CMS-1506-FC-1 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : Dr. Samuel Putnam **Date & Time:** 11/28/2006

Organization : Fornance Physician Services

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-1506-FC-1-Attach-1.DOC

November 28, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-FC Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Final Rule with Comment Period

Dear Ms. Norwalk:

I am writing to express my serious concern regarding the forthcoming reductions in the 2007 Medicare reimbursement rates for a treatment that helps extend my patients lives, called Yittrium-90 (Y-90) microspheres (or "SIR-Spheres" microspheres). SIR-Spheres microspheres are classified by the FDA as a brachytherapy device, and approved to treat metastatic colorectal cancer of the liver. I have been performing brachytherapy procedures using SIR-Spheres microspheres for 4 years, and can attest to what an important innovation they and other brachytherapy treatments represent, both from the patient's quality of life perspective and from a cost perspective. Brachytherapy has markedly fewer debilitating side effects than traditional external radiation and chemotherapy. In addition, virtually all brachytherapy procedures can be performed (on an outpatient basis) as a single treatment unlike traditional external radiation and chemotherapy infusions which must be repeated monthly or weekly

I understand that the total payment amount for Y-90 in the CY 2007 Hospital Outpatient Final Rule *dropped by more than 1/3 from the payment amount in the Proposed Rule.* The final rate CMS published is *less than the product costs.* This is unacceptable. SIR-Spheres microspheres are often the only viable treatment when patients have failed multiple chemotherapy regimens. While, I support Congress' and CMS' desire to pay appropriately for medical care, I do not think it is reasonable to set payment levels so low that physicians are forced to choose between suffering a financial loss or providing the treatment their patients need. I cannot believe Congress intended for physicians to be faced with such a dilemma. If reimbursement rates are reduced so drastically, I am afraid I may not be able to continue to provide what is often the only viable for my patients. Thank you for your consideration of this important issue.

Sincerely,

Samuel G. Putnam, M.D.

Chief, Section of Interventional Radiology

Fox Chase Cancer Center and Montgomery Hospital

Submitter : Mr. BILL DAVIS **Date: 11/30/2006**

Organization : DIGESTIVE DISEASE SPECIALISTS, INC.

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

On October 3, 2006 we submitted a comment regarding CY 2008 ASC Impact. The point of our argument has since found it's way into our legal system. (See Attached News Report). Again, I am urgently requesting an opportunity to speak with a decision maker regarding this matter.

CMS-1506-FC-2-Attach-1.PDF

#2

By Kevin P. Casey for USA TODAY

Getting money back: DeLois Gibson was a plaintiff in a case against Virginia Mason Medical Center in Seattle. She received a settlement.

'Hospital-based' clinics can charge more

Use of 'facility fees' could lead to lawsuits, legal advisers say

By Julie Appleby
USA TODAY

Concerned about a possible toenail infection, Lori Mill went to her doctor's office in an outpatient clinic owned by the Virginia Mason Medical Center in downtown Seattle. Her doctor clipped off a piece of nail and sent it to the lab. Total tab: $1,133.

Mill found out later that she could have paid hundreds less for the same thing had she gone to one of Virginia Mason's seven other, more suburban, outpatient clinics, where her doctor also practices.

Health care

Her situation illustrates a practice that is legal and common, but little known to patients: Some medical clinics are considered "hospital-based" and charge additional fees for the same services, even if they aren't inside an actual hospital.

With high-deductible insurance and 20% co-payments becoming increasingly common, more consumers such as Mill are noticing such "facility fees," and the hospital industry's legal advisers say the charges may become the next court battleground.

From nail clipping to lawsuit

Mill's toenail clipping in 2004 led to a class-action lawsuit. The lawsuit argued that, under state consumer protection laws, patients should have been told in advance about additional fees.

Earlier this month, Virginia Mason settled, agreeing to refund money to thousands of patients, to tell patients that it charges more at some clinics in its system than others and to find ways to help patients estimate upfront their costs for some outpatient procedures.

"When consumers are making decisions about where to go for health care, the court in this case is saying they have a right to know about these price differences," says attorney Matt Geyman of the Phillips Law Group in Seattle, which represented Mill and another patient, DeLois Gibson.

That settlement — along with a similar agreement reached in September with Seattle's University of Washington Medical Center — may further efforts to make medical price and quality data more available.

"This is the first real development giving health care consumerism some teeth," says Jim Unland of the Health Capital Group, a health care consulting firm.

The settlements come as the hospital industry is under increasing pressure to release more information about prices and is facing market pressure from private physicians who offer similar outpatient services in their offices or ambulatory surgery centers.

Unland says another decision by the University of Washington could herald other changes for some hospitals. The university hospital, after comparing prices for a number of minor outpatient surgical procedures to the local average, cut prices. If hospitals nationally begin to disclose prices — either voluntarily or because courts, employers or the government require them to — market forces may drive prices down in areas where doctors directly compete with hospitals.

"Once they disclose prices, and reveal their vulnerability to being either way overpriced or outside the market, that could lead to a chain reaction," says Unland.

Hospitals say fees needed to offset costs

Hospitals say facility fees are needed to cover additional administrative costs of clinics that are closely associated with a hospital and to help offset thin margins or losses on other hospital services, including free care given to the poor.

"We run between a 1% to 4% margin for the hospital, so, overall, we're really just covering the cost," says Lisa Brandenburg at the University of Washington Medical Center, which has five satellite clinics. "If you want to look at facility fees in the global sense, how do we simplify how we pay for health care and yet still support folks like us that are part of the safety net?"

It is not known how many hospital systems charge facility fees at their outpatient clinics, or how many charge fees at some clinics but not others. Medicare does not keep count.

But in court filings from February 2005, Virginia Mason said that "the practice of hospital-based billing is widespread across the United States," and said the fees help cover the costs of running a hospital, which often includes emergency services, special labs and radiology services that doctor's offices and non-hospital-based clinics do not provide.

Mill learned about the price differences between the suburban clinics and the downtown center only after she questioned a $418 facility fee on her bill.

"I could have gone to another clinic close to where I live and avoided this fee altogether," Mill says.

She eventually got her doctor to call administrators and have the fee waived. Because she never paid the fee, she was *not* part of the class-action settlement.

Some 3,200 patients eligible for refunds

The other patient named in the lawsuit, Gibson, went to the downtown Virginia Mason outpatient clinic to have a small skin spot removed. She later learned that the procedure included an $846 hospital fee.

"I didn't consider removing this thing a surgery. It took like one minute, and I wasn't in the hospital," says Gibson, who says she would have gone to another of the hospital's clinics if she had known.

Gibson will be refunded $157.97 — her share of the facility fee — as part of the resolution agreed to by Virginia Mason. Attorney Geyman says about 3,200 other patients responded to the class-action case and will be eligible for refunds.

The hospital says it settled to avoid the costs of litigation. Instead, it will pay about $500,000 in refunds.

"The primary issue is creating transparency around costs for patients. Virginia Mason is working hard to provide additional information so that patients can make informed decisions about their care," a written statement from Sarah Patterson, executive vice president, says.

As a result of the settlement, hospital systems nationally are reviewing their price disclosure policies for outpatient clinic treatments, says Kathy Butler Polvino partner at Powell Goldstein in Atlanta, whose clients include hospitals.

The settlement comes after a spate of lawsuits about another common hospital industry practice: charging the uninsured higher prices than insured patients for the same services. Many hospitals now offer the uninsured discounts close to what insurers get.

The hospital facility fees, although allowed under Medicare rules, may come under similar scrutiny.

"People are going to start doing copycat lawsuits," says Stephen Weyl, partner at the law firm of Hinckley Allen and Snyder in Concord, N.H.

Polvino says she advises hospitals to look at their disclosure policies. Some already tell patients about the facility fees before they come in, she says.

"Even if they don't legally have a duty to disclose (the fee), if there is a risk of litigation, they may want to re-evaluate their disclosure policies," says Polvino.

Submitter : Mr. BILL DAVIS **Date:** 12/06/2006

Organization : DIGESTIVE DISEASE SPECIALISTS, INC.

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

.I submitted a comment with an attachment 11/30/06 and received a Temporary Comment Number: 98480. I have not received a "Unique Confirmation Number". When and how do I receive this number? My email address is: diana.mock@okddsi.net.

Thank you.

Submitter : **Dr. Gregory Searcy** **Date: 12/11/2006**

Organization : **East Columbus Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

$954 for CPT 66984 has not been updated since 1989 and we've seen a huge increase in costs across the board, particularly RN wages, which have increased far higher than inflation!

Submitter : Dr. Harvey Neiman **Date:** 12/20/2006

Organization : American College of Radiology

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-FC-5-Attach-1.PDF

#5

ACR™
AMERICAN COLLEGE OF RADIOLOGY

December 20, 2006

Leslie Norwalk
Acting-Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Final Rule with Comment Period

Dear Ms. Norwalk,

The American College of Radiology (ACR), representing 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists, appreciates this opportunity to comment on the final rule on "Hospital Outpatient Prospective Payment System (HOPPS)" published in the *Federal Register* on November 24, 2006.

Recommendations on How Hospitals Can Better Report Their Costs

The ACR continues to remain concerned that hospitals do not report their costs in a consistent and accurate way nor do they update their charge masters regularly with charges that reflect appropriate relativity. These inconsistencies cause inaccurate payment levels to be set for APCs including many of the newer technologies like CTA, magnetoencephalography (MEG), cardiac CT, and coronary CTA. The ACR understands that CMS requires hospitals to report their costs and charges through the cost report and that CMS believes that this is sufficient specificity to support the use of cost report data for monitoring and payment. However, the ACR believes that requiring hospitals to specify exact components of individual cost centers, charge masters, etc. would provide better data to support the payment levels being set that affect both the hospital outpatient and physician office settings for imaging procedures. The greater accuracy of cost-to-charge ratio (CCR) calculations is vital in order to further refine this prospective payment system which is still somewhat in its development and refinement stages.

