Submitter : Mr. Richard Nee

Organization : RMS Lifeline Inc.

Category : End-Stage Renal Disease Facility

Date: 10/04/2006

Issue Areas/Comments

GENERAL

GENERAL

See Comment

CMS-1321-P-422-Attach-1.PDF

4160 R
422

Lifeline Inc.

September 25, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: CMS-1321-P; (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B)

Dear Ms. Norwalk:

I am the general manager of RMS Lifeline. At RMS Lifeline, we manage interventional nephrologists' vascular access offices. Interventional nephrologists in Lifeline managed centers have performed over 125,000 procedures on end stage renal patients over the last seven years.

Interventional nephrology is one of the newest and most rapidly growing specialties in medicine. The practices that we manage are on the leading edge of advances in imaging-guided minimally-invasive medicine. Procedures performed by interventional nephrologists -- through small catheters and other devices under radiological imaging -- are often less costly and significantly less invasive than alternative surgical therapies.

In addition, the outpatient vascular access centers that we manage have consistently outperformed traditional benchmarks along two key criteria: patient satisfaction and clinical success/safety. Historically, the patient satisfaction scores of centers that we manage have averaged 91%, while maintaining a 97% clinical success rate and a low 1.7% complication rate. I have included these results with this letter as additional support. These patient satisfaction rates clearly show that patients prefer the prompt, quality healthcare services they receive in a dedicated vascular access center over the cumbersome and lengthy process of being worked into a hospital surgical schedule.

I am writing today to express my grave concern that CMS 2007 Update to the PE RVUs for Interventional Radiology CPT codes will reduce patient access to efficient access services.

Impact – Work and PE RVU Changes for Interventional Radiology

I urge CMS to reconsider the drastic 2007 cuts to the PE RVUs for interventional radiology stemming from the changes to the PE calculation methodology.

I fully understand CMS need to make difficult budgetary decisions to maintain the solvency of the Medicare trust funds. However, we have serious concerns with the proposed practice expense reductions for interventional radiology. Per Table 7 of the CMS-1321-P, the combined 2007 impact of Work and PE RVU Changes for Interventional Radiology is estimated to be -14%, the third hardest hit specialty.

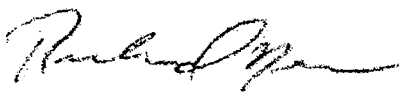
Three Hawthorn Parkway, Suite 410, Vernon Hills, IL 60061 Phone: 847.388.2055 Fax: 847.388.2020

A significant portion of the vascular access procedures involve imaging, and as such, these reductions will have a dramatic impact on interventionalists' ability to treat patients in the physician office setting. We would not want to see CMS inadvertently limit patients' access to convenient, efficient and clinically successful vascular access care. Their only alternative is to go back to the hospital for these services. This result is truly unfortunate since these services can be provided in the physician office setting in their entirety for on average 30% - 40% of hospital rates. Most vascular access problems are identified when an end stage renal patient arrives for their scheduled dialysis visit. If a patient has to be worked into a hospital surgery schedule when an access problem is identified, it is much more likely that the patient will not be treated and returned to their usual outpatient dialysis center during business hours, potentially requiring hospital admission for acute dialysis and exposure to hospital based organisms. Therefore, beyond the lower costs of office based procedures, additional costs to federal healthcare programs and patient complications can be avoided when patients are treated in a dedicated access center since the patients are much more likely to be treated and returned to their usual dialysis center for dialysis during normal business hours.

In addition, we are concerned that the reductions did not adequately take into account the costs of providing imaging services. For example, a significant driver of costs is tied to the equipment. The current system does not have a specific mechanism for capturing those costs thus they may have been overlooked.

In closing, I thank you in advance for your thoughtful consideration of these comments. If I can further assist your understanding of the benefits of outpatient vascular access patient care, I would be delighted to do so.

Respectfully submitted,



Richard Nee
VP & General Manager

RN/cf

Three Hawthorn Parkway, Suite 410, Vernon Hills, IL 60061 Phone: 847.388.2055 Fax: 847.388.2020

Submitter : Dr. **Date:** 10/04/2006

Organization : Dr.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

CMS has proposed a change in policy that would bill the technical component of all reference testing for Medicare inpatients BACK to hospitals as opposed to Medicare as is currently done. The financial impact on our medical center, and all community hospitals, will be monumental, and would likely make drug resistance testing unavailable for Medicare patients. The cost to hospitals would be too great.

