47-0

(49) [redacted]

Benjamin Yeh
520 Beacon Landing
Tinton Falls, NJ 07753

Sept 8, 2001

Centers for Medicare & Medicaid Services
Dep't of Health & Human Services
Attention: CMS-1392-P
P O Box 8011
Baltimore, MD 21244-1850

Drugs

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patie
access to care while simultaneously keeping down the related costs
trying to eliminate abuse of services. However, as a patient with
Blepharospasm, I have serious concerns about CMS's proposal to
reduce the payment rate to hospitals for physician-injected drugs.
receive injections of Botox to alleviate the debilitating dystonic sympt
These injections are critically important to my ability to function nor

I respectfully request that CMS not change the payment formu
for physician-injectable drugs for 2008, and instead maintain the curr
payment formula. Any reduction in reimbursement will lead to fe
injectors in an area where we have too few knowledgeable injectors
in the first place. Anyone can inject botulinum toxin. Not just
anyone can inject it successfully to relieve the spasms. Also, th
change in policy would destroy the uniformity of payments made
across settings that ensures there are no economic rewards or pen
ties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

Benjamin Yeh

Rebecca (2)
Carol
Alberta

(1K)

September 6, 2007

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Blepharospasms, a movement disorder resulting from sustained involuntary muscle spasms. I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the bebilitating dystonic symptoms.

These injections are critically important to my ability to function normally. I get my injections every 3 months. I am able to continue to work driving a metro transit city bus daily in Minneapolis, St. Paul and suburbs, 8-10 hours daily, 5-6 days a week. I am at retirement age, 63 this November, but plan to continue to work. When I retire I would like to have a choice of where and who gives me my injections.

My doctor is very skilled at injections around my eyes, 6 to 7 around each eye. I have only had two (as little as a ladies little finger- nail) black and blue spots in almost 20 years. I have seen **whole** black eyes on many of the people in the Minneapolis, St. Paul Metro area, who get shots around their eyes (from many butcher doctors). I was the Minnesota area representative for meetings and information for over 14 years. As a woman I do not like black and blue eyes. If the injection is given wrong sometimes the eyes won't open, or won't close or eyes cross and will not focus properly, or the spasms don't quit..

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008 and later years, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where **we have too few knowledgeable injectors** in the first place. Anyone can inject botulinum toxin. Not just anyone can injedct it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

I do like being able to call a week or two ahead and get into my doctor without having to wait until he has 2 or 3 or 4 people who need injections to share all the medicine, I know many have to wait. Not every person has the same schedule as the next person across town.

Thank you for allowing me to provide these comments.

Sincerely,

Marnell Wilber

Marnell Wilber
3510-136 Lane N.W.
Andover, Mn. 55304

MR. KERRY WEEMS
DIRECTOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTN:CMS-1392-P
P.O. BOX 8011
BALTIMORE, MD 21244-1850

DEEAR MR. WEEMS:

I WOULD LIKE TO COMMEND CMS FOR SEEKING TO IMPROVE PATIENT ACCESS TO CARE WHILE TRYING TO KEEP DOWN RELATED COSTS AND TRYING TO ELIMINATE ABUSE OF SERVICES.

HOWEVER, AS A PATIENT WITH BLEPHAROSPASM SINCE 1999, I HAVE REAL CONCERNS ABOUT CMS's PROPOSAL TO REDUCE THE PAYMENT RATE TO HOSPITALS FOR PHYSICIAN-INJECTED DRUGS. I RECEIVE BOTEX INJECTIONS TO SOMEWHAT EASE THE EFFECTS OF THIS DISTURBING AILMENT.

AS A WIDOWED SENIOR CITIZEN, LIVING ON A LOW FIXED INCOME, I AM ASKING THAT CMS MAINTAIN THE CURRANT FORUMLA FOR PAYMENT FOR PHYSICIAN-INJECTABLE DRUGS FOR 2008. CHANGES IN THE CURRENT WOULD INFLICT HARDSHIPS ON MANY.

THANK YOU FOR READING THESE COMMEMTS.

SINCERELY,

PATRICIA F. JOYCE
99 HANCOCK AVENUE
JERAEY CITY, NJ 07307-2117

(50)

September 7, 2007

Mr. Kerry Weems, Director
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P. O. Box 8011
Baltimore, Maryland 21244-1850

Dear Mr. Weems,

This letter is written to voice my concerns to you about proposed changes, 1392- P, for 2008 that CMS is contemplating concerning payments to physicians who inject Botox around the muscles of the eyes in order for blepharospasm patients, like myself, to do our daily routine. Without the paralyzing effect that Botox brings about in those squeeze muscles, we would be functionally blind.

I was diagnosed with Benign Essential Blepharospasm of the Eyelids in l989 and have received Botox injections in ten places around my eyes every three months by Dr. John Harrington in Dallas, Texas, since that time in order for my eyelids to stay open. When I began having the injections, Botox had not been approved by the FDA. Walking becomes one of the hardest things I do when my eyelids involuntarily close, and this would be almost constant without the effects of Botox.

As you can tell from my brief description of my personal experience with BEB, I have serious concerns about CMS's proposal to reduce the payment rate to doctors who use their expertise to inject Botox. I am requesting that CMS continue its present policy of paying to the physician who administers Botox, whether it be in an office setting or a hospital, the amount of the average sale price of the drug plus 6 percent. **Please keep your current payment formula at CMS concerning the injectable drug, Botox, to the dedicated doctors who help patients, like me, maintain a reasonable amount of independence in their lives.**

Thank you for your time taken to read this letter.

Sincerely,

Barbara J. Mackey

Barbara J. Mackey
1350 Independence Springs
Sherman, Texas 75090

51

September 8, 2007

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while Simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (or the form dystonia you have), both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. "These injections are critically important to my ability to function normally!"

You see in 1992, my eyelids started to close, and I was not able to keep them open, only by using scotch tape, stuck on my lids and head! At that time I was a Director of a large Day Care Center, and how frustrating it was! After a year of going to 11 Doctors, I was sent to The Dean McGee Institute in Oklahoma City, where they were able to name the disease I had and was able to give me the botox injections. Now that I am 75 years old, and I'm still working, and I must take these injection that are provided for me from Greene Vision in Wichita, Ks, Dr Amultz I have extended my injections from 3 to 4 months, hoping to help insurance, but any farther, I have severe pain in and arround my eyes. You see these injections, are not for cosmetic purposes, but are important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to few injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the iniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

Betty Dody
1212 Parkwood Ln.
Newton
Ks. 67114

52-0
(10)

EJGH

Louisiana's *First* Nurse Magnet Hospital

August 29, 2007

Mr. Kerry Weems
Administrator, Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

APC

ATTN: CMS-1392-P

Re: Medicare Program; Proposed changes to the Hospital Outpatient Perspective Payment System and CY 2008 Payment Rules: **Skin Repair Procedures**

Dear Administrator Weems:

I appreciate this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. My comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. I am an R.N. currently working in a leading Wound Care Center that treats Medicare beneficiaries for diabetic foot and venous leg ulcers. **In order to continue caring for patients with the appropriate products, I urge you to place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost associated with the application of Apligraf. This is consistent with other skin substitute products.**

I am concerned that the proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf, a unique human skin substitute for patients with diabetic and other chronic ulcers. I have seen many patients avoid limb amputations with wound treatment including Apligraf. In the proposed rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource and clinical utilization. While I support appropriate use of products, in this case I am concerned that the change will not reflect the *actual* clinical resource use. As a result of a 2006 coding change, there has been substantial confusion on proper allocation of costs associated with application and resources.

I appreciate your time and concern for the welfare of your Medicare constituents who live with chronic wounds. Please consider supporting the placement of CPT codes 15340 and 15431 into APC 0135 in order to allow us to best care for these patients while being cost conscious.

Sincerely,
Denise Becklehimer RN CWS
Denise Becklehimer RN, CWS

Marjorie (2)
Carol
Alberta
Sheila

East Jefferson General Hospital
Wound and Diabetes Management Center 4320 W...

InnerWisdom, Inc.
Counseling Centers

INNERWISDOM, INC.
1325 La Concha Lane
Houston, Texas 77054

53-0
(175)

September 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Sirs:

Re: Response to Proposed Changes to the CY2008 Hospital Outpatient PPS-CMS-1392-P Partial Hospitalization (APC 0033)

On behalf of InnerWisdom, Inc., we appreciate the opportunity to submit comments regarding CMS's proposed OPPS rates concerning APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient Psychiatric Services

InnerWisdom, Inc. is deeply concerned about the direct impact a fourth consecutive rate reduction will have on partial hospitalization and hospital outpatient services. We believe this rate cut will jeopardize the very existence of the partial hospitalization benefit itself.

InnerWisdom, Inc. is a member of The Association of Ambulatory Behavioral Healthcare (AABH) and we support their response to this situation which is as follows:

1. **CMS data does not support a PHP per diem rate of $179.88 by its' own methodology of calculation.**

CMS-1392-p, on pp. 255-256, describes the CMS methodology utilized to calculate the current proposed rates. Page 255 states "We use CCRs from the most recently available hospital and CMHC cost reports". Unfortunately, this data is aggressively **stale**. The costs utilized are at least **1 to 3 years old and are used to project rates 2 years forward.** A review of the data utilized for the CY 2008 rates would indicate that as much as 50% of the cost data could be 3 years old from 2004. Page 255 of the report goes on to say that "All of these costs are then arranged from lowest to highest and the middle value of the array would be the median per diem cost". This process guarantees that 50% of the providers will be providing services and be receiving reimbursement below their daily costs. Combining cost data several years old with recent units of service does not accurately reflect the costs the providers endure.

2. CMS does not support a PHP per diem rate of $179.88.

CMS has identified the true Median Cost of APC 325 for group therapy at $66.17. With a minimum of 4 services per day (many programs offer more), CMS would recognize the minimum cost at

$264.68 per day. These data are inconsistent with a rate of $179.88 and indicate that a higher payment rate is necessary to prevent providers from running substantial deficits that will risk financial viability.

3. The current methodology is not conducive to this APC code.

Unlike the other 1100+ APC codes which generally represent individual medical procedures, Partial Hospitalization is a complete service industry, that encompasses a complete business setting rather than one simple process such as a Corneal Transplant (0244) or a Transfusion (0110). There is precedent in other CMS OPPS service industries to exclude the services from the APC code listing and treat them independently. Two examples are Home Health and Hospice Care. Home health was just finalized for CY2008 with a set rate and a 3 percent increase if certain quality data standards are met or a 1 percent increase if the standards are not met. Positive performance results in reimbursement rewards. PHP could be treated the same. This would stabilize the rates and generate future rate predictability for these services.