The ACR would like to continue to work with CMS to determine how hospitals can further refine their process of reporting costs and updating charge masters in order for CMS to set the most accurate rates possible for imaging.

ACR™
AMERICAN COLLEGE OF RADIOLOGY

New Codes for Stereotactic Radiosurgery

The ACR is aware that there are new CPT® codes for the services described by the G codes for stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) which will become effective January 1, 2007. These new codes are 77435, 77371-77373.

The ACR would like to request that CMS work with the specialty societies to develop appropriate crosswalks from the G codes to CPT® codes and the assignment of the new codes to APCs.

This is vitally important to make sure that hospital coders are using the most current codes and reporting costs at the correct levels so that payment rates are consistent in the future.

Conclusion

Thank you for the opportunity to comment on this final rule with comment period. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Pam Kassing at 1-800-227-5463, ext. 4544 or via email at pkassing@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD

Harvey L. Neiman, MD, FACR
Executive Director

Cc: Alberta Dwivedi, CMS
Edith Hambrick, MD, CMS
John A. Patti, MD, FACR, Chair, ACR Commission on Economics
James Rawson, MD, FACR, Chair, ACR Economics Committee on HOPPS/APC
Pamela J. Kassing, ACR
Maurine Spillman-Dennis, ACR
Angela J. Choe, ACR

Submitter : **Dr. George Laramore** **Date: 12/20/2006**

Organization : **University of Washington Medical Center**

Category : **Physician**

Issue Areas/Comments

ASC procedures that were not proposed for addition to the ASC list

ASC procedures that were not proposed for addition to the ASC list

CPT code 77423

GENERAL

GENERAL

I would like to comment on the proposed final OPPS rule relating to reimbursement for neutron beam radiotherapy, CPT Code 77423. This code has been dramatically undervalued. The proposed payment rate of $137.04 is far below the cost data which we at the University of Washington provided you when the American Society for Therapeutic Radiology and Oncology (ASTRO) applied for this code. You now have a yearys worth of cost data to verify this. Furthermore, the proposed payment violates the y2 timesy rule. The code should be more on the order of APC 313 for which the payment is $789.70.

As background please recall that fast neutron radiotherapy is a highly technical method of delivering radiotherapy using a neutron beam which has different biological properties than standard radiotherapy. Certain tumors such as salivary gland cancers respond much better to neutron radiotherapy than standard radiotherapy and there has been a phase III randomized trial supporting this. Neutron radiotherapy beams are produced at only 3 centers in the United States. Our own facility uses a cyclotron to accelerate protons which then impact a beryllium target. Hence, the degree of physics and engineering support required for a neutron facility is similar to that required for a proton beam treatment facility and the operating costs are comparable. The technical reimbursement needs to be sufficient to support the operation of such facilities.

Submitter : Dr. Timothy Mate **Date:** 12/27/2006

Organization : Swedish Cancer Institute

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-1506-FC-7-Attach-1.DOC

#7

SWEDISH CANCER INSTITUTE

December 12, 2006

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-FC Hospitals

Re: **Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program--HCAHPS Survey, SCIP, and Mortality**

Dear Administrator Norwalk:

I am writing on behalf of Swedish Cancer Institute to address an issue of great importance to Medicare beneficiaries with cancer. Swedish Cancer Institute is a radiation therapy center, which provides radiation therapy for cancer patients. We serve approximately 600 prostate cancer patients annually, many of whom are treated with external beam radiation therapy and would benefit from accurate and precise radiation therapy treatment by having fiducial markers implanted into the prostate to indicate the position and relative motion of the prostate during radiation therapy.

I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. The new CPT Code, 55876, covers placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial marker, dosimeter) for the prostate (via needle or any approach) whether single or multiple. It is understood that the intent of this new CPT code was established as a new procedure code for implant of fiducial markers in the prostate – during the Final Rule review process a question was raised about whether fiducial markers should be included in the payment.

It should be recognized that there are a variety of types of devices that may be implanted in the prostate, each having very different functionality and costs associated. For example, some types of devices (gold fiducials and electromagnetic transponders), may be implanted in the prostate to locate the prostate, align it with the radiation beam at initial radiation setup every day for 40 or more days. Other devices such as electromagnetic transponders not only provide an initial setup function but also continuously monitor the three-dimensional position of the prostate during radiation beam delivery. Based on my literature review, the benefits of continuous, real-time

tracking during radiation with electromagnetic transponders over simple gold fiducials (setup only) are potentially more significant. Real-time continuous tracking I expect will ultimately improve disease control and reduce the number of complications - such as rectal bleeding, incontinence, sexual dysfunction—that may occur during radiation therapy treatment or in the years subsequent to the treatment.

Thus, it is important to realize that there are a variety of fiducial marker types of very different complexity and functionality ranging from simple gold markers ($200) to implantable dosimeters ($900) to electromagnetic transponders ($1200). If the cost of the devices implanted were bundled there would be a significant discrepancy in payment for devices, which does not account for the range in complexity and functionality and potential benefit to the patient.

The hospital outpatient proposal does not recognize the importance between the various types of fiducial markers, particularly the difference between gold markers, implantable dosimeters or electromagnetic transponders. In fact, the costs to Swedish Cancer Institute of acquiring, maintaining, and utilizing the electromagnetic transponders and the technology to monitor them is costly. The payment rate for implanting markers in the prostate should not incorporate dollars for the fiducial markers, as there is a range of device types and those at either end of the cost scale with is inappropriate.

Many cancer patients benefit from more accurate radiation therapy delivery requiring implantation of fiducial markers to guide treatment setup and delivery. The proposed payment rate for 55876, Placement of Device for Radiation Therapy Guidance, w ould seriously underpay clinicians using electromagnetic transponders, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the proposed rate be reviewed ***without*** bundling the cost of the fiducial markers into the final payment. In addition, the procedure for implanting fiducial markers is very similar to the prostate insertion procedure and should be compensated based on the skills required for the procedure reflected in the New Technology APC 1511: Level XI or APC 1512: Level XII, identified by the American Society for Therapeutic Radiology and Oncology in their letter to CMS dated October 9, 2006.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Timothy P. Mate, M.D.
tmate@seanet.com
206-386-2323

Submitter : **Dr. Patrick Kupelian** **Date: 12/27/2006**

Organization : **MD Anderson Cancer Center Orlano**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-FC-8-Attach-1.DOC

CMS-1506-FC-8-Attach-2.DOC

#8

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1321-FC

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B

Dear Administrator Norwalk:

I am writing on behalf of MD Anderson Cancer Center Orlando to address an issue of great importance to Medicare beneficiaries with cancer. MD Anderson Cancer Center Orlando has a radiation therapy center, which provides radiation therapy for cancer patients. We serve approximately 250 prostate cancer patients annually, many of whom are treated with external beam radiation therapy and would benefit from accurate and precise radiation therapy treatment by having fiducial markers implanted into the prostate to indicate the position and relative motion of the prostate during radiation therapy. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. The new CPT Code, 55876, covers placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial marker, dosimeter) for the prostate (via needle or any approach) whether single or multiple. It is understood that the intent of this new code was established to a new procedure code for implant of fiducial markers in the prostate – during the Final Rule review process a question was raised about whether fiducial markers should be included in the payment.

There are a variety of types of devices that may be implanted in the prostate, each having different functionality and costs associated. One type of implantable device, electromagnetic transponders, may be implanted in the prostate to locate the treatment target, align it with the radiation beam and monitor treatment setup every day for 40 or more days. The electromagnetic transponders also monitor the position of the prostate and highlight motion, away from the radiation beam during therapy. It is important to realize that there are a variety of fiducial marker types which range in complexity ranges from simple gold markers ($200) to implantable dosimeters ($900) to electromagnetic transponders ($1200). Electromagnetic transponders provide three-dimensional tracking when precision radiation therapy delivery is required.

Medicare payment rates for are being established in 2007 for the new CPT code 55876 and the Final Rule from CMS on November 1, 2006 highlights a comment period ending on January 2, 2007 to address what is included in the payment rate for this code. It had been proposed by professional societies that the payment bundle in the cost of fiducial markers, estimated by CMS to cost $119.

Over the past few years, use of localization technologies, including use of gold markers, has become a standard of care for many cancer patients. The availability of electromagnetic transponders or electronic fiducial markers adds another dimension in the monitoring and guidance of radiation therapy delivery. These benefits are expected to ultimately reduce the number of complications—such as rectal bleeding, incontinence, sexual dysfunction—that may occur during radiation therapy treatment or in the years subsequent to the treatment. If the cost of the devices implanted were bundled in there would be a significant discrepancy in payment for devices, as there is a range of complexity and costs which varies significantly from $200 (gold markers) to $1200 (transponders).

The physician final rule proposal does not recognize the importance between the various types of fiducial markers, particularly the difference between gold markers, implantable dosimeters or electromagnetic transponders. In fact, the costs to Anderson Cancer Center Orlando acquiring, maintaining, and utilizing the electromagnetic transponders and the technology to monitor them is costly. The payment rate for implanting markers in the prostate should not incorporate dollars for the fiducial markers, as there is a range of device types and those at either end of the cost scale with is inappropriate.

