1-8).

There are really 2 questions to be answered: First – if it is better than surgical and second – if it is safe in an outpatient basis.

The article written by Beathard et al (8) published in Kidney International analyzed 10,020 interventions. This is not an opinion based article but a solid evidence for safety and effectiveness of these procedures in outpatient/ASC setting which can not be refuted or simply ignored.

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).

No surgical literature article showed better results on such case series volume.

Other authors using the same endovascular method have documented successful and safe performance of endovascular procedures on arterio-venous dialysis accesses.

Since the negative comments were all made by surgeons, the question asked is whether endovascular procedures are safer and more effective than the open surgical technique? To cite all articles showing this would take a long time.

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There is no evidence to the contrary.

Outpatient centers cater for their patients at a lower cost both for the patient and insurance companies, while patient satisfaction, time effectiveness and outcome are better.

There is no doubt that if careful and impartial review of the evidence available is performed, 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 will be allowed in the outpatient facilities.

References:

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2. Beathard GA, Arnold P, Jackson J, Litchfield T: Aggressive treatment of early fistula failure. *Kidney Int* 64:1487-1494, 2003
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CMS-1478-IFC-9 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Dr. Terry Behrend

Date & Time: 05/26/2005

Organization : Dr. Terry Behrend

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1478-IFC-9-Attach-1.DOC

Terry Behrend, MD
David Namazy, MD
Co-Medical Directors
San Diego Vascular Access Center
5854 El Cajon Blvd
San Diego, CA 92115

May 31, 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 or 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.

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Position:

We disagree with the proposed deletion of codes 37205, 37206, 35475 and 35476 and the associated supervision and interpretation codes from being authorized for reimbursement in the setting of an ambulatory surgical center (ASC). In responding to this proposal we wish to rely on documentation rather than simply opinion.

In a recent publication, Beathard et al, *Kidney Int.* 2004, 66: 1622-32, reported their success rate and complication rate performing interventional nephrology procedures for dialysis vascular access. All procedures were performed in an outpatient setting. Within this publication he reported on 1561 angioplasties [35476] on A-V fistulas. Success rate was 97 percent and the major complication rate was at the 0.2 percent. 3560 procedures were on AV grafts for dialysis. The success rate was 98 percent and the major complication rate was is 0.1 percent. An additional 228 cases on A-V fistulas and 4671 cases on A-V grafts involved thrombectomy procedures in concert with angioplasties. The success rate was 93 percent for grafts and 78 percent for fistulas and the major complication rates were 0.6 percent for grafts and 0.4 percent for fistulas respectively. In this study procedures in the artery, the access body and the drainage were not separated out.

I would like to provide data from our own outpatient Access Center. Our center is devoted to caring for the vascular access of dialysis patients in San Diego County. In calendar year 2004, we performed 889 procedures on dialysis grafts and fistulas that included the code 35476 and/or 35475. Of these 889 procedures, there were 3 major complications giving a major complication rate of 0.3%. These complications were all vein ruptures and were treated successfully with graft occlusion. In all cases, the patients were hospitalized overnight for observation and discharged home the following morning.

We are confident that performing these procedures in an ASC setting is absolutely safe and appropriate and in no way represents "substandard care". We respectfully request the codes 35476, 35475, 37205, 37206 when applied to dialysis vascular access be allowed in the outpatient ASC setting.

CMS-1478-IFC-10 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Mrs. Catherine Morris

Date & Time: 05/28/2005

Organization : Diomed, Inc.

Category : Device Industry

Issue Areas/Comments

Background

Background

RE: File code CMS -1478-IFC

Issue:

We are pleased with CMS decision to add codes 36478 and 36479 to the ASC list. However, we are concerned that placement in Group 3 is incompatible with the financial ability to provide that service and request that codes 36478 and 36479 be moved to Group 9.

GENERAL

GENERAL

We request that codes 36478 and 36479 be moved from category 3 to category 9, with codes 52647, Laser surgery of the prostate and 52648, laser surgery of the prostate, to more accurately reflect similarity of clinical indications and consumption of resources.we

Issue

Background

BACKGROUND

CMS -1478 ?IFC 6:

Considers the element of cost to the facility to provide services and provides a standard overhead amount based on estimate of a fair fee taking into account the costs incurred by the ASC.

Laser ablation is a new technology. The cost of a laser, ultrasound guidance and the laser fiber add cost to the `standard overhead amount?. Code 36478 has a non-facility PE RVU of 46.77 a non-facility total of 53.86. The 2005 APC group for 36478 is 0092. Payment for 0092 is \$1,528.27.