Based on the ability of drug resistance testing to provide valuable information to guide treatment of cancers our oncology group uses such testing when indicated. Most of the patients we treat are in the Medicare age range. The policy under review would have a tremendous negative impact as it would virtually eliminate availability of this services to our patients.

Submitter : **Dr. Anonymous** **Date: 10/04/2006**

Organization : **Anonymous**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

For IDTFs-the liability insurance should be $300,000 per location. Larger suppliers wtih multiple locations should have $300,000 of coverage per locationm not a comprehensive policy that has $300,000 total.

Submitter : **Dr. Luan Tran** **Date: 10/04/2006**

Organization : **North Carolina Phlebology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule -Practice Expense
Proposal dated September 21, 2006

I would like to respond to the CMS proposal of 9/21/06 regarding the proposed changes in the physician fee schedule for 36478 and 36479 Endovenous Laser Ablation - office based.

I have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479 and find several issues of great concern:

1. RVUs have consistently been reduced from 2005 levels:
a. 2006: 46.91
b. 2007: 43.53
c. 2008: 40.84

While my practice expenses consistently rise, (salaries, utilities, etc.) it has become increasingly difficult to provide these necessary services. In order to comply with CMS guidelines, the ultrasound component of the procedure requires that the physician employ a Registered Vascular Technologist (RVT) to provide imaging services. These highly skilled technologists are in drastic shortage and therefore are in high demand and as such command extremely high salaries in excess of $70,000 per year plus benefits. It will be impossible to comply with CMS guidelines if the RVUs and subsequent reimbursements continue to drop!

As you know, the 2007 Medicare Physician Fee Schedule is already scheduled for a 5.1% across the board cut in reimbursement. Additionally, there are proposed cuts for non-invasive vascular imaging (vascular ultrasound). All these cuts will cripple the ability of physicians to perform this extremely important procedure and ultimately result in a loss of access to care for Medicare beneficiaries.

2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

Each of these technologies are comparable especially when we look at both the initial capital acquisition cost ($37,900 for laser and $25,000 for RF) and the, per patient supply costs ($360 for laser and $750 for radiofrequency for the procedure kits PLUS disposable sterile supplies such as drapes, gowns, Anesthetic solution, IV bags and tubing to name just a few). While the per patient supply cost may be slightly higher for 36475 (radiofrequency ablation), the significantly higher acquisition cost for 36478 (laser ablation) raises the overall physician s cost of delivering the service to the same level (possibly even higher).

I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

Thank you very much for the opportunity to give my input.

Respectfully,

Luan V. Tran, M.D.

Submitter : Dr. James Doty **Date:** 10/04/2006

Organization : Memorial Hospital CyberKnife Radiosurgery Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : **Dr. Karl Hubach** **Date: 10/04/2006**

Organization : **Inlet Vein Specialists, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment

Physician Fee Schedule Practice Expense

Proposal dated September 21, 2006

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IV bags and tubing to name just a few). While the per patient supply cost may be slightly higher for 36475 (radiofrequency ablation), the significantly higher acquisition cost for 36478 (laser ablation) raises the overall physician s cost of delivering the service to the same level (possibly even higher).

4. The field of Phlebology is a growing field that has been shown to have a great need and value to the public. It is growing so rapidly and has such a great need, the AMA has recently recognized it as a new specialty field. The impact of lowering reimbursment on a new field of medicine, that has been shown to have such great need in the communities, would bring unnecessary hardship to both physicians and patients.

I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

I would be happy to discuss this further with members of your committee.

Respectfully submitted,

Karl S. Hubach, MD
Inlet Vein Specialist, PC
912 Inlet Square Drive
Murrells Inlet, SC 29576

Submitter : **Dr. Ted King** **Date: 10/04/2006**

Organization : **Dr. Ted King**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am responding to the CMS proposal of 9/21/06 regarding the proposed changes in the physician fee schedule for 36478 and 36479 Endovenous Laser Ablation - office based.

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I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

I would be happy to discuss this further with members of your committee.

Respectfully submitted,
Ted King, M.D.

Submitter : **Dr. Leonard Valentino** **Date: 10/04/2006**

Organization : **Bone Density and Body Composition Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services:

Document 1321-P

I am gravely concerned about the proposed drastic cuts in payment for dual energy X-ray absorptiometry (DXA: CPT code 76075) and vertebral fracture assessment (VFA: CPT code 76077).