4. The preliminary rate of $179.88 is excessively severe.

The CMS table on p. 257 of CMS-1392-p reflects 4 median per diem costs as determined by CMS. The projected rate of $179.88 is the lowest of the four samples. This would penalize all CMHCs providing four or more units of service per day and all hospitals in either category. All current PHP LCD's of the Fiscal Intermediaries state the CMS requirements that "Partial Hospitalization Programs must **offer** a minimum of 20 hours a week of structured program provided over at least a five-day period." The minimum patient participation is three hours per day of care with a minimum of 12 hours per week." AABH would offer 2 suggestions. First, enforce the minimum service requirement to assure PHPs are **offering** at least 20 hours of structured programming per week. Second, days of service with less than 4 services are being paid within the rules of CMS and Medicare. Programs should not be penalized for following the rules.

In further regard to the Hospital-based PHPs, CMS data indicated that over 66% of paid claims were for 4 or more units of service. The median cost of $218 for hospitals is $40 below the projected reimbursement rates. A decision of this nature would end these services in Hospital-based locations.

5. CMS's calculations for the CY 2008 PHP per diem payment are diluted.

CMS states that per diem costs were computed by summarizing the line item costs on each bill and dividing by the number of days on the bills. This calculation can severely dilute the rate and penalize providers. All programs are strongly encouraged by the fiscal intermediaries to submit all PHP service days on claims, even when the patient receives less than 3 services. Programs must report these days to be able to meet the 57% attendance threshold and avoid potential delays in the claim payment. Yet, programs are only paid their per diem when 3 or more qualified services are presented for a day of service. If only 1 or 2 services are assigned a cost and the day is divided into the aggregate data, the cost per day is significantly compromised and diluted. Even days that are paid but only have 3 services dilute the cost factors on the calculations. With difficult challenges of treating the severe and persistently mentally ill adults, these circumstances occur frequently.

6. The proposed PHP per diem rate also severely compromises Hospital Outpatient Services.

CMS pays hospital facilities for Outpatient Services on a per unit basis **up to** the per diem PHP payment. As previously shown, CMS has identified Group Therapy APC 0325 with a true Median Cost of $66.17. Most patients involved in the Outpatient Services are participating 1-3 days and generally receive 4 or more services on those days. While programs provide 4 services the per diem

limit will only allow them to be "paid their cost" for about 2.75 services (3 x $66.17 = $198.51). The program is $18.63 short for the 3rd service and the 4th service is provided for no reimbursement.

7. **Cost Report Data frequently does not reflect Bad Debt expense for the entire year.**

As the cost report data is proposed surrounding Bad Debt, many "recent" bad debt copays of the last 4-5 months of the fiscal year have not completed the facility's full collection efforts and therefore are not eligible for consideration of bad debt on the cost report. Those that are, can only be recovered up to 55%. These costs are not being considered in the CMS data and severely short change the rate calculations.

8. **Data for settled Cost Reports fail to include costs reversed on appeal.**

CMS historically has reduced certain providers' cost for purposes of deriving the APC rate based on its observation that "costs for settled cost reports were considerably lower than costs from "as submitted cost reports". (68 Federal Register 48012) While CMS's observation is true, it fails to include in the provider's costs, those costs denied/removed from "as submitted" cost reports, and subsequently reversed on appeal to the Provider Reimbursement Review Board ("PRRB"), subsequently settled pursuant to the PRRB's mediation program, or otherwise settled among the provider and intermediary. During the relevant years at issue, providers of PHP incurred particularly significant cost report denials, but also experienced favorable outcomes on appeal. Because the CMS analysis did not take into consideration what were ultimately the allowable costs, its data are skewed artificially low. The cost data used to derive the APC rate should be revised to account for these costs subsequently allowed.

Based on the above issues, AABH would recommend that CMS take the following course of action:

1. Allow the PHP per diem to remain the same as the CY2007 per diem rate of $234.73.

2. YOUR NAME OR ORGANIZATION encourages CMS to go with AABH to the legislature and support a legislative amendment to:

    - Remove PHP from the APC codes and have independent status using Home Health as an example
    - Establish the current rate of $234.73 as the base per diem rate for services
    - Annually adjust the base rate by a conservative inflation factor such as the CPI
    - Establish quality criteria to judge performance and that influences future rate reimbursement

Thank you, for the opportunity to respond to this critical issue.

Respectfully,

JoAnne Mandel CNS, RN, LMSW
Chief Executive Officer
InnerWisdom, Inc.,

54

endocare
extending life everyday

Office of the CEO, President & Chairman of the Board
201 Technology Dr. • Irvine • California • 92618
Main Line: (949) 450-5475
Facsimile: (949) 450-5319
Website: www.endocare.com

September 12, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1392-P, Medicare Program; Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

HCPCS 0135T, Percutaneous Ablation of Renal Tumors within APC 423

Dear Mr. Weems:

On behalf of Endocare, Inc., I am writing in response to the Proposed Rule for the CY 2008 Medicare hospital outpatient prospective payment system, published in the *Federal Register* on August 2, 2007. Our concern is that **the payment rate for APC 423 does not cover the costs associated with Percutaneous Ablation of Renal Tumor procedures, identified by HCPCS 0135T,** that are assigned to this APC.

Endocare is a medical device manufacturer focused on the development and distribution of minimally invasive technologies for tissue and tumor ablation treatments in patients diagnosed with cancer. Our mission as a Company is to assist physicians in improving the health and quality of their patients' lives through safe, cost effective, proprietary cryoablation technologies for treating cancerous tissue and tumors.

Percutaneous Ablation of Renal Tumors

Over the past several years, significant positive results have been published in the literature for the treatment of renal tumors with cryoablation. Smaller renal tumors have been successfully treated in an outpatient setting with a minimally invasive percutaneous ablation approach. The technique has been shown to be an effective clinical alternative

to open or laparoscopic surgery for small tumors, and a more cost-effective treatment alternative with little or no inpatient stay required and a very low complication rate.[1]

Inadequacy of Proposed CY 2008 APC Rate

Many hospitals performing this procedure have not accurately reported their associated costs in the claims data used by CMS for CY 2008 OPPS rate-setting. This is due to two factors: 1) this is a relatively new procedure, and 2) the HCPCS code to identify the procedure was only recently assigned and effective January 2006. As a result, CMS has proposed a CY 2008 payment rate for APC 423, the APC to which percutaneous ablation of renal tumor procedures are assigned, that represents a significant financial shortfall to the hospital.

The proposed payment for this APC --now inclusive of guidance technology such as CT or ultrasound under the proposed new OPPS packaging policy -- is actually less than the acquisition costs hospitals incur for the cryoprobes used in the procedure. Further, this proposed rate does not cover the expenses hospitals incur for the radiology procedure room, the special argon and helium gases that are used, the nursing time involved, and the pharmacy and recovery expenses associated with this procedure.

The table below displays the proposed CY 2008 payment rate for APC 423 and an estimate of the degree to which this payment rate varies from a hospital's operating costs in performing percutaneous ablation of renal tumor procedures.

Comparison:
Proposed CY 2008 Payment Rate for APC 423
and
Estimated Hospital Costs to Perform HCPCS 0135T,
Percutaneous Ablation of Renal Tumors

HCPCS Code	Description	Proposed CY 2008 Payment (bundled payment w/ CT guidance)	Hospital Cryoprobe Expense (est.)	~Shortfall or Variance (Hospital Operating Costs v Payment)
0135T	Percutaneous Ablation of Renal Tumors	$2,801	~$1,000 per cryoprobe x 3 = $3,000 (2.5 average usage/case[2])	**$1,000 -$2,000** depending on facility[3]

[1] Hinshaw, JL. Abstract Society of Interventional Radiology 2007. "Comparison of Percutaneous and Laparoscopic Renal Cryoablation." (See Attachment I.)

[2] See presentation to CMS in December, 2005 regarding typical treatment approach for small renal tumor using percutaneous renal ablation. The percutaneous renal cryoablation procedure uses a uniquely designed "angled" probe that will fit under the CT gantry. This "angled" probe is not used in prostate cryoablation procedures. (See Attachment II.)

[3] Significant variance between Proposed 2008 payment and cost of cryoprobes + cost of CT scan(s) + argon/helium gases+ nursing care + recovery + pharmacy + surgical supply, etc.

Given our understanding of hospital costs associated with percutaneous ablation of renal tumor procedures, and the apparent inadequacy of the proposed ASC payment rate for APC 423, we commissioned a claims data analysis from The Moran Company (see Attachment III). This analysis indicates that:

1) Of the 110 Medicare claims submitted for the percutaneous ablation procedure, only 44 single claims met the requirements for use in the payment methodology.

    - It is important to note that of these 44 claims, only 40% include C-codes on the claims.

2) The median cost for HCPCS 0135T is $3,519.62.

    - This median cost is 30-32% more than the other two procedures grouped with HCPCS 0135T into APC 423 (i.e., HCPCS 47382- RF liver tumor ablation @$2725.35, and HCPCS 50592 – RF renal tumor ablation @$2657.51).[4]

Based on these two points, we believe that: (1) the frequent omission of the C-code for cryoprobes in many cases indicates to the omission of cryoprobe cost information, resulting in underweighting; and (2) the variance in cost among the three procedures grouped into APC 423 serves to document why a separate APC should be established for higher-cost percutaneous ablation of renal tumor procedures.

Policy Context

It is important to provide some background on this matter. Two years ago, Endocare requested the APC Advisory Panel to move the percutaneous ablation of renal tumor procedures into the same APC with other ablation procedures. This request was made subsequent to a meeting with CMS where we learned that CMS did not think the procedure should be assigned to a "New Technology" APC (our preference) because the procedure was not considered "new" (i.e., the cryoprobe technology used in the treatment of renal tumors was not that dramatically different than the cryoprobe product used in prostate cryoablation).

It seemed logical at the time to group "like ablation procedures together" to facilitate hospital education and correct billing and payment. While a logical position to take at the time, the claims data from 2006 now available to us clearly demonstrates that, the costs for the percutaneous renal cryoablation procedures are much more costly to the hospital than the other two procedures in APC 423. We believe this cost information warrants the assignment of the percutaneous renal cryoablation procedure to its own unique APC. The creation of a unique APC for this procedure would be comparable to CMS' decision to establish a separate APC for prostate cryoablation procedures (APC 674).

[4] HCPCS 47382 and HCPCS 50592 are assigned to APC 423, along with percutaneous ablation of renal tumor procedures. The two procedures are radiofrequency (RF) procedures that use a single device to ablate tumors. The RF device does not have an associated C-code.

Recommendation

For the reasons set forth above, Endocare respectfully requests that CMS:

- **Increase the payment for CPT 0135T to an amount that will at a minimum cover the cost of the cryoprobes, the guidance technology and operating expenses (argon and helium gases, Radiology Procedure Suite time, pharmacy, surgical supplies, nursing and recovery time, etc.) associated with the percutaneous renal cryoablation procedure.**

- **Establish a unique clinical APC for percutaneous ablation of renal tumors procedures, and should designate this APC as a "device-dependent procedure."**

Impact of Not Increasing the Payment for HCPCS 0135T.