Many cancer patients benefit from more accurate radiation therapy delivery requiring implantation of fiducial markers to guide treatment setup and delivery. The proposed payment rate for 55876, Placement of Device for Radiation Therapy Guidance, would seriously underpay clinicians using electromagnetic transponders, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the proposed rate be reviewed without bundling the cost of the fiducial markers into the final payment. In addition, the procedure for implanting fiducial markers is very similar to the prostate insertion procedure and should be compensated based on the skills required for the procedure reflected in the New Technology APC 1511: Level XI or APC 1512: Level XII, identified by the American Society for Therapeutic Radiology and Oncology in their letter to CMS dated October 9, 2006.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Patrick Kupelian, M.D.
Director of Research
Department of Radiation Oncology
M. D. Anderson Cancer Center Orlando
1400 S. Orange Avenue
Orlando, Florida 32806
(321) 841-8666
(407) 649-6895fax
patrick.kupelian@orhs.org

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1321-FC

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment Under Part B

Dear Administrator Norwalk:

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There are a variety of types of devices that may be implanted in the prostate, each having different functionality and costs associated. One type of implantable device, electromagnetic transponders, may be implanted in the prostate to locate the treatment target, align it with the radiation beam and monitor treatment setup every day for 40 or more days. The electromagnetic transponders also monitor the position of the prostate and highlight motion, away from the radiation beam during therapy. It is important to realize that there are a variety of fiducial marker types which range in complexity ranges from simple gold markers ($200) to implantable dosimeters ($900) to electromagnetic transponders ($1200). Electromagnetic transponders provide three-dimensional tracking when precision radiation therapy delivery is required.

Medicare payment rates for are being established in 2007 for the new CPT code 55876 and the Final Rule from CMS on November 1, 2006 highlights a comment period ending on January 2, 2007 to address what is included in the payment rate for this code. It had been proposed by professional societies that the payment bundle in the cost of fiducial markers, estimated by CMS to cost $119.

Over the past few years, use of localization technologies, including use of gold markers, has become a standard of care for many cancer patients. The availability of electromagnetic transponders or electronic fiducial markers adds another dimension in the monitoring and guidance of radiation therapy delivery. These benefits are expected to ultimately reduce the number of complications—such as rectal bleeding, incontinence, sexual dysfunction—that may occur during radiation therapy treatment or in the years subsequent to the treatment. If the cost of the devices implanted were bundled in there would be a significant discrepancy in payment for devices, as there is a range of complexity and costs which varies significantly from $200 (gold markers) to $1200 (transponders).

The physician final rule proposal does not recognize the importance between the various types of fiducial markers, particularly the difference between gold markers, implantable dosimeters or electromagnetic transponders. In fact, the costs to Anderson Cancer Center Orlando acquiring, maintaining, and utilizing the electromagnetic transponders and the technology to monitor them is costly. The payment rate for implanting markers in the prostate should not incorporate dollars for the fiducial markers, as there is a range of device types and those at either end of the cost scale with is inappropriate.

Many cancer patients benefit from more accurate radiation therapy delivery requiring implantation of fiducial markers to guide treatment setup and delivery. The proposed payment rate for 55876, Placement of Device for Radiation Therapy Guidance, would seriously underpay clinicians using electromagnetic transponders, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the proposed rate be reviewed without bundling the cost of the fiducial markers into the final payment. In addition, the procedure for implanting fiducial markers is very similar to the prostate insertion procedure and should be compensated based on the skills required for the procedure reflected in the New Technology APC 1511: Level XI or APC 1512: Level XII, identified by the American Society for Therapeutic Radiology and Oncology in their letter to CMS dated October 9, 2006.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Patrick Kupelian, M.D.
Director of Research
Department of Radiation Oncology
M. D. Anderson Cancer Center Orlando
1400 S. Orange Avenue
Orlando, Florida 32806
(321) 841-8666
(407) 649-6895fax
patrick.kupelian@orhs.org

Submitter : **Ms. William Conway** **Date: 01/14/2007**

Organization : **Citizen**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I live in a small town in the Southeast Arkansas delta, one of the poorest area of my Amcrica. Our small Critical Access hospital is owned by both the City of McGehee and the County of Desha. Some years ago the citizens of our town (population 4,400) votcd a one cent sales tax to keep their small hospital and its emergency room open. We have tried, within the limits of our ability, to help fund the shortfalls in unreimbursed care so essential in an agricultural community such as ours. We have no big insurance payors, no one to come to our rescue should we fail.

The costs of providing care in our isolated corner of the state are the same or greater than in the big cities such as Little Rock, over a hundred miles away. With an unemployment rate of 10.4%, we have a great deal of poverty which we try to soften with our food pantry, our salvation army store and our boys and girls club. Ours is a giving community for we know that government does not even know where we are except that we are somewhere in fly-over-country.

I urge you to look at these essential healthcare institutions more as infractructure and utility rather than something else to cut while other government programs continue to increase.

The people of McGehee, Arkansas - Black and White, Well off and poor, have joined together to keep their small hospital - please do not be the agent that forces it to close, another casuality to the urbanization of America. We grow the food and fiber - help keep us healthy as well.

thank you for your time and interest

Bill Conway
310 North 3rd Street
McGehee, AR 71654
wconway@sewark.net

Submitter : **Ms. Belinda Stanley** **Date: 01/19/2007**

Organization : **Medical Asset Management, Inc.**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

Two new codes were created to allow for arterial and venous angioplasty related to dialysis graft procedures in the ASC (Fistula First)- G0392 and G0393. As it relates to the ASC list, there is no S&I code because the ASC fee schedule pays by ASC grouper (Group 9). The language in the final rule states that these codes should be used in the outpatient hospital and the ASC setting. These two codes are also on the OPPS APC list and the physician's fee schedule. Are the physician's supposed to use these codes also to report the same procedures? If so, are they supposed to be reported with an S&I code - 75962 or 75964 (arterial) or 75978 (venous)? Since the purpose of the codes is to allow payment in the ASC setting, why are these codes applicable to the outpatient hospital and the physician? There are no CCI edits related to these codes and no instructions that provide for the correct reporting on the physician side. Is the addition of these codes on the physician fee schedule an error? Is the Outpatient Hospital affected because some ASC's are hospital based? Please provide clarification. From the published comments, these procedures are already safely performed in the hospital setting, which would appear not to require the new codes in an outpatient setting.

Submitter : Mrs. Denise Merlino **Date:** 01/22/2007

Organization : Society of Nuclear Medicine

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1506-FC-11-Attach-1.PDF

#11

snm
advancing molecular imaging & therapy

1850 Samuel Morse Drive
Reston, VA 20190-5316
Tel: 703.708.9000
Fax: 703.708.9015
www.snm.org

January 22, 2007

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

Administrator Leslie Norwalk
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1506-FC

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

Dear Administrator Norwalk:

We are writing in response to the 2007 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule, 71 Fed. Reg. 226, November 24, 2006. The Society of Nuclear Medicine (SNM) representing more than 16,000 physicians, scientists, pharmacists and nuclear medicine technologists appreciates the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the HOPPS.

The SNM appreciates CMS conclusion to finalize the decision to apply status indicator Q to CPT 38792. We believe this new status Q ensures hospitals will be paid appropriately providing the special options needed for their varying billing practices of these services. Additionally, the SNM thanks CMS for recognizing the differences and appropriately separating APC placement of the PET and PET/CT CPT codes. Similarly, we appreciate CMS moving CPT 78806, single study, back to APC 406 and place the multi-day study CPT 78804 in ACP 408 which will maintain clinical and resource homogeneity.

The SNM remains concerned and is disappointed that CMS continues to ignore what we believe are obvious ***clinical*** and ***resource*** differences for a variety of nuclear medicine CPT codes. We understand CMS is basing decisions on the hospital claims data, however we caution that reliance on this single fiscal data point without taking into consideration other clinical and other external information may be misleading. We strongly support CMS use of external data and information supplied by specialty societies in making these decisions and not to rely only on the claims data, which we believe, are flawed when volumes are low. We believe CMS heavy reliance on the claims data is skewing decisions on some APC clinical grouping.. Therefore, we continue to request consideration of separating brain PET from tumor PET imaging for obvious clinical reasons, and we strongly encourage CMS to remove all Cardiac CTA codes from nuclear medicine and place them in their own or other CT APCs to maintain clinical and resource homogeneity. Cardiac CTAs are not nuclear medicine procedures, do not use the same resources, and, they just do not

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belong in any Nuclear Medicine APC. We support ACC and ACR specific recommendation on the Cardiac CTA codes. For similarly reasons of maintaining APC clinical homogeneity we again strongly request that CMS separate single (rest or stress) from multiple (rest and stress) PET myocardial perfusion imaging studies.

The SNM appreciates CMS willingness to continue the 2006 Radiopharmaceutical payment methodology in 2007. The nuclear medicine community is assessing other feasible means to obtain accurate radiopharmaceutical hospital acquisition cost data. The SNM is working with the nuclear medicine community; however, this process is difficult and slow. We will continue to work with CMS to develop the best payment methodology for all radiopharmaceuticals. Of importance to this process is our ability to analyze the current radiopharmaceutical data. CMS made its 2005 claims data available at the 2006 winter/spring APC Panel Meeting, This data and the analysis that CMS shared were extremely helpful. The SNM **encourages CMS to run the 2006 claims data and make it available to the public as soon as it is available.** Such data and analyses are critical in development of an accurate payment methodology for the upcoming year.

We appreciate CMS willingness to understand and account for the unique and varying attributes of radiopharmaceuticals and processes used in Nuclear Medicine procedures provided to Medicare beneficiaries. Again, the SNM appreciates the opportunity to comment on this HOPPS 2007 Final Rule to the CMS. Should you find it appropriate to do so, the SNM is ready to discuss any of its comments on the above issues. Please contact the Society of Nuclear Medicine coding and reimbursement advisor, Denise A. Merlino at dmerlino@snm.org, or at 781-435-1124.

Respectfully Submitted,

Gary Dillehay, M.D., FACR, FACNP
Chairman, Coding & Reimbursement Committee

Kenneth McKusick, M.D., FACR, FACNP
SNM Member, CPT Advisory Committee

cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
James Hart, CMS
Carol Bazell, MD, CMS
Joan Sanow, CMS
SNM Coding & Reimbursement Committee
Nuclear Medicine APC Task Force

Submitter : **Ms. Anne Marie Bicha** **Date: 01/23/2007**

Organization : **American Gastroenterological Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1506-FC-12-Attach-1.DOC

#12

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January 23, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington DC 20201

Re: Medicare Program - Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final rule [CMS-1506-FC]

Dear. Ms. Norwalk:

The American Gastroenterological Association (AGA) appreciates the opportunity to provide comment on the Centers for Medicare and Medicaid Service's (CMS) Final Rule on Revisions to Hospital Outpatient Prospective Payment System (OPPS) for Calendar Year 2007 (CMS-1506-FC, Federal Register, Vol. 71, No. 226, November 24, 2006, p. 67960).