As the owner of an independent bone density testing facility in the San Francisco Bay Area, the proposed cuts will inevitably prohibit me from operating. As approximately 55% of our clientele are Medicare recipients, the proposed reduction would have a profound impact on the majority of our reimbursements. Additionally, there will be a cascading effect as Medicare is the standard by which other payors reimburse. This measure not only affects those with Medicare, but other insurance payors. Ultimately, we would no longer be able offer our high quality service.

Of primary concern is that the argument for the proposed reduction is based on some faulty assumptions. It is suggested that bone densitometers are typically utilized less than 50% of the time; however, our utilization rate is about 85%. We are a specialty office that performs DXA scans at a higher than expected volume; thus, the drastic reduction in reimbursements for the majority of our claims could only have a catastrophic effect on our operation. Secondly, CMS concluded that the actual time dedicated to DXA interpretation by the physician is less intense and more mechanical than previously accepted. However, DXA reporting requires skilled interpretation. I have over 10 years of osteoporosis specialty experience and have adopted a high standard of reporting that patients and referring physicians alike have come to rely upon in the management of this disease (see attached sample reports).

DXA and VFA testing are the clinical gold standard in the evaluation and management of osteoporosis. This action will undoubtedly reduce the availability of high quality bone mass measurements. Thus, it follows that patient access to appropriate therapeutic interventions for osteoporosis will be adversely impacted and preventative measures to maintain bone health will greatly decline. This expected outcome is contrary to what is desired by multiple federal initiatives: the Bone Mass Measurement Act, the US Preventive Services Task Force recommendations, and the Surgeon General s Report on Osteoporosis. Further, your Welcome to Medicare letter specifically addresses the value of DXA in reducing the personal and societal burden of osteoporosis.

DXA, coupled with new medications, has allowed Medicare to save millions of dollars by improving bone health and reducing osteoporotic fractures. In conclusion, DXA is a highly effective, low cost measure when considering the alternative burden of cost of an increased fracture rate in our ever growing aged population.

Leonard A. Valentino, M.D.
Medical Director
Bone Density and Body Composition Center
77 Birch Street, Suite A
Redwood City, CA 94062

CMS-1321-P-429-Attach-1.DOC

CMS-1321-P-429-Attach-2.DOC

September 12, 2006

Referring Physician, M.D.

JAM, a 75-year-old man, underwent bone density testing on 09/07/06 on a Lunar Prodigy instrument in order to assess fracture risk.

Clinical information and possible risk factors

- has taken medications for epilepsy from age 16 to the present and has been treated with Dilantin for the past nine years
- takes a number of other medications regularly; none of likely have an adverse effect on calcium or bone metabolism
- has been treated with alendronate for the past 6-12 months
- has lost 2-2½ inches in height and weighs 109 pounds
- family history is uncertain for osteoporosis
- experiences intermittent upper back pain
- takes 1000 mg of supplemental calcium and probably receives some supplemental vitamin D in the form of a multivitamin
- diet includes probably less than one serving a day of dairy products
- rides a stationary bike daily for 10-15 minutes
- does not presently smoke, but did for many years and quit about seven years ago
- diet includes no alcohol; diet includes caffeinated products in moderation
- has experienced no falls in the past year
- has a diagnosis of hypogonadism and has apparently experienced compression fractures

Spine

The bone mineral density of the lumbar spine measures 0.60 g/cm2. This value is 5.2 standard deviations below the young adult mean value and 3.6 standard deviations below the mean of his age-matched peers. Review of the images indicates the study is adequate for evaluation, although some arthritic changes may be present.

Hip

The mean bone density for the total hip area bilaterally measures 0.63 g/cm2. This value is 3.2 standard deviations below the young adult mean value. His left femoral neck value is 3.7 standard deviations below the young adult mean value, while the right trochanteric value is 4.1 standard deviations below the young adult mean value.

Vertebral Fracture Assessment

Assessment of vertebral morphology was performed in the left lateral projection. The image was analyzed us ing t he s emiquantitative t echnique o f Ge nant. Ar thritic c hanges a re no ted. T he appearance of T7 is consistent with a severe or grade 3 compression fracture. Also the appearance of T8, T9, T11 and T12 are consistent with mild or grade 1 compression fractures. All of the findings are confirmed by six point morphometry.