In past comment letters to CMS concerning APC payment rates, we have made the point that an inadequate or low Medicare reimbursement rate for cryoablation in any setting serves as a barrier to treatment for Medicare beneficiaries. This procedure is the least intensive, least intimidating and one of the least costly alternatives for the treatment of renal tumors.

Ironically, underpayment for this renal tumor cryoablation procedure by Medicare could lead to more-expensive inpatient admissions and more costly, more invasive treatments for renal cancer.

*****

We thank you for allowing us the opportunity to comment on this proposed rule. Please do not hesitate to contact me if you have questions or require additional information.

Sincerely,

Craig T. Davenport

Craig T. Davenport
Chief Executive Officer
Chairman of the Board

Enclosures:

Attachment I: JL Hinshaw abstract
Attachment II: CMS Presentation made in December 2005
Attachment III: Moran Data Memorandum

ATTACHMENT I

JL Hinshaw, MD Abstract
Society of Interventional Radiology 2007

Society of Interventional Radiology 2007
Abstract

Comparison of Percutaneous and Laparoscopic Renal Cryoablation

OBJECTIVE: Percutaneous renal cryoablation has been gaining acceptance as an effective minimally invasive option for the treatment of solid renal masses. The goal of this study is to compare the cost, complications and outcome of percutaneous renal cryoablation (PRC) and laparoscopic renal cryoablation (LRC) of solid renal masses.

SUBJECTS & METHODS: This is a retrospective review of the combined experience of the urology and radiology departments at the University of Wisconsin Hospital and Clinics. A total of 19 PRCs (mean tumor size, 2.0 cm) in 19 patients (68.6 +/- 9.3 years) and 48 LRCs (mean tumor size, 2.6 cm) in 46 patients (68.2 +/- 11.5 years) were compared. Tumor size, complications, hospital charges, length of hospital stay, and follow-up parameters were recorded, along with other possible confounding variables.

RESULTS: PRC was associated with significantly lower hospital costs ($14,153.69 vs. $22,556.93), a shorter hospital stay (1.1 +/- 0.2 days vs. 2.5 +/- 2.3 days), fewer complications (0 vs. 3 major complications (including: severe respiratory distress, intra-operative bowel injury and post-operative atrial fibrillation)), and comparable local recurrence rates (10.5% vs. 12.5%) as compared with LRC.

Two of the patients in the PRC have undergone successful retreatment with repeat PRC, while one patient in the LRC has undergone retreatment at the time of this study. The other five patients in the LRC group who have suspected recurrence are being followed with imaging.

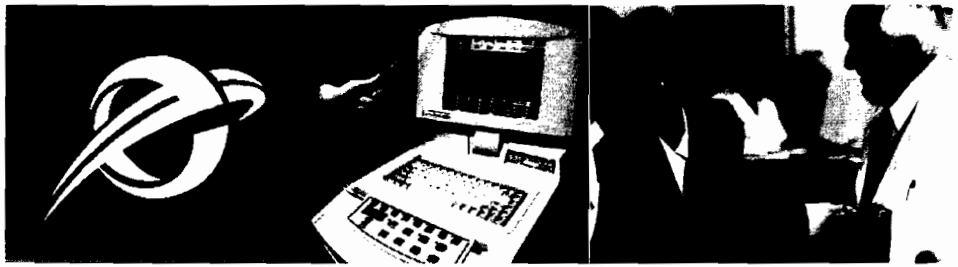
Mean follow-up is significantly shorter in the PRC group (7.3 vs. 13.3 months), primarily because PRC is a relatively new innovation.

CONCLUSIONS: In select patients, PRC has proven to be a safe, effective and more cost effective therapy for small renal tumors than LRC.

J. Louis Hinshaw, MD
University of Wisconsin School of Medicine and Public Health

ATTACHMENT II

Endocare Presentation to CMS on December 14, 2005



CPT III Assignment to APC
Cryoablation of Renal Tumors

Discussion with Jim Hart, Deputy Director
Center for Medicare Management
Centers for Medicare and Medicaid Services
December 14, 2005

Endocare, Inc.
Mary Syiek, VP and Sharon Whalen, Sr. Director

Today's Agenda

- What is Percutaneous Renal Cryoablation
- New 2006 CPT III
- Assignment of Renal Cryoablation to APC
- Request to change APC Assignment

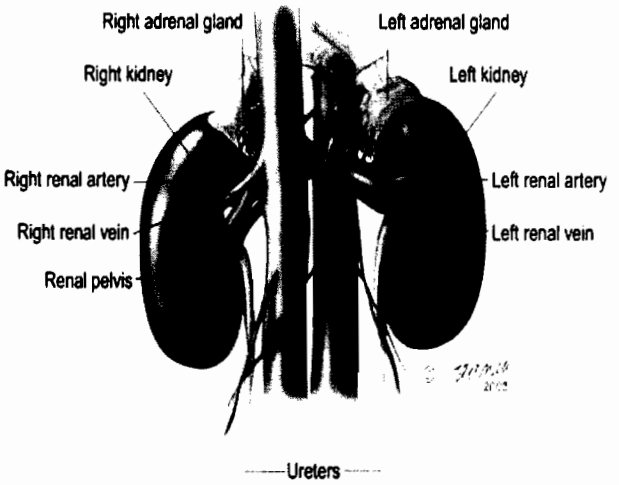
Renal Cancer

- Renal Cancer Incidence estimated to be 36,000 new cases in 2005

- 90% is Renal Cell Carcinoma (RCC)

- Renal Cancer presentation
  - Later stage (pain & hematuria)
  - Early stage – incidental finding due to increase use of diagnostics and improved imaging.

- RCC Treatment options: Surgical removal (partial or radial nephrectomy), ablation and surveillance.

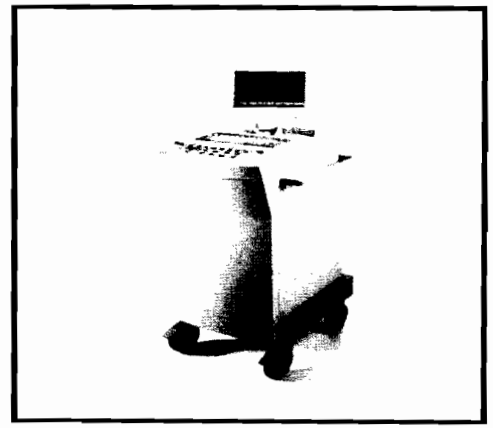


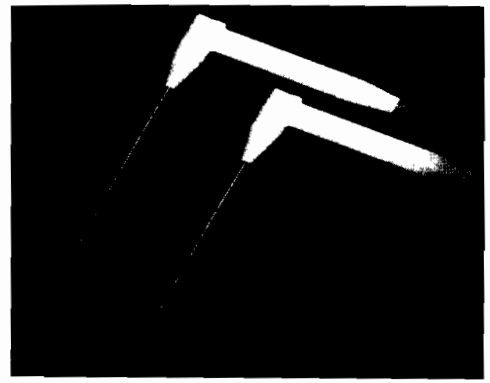
Ablation Treatment Option

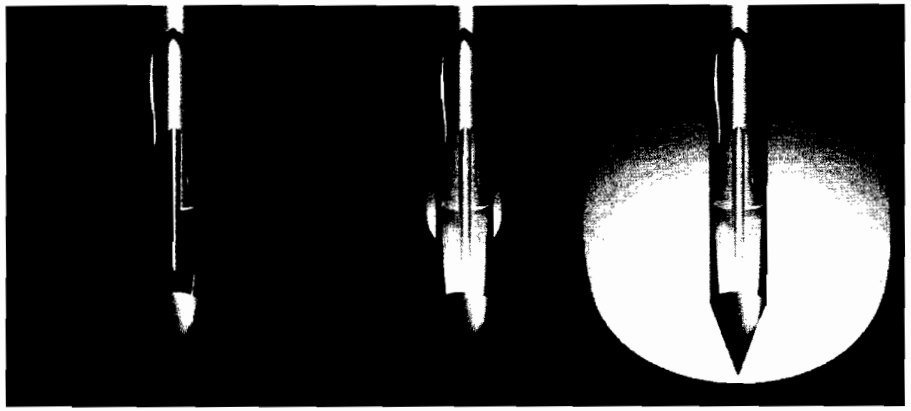
- Ablation treatment goal = destroy a pre-determined volume of tissue either open, laparoscopically or percutaneously.
- Ablation is a minimally invasive treatment option & nephron-sparing.
- Nephron sparing surgery has emerged as a preferred option in the treatment of most renal tumors in patients with an existing or potential compromise of renal function and selected patients with a normal contra-lateral kidney.
- Cell death from cryoablation is caused by direct freezing, cell dehydration and ischemic hypoxia. The procedure generally involves two freeze and thaw cycles.

CRYO System

- Delivery of Argon gas to produce "Ice Ball"
- Delivery of Helium for "thaw" phase
- Multiple Probe System (8 probes) and independently controlled
- CT-Compatible probes which fit within constraints of CT Gantry

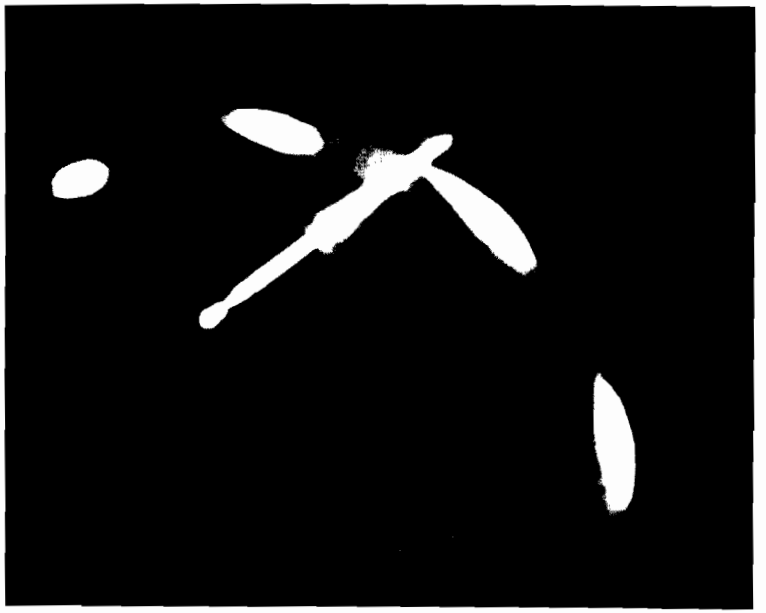






How Does Cryoablation Work?