Ambulatory Payment Classification Assigned to CPT 43647 (comment code NI), Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum

In Addendum B of the final rule, CPT 43647 is assigned to APC 0130, Level I Laparoscopy. CPT 43647, a new code effective on January 1, 2007, describes the lead implantation procedures associated with placement of gastric electrical stimulation leads for Enterra Therapy. This neurostimulation therapy may be considered as a treatment option for patients who have chronic nausea and vomiting due to gastroparesis or delayed gastric emptying.

During the procedure, two neurostimulation leads are implanted in the wall of the stomach (antrum area) and are connected to a neurostimulator pulse generator (CPT 64590 is used for implantation of the pulse generator).

It may appear that this new CPT code solely describes a laparoscopic surgical procedure. However, it is important to recognize that this laparoscopic procedure involves placement of neurostimulation leads to stimulate the wall of the stomach. In other words, a laparoscopic technique is used for lead implantation, versus an open surgical procedure.

Since this is a neurostimulation procedure, it should be assigned to an APC that is dedicated to lead implant procedures. In doing so, the clinical and cost characteristics associated with this procedure would be accounted for while APC 0130 does not accurately recognize those. Since incisions are involved in laparoscopic procedures, it would appear that APC 0061, Laminectomy or Incision for Implantation of Neurostimulation Electrodes, would be the most appropriate alternative.

Please contact Anne Marie Bicha, AGA Director of Regulatory Affairs, at 240-482-3223 or abicha@gastro2.org if you have any questions. Thank you.

Sincerely,

David A. Peura, M.D.
Chair, American Gastroenterological Association

Submitter : Mr. Sam D. Finkelstein **Date:** 01/23/2007

Organization : Riverain Medical

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-FC-13-Attach-1.DOC

CMS-1506-FC-13-Attach-2.PDF

#13

Riverain MEDICAL

Early. Detection. Now.

January 22, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1506-FC; Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates - Final Rule

Dear Center for Medicare and Medicaid Services:

Riverain Medical appreciates the opportunity to submit these comments regarding the Outpatient Prospective Payment System (OPPS) Final Rule for Calendar Year (CY) 2007. Riverain Medical is a healthcare company that offers chest radiography (CXR) computer-aided detection (CAD) hardware and software for early lung cancer detection, which is PMA approved by the FDA. Riverain Medical is committed to being a leader and innovator in CAD and diagnostic technologies that significantly aid medical practitioners in the early-stage detection of diseases.

Riverain Medical is commenting on the proposed payment of CXR CAD in the final OPPS Rule for CY 2007. Under the final rule CXR CAD, described by Category III Current Procedural Terminology (CPT) codes 0174T and 0175T, will not receive a separate APC payment in CY 2007 because of CMS' decision to assign it a status indicator of "N." CMS also decided to bundle payment for CXR CAD into payment for APC 0260, Level I Plain Film Except Teeth.

Riverain Medical disagrees with CMS' decision to assign CXR CAD a status indicator of "N" and bundle it into payment for APC 0260 for CY 2007. CXR CAD should be assigned to APC 1492 with a status indicator of "S".

Background

For your convenience, the CPT codes are provided on the AMA web site (http://www.ama-assn.org/ama1/pub/upload/mm/362/07catiiicodes121506.pdf are:

> 0174T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation, and
>
> 0175T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.

Extensive data on the ability of CXR CAD to detect lung cancers from numerous studies was presented to the Advisory Panel on Ambulatory Payment Classification Groups (Advisory Panel). Having heard the evidence, the Advisory Panel voted that 0175T should be packaged

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with additional payment using a status indicator of "Q". However, the final minutes of the meeting indicate that the Advisory Panel's final recommendation was not to provide additional payment, and CMS accepted this final recommendation.

While we accept that the Advisory Panel recommended CMS assign status indicators of "N" to 0174T and 0175T for CY 2007, we respectfully disagree with their final recommendation and ask that CMS assign status indicators of "S" and place them in New Technology APC 1492 with a payment rate of $15. We maintain that a modest new technology payment under APC is consistent with payment precedents, will improve outcomes for Medicare beneficiaries, and may be less costly.

Summary of supporting rationale

We understand that this letter is long because of all the reasons that support our request for reassignment. Consequently, we summarize the key reasons to change CMS' decision below. Each point is addressed at length after the summary. The numbers match the section where the reason is addressed.

1. Third-party payers paid $27.00 for use of CXR CAD
   - Private payer payment of $27 is consistent with Medicare payment of $15.
2. The original vote by the APC panel on August 23, 2006 was to assign a "special" packaged code ("Q" status) to 0175T
   - "Remote" can be a different time, place, or physician.
   - Providers may not have "arrangements" for reimbursement for CXR CAD.
3. CXR CAD will *not* be reimbursed when bundled with chest x-ray by driving the median cost higher
   - The median will be increased only by $2.00 with 50% utilization of CXR CAD.
   - Riverain Medical is not promoting over-utilization of CXR CAD but CMS's decision may cause over-utilization in order to obtain reimbursement.
4. Continuous product improvement lowers false positives
   - Lower false positives should reduce the call back rate.
5. CT, MRI, and PET are expensive ways to detect lung cancer
   - CT, MRI, and PET could be used routinely when CXR CAD is not available.
   - CT, MRI, and PET will likely be used only when the radiologist using CAD suspects lung cancer.
   - CT, MRI, and PET payment for 2007 are $298, $349, and $855, respectively, based on the final rule.
   - The cost of CT screening is estimated to be $115 billion. The estimated cost of paying for the use of CXR CAD, which is not screening, is $250 million over 5 years and $1 billion over 10 years.
   - CT subjects patients to large amounts of radiation. CXR CAD does not add any radiation because it uses existing chest x-rays taken for medical reasons.
   - More lung cancers are detected from chest x-rays than from chest CT.

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- CXR CAD was proven to help radiologists detect more than 20% additional cancers 9-14 mm.

6. CXR CAD is a diagnostic tool, not a screening test
   - There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.
   - Riverain Medical's CXR CAD was developed and was shown, to help radiologists detect early stage lung cancer.
   - Studies show that CXR CAD identified 37% of cancers, and 38% of patients, whose cancers were *not* detected by radiologists in clinical practice. These results were reported by researchers at the University of Chicago and University of Maryland. These patients could have been diagnosed earlier with CXR CAD.
   - One study showed that approximately two-thirds of patients with early stage lung cancer present with pulmonary symptoms. The authors concluded that "a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis."
   - The American College of Chest Physicians' guidelines recommend a chest x-ray for patients with cough and risk factors for lung cancer or metastatic cancer.
   - CXR CAD is a diagnostic tool that identifies patients who are most likely to benefit from further work-up; potentially avoiding a more expensive workup.
   - Therefore, CXR CAD should improve the early detection of lung cancer and the clinical outcomes for such patients.
   - CXR CAD is used by the radiologist separately from and after s/he interprets the chest x-ray.
   - CMS could establish reasonable coverage restrictions to limit the use of the technology, instead of not paying for its proper use.
   - The cost-effectiveness is very high for a $15 payment for CXR compared to using CT, MRI, or PET before further workup is indicated.
7. Use of CXR CAD *acts* like a prevalence screen and will therefore find lung cancers
   - Prevalence screens detect more lung cancers than incidence screens.
   - Chest x-rays are typically taken on different patients each year.
   - Therefore, use of CXR CAD is likely to be a highly effective and highly cost-effective way of detecting lung cancers in early stages in patients who are symptomatic *without screening*.
8. CXR CAD should *not* be bundled into the APC Payment for chest x-ray (APC 0260).
   - CMS policy is to bundle payments for two procedures when the resources used to provide those procedures cannot be distinguished.
   - If the median of APC 0260 drives reimbursement, then hospitals that use CXR CAD are penalized; those who do *not* are rewarded. Users need to buy separate equipment and thus have expenses related to its use.
   - $15 is 34.4% of $43.60, the payment for APC 0260 in 2007. This percentage is too high for hospitals to absorb.

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- Other radiologic procedures that are similar to CXR CAD are paid separately:
  - Three dimensional post-image processing,
  - Mammography CAD, and
  - Radiology guidance procedures.
- By not making separate payment for CXR CAD, CMS has made it more likely that hospitals will not make CXR CAD available to Medicare beneficiaries.
- CXR CAD should be paid separately under OPPS as a matter of policy consistency.
- CXR CAD should be paid separately under OPPS as a matter of fairness.
- CXR CAD should be paid separately under OPPS to allow access to Medicare beneficiaries.

9. APC Assignment for CXR CAD

- CXR CAD is a new technology, has a CPT Category III code and should be assigned to new technology APC 1492, with a category "S" status indicator.

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Supporting Rationale

1. Third-party payers paid $27.00 for use of CXR CAD

Third-party payers paid $27 for the use of CXR CAD (via CPT code 0152T in CY2006)[1]. The payers represent approximately 60 million covered lives. Payment of $27 by third-party payers is consistent with a payment of $15 by Medicare.