Comments
The findings at the spine and the hip satisfy the WHO criteria for the diagnosis of osteoporosis. His risk of a fragility fracture based on these values alone is 10-12 times that of the reference population. Since he has already experienced compression fractures, his risk is increased to a far greater degree. The following recommendation should be considered.

Recommendations
- verify accuracy of information provided
- if not done previously, measure 25-hydroxyvitamin D level and if value is decreased, treat with 50,000 IU of supplemental vitamin D a week for 8-12 weeks and then with 1000 IU of supplemental vitamin D a day thereafter
- take 1500 mg of supplemental calcium a day, in multiple doses, regularly, particularly in view of his modest intake of dairy products
- since his fracture risk is so dramatically increased consider treatment with teriparatide for the next 18 to 24 months instead of treatment with alendronate
- if treated with teriparatide, when treatment is completed, resume treatment with alendronate
- engage in weightbearing exercise on a regular basis and if possible, exercise for 30 minutes or more, 4-7 times a week, also incorporate exercises that involve the upper extremities
- provide information on fall prevention and fall protection
- repeat bone density evaluation in one to two years

Leonard A. Valentino, M.D.

June 14, 2006

Referring Physician, M.D.

KL, a 58-year-old woman, underwent bone density testing on 06/07/06 on a Lunar Prodigy instrument in order to assess postmenopausal bone loss and fracture risk.

Clinical information and possible risk factors

- is 26 years post early surgical menopause
- had a hysterectomy with removal of her ovaries at age 32; for endometriosis and ovarian cyst
- took HRT intermittently for a total of five years after her hysterectomy, but stopped because of side effects
- previously was treated with alendronate and risedronate, but stopped because of digestive symptoms
- has been treated with thyroid medication for the past seven years and has taken Lasix for 20 years, also has used albuterol almost daily for four years
- was diagnosed with COPD four years ago and reportedly had elevated cortisol levels two years ago, but had no evidence of tumor on MRI or CT
- has reportedly lost 9.5 inches in height and weighs 73 pounds
- experiences severe chronic back pain and has marked dorsal kyphosis
- has had five vertebral fractures after age 50 and experienced a spontaneous pelvic fracture five to six years ago
- family history is positive for osteoporosis
- takes 1500 mg of supplemental calcium, but receives no supplemental vitamin D
- diet includes no dairy products, because of digestive symptoms; drinks a half serving a day of calcium-fortified orange juice
- walks for 30 minutes three times a week
- has smoked intermittently for the past 20 years, currently a half pack of cigarettes a day
- diet includes no alcohol
- diet includes caffeinated products in moderation
- had a prior bone density study done elsewhere in 1987 and was told she had severe osteoporosis
- has used a walker from the time of her pelvic fracture
- has had multiple abdominal surgeries and was diagnosed with an arterial syndrome in 02/06
- suffers chronic abdominal pain because of severe dorsal kyphosis

Spine
The bone mineral density of the lumbar spine measures 0.56 g/cm2. This value is 5.1 standard deviations below the young adult mean value and 3.0 standard deviations below the mean of her age-matched peers. Review of the images and the individual values indicates presence of changes that falsely elevate the BMD value. Her measurements are actually even lower.

Hip
The mean bone density for the total hip area bilaterally measures 0.40 g/cm2. This value is 4.9 standard deviations below the young adult mean value and 3.2 standard deviations below the mean of her age-matched peers.

Forearm
The bone density at the distal aspect of the left radius measures 0.39 g/cm2. This value is 4.6 standard deviations below the young adult mean value. Her measurement at the ultradistal aspect of the radius, a region which is rich in cancellous bone is even lower to a significant degree and is 7.3 standard deviations below the young adult mean value and 6.5 standard deviations below the mean of her age-matched peers.

Vertebral Fracture Assessment
Assessment of vertebral morphology was performed in the left lateral projection. The image was analyzed using the semiquantitative technique of Genant. Three severe compression fractures are demonstrated at L1, L2, and L3. All are biconcave. In addition, at least moderate compression fractures are present at T10, T11, and T12. All of these interpretations are confirmed by six-point morphometry.