Able to monitor "Ice Ball" by CT Imaging



Cryoablation Clinical Efficacy - Laparoscopic

- Gill, (2005) from the Cleveland Clinic reported 3 year results :
  - 56 laparoscopic renal cryoablation patients
  - Mean tumor size was 2.3 cm
  - Tumor size reduction of 75% at 3 years and 38% had completely disappeared
  - Survival rate of 98%

Cryoablation Clinical Efficacy - Percutaneous

- Silverman (2005) 23 patients, mean tumor 2.6 cm, complete ablation in 92%, two complications (bleeding & abscess).

- Shingleton, (2003) 14 patients, mean tumor 3.1, 80% complete ablation, no complications.

- Shingleton (2001) 20 patients, mean tumor size 3.0, only one patient for re-treatment.

2006 New CPT III Code

- January, 2006 New CPT III Percutaneous Cryoablation, unilateral renal tumors
- AMA assigned as "new and emerging"
- Final 2006 Outpatient Rule assigned to APC 163 Level IV Cysto-Urethroscopy & Other GU procedures
- APC 163 Average payment ~$1,999

Request to change APC assignment

- Identification of more clinically and financially aligned APC
- CPT III is new & emerging and may be more appropriately aligned to New Technology APC.
- Other Options to consider:
  - 50592 - Percutaneous Renal Ablation for renal tumors, Radio-Frequency assigned to APC 423 Level III Perc Abdominal & Biliary Procedure

Practice Patterns

- Current Percutaneous Cryoablation for Renal Tumors is performed utilizing a CT monitoring system, occasionally ultrasound for probe placement

- Typical case positions cryo probe and ice ball formation around tumor to effectively freeze entire area versus one probe only.

- Average of 2.5 cryoablation probes.

- Conscious sedation / or general anesthesia

Cost of Percutaneous Cryoablation Renal Tumors

- Probe Expense to Hospital
  - ~$1000 per probe (see invoices/cancelled checks provided)
  - Average probe use for percutaneous renal cryoablation is 2.3 probes (Dr. Peter Littrup, Karmonos Cancer Institute, 2005)
- Hospital Costs
  - Mayo Clinic estimates costs to be ~$9,100 (for 1.23 days).
  - Dr. Steve Solomon at Johns Hopkins presented costs at RSNA of $3,000 for the outpatient procedure.

Other APC Options

CPT	Description	APC	Payment
50592	Percutaneous Renal Ablation for renal, Radio-Frequency	**423** - Level III Perc Abdominal & biliary Procedure	**$2355**
		1524 - New Technology XIV	**$3,250**

In Summary

- Current procedure costs in $3,000 to $9,000 range.
- On average 2.5 cryoprobes are used for renal cryoablation; average probe purchase price is ~$1000/probe.
- Costs of cryoprobes alone exceed the total APC 163 payment of ~$1,999.
- Request CMS to move the CPT III 0135 T to a more clinically and financially aligned APC such as APC 423; or assign to a New Technology APC that provides sufficient payment to cover hospital costs.
- This change will ensure that this new technology is not discriminated against in favor of more costly inpatient procedures.

Thank You

ATTACHMENT III

Moran Company Memorandum August 23, 2007
"Findings on analysis of APC 0423"

1655 N. FORT MYER DRIVE, SUITE 1250 ARLINGTON, VA 22209 (703) 465-9970 FAX (703) 465-9969

Memorandum August 23, 2007

TO: Lisa Hayden, Galil and Mary Syiek, Endocare

FROM: Mary Jo Braid-Forbes, The Moran Company

SUBJECT: Findings on analysis of APC 0423

In this memorandum, we present our replication of the CMS methodology for all your codes of interest and our analysis of APC 0423. The analysis of the other codes will follow in another memorandum.

Regarding APC 0423 we found:

- The claims used in rate-setting for APC 0423 have a lower percentage of costs related to newly packaged guidance procedures as a proportion of the procedure code costs than do the claims overall. These additional guidance procedures and costs could be related to the other major procedures on the claims not used for rate-setting.
- The other procedure most often billed with 0135T causing the claims not to be used for rate-setting is 50200 Biopsy of kidney.[1]
- Contract agents and observation services which are now packaged are also common on the claims in APC 0423. Observation is less common on 0135T than on the other procedures codes.

Replication of CMS mythology

Table 1 below shows the results of our replication of the CMS rate-setting methodology. We are within a couple percentage points of CMS on both the counts and the median costs for all the codes.

Table 1: TMC replication of CMS rate-setting methodology

				TMC		CMS		Percent Difference	
HCPCS	Description	Status Indicator	APC	Single Count	Median Cost	Single Count	Median Cost	Single Count	Median Cost
47382	Percut ablate liver rf	T	0423	450	$2,725.35	439	$2,705.94	2.5%	0.7%
50592	Perc rf ablate renal tumor	T	0423	206	$2,606.24	203	$2,657.51	1.5%	-1.9%
0135T	Perq cryoablate renal tumor	T	0423	45	$3,479.46	44	$3,519.62	2.3%	-1.1%
50542	Laparo ablate renal mass	T	0132	34	$4,807.75	34	$4,791.78	0.0%	0.3%
55873	Cryoablate prostate	T	0674	2,071	$7,759.59	2,066	$7,721.49	0.2%	0.5%

[1] CPT codes, descriptions and material only are copyright 2006 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS Restrictions Apply to Government Use.

APC 0423 analysis

CMS used 40% of the 111 claims for 0135T, which is a slightly lower percentage than the other codes in APC 0423. Table 2 below shows the single counts compared to the total.

Table 2: Single versus total counts

HCPCS	Description	Single Count	Total Count	Single % of total
0135T	Perq cryoablate renal tumor	44	111	40%
47382	Percut ablate liver rf	439	800	55%
50592	Perc rf ablate renal tumor	203	442	46%

For the 67 occurrences of 0135T that could not be used for rate-setting, the other major payable procedure codes not on the bypass list that appear on the claim on the same date are listed in table 3 below. The code appearing most often is 50200 Biopsy of kidney which occurred 32 times on these claims.

Table 3: Other major payable procedure codes on 0135T claims not used

HCPCS	Description	Status Indicator	Occurances
50200	Biopsy of kidney	T	32
10022	Fna w/image	T	9
53899	Urology surgery procedure	T	7
86920	Compatibility test, spin	X	6
74170	Ct abdomen w/o & w/dye	S	5
94640	Airway inhalation treatment	S	5
C8952	Injection; intravenous push	S	4
C8950	Intravenous infusion; up to 1 hour	S	3
50592	Perc rf ablate renal tumor	T	2
74183	Mri abdomen w/o & w/dye	S	2
76380	CAT scan follow-up study	S	2
94664	Evaluate pt use of inhaler	S	2
37204	Transcatheter occlusion	T	1
37799	Vascular surgery procedure	T	1
45385	Lesion removal colonoscopy	T	1
50390	Drainage of kidney lesion	T	1
50392	Insert kidney drain	T	1
50393	Insert ureteral tube	T	1
52005	Cystoscopy & ureter catheter	T	1
74160	Ct abdomen w/dye	S	1
74181	Mri abdomen w/o dye	S	1
74420	Contrst x-ray, urinary tract	S	1
93701	Bioimpedance, thoracic	S	1
94656	Ventilation assist and management	S	1
94799	Pulmonary service/procedure	X	1

The claims used in rate-setting for APC 0423 have a lower percentage of costs related to newly packaged guidance procedures as a proportion of the procedure code costs than do the claims overall. Table 4 below shows the sum of the costs associated with procedures in each category of packaging as a percent of the costs associated with the procedure code. There is also a difference in costs of contrast material between the claims overall and the claims used for rate-setting, but these costs are very small. Observation service costs look more similar.

These additional guidance procedures and costs could be related to the other major procedures on the claims not used for rate-setting. We provided the procedures associated with the multiple procedure claims for 0135T in table 3 above so that you could assess this from a clinical perspective. The other major payable procedures on claims for 50592 and 47382 are provided in an excel spreadsheet that accompanies this document.

Table 4: Newly packaged category COSTS on all claims versus single claims as percentage of procedure code costs

	All Claims			Singles Used in Rate-setting		
Category	0135T	50592	47382	0135T	50592	47382
Contrast Material	0.5%	0.9%	0.6%	0.4%	0.3%	0.3%
Diagnostic Radiopharmaceutical			0.0%			
Guidance	15.7%	20.6%	14.9%	10.2%	14.3%	13.9%
Image Processing			0.0%			
Imaging Supervision and Interpretation	0.8%	0.2%	1.6%			0.5%
Intraoperative			0.1%			
Observation	0.5%	5.9%	4.6%	0.5%	4.5%	3.6%
Total	***17.6%***	***27.6%***	***21.9%***	***11.1%***	***19.1%***	***18.3%***

It appears that the higher guidance costs are due to more procedures being done on the claims not used for rate-setting rather than higher costs for the same number of procedures. Table 5 below shows the sum of the number of lines associated with procedures in each category of packaging as a percent of the number of procedures. Percentages over 100% indicate that there were claims with more guidance procedures than the primary procedure.

Table 5: Newly packaged category LINES on all claims versus single claims as percentage of procedure code lines

	All Claims			Singles Used in Rate-setting		
Category	**0135T**	**50592**	**47382**	**0135T**	**50592**	**47382**
Contrast Material	16.2%	20.2%	13.4%	13.3%	7.8%	5.1%
Diagnostic Radiopharmaceutical			0.3%			
Guidance	115.3%	113.8%	99.5%	95.6%	99.0%	97.8%
Image Processing			0.4%			
Imaging Supervision and Interpretation	5.4%	0.9%	3.4%			1.6%
Intraoperative			0.8%			
Observation	10.8%	20.2%	19.0%	13.3%	16.0%	20.2%
Total	***147.7%***	***155.1%***	***136.7%***	***122.2%***	***122.8%***	***124.7%***

Provider Table Data Explanation

	Column Heading	Explanation
	Provider ID	Medicare provider number
	Name	Name of hospital on Provider of Services File
	Street	Street address of hospital on Provider of Services File
	City	City of hospital on Provider of Services File
	State	State of hospital on Provider of Services File
All Claims	Claims	Number of unique claims for code on the OPPS file
	Lines	Number of occurrences of code on the claims. Can be more than one per claim.
	Mean Charges	Average charges reported by hospital on the same line as the code. Does not include other related charges on the claim.
	Mean Cost	Average CMS estimated cost for the code line. Does not include other related costs on the claim. CMS calculates this cost by multiplying the charges by the hospital's matching department's cost-to charge ratio calculated from the cost report.
Pseudo-Singles Used for Rate-setting	% Singles	Percent of the lines (total occurrences of the code) that CMS used in setting the payment weight. CMS calls these 'single' or 'pseudo single' claims. Identification of single claims is based on our replication of CMS methodology. This is not on the file that CMS releases.
	% Devices	Percent of the single claims used for setting the payment weight that had the device code one the claim.
	Mean Single Charges	Average charge for the procedure code line for the single claims. Does not include other related costs on the claim.
	Mean Single Cost	Average CMS estimated cost of the procedure code line for the single claims. Does not include other related costs on the claim.
	Mean Cost Inc Packaging	Average cost on the single claims for the procedure code and for associated services that are considered packaged and not paid separately.
	Mean Cost Inc Packaging Std	Average packaged costs adjusted for the hospitals wage index to reflect a national average. This calculation backs out regional differences in cost due to different wage levels assuming 60% of the costs are labor. CMS does this adjustment prior to calculating the median for the code.