2. The original vote by the APC Advisory Panel on August 23, 2006 was to assign a "special" packaged code ("Q" status) to 0175T

Riverain Medical is not certain how and why this APC Advisory Panel vote was overturned. However, based on the comments with the final rule, "They questioned the meaning of the word "remote" in the code descriptor for CPT code 0175T, noting that is was unclear as to whether "remote" referred to time, geography, or a specific provider. They thought it was likely that a hospital without a CAD system that performed a chest x-ray and sent the x-ray to another hospital for performance of the CAD would be providing the CAD service under arrangement and, therefore, would be providing at least one other service (chest x-ray) that would be separately paid." While all three conjectures are accurate, it is important to note that providers of CAD do not necessarily have "arrangements" to read CAD. The attached letter indicates that "arrangements" may not exist and reimbursement for the CAD reading is necessary to provide the service.

3. CXR CAD will not be reimbursed when bundled with chest x-ray by driving the median cost higher

We disagree with CMS's supposition, "To the extent that CAD may be more frequently provided in the future to aid in the review of diagnostic chest x-rays as its clinical indications evolve, we expect that its cost would also be increasingly reflected in the median costs for chest x-ray procedures." Chest x-rays make up 51% of the utilization of APC 0260. Consequently, even with 50% utilization of CXR CAD, only 25.5% of the APC class is affected. Using CMS data provided with the preliminary rule and a $15 payment amount the actual reimbursement changes according to the chart and numbers below, based on a simulation. In particular, note that with a 50% utilization of CAD on existing chest x-rays the hospital can expect to receive only $2; $1 for the CXR CAD and $1 for the 49% of other procedures in the APC. $9 is paid when 75% of chest x-rays are read with CAD. $14 is paid for 95% utilization. Riverain Medical is neither promoting over-utilization of CXR CAD nor screening; CXR CAD is not expected to have high enough utilization to materially affect the median. CMS policy of not providing separate payment may promote over-utilization in order to obtain reimbursement.

[1] *Aunt Minnie* October 24, 2006. Aunt Minnie is the largest and most comprehensive community Web site for medical imaging professionals worldwide.

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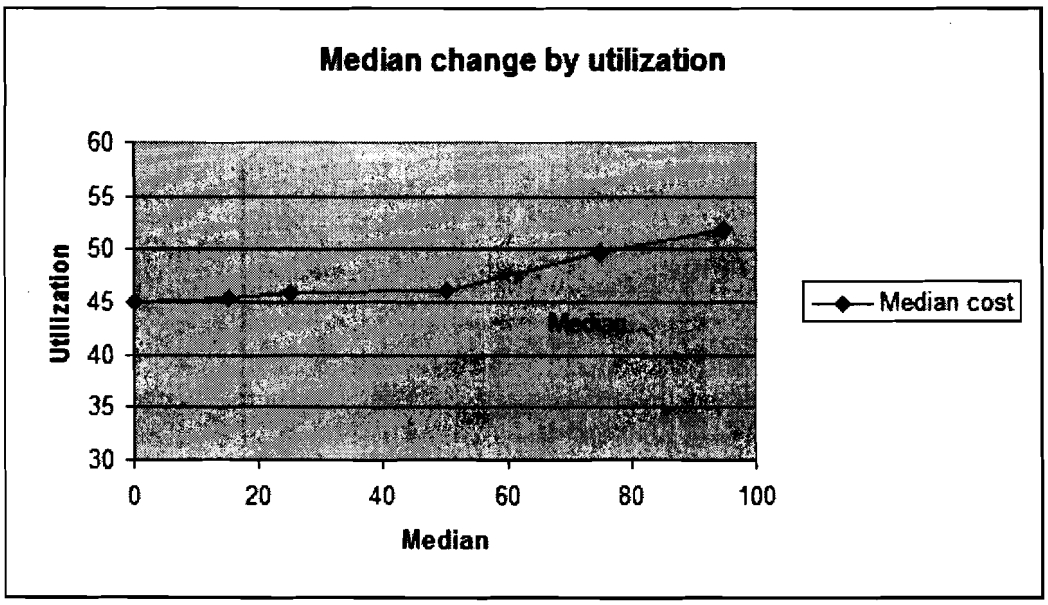

Hospital Analysis; Every procedure in APC 0260 is paid more when median increases

Example 1: 95% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$7	chest x-ray
Other APC 0260	49	$7	Other APC 0260
		$14	Total to hospital

Example 2: 75% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$5	chest x-ray
Other APC 0260	49	$5	Other APC 0260
		$9	Total to hospital

Example 3: 50% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$1	chest x-ray
Other APC 0260	49	$1	Other APC 0260
		$2	Total to hospital

* Note that % utilization refers to % of the APC group. The utilization of chest x-ray remains at 51% because Riverain Medical is *not* advocating screening. The examples given here change the usage of CXR CAD on the constant number of chest x-rays.

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4. Continuous product improvement lowers false positives

On November 1, 2006 FDA approved Riverain Medical's PMA supplement for the newest version of its CXR CAD, which lowers the false positive rate by 30%. This achievement should translate into fewer call backs for further work up.

5. CT, MRI, and PET are expensive ways to detect lung cancer

The results of a large collaborative study conducted by the International Early Lung Cancer Action Program (I-ELCAP) investigators were reported in the October 26, 2006 New England Journal of Medicine[2]. The investigators concluded, "We found CT screening for lung cancer to be highly cost-effective". However a study published in JAMA in 2003[3] indicated that "The total societal cost for an annual helical CT screening program of at-risk ever-smokers is very high. An estimated 50 million men and women in the United States are ever-smokers between the ages of 45 and 75 years. If 50% of this group received periodic annual screening, the program costs are approximately $115 billion (discounted) based on our study estimates." Compare that to the Congressional Budget Office's (CBO) estimate of the cost of CXR CAD, $250 million over 5 years and $1 billion over 10 years[4].

Another cost besides the dollar cost of finding lung cancer with CT screening is the radiation cost. Radiation causes cancer. CXR CAD does not add any radiation to that of the chest x-ray.

CXR CAD used on existing chest x-rays is a cost-effective alternative. More lung cancers were found on routine chest x-rays (101) than CT scan (32) in a retrospective chart review covering more than 5 years of lung cancer patients referred to the Weill-Cornell Medical College thoracic surgery service with biopsy proven non-small-cell lung cancer (NSCLC) who were asymptomatic at presentation[5]. Weill-Cornell Medical College is one of the ELCAP centers. The actuarial 5-year survival in the CXR group was 84% of stage IA, 55% for stage IB and 28% for all other stages combined. Unfortunately, only 39% of cancers in stage IA were found on chest x-rays. More lung cancers could have been found with CXR CAD because CXR CAD was proven to help radiologists detect more than 20% additional 9-15 mm lung cancers.[6] It makes more sense to allow CXR CAD to be used on chest x-rays than to subject patients to CT because CXR CAD costs less in dollars and in radiation exposure to patients. CMS can help the fight against lung cancer by providing a separate reimbursement for CXR CAD.

The cost for a CRX CAD image is too high for a hospital to absorb under the $43 payment obtained for an X-ray. Hospitals without CRX CAD are more likely to refer patients internally to a spiral CT, MRI, or PET scan if the diagnosis is uncertain. The payment for a CT (HCPCS 71275), MRI (HCPCS 71550), or PET (HCPCS 78811) are $298, $349, and $855, respectively. Contrast that with the situation that the physician chooses a CXR CAD image. S/he would

[2] The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med* 2006;355:1763-71.
[3] Mahadevia PJ, Fleisher LA, Frick KD, et al. Lung cancer screening with helical computed tomography in older adult smoders; A decision and cost-effectiveness analysis. *JAMA* 2003;289:313-322.
[4] Analysis by Congressional Budget Office November 2006.
[5] Altorki N, Kent M, and Pasmantier M. Detection of early-stage lung cancer: computed tomographic scan or chest radiograph? *J Thorac Cardiovasc Surg* 2001;121:1053-7.
[6] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

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simply refer the x-ray to a center that has that technology and let that center file for reimbursement.

6. CXR CAD is a diagnostic tool, not a screening test

There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.[7] Patients who have smaller primary lung tumors at diagnosis have better clinical outcomes than patients with large tumors at diagnosis. CXR is currently the most frequently used test to detect lung lesions that are suspicious for lung cancer. Unfortunately, CXR is a poor test for detecting cancers that are less than 14 mm in size. For example, one study found that radiologists missed 71%, 28%, and 12% of lesions $\leq$ 10 mm, 10-30 mm, and 30-40 mm, respectively. The authors estimate a 23% drop in five-year survival for those patients whose lung cancers were missed.[8] Another study indicated that survival is correlated with pathological stage (pStage) of detection where pStages IA, IB, IIA, IIB, and IIIA were associated with 67%, 57%, 55%, 39%, and 23%, respectively[9]. Therefore, a diagnostic tool that can detect lung lesions when they are small in diameter and in an early pathological stage should result in earlier detection and treatment of lung cancer. Riverain's technology for CXR CAD is a PMA approved diagnostic tool available for this purpose. Moreover, recent evidence has shown that early detection and treatment of lung cancer with chemotherapy is correlated with prolonged five-year survival rates.[10] The I-ELCAP investigators reported a 92% 10-year actuarial survival rate of patients with clinical stage I cancer who underwent surgical resection within 1 month after diagnosis[11]. The body of evidence indicates that CXR CAD should improve clinical outcomes for these patients.
CXR CAD identifies regions of interest on CXRs that may represent nodules, which could be early-stage lung cancer. It employs a multi-step image enhancement and analysis processing system that consists of a series of algorithms and classification technologies to identify regions that may contain indications of cancer and isolating them from the normal structure of the heart, blood vessels, ribs and other structures of the chest. The system includes digital image processing for noise reduction, image enhancement, anatomy segmentation, feature extraction, pattern recognition, neural network computing, and fuzzy logic.

A recent study conducted at the University of Chicago indicated that 37% of missed lung cancers could have been detected earlier if CXR CAD was used. Similarly, a recent study at the University of Maryland demonstrated that 38% of the patients with missed lung cancer could have been detected earlier if the x-rays were interpreted with CXR CAD.