CMS ? 1478 ? IFC 7:

The overhead factor is expected to be calculated on a prospective basis using sample survey and similar techniques to

establish reasonable estimated overhead allowances, taking into account volume for each of the listed procedures.

Endovenous laser therapy (EVLT?) received FDA approval in 2002. Currently, there is insufficient data to calculate reasonable overhead allowances. There is insufficient data to calculate volume. There is insufficient data to calculate cost per patient based on the new technology.

The current overhead is based on 1986 data. Payment considerations include facility overhead (rent, utilities), labor and routine medical and surgical supplies. It does not consider the cost to the facility for capital acquisition of a laser and the per patient cost of a laser fiber. Facility cost of the laser ranges from \$30,000 to \$32,000. Per patient kit cost ranges from \$350 to \$750. This is in addition to routine overhead. If 36478 remains in group 3, it will be financially prohibitive for ASCs to provide this service. Treatment location will be shifted to acute care hospital outpatient departments.

CMS ? 1478 ? IFC 15:

OIG recommendation to conduct surveys to reevaluate ASC payment rates. Payments for Groups 1 through 8 are based on a survey of ASC costs conducted in 1986.

There is no clinical consistency among procedures. Assignment to a payment group is based on an estimate of facility costs.

Laser technology was unavailable in 1986 and could not be evaluated for ASC costs.

CMS ? 1748 ? IFC 18:

CMS is required to base payment for ASC services on survey data before implementation, therefore additions to the ASC list are assigned to a group based on data collected in the 1986 survey of ASC costs, updated for inflation. Additions are placed in the group to which procedures currently on the list, which CMS medical advisors judged to be similar in terms of time and resources.

Laser technology was unavailable in 1986 and could not be evaluated for ASC costs. 36478 has been grouped with other venous procedures. While clinical indications are similar, they are divergent in relation to the procedure for care and the time and resources required to provide that care.

Ligation and surgical stripping of larger varicose veins is a standard surgical treatment for venous reflux disease. During this surgery, one or more incisions are made over the vein, and the vein is tied off (ligated). If several valves in the vein and the vein itself are heavily damaged, the vein is usually removed (stripped). An incision is made below the varicose vein, a flexible instrument threaded up the vein to the first incision, and the vein is grasped and removed. This procedure can be done with regional or general anesthesia.

Endovenous laser ablation emits highly targeted energy to the inside of the saphenous vein. A guidewire is introduced into the saphenous vein, followed by an introducer sheath, advanced to within 1-2cm of the saphenofemoral junction. The introducer is removed and replaced with a 600µm optical fiber, which carries the laser energy. Once the fiber is correctly placed, the laser is activated at 14 watts and in continuous mode. The laser is fired continuously while the fiber/sheath is slowly withdrawn at a rate of 1-2mm/second. Hemoglobin absorbs laser energy which is converted to heat, then to energy.

Provisions of this interim final rule with comment period

The laser energy contacts tissue within the vein wall, shrinking the vein and denaturing protein in the wall creating fibrous scarring, thus sealing the vein shut and shrinking the branch veins.

Prior to the procedure, the GSV is fully mapped under ultrasound guidance, followed by . administration of tumescent

local anesthesia. Tumescant anesthesia provides complete analgesia while constricting the vein and providing a 'heat sink' (fluid pooled between the vein and subcutaneous tissue). This heat sink absorbs excess heat, preventing injury to surrounding tissue.

A more appropriate grouping is with codes: 52647 ? Laser surgery of the prostate of 52648 ? laser surgery of the prostate, both in group 9.

Two lasers have been cleared diode operating in the 800 nm range, cleared in 1996, and green light operating at 532 nm, cleared in 2004. Both laser systems work in the same manner using the laser energy to ablate or remove tissue of the prostate from the urethra. Tissue is ablated using principles of selective thermolysis, established by Dr. RR Anderson of the Wellman Labs located in Mass General Hospital, of a specific wavelength. For example, hemoglobin absorbs laser energy at 810 nm, which is converted to heat. The heat creates vaporizes tissue at the surface and denatures tissue deeper. The tissue is sloughed off over time and results in a wider opening thus relieving pressure, creating a stronger urine stream and limiting urinary retention.