The Moran Company

Providers of HCPCS 0135T

HOPPS 2006 Proposed Data

Prepared For: Galil Medical and Endocare

Date: August, 2007

				All Claims				Pseudo-Singles Used for Ratesetting					
Provider ID	Name	City	State	Claims	Lines	Mean Charges	Mean Cost	% Singles	% Device C2618	Mean Single Charges	Mean Single Cost	Mean Cost Inc Packaging	Mean Cost Inc Packaging Std
TOTAL				*110*	*111*			*41%*	*36%*				
020017	ALASKA REGIONAL HOSPITAL	ANCHORAGE	AK	*	*	$ 6,612.50	$ 2,884.37	0%					
030065	BANNER DESERT MEDICAL CENTER	MESA	AZ	*	*	$ 4,995.00	$ 582.41	100%	200%	$ 4,995.00	$ 582.41	$ 4,739.73	$ 4,707.40
050100	SHARP MEMORIAL HOSPITAL	SAN DIEGO	CA	*	*	$ 1,069.00	$ 222.13	50%	0%	$ 1,069.00	$ 222.13	$ 846.46	$ 776.14
050108	SUTTER GENERAL HOSPITAL	SACRAMENTO	CA	*	*	$ 15,026.99	$ 2,772.47	100%	0%	$ 15,026.99	$ 2,772.47	$ 6,136.25	$ 5,286.83
050262	UCLA MEDICAL CENTER	LOS ANGELES	CA	*	*	$ 6,650.00	$ 1,409.80	0%					
070022	YALE-NEW HAVEN HOSPITAL	NEW HAVEN	CT	*	*	$ 6,983.76	$ 2,727.15	100%	100%	$ 6,983.76	$ 2,727.15	$ 3,486.06	$ 3,075.94
070025	HARTFORD HOSPITAL	HARTFORD	CT	*	*	$ 2,998.99	$ 1,652.74	20%	0%	$ 3,531.65	$ 1,946.29	$ 13,114.68	$ 11,571.79
090011	WASHINGTON HOSPITAL CENTER	WASHINGTON	DC	*	*	$ 4,078.48	$ 835.99	0%					
100038	MEMORIAL REGIONAL HOSPITAL	HOLLYWOOD	FL	*	*	$ 3,609.33	$ 1,387.42	100%	0%	$ 3,609.33	$ 1,387.42	$ 4,996.83	$ 4,925.13
100286	PHYSICIANS REGIONAL MEDICAL CENTER	NAPLES	FL	*	*	$ 6,300.00	$ 1,587.60	0%					
110082	SAINT JOSEPH'S HOSPITAL OF ATLANTA, INC	ATLANTA	GA	*	*	$ 814.86	$ 210.23	0%					
140067	SAINT FRANCIS MEDICAL CENTER	PEORIA	IL	12	12	$ 2,976.25	$ 1,020.26	*	75%	$ 2,976.25	$ 1,020.26	$ 3,507.12	$ 3,647.64
140135	DECATUR MEMORIAL HOSPITAL	DECATUR	IL	*	*	$ 6,000.00	$ 1,962.00	0%					
140148	MEMORIAL MEDICAL CENTER	SPRINGFIELD	IL	*	*	$ 6,333.33	$ 1,658.07	33%	0%	$ 11,000.00	$ 2,879.80	$ 3,920.22	$ 4,197.05
150009	CLARK MEMORIAL HOSPITAL	JEFFERSONVILLE	IN	*	*	$ 2,774.39	$ 659.75	0%					
150082	DEACONESS HOSPITAL	EVANSVILLE	IN	*	*	$ 1,125.00	$ 446.73	0%					
180056	METHODIST HOSPITAL	HENDERSON	KY	*	*	$ 7,360.00	$ 1,866.49	0%					
190098	LSU HEALTH SCIENCES CENTER, SHREVEPORT	SHREVEPORT	LA	*	*	$ 11,855.00	$ 11,553.88	50%	0%	$ 11,855.00	$ 11,553.88	$ 11,930.62	$ 13,081.44
220110	BRIGHAM AND WOMEN'S HOSPTIAL	BOSTON	MA	*	*	$ 8,569.00	$ 1,373.61	0%					
220175	METROWEST MEDICAL CENTER	FRAMINGHAM	MA	*	*	$ 60.50	$ 17.21	0%					
230046	UNIVERSITY OF MICHIGAN HEALTH SYSTEM	ANN ARBOR	MI	*	*	$ 1,625.00	$ 710.77	100%	0%	$ 1,625.00	$ 710.77	$ 3,020.41	$ 2,933.46
240053	METHODIST HOSPITAL	SAINT LOUIS PARK	MN	*	*	$ 7,966.00	$ 2,810.40	50%	100%	$ 7,432.00	$ 2,622.00	$ 4,731.76	$ 4,482.85
240078	FAIRVIEW SOUTHDALE HOSPITAL	EDINA	MN	*	*	$ 973.50	$ 454.72	0%					
260032	BARNES JEWISH HOSPITAL	SAINT LOUIS	MO	*	*	$ 2,278.00	$ 935.11	80%	0%	$ 2,278.00	$ 935.11	$ 1,293.41	$ 1,390.80
260068	BOONE HOSPITAL CENTER	COLUMBIA	MO	*	*	$ 4,123.00	$ 1,389.45	100%	0%	$ 4,123.00	$ 1,389.45	$ 3,054.45	$ 3,366.51
280013	THE NEBRASKA MEDICAL CENTER	OMAHA	NE	*	*	$ 5,194.79	$ 823.89	0%					
330024	MOUNT SINAI HOSPITAL	NEW YORK	NY	*	*	$ 4,800.00	$ 1,691.52	100%	0%	$ 4,800.00	$ 1,691.52	$ 1,797.18	$ 1,534.84
330125	ROCHESTER GENERAL HOSPITAL	ROCHESTER	NY	*	*	$ 2,541.90	$ 1,478.36	0%					
330203	CROUSE HOSPITAL	SYRACUSE	NY	*	*	$ 4,110.00	$ 2,190.21	100%	0%	$ 4,110.00	$ 2,190.21	$ 2,761.42	$ 2,776.13
330214	NYU HOSPITALS CENTER	NEW YORK	NY	*	*	$ 1,500.00	$ 1,924.95	100%	0%	$ 1,500.00	$ 1,924.95	$ 3,599.07	$ 3,073.71
330232	SETON HEALTH SYSTEM-ST MARY'S CAMPUS	TROY	NY	*	*	$ 1,807.00	$ 879.46	0%					
340002	MEMORIAL MISSION HOSPITAL AND ASHEVILL	ASHEVILLE	NC	*	*	$ 7,210.00	$ 2,345.41	0%					
340030	DUKE UNIVERSITY HOSPITAL	DURHAM	NC	*	*	$ 1,616.60	$ 1,204.36	100%	0%	$ 1,616.60	$ 1,204.36	$ 4,299.85	$ 4,348.75
340047	NORTH CAROLINA BAPTIST HOSPITAL	WINSTON-SALEM	NC	*	*	$ 1,943.25	$ 785.07	0%					
350011	MERITCARE HEALTH SYSTEM	FARGO	ND	*	*	$ 863.05	$ 396.22	0%					
350019	ALTRU HOSPITAL	GRAND FORKS	ND	*	*	$ 3,000.00	$ 1,291.50	0%					
360035	MOUNT CARMEL HEALTH	COLUMBUS	OH	*	*	$ 2,499.00	$ 427.57	100%	0%	$ 2,499.00	$ 427.57	$ 3,280.04	$ 3,270.64
360090	ST LUKE'S HOSPITAL	MAUMEE	OH	*	*	$ 9,070.00	$ 4,268.34	0%					

				All Claims				Pseudo-Singles Used for Ratesetting					
Provider ID	Name	City	State	Claims	Lines	Mean Charges	Mean Cost	% Singles	% Device C2618	Mean Single Charges	Mean Single Cost	Mean Cost Inc Packaging	Mean Cost Inc Packaging Std
360180	CLEVELAND CLINIC FOUNDATION	CLEVELAND	OH	*	*	$ 3,056.20	$ 760.99	20%	100%	$ 3,501.00	$ 871.74	$ 5,418.77	$ 5,639.22
380017	LEGACY GOOD SAMARITAN HOSPITAL	PORTLAND	OR	*	*	$ 3,736.00	$ 1,613.57	0%					
440073	MAURY REGIONAL HOSPITAL	COLUMBIA	TN	*	*	$ 1,349.00	$ 656.15	100%	100%	$ 1,349.00	$ 656.15	$ 2,650.46	$ 3,069.12
440133	BAPTIST HOSPITAL	NASHVILLE	TN	*	*	$ 2,931.74	$ 1,161.85	14%	100%	$ 3,500.00	$ 1,387.05	$ 7,363.93	$ 7,512.35
450358	METHODIST HOSPITAL,THE	HOUSTON	TX	*	*	$ 3,934.61	$ 1,511.68	0%					
490007	SENTARA NORFOLK GENL HOSP	NORFOLK	VA	*	*	$ 3,607.00	$ 1,381.12	0%					
490063	INOVA FAIRFAX HOSPITAL	FALLS CHURCH	VA	*	*	$ 4,221.50	$ 1,768.80	100%	0%	$ 4,221.50	$ 1,768.80	$ 2,461.46	$ 2,367.56
500014	PROVIDENCE EVERETT MEDICAL CENTER	EVERETT	WA	*	*	$ 2,999.03	$ 657.68	100%	100%	$ 2,999.03	$ 657.68	$ 5,300.72	$ 4,922.18
500024	PROVIDENCE ST PETER HOSPITAL	OLYMPIA	WA	*	*	$ 4,998.00	$ 796.18	100%	0%	$ 4,998.00	$ 796.18	$ 2,578.25	$ 2,380.82
510001	WEST VIRGINIA UNIVERSITY HOSPITALS	MORGANTOWN	WV	*	*	$ 7,321.50	$ 2,820.24	50%	100%	$ 7,321.50	$ 2,820.24	$ 4,895.86	$ 5,450.81
520049	BELLIN MEMORIAL HSPTL	GREEN BAY	WI	*	*	$ 1,951.00	$ 809.27	100%	100%	$ 1,951.00	$ 809.27	$ 7,697.69	$ 7,872.66
520098	UW HEALTH UW HOSPITALS AND CLINICS	MADISON	WI	*	*	$ 2,230.90	$ 924.26	33%	0%	$ 2,121.00	$ 878.73	$ 2,473.00	$ 2,316.27
530012	WYOMING MEDICAL CENTER	CASPER	WY	*	*	$ 1,640.00	$ 669.77	100%	100%	$ 1,640.00	$ 669.77	$ 3,749.42	$ 3,924.75

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September 10, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

Dear Mr. Kuhn:

The American Society of Interventional Pain Physicians (ASIPP) would like to thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. Our comments cover two main issues arising under the HOPPS and ambulatory surgery center (ASC) payment methodologies.