One study showed that approximately 2/3 patients with early stage lung cancer present with pulmonary symptoms[12]. The authors concluded that, "...a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis." The American College of Chest

[7] Mery, C.M., Pappas, A.N., Burt, B.M., et al. Diameter of non-small cell lung cancer correlates with long-term survival implications for T stage. *Chest, 2005*(128), 3255-3260.
[8] Quekel L, Kessels A, Goei R, et al. Miss rate of lung cancer on the chest radiograph in clinical practice. *Chest*, 1999(115), 720-724.
[9] Mountain, C.E., Revisions in the international system for staging lung cancer. *Chest*, 1997(111), 1710-1717.
[10] Winton, T., Livingston, R., Johnson, D., et al. Vinorelbine plus cisplatin vs. observation in resected non-small-cell lung cancer. *N Engl J Med, 2005*(352), 2589-2597.
[11] The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med* 2006;355:1763-71.
[12] Christensen ED, Harvald T, Jendresen M, et al. :The impact of delayed diagnosis of lung cancer on the stage at the time of operation *European Journal of Cardio-thoracic Surgery* 12 (1997), 880-884.

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Physicians' guidelines recommend a chest x-ray for patients with cough and risk factors for lung cancer or metastatic cancer[13]. Such patients with suspicious chest x-rays could benefit from CXR CAD.

CXR CAD is not a chest x-ray and is not a screening test. CXR CAD is not a screening test; it is a diagnostic tool that identifies symptomatic patients who are most likely to benefit from additional workup.

CXR CAD is performed separately from, and after, a CXR when there is a finding from the patient's history and physical (e.g., a smoker with bloody sputum) that indicates a high risk of lung cancer and/or the radiologist continues to be suspicious of lung cancer after interpreting the CXR. CXR CAD results in the production of new images, which must be read by a radiologist, in addition to the initial CXR images. Typically, the radiologist will review the CXR CAD images side-by-side with the CXR images in order to determine whether a lesion requires further work-up. CXR CAD independently identifies suspicious and/or subtle nodules the radiologist may have not seen on the CXR.

Data submitted by Riverain Medical to the FDA[14] in order to obtain PMA (premarket approval) shows that use of CXR CAD for select patients results in a significantly higher sensitivity for lung cancer detection. Ultimately, because CXR CAD is able to identify patients who may benefit most from chest CT, CXR CAD use may result in an increase in true positives found on chest CT scans and a significant reduction in total chest CT scans performed to follow up on suspicious CXR findings.

There is no basis for believing that CAD will increase the number of CXRs performed in the outpatient or office setting because CXR CAD is not a screening tool and is not applied "automatically" to screening CXRs. It should be applied only to CXRs suspicious for lung cancer on the basis of a high prior probability of lung cancer based on a patient's history or physical examination. Using CXR CAD for screening is not its proper use.

CMS is justifiably concerned about the impact of costs of new technology on the Medicare Trust Fund. We often heard behind the scenes that CMS is concerned that every lung X-ray will receive CRX CAD. We disagree. As an alternative to effectively making the technology non-covered for all indications through payment policy, CMS could establish reasonable payment and then have appropriate coverage restrictions to prevent inappropriate overuse of this technology. CMS may wish to consider the savings from avoiding substantially more expensive imaging modalities. At $15, the cost-*effectiveness* of CRX CAD is very high. Contrast that cost with the cost of CT, MRI, or PET.

Riverain Medical understands that Medicare does not pay for screening. Comparisons made in sections *§5. CT, MRI, and PET are expensive ways to detect lung cancer* (above) and *§7. Use of CXR CAD acts like a prevalence screen and will therefore find lung cancers* (below) should not be misconstrued to think that CXR CAD is screening. These comparisons are made to show that CXR CAD can be a cost-effective alternative to CT screening. Expected results would be that many lung cancers could be detected early at a fraction of the costs. Annual screening

[13] Kvale, P.A. Chronic cough due to lung tumors: ACCP evidence-based clinical practice guidelines. *Chest, 129*(1), 147S-153S, January 2006 Supplement.
[14] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

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with CT would find more lung cancers but at a much higher price, as discussed in §5. *CT, MRI, and PET are expensive ways to detect lung cancer.*

7. Use of CXR CAD acts like a prevalence screen and will therefore find lung cancers

The I-ELCAP study discussed above found 348 (84%) lung cancers on baseline (prevalence) screening. Only 64 (16%) lung cancers were found on annual (incidence) screenings. The use of CXR CAD on existing chest x-rays will be similar to prevalence screening because typically new (different) patients are x-rayed each year, not the same patient x-rayed at designated intervals. CXR CAD may be an effective alternative to instituting a costly CT screening program.

8. CXR CAD should not be bundled into the APC Payment for CXR

It is inappropriate to bundle payment for CXR CAD into the payment for CXR, APC 0260.
CMS policy is to bundle the costs of two procedures when the resources used to provide those procedures cannot be distinguished. For example, the vast majority of radiology related procedures with status indicator "N" are "injection" procedures (e.g., injection of contrast into a blood vessel) where the hospital also bills for the actual x-ray as well. It is extremely difficult, if not impossible, for the hospital or CMS to distinguish between the cost of the "injection" and the cost of the x-ray itself.

Bundling APC 0260 does not and is not likely to ever cover costs of CXR CAD. For those who use CXR CAD, cost is never recovered because it applies to only one procedure in the APC (CXR) and to a vast minority of those procedures. Costs will always be incompletely reflected in APC payment. A user of CXR CAD always ends up with incomplete reimbursement for expense of providing CXR CAD. In effect, those hospitals that do *not* use CXR CAD are rewarded while those that use CXR CAD are penalized. As discussed in §3. *CXR CAD will not be reimbursed when bundled with chest x-ray by driving the median cost higher.* An analysis of the utilization data that CMS provided with the proposed rule indicates that the median is not likely to be impacted unless CXR CAD is used in a very high percentage of chest x-rays. Riverain Medical does not expect that utilization of CXR CAD, if it is assigned a status indicator of "N," will ever be high enough to appropriately and adequately change the median cost of procedures in APC 0260.

Please note that $15.00, the requested payment amount, is 34.4% of $43.60, the payment for APC 0260 in 2007. 34.4% is a very high percentage of total payment. It is much higher than is typically associated with bundled procedures. In fact, CMS recognizes that low-cost new technologies should be paid separately because it established new technology APC's for that very purpose. Note also that $15.00 is consistent with payments by third-party payers, as discussed in §1. *Third-party payers paid $27.00 for use of CXR CAD.* The cost for a CRX CAD image is too high to absorb under the $43 payment obtained for an X-ray. Hospitals without CRX CAD are more likely to refer patients internally to a spiral CT, MRI, or PET scan if the diagnosis is uncertain. However, if the physician prefers a CXR CAD analysis, they would simply refer the x-ray to a center that has CXR CAD technology and let that center file for reimbursement.

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Separate resources are necessary for CXR CAD. The resources, including the staff and equipment needed to deliver CXR CAD, are completely different, and distinguishable from those required to perform a CXR. Specifically, CXR CAD requires special software, hardware, information systems, and information technology staff whereas taking a CXR requires an x-ray machine, a radiology technician, and software that is entirely different from CXR CAD software.

Furthermore, CXR CAD is not only performed separately from a CXR, but is performed, not infrequently, at a different time and/or location and/or by a different radiologist from the CXR ("remote"). Typically this happens when a CXR is obtained in the emergency department at one time with the interpretation performed (by a radiologist) at another time. The interpretation would include a recommendation that CAD be applied to the images. Subsequently, after discussion with the treating physician, CAD is ordered and applied to the original CXR images on a different day. In this situation it is appropriate for the hospital to bill separately for CAD because it is an entirely different procedure performed on an entirely different day from the CXR. This example illustrates that the resources required for CXR CAD are entirely different from the resources required for CXR and thus it is inappropriate to bundle payment for CXR CAD into payment for CXR.

The FDA recognized that CAD would be performed after reading the chest x-ray. The labeling for the device states, "The device is intended for use as an aid only after the physician has performed an initial interpretation of the radiograph."

The American Medical Association (AMA) recognizes that CXR can be read remote from the chest x-ray and created CPT Code 0175T for that use.

Below are several examples of radiologic procedures that are similar to CAD yet paid separately:

- **Three-dimensional post-image processing** - CMS, in the OPPS final rule for CY 2006, announced it would make separate payment for CPT codes 76376 and 76377, "3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image post-processing on an independent workstation" (76376), and "requiring image post-processing on an independent workstation" (76377). These codes are used to report the use of image post-processing technologies similar to CXR CAD and, just like CXR CAD, the resources (e.g., the software, hardware, and staff time needed to apply computer algorithms to radiologic images) used to generate these new images are entirely different, and distinguishable from, the resources used to generate the original images (e.g., the CT scan). These technologies, like CXR CAD, generate new images that must be interpreted in addition to (i.e., side-by-side with) the original radiologic (or MRI) images. CMS assigned CPT codes 76376 and 76377 to APC category 0340 and 0282 with a payment rate of $37.51 and $37.81, respectively, for CY2007.

- **Mammography CAD** - Mammography CAD, CPT code 76082, Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography, is paid separately under OPPS. Because separate payment, at the same rate as under the Medicare Physician Fee Schedule (MPFS), is required by statute, the same policy should be applied to CXR CAD.

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- **Radiology "guidance" procedures** - CMS makes separate payment for radiology "guidance" procedures. These are procedures where radiology equipment such as a CT scanner is used at the time of a surgical procedure to help "guide" the surgeon to improve the outcome or reduce the risk of a procedure such as a tumor removal or biopsy. This policy exists because CMS recognizes that the resources used to provide "guidance" are different and distinguishable from the resources used to perform the surgical procedure.