With the patient under sedation and local or spinal anesthesia, the area of obstruction is located using an endoscope inserted into the urethra. A disposable fiber is advanced into the urethra either in the scope or after it is removed. The tissue is then ablated using continuous or pulses of laser energy until the physician has determined the depth of treatment needed for the particular patient.

Lasers are used in the same manner during treatment of reflux of the greater saphenous vein. A laser is used with a disposable component, delivered to an organ system in the body, activated where energy is absorbed by tissue with a result if tissue-laser interaction resulting in the desired result.

CMS ? 1748 ? IFC 26:

The existing fee schedule is comparatively crude, with only nine payment rates for approximately 2500 different surgical procedures. Each cell contains a broad set of heterogeneous services. The rate structure has not been updated since 1990. The GAO is about to conduct a survey to determine the relative costs as part of a report to Congress.

A comparison of ASC payments to APC payments demonstrates that group 3 payments average 31.3% of the APC payment amount and group 9 averages 72.1% of the APC payment amount. Group nine is a new group. As such, it seems to be more consistent with current APC payments. In fact, 2005 ASC payment for group 9 is \$30.26 less than the 2004 APC payment for category 0092.

CMS ? 1748 ? IFC 27:

ASC payment reform scheduled for January 1, 2008, potential to relate ASC fee to the outpatient prospective payment system, using the same ambulatory payment classifications.

36478 is in the ambulatory payment classification 0092. Medicare national average payment for 0092 is \$1,538.27. If 36478 was placed into group 9 of the ASC fee schedule, it would be 87% of the APC payment.

CMS ? 1748 ? IFC 81:

Codes 36478 and 36479 represent a new technology and do not have site of service data based on clinical information and, they will be assigned to Group 3 consistent with other procedures with similar clinical indications.

Regulatory Impact Statement

Clinical indications for 36478 are similar to other procedures in group 3. However, the procedure varies greatly in terms of technology, skill, time

and resource consumption. It is reasonable to expect that long standing clinical issues can and will be approached differently as technology and medical care advance. Though the disease is the same, the treatment is not.(see CMS ? 1748 - IF 17)

CMS-1478-IFC-11 Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures

Submitter : Dr. Mark Vannorsdall

Date & Time: 05/29/2005

Organization : Easter Nephrology Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir/Madam;

As an interventional nephrologist helping to care for over 800 hemodialysis patients in rural eastern North Carolina, I feel that it is critical to allow medicare/medicaid reimbursement of hemodialysis related access procedures such as graft and fistula angioplasties and thrombectomies performed in an ASC.

Apparently some prejudicial and, perhaps, ignorant comments have been submitted by surgeons speaking against reimbursement in the ASC setting. The implication has been made, without substantiation, that these procedures may be performed safely only in the hospital setting. May I suggest that these surgeons are unfamiliar with interventional nephrology and the safety and outcome data in this field(RMS lifeline, Beathard and others. May I also suggest that anti-competitive motives may be at play here!

Not only is it safe and effective to perform vascular access procedures in an ASC, but it is highly cost effective and often more convenient for the patient.

Furthermore, it is imperative to keep dialysis patients out of the hospital as much as possible for well documented infectious control reasons, including the risk of acquiring/spreading MRSA/VRE and C. difficile(Sheth, Piraino, et al.)

The end result of disallowing medicare/medicaid reimbursement for vascular access procedures performed in the ASC setting would be to drive up medical costs, increase patient morbidity and mortality and reduce patient quality of life and convenience. I might add that the impact of this decision would be felt disproportionately by minority and chronically disabled patients living near or below the poverty line.

Sincerely,

Mark D. Vannorsdall, MD
Eastern Nephrology Associates
511 Paladin Drive
Greenville, NC 27834
(252) 752-8880

Submitter : Mrs. Nancy Petty
Organization : Grand Valley Surgical Center LLC
Category : Ambulatory Surgical Center

Date: 06/03/2005

Issue Areas/Comments

GENERAL

GENERAL

New 2005 CPT Code 36818 not reviewed (possibly overlooked). No comments or responses were listed in the CMS 1478 IFC Summary on this Arteriovenous anastomosis vein transposition.

We just assumed that it would be included as a Level 3 procedure like the other Hemodialysis Access, Intervascular Cannulation for Extracorporeal Circulation codes (36800, 36810, 36815, 36819, 36820, 36821).

If there is a mechanism for CMS to include this code (36818) in the ASC list for the July 5, 2005 effective date, it would be greatly appreciated by ASC's, surgeons, and patients involved in dialysis treatments. Our surgeons would be very disappointed if they had to do this procedure in the hospital setting. Thank you for your consideration.