ASIPP is a not-for-profit professional organization comprised of nearly 3,700 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 7,000 physicians practicing interventional pain management in the United States. Hospital outpatient departments and ambulatory surgery centers, along with physician offices, are important sites of service for the delivery of interventional pain services.

I. ASC Procedures

There are several specific procedure issues we ask CMS to review and address. We believe that two procedures that have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. We ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable

separately in the HOPD in certain circumstances and we believe that the same should be true for ASCs.

Lastly, we ask CMS to please recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While we recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

ASIPP recommends that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

ASIPP is concerned that CMS's proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

Approximately 25 to 30 percent of all the neurostimulator implant procedures performed each year are required to replace a depleted, non-rechargeable battery. Thus, in the long term, the use of rechargeable devices likely would result in cost savings to the Medicare program and beneficiaries due to the decreased need for battery replacement procedures. The need for fewer surgeries also would reduce the chances that patients will experience operative complications such post-operative infection or other possible co-morbidities.

We ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable

neurostimulators ($11,608 median cost). While we recognize that this difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a two times rule violation and for median costs differences significantly less than $1,000. We urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary we recommend that CMS:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

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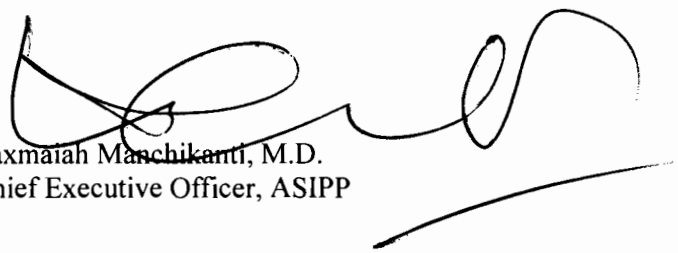
Thank you for your consideration of our comments. We would be happy to answer any questions you may have regarding our comments or to provide CMS with additional information.

Respectfully submitted,



Laxmaiah Manchikanti, M.D.
Chief Executive Officer, ASIPP

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Cochlear™ Hear now. And always

Cochlear Americas
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Englewood, CO 80112 USA
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www.cochlear.com

September 11, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1392-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: [CMS-1392-P] Medicare and Medicaid Program; CY 2008 Proposed Changes: Proposed Rule

Dear Sir or Madam:

Cochlear Americas, the world's largest manufacturer and distributor of cochlear implants, welcomes the opportunity to submit the following comments regarding the above-referenced proposed rule (Proposed Rule)[1] as it relates to cochlear implantation.

Cochlear Americas appreciates the considerable effort put into the outpatient prospective payment system (OPPS) and is encouraged by the proposed increased payment rates for the cochlear implant and related services. However, the proposed payment is still significantly less than the hospital's cost to provide the device and associated services. We are providing comments on issues that pertain to sections: OPPS: Device-Dependent APCs and APC Relative Weights.

RE: OPPS: Device-Dependent APCs

While the proposed CY2008 payment for the cochlear implantation (APC 0259 – Level VI ENT Procedures) is increasing, it includes payment for services that currently receive separate reimbursement (e.g. 95920 – intraoperative nerve test). When the packaged services effect is taken into account, the 2008 proposed APC payment level of $25,753.49 is still significantly less than the average cost of $31,988.81[2] for the hospital to acquire the cochlear implant and the associated costs to provide the implantation service.

The proposed 2008 regulations indicate a change to the median cost calculation for device-dependent APCs. Thank you for this proposal to refine this method and we are in agreement with your proposal as it applies to the rate setting for CY2009 year and forward. However, for the CY2008 rate year, we believe there should be an adjustment to the calculation as it pertains to the FB modifier. During the 2006 claim year, the FB modifier was used only when a device was provided at no cost. Therefore, the data pool used to determine the median cost of the 2006 data likely includes claims for devices provided at a reduced cost or for which the hospital received credit. While the number of these claims

[1] 72 Federal Register 42628 (Aug. 2, 2007).
[2] Average hospital invoice device cost of $24,342 plus $6,328 for hospital implant services adjusted by 4.3% CPI increase in medical care costs for the 12-months ending July 2007. Costs estimated using the 2006 Lewin Group Analysis (see footnote 4) and industry comments to the CY2007 proposed rule.

may be small, they are significant because of their power to lower the median cost used to calculate the 2008 payment rates.

Recommendations and CMS Actions Requested

- We recommend CMS redefine the "token charge" criteria for the CY2008 rate year only to take into account any device provided at a reduced cost. As the definition of "token charge" applies to APC 0259, we recommend defining it to be when the "device charge is in excess of $25,388 (the average "hospital invoice price" of $24,342 detailed in the September 28, 2006 The Lewin Group analysis[3] adjusted by a 4.3% increase in CPI for all Urban Consumers[4]). While this recommendation will make the data pool smaller, it should also more accurately reflect the hospital's cost to provide a cochlear implant. We believe the modification to the FB modifier definition implemented 1/1/2007 will solve this data anomaly for future OPPS rate setting.

- We recommend CMS use the external data developed by The Lewin Group in 2006 and provided in last year's comments to the proposed CY2007 payment rates and adjust the costs using the U.S. Department of Labor's Bureau of Labor Statistics reported Consumer Price Index of a 4.3% increase to all urban consumers for medical care[5]. We have included a copy of last year's report by The Lewin Group entitled "Evaluation of the Effect of Charge Compression on Proposed FY2007 Medicare Payment Rates for Cochlear Implant Devices/Systems" (September 28, 2006).

RE: APC Relative Weights

Proposed Calculation of CCRs

The Consortium appreciates CMS' commitment to address issues related to payment rate accuracy, however, problems with the claims data and the methods used by CMS to set payment rates under OPPS continue to result in inadequate payment rates for a number of procedures utilizing advanced technologies.[6,7] Payment rate inaccuracies continue under OPPS because the methods to calculate relative payment weights do not recognize or adequately adjust for charge compression, a hospital's practice of applying a lower percentage markup to higher cost items and services. The RTI study, commissioned by CMS, confirmed that charge compression introduces a systematic bias into payment rates and recommended short, medium, and long-term interventions to substantially reduce this bias. Specifically, RTI recommended using regression-based estimates to disaggregate the departmental CCR for medical supplies to improve payment rate accuracy.

RTI's recommendations will improve OPPS payment rate accuracy

In the proposed rule, CMS concluded that the OPPS rate setting methodology is already more specific than RTI's recommendation. However, the use of more cost centers or

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[3] *Evaluation of the Effect of Charge Compression on Proposed FY2007 Medicare Payment Rates for Cochlear Implantation Devices/Systems.* The Lewin Group, Inc. September 28,2006.
[4] July 2007 Consumer Price Index News Release: http://www.bls.gov/news.release/pdf/cpi.pdf
[5] July 2007 Consumer Price Index News Release: http://www.bls.gov/news.release/pdf/cpi.pdf
6 GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf
7 The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003

hospital-specific cost centers does **not** equate to more specific rate setting. Implementation of RTI's recommendations will lead to improvements over the current method because RTI's methodology 1) ensures cost centers are designed to reduce markup variation and 2) uses regression-based estimates to adjust, or disaggregate, existing departmental CCRs. Below is a detailed example of how RTI's recommendation will improve OPPS rate setting.

The OPPS currently has two cost centers for medical supplies: cost center 5500 (Med Supplies Charged to Patient) and cost center 3540 (Prosthetic Devices), but the cost centers are not designed to reduce markup variation. In the OPPS, revenue code 278 (Other implants) currently cross walks to cost center 5500, which is the cost center representing lower-cost medical supplies. However, using RTI's recommendations as guidance, Revenue code 278 should instead crosswalk to cost center 3540, which represents higher-cost medical technologies. This improvement in cost center alignment will dramatically improve the variation in mark-ups with each cost center. RTI's recommendation then uses the CCRs for these disaggregated cost centers, and not departmental CCRs, for rate setting. Both the proper alignment of cost centers and the use of disaggregated CCRs are necessary for the OPPS to reduce the systematic bias introduced through charge compression.

CMS should take steps to reduce the impact of charge compression for CY 2008

CMS also proposed the development of an all-charges model, using both outpatient and inpatient claims, to evaluate the RTI's recommendation. While we are encouraged that CMS continues to evaluate this issue, it is important for CMS to implement short-term adjustments to this known payment rate accuracy issue for CY 2008 while, at the same time, CMS further investigates longer term solutions. An adjustment or correction to charge compression has been discussed since 2000, yet the underlying claims data and rate setting mechanisms continue to be inaccurate. Applying either the inpatient disaggregated CCRs or using outpatient intradepartmental CCRs, i.e., one CCR for cost center 5500 (Med Supplies Charged to Patient) and a separate CCR for cost center 3540 (Prosthetic Devices), would be a step in the right direction even if an all-charges model were to be implemented at a later date. RTI's recommendation for disaggregating the CCR for devices and implants from the CCR for other supplies improves the accuracy of CMS data, reduces the systematic payment rate bias from charge compression, and can be executed in a simple and concise manner using CMS's own data files.

If CMS is convinced that an all-charges model needs to be developed before implementing RTI's recommendations, we would request that CMS develop a joint OPPS and IPPS task force to ensure that all possible issues, i.e., all-charges model, MS-DRG interactions, potential HSRV impact, etc. are analyzed in time for implementation in the inpatient and outpatient proposed rules for 2009.

Recommendations and CMS Actions Requested

- CMS should apply RTI's recommendations in CY 2008 by either applying the inpatient disaggregated CCRs or using outpatient, regression-based intradepartmental CCRs to calculate OPPS payment rates.

- If CMS deems that implementing RTI's recommendations in the outpatient setting is not feasible for CY 2008, CMS should develop a joint OPPS and IPPS task force to ensure an all-charges model is analyzed and implemented in the inpatient and outpatient setting for 2009.

RE: Revisions to the ASC Payment System APC Relative Weights

In general, Cochlear Americas is encouraged with the increased reimbursement in the ASC setting and preserving the cochlear implant device costs in the ASC payment structure. This payment package should decrease billing and reimbursement errors while simplifying claims filing and processing.