By not making separate payment for CXR CAD, CMS has made it more likely that hospitals will not make CXR CAD available to Medicare beneficiaries. CXR CAD represents an additional and non-reimbursable cost to the hospital above and beyond the cost of a CXR. If hospitals, especially rural and smaller community hospitals, are not paid separately for CXR CAD, they may be less likely to invest in this technology, thereby denying beneficiary access to CXR CAD. In addition, mammography CAD and three dimensional post-processing imaging are paid separately, creating an incentive for hospitals to provide those technologies but not CXR CAD. This is unfair and does not permit the marketplace to assess the true value of CXR CAD as it does for the other comparable technologies. Bundling creates an unfair playing field and does not allow the marketplace and the medical community to determine the value of CAD and make a judgment as to its relative costs and benefits. CMS should not substitute its own value judgment for that of the marketplace. More importantly, however, not having CXR CAD available may limit the quality of care afforded to patients who may have lung cancer. Please note that two-thirds of lung cancer patients are diagnosed at age 65 years old or older. Denying beneficiary access to CXR CAD is effectively delaying their chance of early detection and treatment (i.e., reducing their chance of surviving lung cancer).

CXR CAD should be paid separately under OPPS both as a matter of policy consistency and as a matter of fairness. Separate payment for post-processing technologies is consistent with current CMS policy and bundling is a deviation from that policy. CXR CAD is a new technology with its own Category III CPT codes and OPPS policy is to assign a payment amount to Category III CPT codes irrespective of their costs or clinical benefits.

9. APC Assignment for CXR CAD

A Payment of $15 should be made for CXR CAD. This technology represents a significant additional cost to the hospital above and beyond the cost of other radiology supplies and equipment. We propose that CXR CAD be placed in APC 1492 with status indicator "S", with a payment rate of $15. A payment rate of $15 will enable hospitals to be reimbursed for the cost of purchasing and using CXR CAD. Alternatively, we propose assigning a status indicator of "Q" to 0174T and 0175T in CY 2007 with a separate payment of $15. We would like to point out that in August 2006 the Advisory Panel on Ambulatory Payment Classification Groups initially voted to recommend a "Q" status for 0175T with additional payment for its use.

Conclusion

CXR CAD identifies regions of interest on CXRs that are suspected nodule sites, an important indicator of early lung cancer. For CY 2007, CMS gave CXR CAD a status indicator of "N" and bundled it into payment for APC 0260. Resources used to deliver CXR CAD are completely different from those required to perform a CXR. Riverain Medical disagrees with the Advisory

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Panel on Ambulatory Payment Classification Groups' final recommendation to assign CXR CAD technology a status indicator of "N" and bundle it into payment for APC 0260. We request, as a matter of policy consistency, fairness, and Medicare beneficiary access, that CMS make a separate payment for CXR CAD and change the status indicator of CPT code 0174T and 0175T in CY 2007 to "S" and assign it to APC 1492 with a payment rate of $15.

We appreciate the opportunity to submit these comments on the Proposed Rule CMS-1506-FC and would be happy to answer any questions you may have. I may be contacted at 800.990.3387 or my mobile phone at 330.284.3264.

Thank you for your consideration of separate payment for chest x-ray computer-aided detection.

Sincerely,

RIVERAIN MEDICAL

Sam D. Finkelstein

Sam D. Finkelstein
President
Riverain Medical

Attachment: Letter from Rocky Pahwa, CEO AZ-Tech Radiology & Open MRI

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AZ-TECH RADIOLOGY & OPEN MRI

Open MRI, MRA Ultrasound, CT, X-Ray, Bone Density, & Mammography

Date: December 18, 2006

To: Riverain Medical
3020 South Tech Boulevard
Miamisburg, OH 45342

Dear Riverain Medical,

I am writing to ask for coding and reimbursement guidance. My radiology group practices in a rural area of Arizona. None of the hospitals or physicians offices in our area offer computer aided detection (CAD) for chest x-rays. As you know, we offer CAD in our practice and we plan to offer CAD to the hospitals and physicians in our area who do not provide it.

These other providers will send us film or digital chest radiographs after they determine that CAD is medically necessary. Because the other providers do not want to enter into a business arrangement with us, we will bill Medicare and other payers for CAD while the other providers will bill for the chest film. The current CPT code for CAD is an add-on code, which means we will be unable to use it because we are not billing for interpreting the chest film. Please advise us on how we can bill for CAD under these circumstances. If we cannot be reimbursed for CAD then we will not be able to provide it.

Thanks,

Rocky Pahwa
CEO

Submitter : **Ms. Tamar Thompson** **Date: 01/23/2007**

Organization : **Bracco Diagnostics Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment letter.

CMS-1506-FC-14-Attach-1.PDF

#14

BRACCO

LIFE FROM INSIDE

January 23, 2007

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

VIA: Electronic Submission

Re: Medicare Program; Revisions to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final Rule
FILE CODE CMS-1506-FC

Dear Administrator Norwalk:

Thank you for providing Bracco Diagnostics Inc. with this opportunity to submit comments on the 2007 revisions to the hospital outpatient prospective payment system (HOPPS) and calendar year 2007 final the November 24, 2006 Federal Register. Bracco Diagnostics Inc. is a global manufacturer of contrast imaging agents and radiopharmaceuticals used in medical imaging procedures. The products that we offer are used in many outpatient hospital procedures performed in radiology departments, cardiac catheterization laboratories, and nuclear medicine departments across the United States.

In this letter, we are specifically commenting on the exemption of Ambulatory Payment Classification (APC) 0307 myocardial PET imaging procedures from the 2 times rule, payment changes for myocardial Positron Emission Tomography (PET) perfusion imaging (multiple studies), and payment policies for drugs, biologicals and radiopharmaceuticals.

HOPPS 2 Times Rule

Bracco is disappointed that the Centers for Medicare and Medicaid Services (CMS) has eliminated the two separate APCs (0306 and 0307) for myocardial PET imaging procedures and excepted myocardial PET imaging multiple studies from the two times rule. We remain firm in our position that splitting the single studies and viability studies into separate APCs from the multiple studies is consistent with the clinical resources and homogeneity of this and other nuclear medicine studies.

107 College Road East Princeton NJ 08540 Telephone (609) 514-2200 Fax (609) 514-2429

Myocardial PET Scans

Bracco is troubled by CMS' decision to reduce payment for myocardial PET procedures by more than 70% for calendar year 2007. We believe that this significant payment reduction will compromise Medicare beneficiary access to high quality services involving new technologies because hospitals may discontinue providing these procedures because they can no longer afford to furnish them under these rates.

Further, we ask CMS to consider the devastating impact that this rate reduction brings to the physician office community because the Deficit Reduction Act (DRA) of 2005 now limits payment for the technical component (TC) in the physician office setting to the lesser of the HOPPS payment rate or the Medicare Part B Physician Fee Schedule (MPFS) payment rate. While we understand that CMS can not set payment rates for the HOPPS environment based on the provisions of the DRA surely, CMS understands that the clinical resource utilization in the physician offices is dramatically different than that of a hospital environment for these procedures.

Radiopharmaceutical Payment Policy

Bracco applauds CMS decision to continue using the 2006 payment methodology for radiopharmaceuticals. And, we appreciate CMS' decision to work with the nuclear medicine community in 2007 to determine the appropriate methodology for obtaining hospital acquisition cost data for radiopharmaceuticals.

Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with Healthcare Common Procedural Code System (HCPCS) Codes, but without HOPPS Claims Data

Bracco continues to disagree with CMS' recommendation to package payment for HCPCS code J2805, Sincalide injection (brand name Kinevac®). We believe that it was inequitable to bundle payments for this product simply because there was not claims data on file to support the separate payment threshold of $55.00.

Bracco recognizes the challenges that CMS faces in revising and finalizing hospital payment methodologies. We welcome the opportunity to meet with CMS to expand upon these comments in greater detail. You may contact me at 609-514-2274 or via email at tamar.thompson@diag.bracco.com.

Respectfully,

Tamar Thompson, RMA, CCS, CCS-P
Manager, Health Economics

107 College Road East Princeton NJ 08540 Telephone (609) 514-2200 Fax (609) 514-2429

Submitter : **Mr. Michael Wittek** **Date: 01/23/2007**

Organization : **Medtronic, Inc.**

Category : **Device Industry**

Issue Areas/Comments

ASC procedures that were not proposed for addition to the ASC list

ASC procedures that were not proposed for addition to the ASC list

CPT 43647 Laparoscopy, surgical implantation or replacement of gastric neurostimulator electrodes, antrum

GENERAL

GENERAL

See attachment

CMS-1506-FC-15-Attach-1.DOC

CMS-1506-FC-15-Attach-2.DOC

#15

Medtronic Gastroenterology and Urology

January 23, 2007

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

ELECTRONIC SUBMISSION

RE: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates [CMS-1506-FC]

Dear Administrator Norwalk:

Medtronic, Inc. is one of the world's leading medical technology companies specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high quality products and to support innovative therapies that improve health outcomes. We appreciate the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2007 Payment Rates published in the Federal Register on November 24, 2006.

Our comments focus on the assignment of new CPT code 43647 *Laparoscopy, surgical implantation or replacement of gastric neurostimulator electrodes, antrum.* In the final rule, this code has a comment indicator of "NI" indicating that the assignment of the code to APC 0130 is interim and that comments will be accepted.

We do not believe that the assignment of code 43647 to APC 0130 is appropriate in terms of the clinical characteristics and resource costs. We recommend that the code be reassigned to APC 0061 *Laminectomy or Incision for Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.* Our rationale for this proposal is provided following a brief description of the therapy, our New Technology APC application and recent changes in CPT.

Gastric Neurostimulation and Medtronic's Enterra® Therapy

Enterra Therapy is indicated for the treatment of intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. Gastroparesis is a stomach disorder in which food moves through the stomach more slowly than normal. In some patients, this condition results in severe, chronic nausea and vomiting that cannot be adequately controlled by available drugs. These patients have difficulty maintaining their nutritional needs, and may require some form of tube feeding to ensure adequate nutrition.