Comments
The findings at all three sites evaluated satisfy the WHO criteria for the diagnosis of osteoporosis. Her risk of a fragility fracture, based on her BMD values alone is 12-15 times that of the reference population. However, because she has experienced multiple fractures, including multiple compression fractures, her risk is increased to a far greater degree and is probably more than a 100 times that of the reference population. Also, because her scores are decreased relative to her age-matched peers, secondary osteoporosis is established and likely has a number of etiologies, including her smoking history. The following recommendation should be considered.

Recommendations

- verify accuracy of information provided
- most importantly inform the patient that smoking has an adverse effect on calcium and bone metabolism, in addition to its other negative effects on health
- consider an alternative to Lasix since loop diuretics are associated with calcium loss
- fully evaluate the patient if not done recently and measure serum NTx, 25 hydroxy-vitamin D level and evaluate for secondary osteoporosis
- consider immediate treatment with teriparatide or intravenous ibandronate
- repeat bone density evaluation in two years

Note
The findings were reported by phone to Referring Physician at 16:40 on 06-08-06.

Leonard A. Valentino, M.D.

Submitter : Mrs. Kaili Shewmaker

Organization : Prostate Oncology Specialists, Inc.

Category : Other Health Care Professional

Date: 10/04/2006

Issue Areas/Comments

Background

Background

Amgen gives us the opportunity to purchase these drugs based on a rebate program. Which we are very grateful for, given the oncology cuts we have received from Medicare. Without these rebates, we would be forced to have patients go to their pharmacy (some patients, loose script, don't have pharmacy benefits, don't have time, can't travel, can't wait--all these result in not getting the drug) b/c the practice couldn't loose money on giving the drug. Using Procrit is not an option for these patients due to the treatment schedule and long distances they travel to see us. i.e. procit is dosed weekly vs. aranesp does q3w.

Impact

Impact

This new rule would greatly burden giving patients efficient treatment. Without contracting, we cannot afford to loose the flexibility to choose how much we purchase for drugs--i.e. our Amgen contract. We use Aranesp and Neulasta b/c of the dosing guidelines. We have patient that are unable to travel long distances weekly and many of their treatments are given q3w anyway. so Amgen's Aranesp/Neulasta prescribing gives us the opportunity to help patients come in less for these products.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

Please let Amgen's PC stay in place--so that we can continue to choose Aranesp/Neulasta as the preferred products for our practice. We are pleased with the results.

Submitter : Dr. jim robelen

Organization : Dr. jim robelen

Category : Physician

Date: 10/04/2006

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule a? Practice Expense
Proposal dated September 21, 2006

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I would request that the fully implemented, non-facility practice expense RVU remain at the 2006 rate for 36475 of 51.5 and that the RVU for 36478 be increased to this same level.

Respectfully submitted,

Jim Robelen M.D., FACS

Submitter : Dr. David Ogburn

Organization : Dr. David Ogburn

Category : Physician

Date: 10/04/2006

Issue Areas/Comments

GENERAL

GENERAL

As the policy currently stands, anesthesiologists and other specialties face huge payment cuts to supplement the overhead cost increases for a handful of specialties.
The proposed change in PE methodology hurts anesthesiology more than most specialties, because the data that CMS uses to calculate overhead expenses is outdated and appears to significantly underestimate actual expenses.
CMS should gather new overhead expense data to replace the decade-old data currently being used.
ASA, many other specialties, and the AMA are committed to financially support a comprehensive, multi-specialty practice expense survey. CMS should take immediate action to launch this much needed survey which will greatly improve the accuracy for all practice expense payments.
CMS must address the issue of anesthesia work undervaluation or our nation s most vulnerable populations will face a certain shortage of anesthesiology medical care in operating rooms, pain clinics, and throughout critical care medicine.

Submitter : Dr. Paul Jackson

Organization : Palo Alto Medical Foundation

Category : Physician

Date: 10/04/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1321-P-433-Attach-1.DOC

Attachment
133

Palo Alto Medical Foundation
Department of Neurosurgery
Dr. Paul S Jackson, MD, PhD

October 4, 2006

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

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of ($1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of ($833.32). These proposed revisions would result in a reduction in payment averaging ($2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request yo ur assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."[1] Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."[2]

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that "***any SRS code changes would be premature without cost data to support a code restructuring***". (CMS-1506-P, page 156).