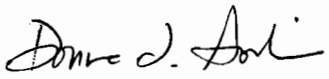
However, as with the comments on the 2008 proposed OPPS, we believe the proposed ASC payment of $22,839 is insufficient to cover the true costs associated with the cochlear implant device and related surgical procedure. We encourage CMS to continue to monitor and adjust payments for cochlear implant claims (69930) paired with L8614 in the ASC and OPPS environments.

We believe the ASC is an option based upon a surgeon's clinical judgment for appropriate patients. We would not recommend the ASC for cochlear implantation because reimbursement has improved, but rather because it is a viable option for specific patients.

Cochlear Americas appreciates the opportunity to comment on this important CMS proposal that will affect the cochlear implant's availability to Medicare beneficiaries. We urge CMS to revisit the proposed payment levels for cochlear implantation in both OPPS and ASC settings.

Thank you again for the opportunity to present our views.

Sincerely,



Donna L. Sorkin
Vice President, Consumer Affairs
Cochlear Americas

The LEWIN GROUP

Evaluation of the Effect of Charge Compression on Proposed FY2007 Medicare Payment Rates for Cochlear Implantation Devices/ Systems

Prepared for:
Cochlear Americas and Med-El Corporation

Prepared by:
The Lewin Group, Inc.

Joan E. DaVanzo, Ph.D., M.S.W.
Allen Dobson, Ph.D.
Jeannine Dollard, MPA
Jean Freeman, MA

September 28, 2006

Evaluation of the Effect of Charge Compression on Proposed FY2007 Medicare Payment Rates for Cochlear Implantation Devices/ Systems

The Lewin Group
September 28, 2006

Introduction

Charge compression (also referred to as cost weight compression), which is the phenomenon where a hospital sets charges for high cost services using a lower percent mark-up than charges for lower cost services, has been noted as a potential pricing problem in Medicare prospective payment systems for many years, especially in the payment for advanced medical technologies.[1] Charge compression makes it very difficult to accurately determine "costs" in a cost-based payment system because a single cost-to-charge ratio for the items and services within a single department, items with differential markups.[2]

In the inpatient setting, compression, very simply refers to the overestimation of relative payment weights of the least-sick patients (or cases) and underestimation for the most-sick patients.[3] In the U.S., cost weight compression has been studied since the early days of DRGs and the introduction of prospective payment for acute inpatients. More recently in a study for MedPAC of hospital charge setting practices, The Lewin Group found that hospitals have many different approaches to setting and updating their charge masters, and most hospitals reported that they do mark up expensive procedures and technologies less than they mark up cheaper services for a variety of reasons.[4]

On August 8, 2006, the Centers for Medicare and Medicaid Services (CMS) issued its proposed changes to the Hospital Outpatient Proposed Payment System (OPPS). The Lewin Group was commissioned separately by Cochlear Americas and MED-EL to provide an assessment of the proposed payment rates for cochlear implant devices/systems. These are surgically implanted prosthetic devices that electrically stimulate the hearing nerve in the cochlea (inner ear), allowing individuals with severe to profound hearing loss to hear sound.

The Lewin Group was asked to (1) conduct a literature review of available internet and research resources of existing English language studies and position papers which report charge compression of comparable high-cost devices and the impact the resultant discounted pricing has on CMS payment to hospitals; (2) synthesize available data and reports that reflect device-related charge compression; and (3) prepare and submit a narrative report with accompanying

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[1] Medicare Payment Advisory Commission: Paying for new technology in the outpatient prospective payment system. In *Report to Congress: Medicare Payment Policy*. March, 2002.
[2] Farkas letter to Hartstein dated 6/12/06.
[3] Botz CK, Sutherland J, Lawrenson J. (2006) Cost weight compression: impact of cost data precision and completeness. Health Care Financing Review, Spring, 2006
[4] The Lewin Group. *A Study of Hospital Charge Setting Practices.* Prepared for: Medicare Payment Advisory Commission. November 2004.

documentation to Cochlear Americas and MED-El prior to the October 10, 2006 final date for submission of comments to CMS' proposed changes to OPPS CY2007.

This report contains our assessment of the extent to which the proposed payment for APC 0259 (Level VI ENT, or cochlear implantation) is impacted by charge compression. The following are the research questions that guided our work:

- Are hospital charge patterns for implanted cochlear devices for Medicare patients inconsistent with charging patterns for other hospital products and services?
- Are hospital mark-ups of cost to charges for these devices comparable to mark-ups for other products and services?
- To the extent that charging patterns are different, examine causes for these differences.
- What is the likely impact of these charging patterns on Medicare payment rates for APC 0259?
- Have the charging patterns impacted the evolution of Medicare payment for implantable cochlear devices?

Background

In August of 2000, Medicare implemented OPPS in response to the Balanced Budget Act of 1997, as an effort to address outpatient hospital payment deficiencies and inconsistencies. Prior to that time, hospitals were paid for outpatient care based on allowable cost as reported by hospital reports along with a series of complex adjustments. This system was not transparent as to how costs were linked to payments. Under OPPS, similar clinical procedures are grouped under Ambulatory Payment Classifications (APCs), and a payment rate is established for each APC. The relative weight of each APC was derived from the median operating and capital cost of the services based on hospital claims data. There is some evidence that the process does not accurately reflect the true costs of drugs, medical devices, or new technology. The APC payment is intended to cover the entire cost: device, supplies and procedure, except in the case of very new technologies.

The APC payment for services includes a limited bundling of ancillary services and supplies, including drugs and medical devices. Given this limited bundling in the OPPS, a specific device can represent a very large share of the total cost of the service. For example, in a recent 2003 study using 2001 claims, The Lewin Group found that that the median APC cost for a cochlear implantation procedure (APC 0259) was about $18,785, of which we estimated a median device cost of $15,451, or 82.25% of the total APC. In an earlier study of Medicare inpatient prospective payment conducted for AdvaMed, The Lewin Group found that despite strong clinical data

supporting the effectiveness of cochlear implants, hospitals had been reluctant to offer the procedure due to low Medicare reimbursement.[5]

Through periodic rule changes, CMS has worked to find fair and efficient ways to pay for new technologies, in the OPPS this would be device-dependent APCs. For example, in CY 2002 OPPS, CMS used external data, in addition to claims data, to establish APC cost medians for weight setting. Additionally that year, many devices were eligible for pass-through payments which helped to ensure adequate payment. However, in its report to Congress in 2002, MedPAC described part of the difficulty associated with pass-through payments:

> "As currently structured, the pass-through payments provide manufacturers and hospitals with incentives to raise their prices and charges, potentially resulting in overpayments."[6]

Over the next five years, CMS tried to overcome data limitations resulting from provider uncertainty concerning the coding of devices. In the CY 2003 OPPS, CMS used a blend of external data with claims data (using only claims that included a device code) to set the medians for device-dependent APCs, adjusting for any APC that declined more than 15 percent. In CY 2004, CMS used a 50/50 blend of external data with claims data containing device codes to set APC medians. In CY 2005, CMS made hospitals' use of the device codes mandatory, and adjusted those device-dependent APC medians for which the CY2005 OPPS payment median was less than 95 percent of the CY2004 OPPS payment median.

In CY2006, CMS set the median cost for device-dependent APCs at the highest of: (1) the median cost of singletons (e.g., claims containing a single procedure), (2) the median cost calculated using only claims containing device codes for which the device cost was greater than $1, or (3) 90 percent of the payment median that had been used to set the CY2005 payment rates.

For the CY2007 payment, CMS proposes to base payment rates for device-dependent APCs solely on median costs calculated using claims with appropriate device codes (e.g., codes that meet device edits) and which have no token charges for devices reported on the claim. At this point, hospitals were required to use device codes on their claims, and coding discrepancies were not as prevalent as in earlier years.

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[5] Lewin Group. Outlook for medical technology innovation: will patients get the care they need? The Medicare payment process and patient access to technology. Washington DC, AdvaMed, July 21, 2000.

[6] In this same report, MedPAC provided recommendations for more equitable solutions to the device pricing issue. Recommendations included:

1. Set fee schedule rates for devices at levels that, if paid to manufacturers, would give them adequate but not excessive return on equity to supply the devices.
2. Consider competitive bidding, which through demonstration projects has successfully reduced program payments for durable medical equipment.
3. And in the interim, base fee schedule rates partially and temporarily on cost data from manufacturers or hospitals.

The concern now is that even with "good" claims data, payment for device-dependent APCs will still not be accurate, due to the time lag between claims data used and the payment period and also charge compression. (Note: the 2007 rulemaking uses claims from 2005.) A recent study for Medtronic looked at total payments and costs per discharge under the current inpatient weight-setting system in a sample of hospitals. The sampled hospitals had sophisticated cost accounting systems and were able to provide procedure-level detail. The analysis found that average payments fell short of average costs ranging from 11 to 22 percent for ICD DRGs and between 17 to 31 percent for pacemaker implants.[7]

Prior Lewin Group Analyses of NPRM

The Lewin Group has provided technical assistance in assessing the methodology used by CMS to develop the proposed payment rates for cochlear implant devices/systems for CY2003, CY2005, and CY2006. Our initial analysis found that the proposed CY 2003 payment did not reflect the actual cost of the device due to fairly extensive provider miscoding of the device. Each of our analyses sought to duplicate CMS' methodology as described in the Federal Register, and then to recalculate the median APC cost by substituting a weighted average invoice price for the device cost found on the claims.[8]

In 2003, there were extensive data limitations. We found errors in device coding (e.g., providers coded the procedure but included a device code for a defibrillator, for example), assignment of the device to the proper revenue center, and claims that included the device L8614 but were for procedures other than cochlear implantation.

In 2004, we found the median APC cost to be underestimated because CMS was including claims with multiple units of the device (which lowered the device cost). Table 1 shows the results of each of the three studies. CMS revised the proposed APC payment rate in the study years such that the final payment rate better reflected the cost of the device to hospitals.

Table 1: Summary of Lewin Group Study Results - APC 0259

	CY 2003	CY 2005	CY 2006
CMS Proposed Median APC Cost	$15,137	$24,086	$21,739
Lewin Median APC Cost	$18,785	$23,686	$21,046
Lewin Median Device Cost	$15,451	$17,945	$16,408
Hospital Invoice Price	$21,844	$22,350	$21,827
Lewin Recalculated APC Cost using Hospital Invoice Price	$20,132	$26,406	$25,743

[7] Miller H. (2006) Issues in the Use of Medicare Cost Reports to Calculate DRG Relative Weights. Prepared by Navigant Consulting for Medtronic and St. Jude, Inc.

[8] Manufacturers submitted confidential price data to Lewin in order to calculate a weighted average hospital invoice price net of discounts.