Submitter : Dr. George Nassar
Organization : Nephrology Dialysis and Transplantation
Category : Physician

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachement

CMS-1478-IFC-13-Attach-1.DOC

INCLUSION OF CPT CODES 35475 AND 35476

Attach#13

AS MEDICARE APPROVED ASC PROCEDURES

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:

- I and my partners operate an office-based, outpatient facility in which we perform percutaneous, transluminal balloon angioplasty (35475 and 35476). We have been in operation since December 2002 and since then we have performed more than 2000 venous angioplasties and more than 400 arterial angioplasties. Our experience and outcomes are available on file and clearly show that these procedures are safe in the outpatient setting and are therefore appropriate for an ASC setting.
- In support of this statement, I presented an abstract in the American Society of Nephrology in October 2004 on a portion of our own data. The abstract was entitled "Salvage of Failing to Mature AVF by Endovascular Therapy". All these procedures were done in an outpatient setting. In this abstract we reported on 65 cases of immature AVF that underwent intervention by angioplasty with a salvage rate exceeding 80% and a remarkable safety record. No major complications were seen in this series. Since then, this series has been expanded to 119 patients and I am in the process of writing a manuscript on this subject.
- We are one facility that is managed by RMS-Life Line. All our data are monitored closely for safety and success rates. I concur with Dr. Beathard's large database that

was published in *Kidney International* and demonstrates the safety and efficacy of these procedures in an outpatient setting:

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

- In this manuscript, Beathard and Litchfield provide a large compilation of data which clearly demonstrates that both venous and arterial angioplasty can be safely and effectively performed in the outpatient setting away from the hospital.
- Our own data as well as the data presented by Beathard in the above manuscript come from centers which are classified as office based. Although these centers are different in legal structure, they are very comparable both in structure and operation to the ASC setting.
- The ASC is a more practical model to facilitate more widespread availability of these procedures for ESRD patients. The extension of practice, office based surgical center model works well for large physician groups with large patient populations. The ASC model would allow smaller physician practices to provide their patients with the same service.
- In view of all of the above, I support adding angioplasty CPT codes 35475 and 35476 to the list of approved ASC procedures.

Sincerely,

George M. Nassar, M.D.
Clinical Associate Professor of Medicine
The Kidney Institute
1415 La Concha Lane
Houston, Texas 77054

Submitter : Dr. Hyunwoo Chung
Organization : New York Endovascular Surgery
Category : Physician

Date: 06/07/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment, PTA Codes

CMS-1478-IFC-14-Attach-1.DOC

Department of Health and Human Services,
Attention: CMS-1478-IFC,
P.O. Box 8017,
Baltimore, MD 21244-8017.

Attach#14

RE: CMS-1478-IFC, PTA Codes

June 7, 2005

Dear Department of Health and Human Services,

We were recently informed that the codes 35475 and 35476 would not be added to the approved ASC list for this year. We were told the reason for denial was that the procedure posed safety reason for doing such a procedure in the ASC setting, however, the code 36870 (Thrombectomy) is already an approved code, which is far more risky a procedure than the 35475 and 35476. In fact the 36870 is always accompanied with the procedures 35475 and 35476, in other words you wouldn't necessarily perform a 36870 without doing a 35476/35475 first.

We would like to present our argument for adding these codes to the ASC list. Aside from the above rhetoric the primary reason is for the patient's improved well being, by allowing for the patient to receive the 35475/35476 in the ASC setting they are gaining by otherwise waiting in the hospital for 5 hours before the procedure compared to 20 minutes with the ASC as well as reducing the 2 day stay in the hospital with a 1.5 HOUR stay at the ASC. Another extremely important factor is that they are then able to receive dialysis the very same day! Which could result in far fewer complications down the road even avoid possible death.

Please take into consideration our comment. I am available for comment at 917-533-8704 or in the office at 866-992-1225 ext 15.

Thank you,
Zachary Martinez
Practice Manager for Dr. Hyunwoo Chung

Submitter : Dr. David Whittman
Organization : University of Arizona
Category : Physician

Date: 06/09/2005

Issue Areas/Comments

Background

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.

o 35475 - transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel

o 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.

o ?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.--? 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.