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[4] Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.***

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that ***CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.***

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition's assertions that:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

   By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

   The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. ***Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.***

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that ***it is a "mature technology [with] stable median costs"*** (CMS-1506-P, p 157). This would be an accurate

reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

	# centers operating Jan 1st	**New centers treating during year**	**% of centers in first year**
2004 CY 2004	12	8	67%
2005 CY 2005	20	15	43%

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities w ith vastly differing resource r equirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

Further, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from $3,479.65 (non-robotic SRS centers) to $6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated, however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge***. We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

►No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

►CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,
Dr. Paul S Jackson
Department of Neurosurgery
Palo Alto Medical Foundation
795 El Camino Real
Palo Alto, CA 94301

Submitter : **Dr. Jaime Furman**

Organization : **jaime Furman M.D P.A**

Category : **Physician**

Date: **10/04/2006**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-P-434-Attach-1.WPD

Attach 11
434

CMS 1321 P

"REASSIGNMENT AND PHYSICIANS SELF –REFERRAL"

Dear Sir/ Madam:

I want to thank you for allowing me to submit my comments. My name is Jaime Furman, I am a physician and a pathologist with fellowships in surgical and urologic pathology. Currently, I am working in a "condo" or "pod" laboratory in San Antonio, Texas.

I am not a lawyer, nor an expert in the Medicare regulations, therefore I am only going to give here some comments about my experience in this type of laboratories.
I am a physician with a specialty in anatomic pathology. During the last 16 years I have worked very hard in order to provide patients and students the best professional and ethical service I could. Before my current job, I worked in the University Hospital and was an Associate Professor of Pathology in the local medical school. I did my training at Washington University in St Louis and the University of Florida at Gainesville. My responsibilities included interpretation and diagnosis of histology samples, teaching urologic pathology to the second year medical students, urology and pathology residents. My professional life in the academic center was successful and promising.

In the year 2004 I learned that a pathology laboratory focusing on urologic pathology was opening in San Antonio. A few months later I joined the urology "condo' lab.
My experience in the new laboratories has been positive. The model of the condo lab allows the pathologist to focus on a specific area of pathology and provide a high of expertise and efficiency that cannot be reached in other type of practices. This high level of expertise allows the pathologist to give the patients a very accurate diagnosis and the clinician the necessary information to initiate the appropriate treatment.

Many students and residents rotate in our laboratories and I have signed a contract with the University of Texas that allows residents to come to our laboratories and benefit from our experience in the diagnosis of urologic cancer. Furthermore, currently I am working on the creation of a guide for urologists to study urologic pathology. This setting also allows me to become involved in academic activities. Periodically I give lectures about urologic pathology. Last September I was invited to Colombia, in South America to give several conferences in urologic pathology

One of the benefits of the "condo" laboratory is that the interaction with the urologist is very close and allows clinician and pathologist to work as a team to the benefit of the patient. The urologists are confident that the same pathologist interprets all the biopsies and provides a level of uniformity and consistency absent in other settings. Urologists have related to me the difficulties they had in the past from "traditional" referral laboratories to obtain an accurate diagnosis. Another positive feature of the model is the

rapid turnaround time to sign the pathology cases. Most of our cases are signed between 24- 48 hours after received, minimizing delays and problems to patients.

Some national pathologist organizations of which I am currently an active member (CAP) have invoked that the level of medical attention we provide is suboptimal. Nothing is further from reality. Hundreds of second opinions requested by clinicians and patients agree with our interpretations and confirm that the quality of diagnosis is excellent. The clinicians in other institutions and patients confirm these findings and no complaints have been received in more than two years. On several occasions we had encounter cases that were erroneously interpreted in other centers and were correctly interpreted by us.

Hundreds of patients went for surgical removal of the prostate gland after our diagnosis of cancer. The pathologists agree with the initial diagnosis we provided and confirmed the diagnosis of cancer in the surgical resection.

Recently, I submitted an abstract for the USCAP (United States and Academic of pathology) meeting for the year 2007 titled:

"EXPERIENCE WITH PROSTATE NEEDLE BIOPSIES IN A SPECIALIZED UROLOGIC PATHOLOGY LABORATORY (CONDO LABORATORY)"

The number of prostate carcinomas (cancer) detected in my laboratory (37.2%) was higher than in most publications from other centers (19 -20%). In other words, I detected many more cases of cancer in a similar number of biopsies. This finding negates the argument presented in the proposed changes that mention "fraud" and "generation of unnecessary biopsies."