Enterra Therapy uses mild electrical pulses to stimulate the stomach. This electrical stimulation reduces the symptoms of nausea and vomiting associated with gastroparesis. Enterra Therapy is an implantable system, which requires a neurostimulator and two implantable leads. These comments address the interim APC assignment for the implantation of the leads only (CPT code 43647).

On September 27, 2006, Medtronic submitted an application for a New Technology APC for the outpatient hospital services associated with Enterra Therapy. At the time this application was submitted, information about the new CPT code 43647 (and three related codes) was not available to the public.[1] On January 18, 2007, we received a letter indicating that our application was not approved for the following reasons:

1. The service is described by existing HCPCS codes or combination of HCPCS codes.
2. The service can reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs.

Following receipt of this denial, we reviewed our application, the CMS median cost data and the current APC coding structure. While we are disappointed by the denial of our application and do not agree with the first reason for the denial, we acknowledge that the code could reasonably be placed in an existing APC. However, in terms of clinical characteristics and resource costs, that APC is not APC 0130 *Laparoscopy, Level I* as CMS decided but rather APC 0061 *Laminectomy or Incision for Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.*

Rationale for Reassignment of Gastric Neurostimulation Code 43647 to APC 0061

The clinical characteristics of CPT code 43647 are much more consistent with the codes for the placement of neurostimulator electrodes in APC 0061 than they are with the codes in APC 0130 which is dominated by diagnostic laparascopy and hernia repair codes.

[1] CPT 2007 includes 4 codes related to Enterra Therapy (43647, 43648, 43881 and 43882). Our comments address only code 43647.

In our New Technology APC application, we provided a detailed description of the implantation procedure (Attachment 1). It is important to note that CPT code 43647 describes the implantation of the electrodes by a laparascopic approach. CPT 2007 also includes new CPT code 43881 *Implantation or replacement of gastric neurostimulator electrodes, antrum, open.* This procedure is appropriately placed on the "inpatient only" list. We make note of this code to highlight the fact that the terminology of code 43881 is focused on the implantation of the electrodes while the terminology of code 43647 is focused on the laparascopy, rather than the implantation. We believe this may be one of the reasons why code 43647 was assigned to APC 0130 *Laparoscopy, Level I.*

We also believe that CMS may have assigned code 43647 to APC 0130 *Laparoscopy, Level I* because this APC also includes the following Category III codes:

- 0155T Laparoscopy, surgical, implantation or replacement of gastric stimulation electrodes, lesser curvature (ie, morbid obesity)
- 0156T Laparoscopy, surgical, revision or removal of gastric stimulation electrodes, lesser curvature (ie, morbid obesity)

While these codes involve gastric neurostimulation, it is important to note that there are no commercial products on the market for these procedures. Consequently, it is unlikely that CMS received public comments on the assignment of these codes to APC 0130 and we ask that CMS not cite them as the basis for assigning Enterra Therapy to APC 0130 *Laparoscopy, Level I.*

In our New Technology APC application, we also provided a detailed description of the resources needed for implantation (Attachment 2). We estimated a total cost of $6,724. Of this amount, $4,400 ($2,200 per lead)* or 65 percent is attributable to the neurostimulator electrodes. There are no procedures assigned to APC 0130 *Laparoscopy, Level I* that require devices of such a nature or expense. More importantly, the 2007 payment rate of $1,975 is clearly inadequate: it does not even cover the cost of one of the two needed neurostimulator electrodes, let alone the costs of the procedure itself.

* Confidential information, not for disclosure

The most appropriate APC for code 43647 is APC 0061 *Laminectomy or Incision for Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.* Every procedure in this device dependent APC involves the implantation of neurostimulator electrodes with significant costs. APC 0061 also has been appropriately identified by CMS as a device-dependent APC.

The following table lists the codes in APC 0061, their frequencies, their "true" median costs and Medtronic's list prices for the neurostimulator electrode (s)/lead used in the procedures listed:

Code	Description	Total Freq	Single Freq	Median Cost	Medtronic List Price of Neurostim Electrode(s)/ Lead*
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural	863	83	$7036	$2,680
64575	Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)	191	32	$5057	$1,680 or $1,900
64577	Incision for implantation of neurostimulator electrodes; autonomic nerve	12	1	$9287	NA
64580	Incision for implantation of neurostimulator electrodes; neuromuscular	12	4	$8379	NA
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)	1522	371	$5329	$2,720

* Confidential information, not for disclosure

The information in this table demonstrates that the costs of the neurostimulator electrodes for gastric neurostimulation are significant and comparable to the costs of the neurostimulation codes already assigned to APC 0061.

Finally, with the reassignment of code 43647 from APC 0130 to APC 0061, all the peripheral neurostimulator lead implantations involving incisions would be assigned to the same APC. This would align the outpatient prospective payment system with the inpatient payment system where all peripheral neurostimulator lead implantations, including those for gastric neurostimulation, are reported using the same ICD-9-CM code: 04.92 *Implantation or replacement of peripheral neurostimulator lead(s).*

Conclusion

The assignment of codes to APCs based on the comparability of clinical characteristics and resource costs is critical to the integrity of the OPPS. We have provided information and data to support our request for the reassignment of code 43647 *Laparoscopy, surgical implantation or replacement of gastric neurostimulator electrodes, antrum* from APC 0130 *Laparoscopy, Level 1* to APC 0061 *Laminectomy or Incision for Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.* We ask that this change be made as soon as possible.

In closing, outpatient services represent a critical means for patient access to innovative and life-saving medical technology. It is critical that OPPS provide appropriate payment for these services to assure continued Medicare beneficiary access. We appreciate the opportunity to submit these comments. Questions or requests for additional information on these comments should be directed to me.

Best regards,

Medtronic Neurological

Michael Wittek
Health Economics
michael.wittek@medtronic.com
763-514-9642
651-303-2824 (cell)

Cc: Carol Bazell, MD, CMS
Barry Levi, CMS

Attachment 1: Procedure Description for 43647 Laparoscopy, surgical implantation or replacement of gastric neurostimulator electrodes, antrum

Under general anesthesia, surgical laparoscopy is performed. A supraumbilical incision is made, and the abdomen is entered using standard techniques for laparoscopy. Pneumoperitoneum is initiated. The viscera are inspected and the pylorus is identified. Two to five working trocar ports are placed in the abdominal wall.

The stomach is visualized and an area along the greater curve using a 10cm measuring device is identified. Two leads are introduced into the abdominal cavity via one of the trocars. The leads are then implanted into the muscle layer between the serosa and the submucosa of the gastric antrum 10 cm proximal to the pylorus, using the needle attached to each lead. To prevent penetration into the lumen of the stomach, the guide needle is driven parallel to the surface. Intra-operative gastroscopy may be performed by a separate physician simultaneously to monitor for possible mucosal penetration. Once the lead is in good position, the lead is anchored to the serosal surface of the stomach. The second lead is implanted parallel to the initial lead, separated by approximately one centimeter. The proximal ends of the leads are guided out of the abdominal cavity through a trocar into the area where a subcutaneous pocket will house the gastric neurostimulation pulse generator (creation of the subcutaneous pocket, and implantation of the gastric neurostimulation pulse generator is covered by CPT 64590).

The leads are connected to the gastric neurostimulation pulse generator and the impedance of the system is tested. If impedance is within 200-800 ohms, the guide needles are removed from the leads and the gastric neurostimulation generator is anchored to the fascia.

After implantation of the gastric stimulator, and confirmation of hemostasis, the trocars are removed, the pneumoperitoneum decompressed, and the surgical wounds are closed. Postoperative x-rays of the abdominal area are taken.

Attachment 2: Resources Required for Enterra Therapy

Description	Units	Cost	# units	Total costs
Disposables				
Surgical gloves	1	$0.12	3.0	$0.36
Drapes	1	$28.00	3.0	$84.00
Steri-stripes	1 pack	$0.60	1.0	$0.60
Surgical gowns	1	$0.86	5.0	$4.28
Pharmaceuticals and anesthesia supplies				
Propofol	200mg	$2.64	1.0	$2.64
Versed	2mg	$0.38	4.0	$1.52
Fentanyl	5ml	$0.15	1.0	$0.15
Decadron	4mg	$0.53	1.0	$0.53
Anzemet (in place of Zofran 4mg)	12.5mg	$8.85	1.0	$8.85
Reglan	10mg	$0.35	1.0	$0.35
Zemuron	50mg	$12.20	2.0	$24.40
Morphine	4mg $0.81 each	$0.81	2.0	$1.62
Angiocath	5 1/4	$4.78	1.0	$4.78
Extension set 30 in	1	$0.82	1.0	$0.82
Three-way stopcock	1	$3.56	1.0	$3.56
Injection cap 0.65	22g catheter	$1.23	1.0	$1.23
Primary IV set	1	$1.27	1.0	$1.27
IV antibiotics	1	$10.59	1.0	$10.59
IV fluids	1	$1.44	3.0	$4.32
Labor Costs				
Circulating Nurse	Hr	$29.04	77 minutes	$37.27
Scrub nurse	Hr	$19.46	77 minutes	$24.97
Nursing care medical surgical floor	Hr	$13.53	1.0	$13.53
Surgical assistant	Hr	$45.00	77 minutes	$57.75
Other				
Post anesthesia Care Unit (PACU)	Hr	$180.00	77 minutes	$231.00
OR cost (equipment)	Hr	$1,261.33	77 minutes	$1,618.71
Patient Care Technician (PCT)	1	$15.21	1.0	$15.21
Respiratory care				
simple spirometry		$132.00	77 minutes	$169.40

Description	Units	Cost	# units	Total costs
Implantable devices*				
Implantable Neurostimulator Electrodes (2 leads)				
(C1778/L8680)	Each (list price)	$2,200.00	2.0	$4,400.00
			Grand Total	**$6,723.71**

* Confidential Information, not for disclosure