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o ?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.--Beathard GA

GENERAL

GENERAL

There are several differences in the patient with end-stage renal failure (ESRD) from the average patient which makes this ruling incorrect. First, there are many percutaneous angioplasties which may be unsafe in an ambulatory surgery center, such as, those to vessels of major organs, i.e., renal artery, mesenteric artery, aorta, and cerebral circulation. Procedures to these vessels may result in complications which may be life threatening and require conversion to open surgical procedures. In contrast, procedures to hemodialysis access are generally limited to an extremity and are extremely safe (see attached). Second, as you are keenly aware, ESRD is increasing in epidemic proportion, and although only one percent of Medicare beneficiaries have ESRD, patients with ESRD account for almost nine percent of Medicare expenditures. Patients with kidney failure are sicker and require more health care than the majority of Medicare beneficiaries. Outpatient ambulatory surgery centers provide a unique opportunity for patients to receive excellent, personal care out of the hospital setting, often by nephrologists who have the most insight and intimate relationship with the patient. In fact, nephrologists who provide vascular access care may provide better, more efficient care than their colleagues who do not have a long-term vested interest in patients with ESRD (KI 66:1622-32; 2004).

I feel it is in the best interests of the patient as well as CMS to continue to allow ambulatory surgery centers to provide angioplasties to patients with ESRD. I would imagine that those who feel these procedures performed in an ASC are providing "substandard care" must be referring to major vessels as mentioned and not to hemodialysis vascular access. Therefore, I would also like to implore to you that CPT codes 35476, 35475, 37205, 37206 when applied to dialysis vascular access associated with one or more of the ICD9 codes 996.73, 585, 459.2, or 447.1 continue to be allowed in the outpatient ASC setting.

Issue

Background

Angioplasty data from managed centers - October 1, 2002 to May 5, 2005 shows the following:

o 16,319 patients had procedures performed, including 14,961 venous angioplasties and 3,078 arterial angioplasties. The reason that the number of procedures performed exceeds the number of patients is due to the fact that some patients require multiple procedures. 15,982 patient encounters (97.9%) were successful as defined by the Society of Interventional Radiology standard of having less than 30% stenosis remaining post procedure. 180 (1.1%) procedures were deemed unsuccessful, and 157 (.9%) were aborted. The complications are detailed below:

Complication Type

Hematoma Grade I	254
Hematoma Grade II	27
Hematoma Grade III	7
Oxygen Saturation < 90%	5
Apnea, Temporary	3

Low BP or Pulse	4
Reaction to Medication	23
Bleeding	4
Foreign Body Failure	12
Foreign Body Retrieved	2
Death	4
Other	8

In total there were 353 complications (2.2 % of the procedures), and of those 25 were major complications and 328 were minor.

? According to the reporting standards of the Society for Interventional Radiology, all complications, including pulmonary and cardiac events that occur within 30 days following the procedure are considered procedure related. Minor complications are those that require either no therapy or only nominal therapy and resolved without any adverse consequence. Major complications are defined as those that require an increase in the level of care, or result in hospitalization, permanent adverse sequelae or death. The threshold for complications using this classification scheme has been defined as 5%.

? A total complication rate of 2.2 % is well below the established threshold. Of these, 2.0 % were minor complications meaning that they resulted in no significant change in medical management and resolved without sequelae. Only 0.2% of the complications were major. The 4 deaths that occurred were not as a direct result of the procedure performed, but did fall within the complication definition.

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

? One-hundred percent of the patients in this series were queried using the Ware Patient Satisfaction survey tool. The response rate for this survey was 40%. Patient satisfaction was found to be very high; 88% of the respondents rated their experience at these centers as either very good or excellent.

? The data shown here come from surgical centers which are classified as office based. Although these centers are different in legal structure, they are very comparable both in structure and operation to the ASC setting.

? The ASC is a more practical model to facilitate more widespread availability of these procedures for ESRD patients. The extension of practice, office based surgical center model works well for large physician groups with large patient populations. The ASC model would allow smaller physician practices to provide their patients with the same service.

Provisions of this interim final rule with comment period

Allow CPT codes 35475, 35476, 37205, 37206

Submitter : Mrs. Gloria Hussar
Organization : Mrs. Gloria Hussar
Category : Individual

Date: 06/10/2005

Issue Areas/Comments

Background

Background

I think that the use of tens units should be paid for by Medicare/Medicaid. As a person with chronic back pain, I used one temporarily, which helped, until I had to return in because my insurance company wouldn't pay the 700.00 per month cost for me to use it. I believe it should be up to the doctor as whether or not a patient would benefit from electronic stimulation.