In addition, the cases of inconclusive diagnosis (atypia) were very small compared to other centers. The findings contradict completely the arguments of abuse of self referral by clinicians. The high number of cancer diagnosis made, clearly validates that the urologists were correct in requesting the biopsies in most of these patients.

I also want to comment that our quality control in my experience is one of the most complete that I have encountered in my practice as a pathologist. The entire process is under the control of the urologist and pathologist and can be corrected immediately if necessary.

An allegation made by pathology organizations is that "others" benefit from our job and that we do not receive the entire professional component and a third party benefit from our work. This is a deceitful argument because in my previous academic jobs the institution I worked for did not give me either the complete professional component for my professional services and I received a salary for far less compensation than now for equal amount of hours. Most institutions do not paid pathologist for the full professional component.

Our work conditions are very favorable and we have the adequate equipment and resources to perform the job. I resent the implication that we perform the job under poor conditions with "minimal equipment." The resources are satisfactory for performing the job and the channels of communication are open to repair or change some of the equipment if necessary. The histology technologists that work in the laboratories are great professionals and some of the more experienced in San Antonio and South Texas. The quality generated in the laboratories of the histology material is very good and allows us to perform our job and provide a good diagnosis.

Many critics of the "condo" laboratories originated from pathology organizations that I respect and I am currently a member. The allegations range from suboptimal medical quality, over-utilization, abusive arrangement and fraud. I want to be clear and definitive that all of these charges are unsubstantiated and false. No one from these pathologist organizations have ever contacted us. Most of the negatives comments are only speculations. The origin of these charges are special interest groups with a financial agenda in ending this new type of laboratories.

New types of practices and models arise in other medical specialties. Pathology is not different. Initial criticisms are expected and should help to improve a new idea. Regulations are also necessary and welcome in order to avoid abuses. At the same time a good functional model should be embraced as a new approach and not destroy under false accusations for pure financial concerns. The objective of medicine is to serve patients well and with dedication. This is a novel approach to serve patients, urologists and pathologists. Today in the United States the health system is facing critical problems that traditional models have not solved. New concepts and models should be studied and regulated but also encouraged. I work hard with great dedication and I am proud of what I am doing.

In summary we :

- provide excellent diagnostic services
-serve patients with dedication
-are efficient
-work hard
-have a great work team
-help urologist to treat patients
-reject fraud and abuse
-welcome well intentioned critics
-serve the community
-want to be treated fairly by all regulatory agencies

I have confidence that the truth and decency are going to prevail over obscure interests and political motivated organizations. I have faith that at the end we will prevail and will continue serving our patients, serving the urologist, and serving the pathology

community. I encourage everybody to look at this model with an open mind and not to falsely implant prejudices. I told the truth on the best of my knowledge in these comments.

I hope I am contacted by any member of your organization or any legislative body that wants to hear the truth and is interested in improving medical services in our country.
My phone is 210- 764 0045
E-mail karja@sbcglobal.net

Thank you

Sincerely,

Jaime Furman, M.D.
Urologic Pathologist

Associate Professor of Pathology
University of Texas Health Science Center San Antonio

Submitter : Dr. Brad Drexler **Date:** 10/05/2006

Organization : Dr. Brad Drexler

Category : Physician

Issue Areas/Comments

Impact

Impact

I am particularly concerned with the negative effect of these changes on the practice expense RVUs for CPT code 58565 Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants, by CY 2010.
I understand that major changes to the PE methodology for CY 2007 were discussed in the June 29, 2006 proposed notice. However, I am concerned that the specific, proposed practice expense RVUs published in this regulation for CPT codes 58565 by the end of the transition period in CY 2010 will negatively impact access to this procedure when performed in a physician s office.
I am concerned that CMS proposed method uses budget neutrality adjustors in three separate steps. I cannot continue to absorb these under-valuations, especially as my practice faces 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. For example, the impact of the budget neutrality adjuster on the direct expenses means over $350 of the direct costs for CPT code 58565 are not included as part of the practice expense valuations for this code under the new methodology. Given that many private insurance companies and Medicaid programs use the Medicare physician fee schedule to set their payment rates, the impact of CMS not accounting for all the costs of the procedure are magnified with each additional payer.

Also, I understand that as CMS calculates the service level allocators for the indirect PEs, which happen to be the direct PE RVUs and the work RVUs, they are using direct PE RVUs or work RVUs that have been adjusted for budget neutrality. Indirect costs for a service need to allocate using all of the costs associated with the inputs for a service.

Provisions of the Proposed Rule

Provisions of the Proposed Rule

It is important that Medicare payment levels are appropriate such that access to permanent birth control that is non-incisional does not become constrained for women of child-bearing age. In my practice, I have treated women with the Essure? micro-insert system and their outcomes have been excellent, with less risk and complications versus an open, surgical tubal ligation procedure. Therefore, CMS needs to be sure that the direct costs for this procedure used in its calculations are accurate and totally accounted for in the PE RVUs. It would be unfortunate if access to this non-incisional, permanent birth control for women with Medicaid or commercial insurance was no longer a viable option for me to offer my patients because of the practice expense formula used to calculate Medicare payments starting in 2007 and beyond.

Please do not hesitate to contact me if I may be of help with regard to providing additional information or answering any questions you or your staff may have.

Submitter : **Dr. Vasana Cheanvechai** **Date: 10/05/2006**

Organization : **Nevada Vascular Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

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

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

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

Submitter : Dr. Eddy Luh **Date:** 10/05/2006

Organization : Nevada Vascular Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

CMS 1321-P

Policy and Recommendation: Comment
Physician Fee Schedule Practice Expense
Proposal dated September 21, 2006

We have reviewed the proposed 2007 fully implemented, non-facility practice expense (PE) RVUs for codes 36478 and 36479

There are three issues of concern;

1. Values have been consistently reduced:
a. 2006: 46.91
b. 2007: 43.53
c. 2008: 40.84
d. Practice expense consistently rises (salaries, utilities, etc.)

2. The proposed conversion factor (CF) for 2007 has been reduced from 2006, thus further decreasing reimbursement for endovenous laser treatment.

3. Values for codes 36475 and 36476, radiofrequency vein ablation have been consistently higher that those for laser ablation:
a. 2006: 51.5
b. 2007: 47.77
c. 2008: 44.52

Each of these technologies are comparable in term of both capital acquisition cost ($37,900 for laser and $25,000 for RF) and per patient supply costs ($360 for laser and $750 for radiofrequency).

We are requesting that the fully implemented, non-facility practice expense RVU for 36478 remain at the 2006 rate for 36475 of 51.5.

We are also requesting that the fully implemented facility practice expense RVU remain at the 2006 value of 2.54.

Impact

Impact

CMS 1506-P

I am responding to the CMS proposal of 9/21/06:

Policy and Payment Recommendations - Comment

ADDENDUM A.--OPPS PROPOSED LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCs) WITH STATUS INDICATORS (SI), RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2007

It appears the codes 36478 (endovenous laser treatment, 1st vein) and 36479 (endovenous laser vein, add on) have been moved from APC 0091 to APC 0092.

Of note, codes 36475 (endovenous RF 1st vein) and 36476 (endovenous RF vein add on) remain in APC 0091. These are very similar technologies. In fact, FDA approval for endovenous laser treatment was based on the predicate device for endovenous radiofrequency.

Both technologies carry an inherent cost of both capital equipment and patient specific device supplies. Acquisition cost of capital for laser equipment is $37,900. Acquisition cost of capital equipment for radiofrequency is $24,000. Patient specific device supplies range from $360 for laser fibers to $750 for radiofrequency fibers.

Technical expertise essential for health care delivery of either procedure is essentially the same.

Codes 36478 (endovenous laser first vein) and 36475 (radiofrequency, first vein treated), have a fully implemented facility RVU of 9.63. However, based on the proposed 2007 APC, code 36478 and 36479 have a weight that is 70% that of 36475 and 36476. This is very inconsistent and impairs the provider s ability to

provide endovenous laser treatment in a fiscally responsible manner.

We are requesting that codes 36478 and 36479 be returned to APC 0091, with a weight of 34.5817.

Code Descriptor CI APC Rel. Weight Payment Rate Nat l Unadjusted Co-Pay Minimum Unadjusted Co-Pay
36478 Endovenous laser treatment, 1st vein CH T 0092 24.5817 $1,513.03 $306.56 $302.61
36479 Endovenous laser vein add on CH T 0092 24.5817 $1,513.03 $306.56 $302.56
36475 Endovenous rf 1st vein T 0091 34.6279 $2,131.38 $426.28
36476 Endovenous rf vein add on T 0091 34.6279 $2,131,30 $426.28