Table 1: Summary of Lewin Group Study Results - APC 0259, continued

	CY 2003	CY 2005	CY 2006
Lewin "New" APC Payment	$25,060	$27,954	$27,192

Findings

In order to answer the five research questions, we reviewed prior Lewin Group analyses of APC 0259 and other published communications and studies. We compared cochlear implantation (APC 0259) with other device-dependent APCs (defined as when the device represents at least 80 percent of the APC.) In 2005, there were ten APCs out of approximately 40 APCs. See Figure 1 below and Appendix A.

We obtained APC payments for the referenced APCs from 2004, 2005, 2006, and the proposed payment for 2007 from the Federal Register and plotted them, using only the APCs that were included in the Federal Register for each year. Four APCs have decreased over time: APC 108 and APC 107, cardiac defibrillation; and APC 39 and APC 222 neurological devices. Three APCs have increased over time: 0259 cochlear implants, APC 655 pacemaker, and APC 227 drug infusion device. Table 2 contains these APC payments, which are plotted in Figure 2.

Figure 1:

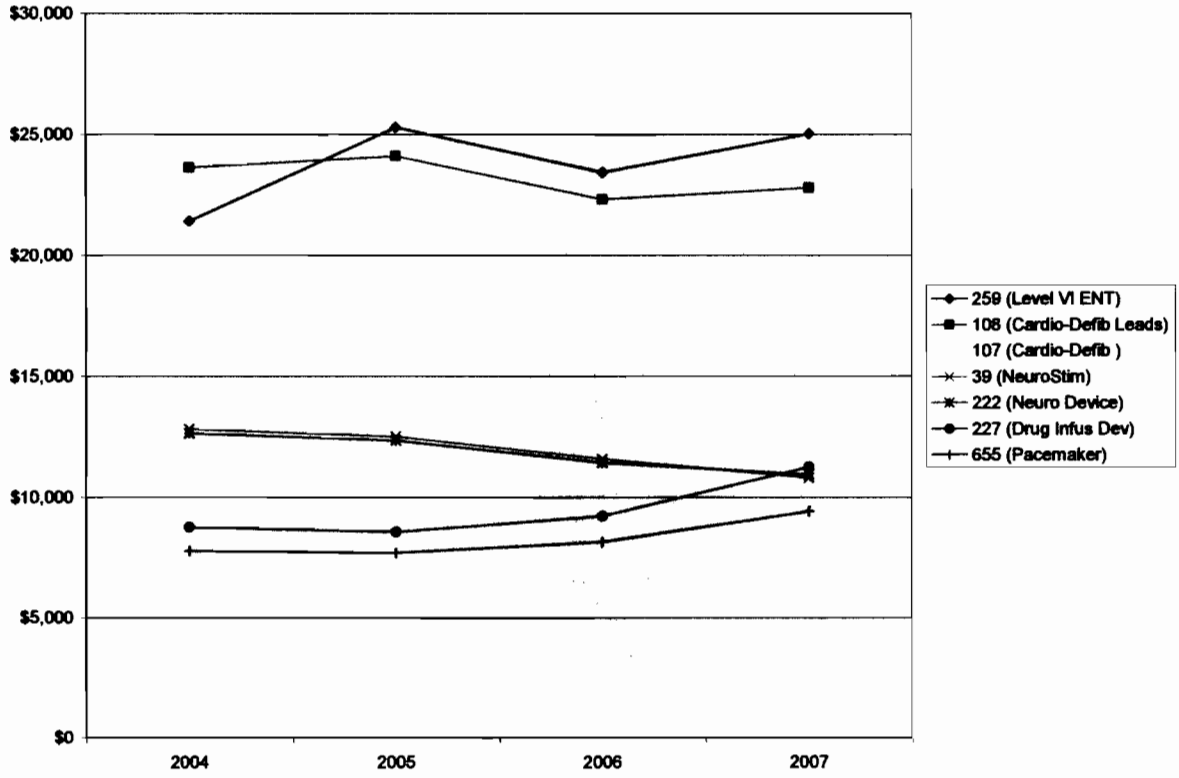
Device Related Percentages of Ambulatory Payment Classification Costs for 2005

APC	DESCRIPTION	APC percent attributed to devices (1)	2005 Device-related portions
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	93.92%	$22,655.11
0107	Insertion of Cardioverter-Defibrillator	92.57%	$16,629.01
0222	Implantation of Neurological Device	86.19%	$10,664.04
0259	Level VI ENT Procedures	85.24%	$21,572.04
0226	Implantation of Drug Infusion Reservoir	85.09%	$2,104.35
0227	Implantation of Drug Infusion Device	82.12%	$7,037.70
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	81.55%	$6,280.21
0119	Implantation of Infusion Pump	81.25%	$5,832.46
0654	Insertion/Replacement of a permanent dual chamber pacemaker	81.07%	$4,868.17
0039	Level I Implantation of Neurostimulator	79.71%	$9,989.03

Table 2: APC Payments for Comparable Device-dependent APCs

APC	Description	2004	2005	2006	2007
39	NeuroStim	$12,832	$12,532	$11,603	$10,829
107	Cardio-Defib	$18,394	$17,964	$16,632	$17,185
108	Cardio-Defib Leads	$23,641	$24,122	$22,334	$22,808
222	Neuro Device	$12,669	$12,373	$11,456	$10,964
227	Drug Infus Dev	$8,775	$8,570	$9,227	$11,276
655	Pacemaker	$7,786	$7,701	$8,144	$9,427
259	Level VI ENT	$21,435	$25,307	$23,431	$25,040

Figure 2: APC Payments for Comparable Device-dependent APCs



We synthesized the available qualitative and quantitative information to determine the following:

a. **Hospital charge patterns for implanted cochlear devices for Medicare patients were found to be most inconsistent with charging patterns for other, lower cost hospital products and services in the inpatient setting.**

   Evidence for this conclusion was found in a series of reports Lewin had prepared for AdvaMed of inpatient reimbursement for medical technology. We found that

cochlear implants had been historically under-reimbursed.[9] Cochlear implants were among the 9 APC codes where over 80% of the payment was attributed to the cost of the device itself.[10]

On the outpatient side, we found that the hospital invoice price ranged between $21,827 and $22,350 between 2003 and 2006, which represents a 2.4 percent difference. In looking at the range of device costs found in the claims, the CY2003 ranged from $2,896 - $84,444 and the CY2004 ranged from $1,839 - $138,506.

b. Hospital mark-ups of cost to charges for these devices are not comparable to mark-ups for other products and services.

In a 2003 Lewin study for Guidant, we found there is a lower percentage mark-up on high-end devices such as implanted permanent pacemakers and cardiac defibrillators. These findings are consistent with what we found for other procedures where the percent attributed to the device is over 80%.[11] Based on interviews with hospitals regarding charging practices, we learned that most hospitals use a tiered mark-up methodology in which the percent mark-up was based on a cost threshold, and under these methodologies, items of lower unit cost received higher mark-ups, while items of higher unit cost received lower mark-ups.[12]

c. **Charge compression is a major contributor to the differences in charges.**

Charge compression is largely responsible for inadequate and inappropriate rates set for device-related procedures in the outpatient setting. "Under OPPS, payment rates for device-related procedures are based on cost data generated by CMS's cost finding principles. Generally, CMS multiplies charges by hospital-specific cost-to-charge ratios (CCRs) to calculate hospitals' costs for all services in a single revenue center, reducing "charges" by a constant factor. This methodology is based on the assumption that each hospital marks up its costs by a uniform percentage within each department to set each service's charge."[13]

Comparably, we have found in two separate studies that hospitals typically have a smaller mark-up for higher-cost devices compared to other items and service. "In practice, CMS's methodology does not recognize hospitals' variability in setting charges. If CMS uses a single CCR to estimate costs, the approach will generally lead to an underestimation of hospitals' costs for higher cost items – a phenomenon referred to as "charge compression."[14]

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[9] *Outlook for Medical Technology Innovation: Will Patients Get the Care They Need? Part 2.The Medicare Payment Process and Patient Access to Technology*, Lewin 2000.
[10] See Table 1 (device related % of APC costs for 2005)
[11] See Appendix A.
[12] Lewin Group: *Hospital Charges and Medicare Payment for Implanted Pacemakers and Cardioverter Defibrillators*, Report submitted to Guidant. September 2003.
[13] David Nexon letter to Kuhn dated 6/8/05.
[14] Hackbarth letter to Scully dated 10/6/03.

Charge compression is a complex issue in the outpatient setting and will require multiple approaches to resolve. CMS has acknowledged this complexity in the final IPPS rule for 2007 by commissioning RTI to study charge compression. A study of charge compression in the outpatient setting seems warranted.

d. **These charging patterns for APC 0259 are likely to result in inadequate Medicare payment rates, which also may result in less access to the technology by beneficiaries.**

Because the mark-up for high cost devices is likely to be lower than the percent markup for other hospital charges, payment levels for these APCs will likely be underpaid. "To the extent that hospitals' mark-up for high cost devices are systematically out of line with the hospitals' mark-up for other items and services, the payment levels for APCs corresponding to these devices are likely to be underweighted and underpaid. The effect on the APC may be especially pronounced when the charge for the device accounts for a high percentage of the total charges associated with an APC, as it would for many implantable devices with high unit costs."[15]

Insufficient payments may result in a cycle of low volume and inadequate reimbursement. Payment for a procedure reflecting hospital financial disincentives will likely be underutilized by providers. As a result, not only will beneficiaries be potentially denied access to the technology, but the lower the frequency of a procedure, the less impact the costs of the procedure will have on the future payment amount.

It is estimated that more than 30 million Americans have hearing loss, including one out of four people older than 65.[16] Therefore, Medicare's payment practices for APC 0259 can potentially influence the quality of life of a large percentage of older hearing impaired patients. Manufacturers estimate that only 16% of cochlear implants are given to Mwdicare patients.

e. **Charging patterns have negatively impacted the evolution of Medicare payment for implantable cochlear devices and continue to do so.**

We found that for CY2007, the hospital invoice price for cochlear implants is $24,342, with the proposed CY2007 payment of $25,040. The hospital invoice price has risen over the period from $21,287 in 2006, yet the proposed payment has not.

As shown above in our work for rulemaking in CY2003, CY2005, and CY2006, in one of the years the APC payment did not even cover the cost of the device. In 2003, the proposed APC cost of $15,137 vs. a hospital invoice price of $21,844. In 2006, the CMS proposed APC cost of $21,739 and payment of $23,431 did cover

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[15] Advamed letter to McClellan dated

[16] Blanchfield BB, et al. The severely to profoundly hearing impaired in the United States: prevalence and demographics. Project Hope Policy Analysis Brief; Center for Health Affairs, October 1999.

the device which cost $21,827. In 2005, the proposed APC payment of $25,307 exceeded the device cost of $22,350. See Table 3.

Table 3: Invoice Price vs. APC Payment

	CY 2004	CY 2005	CY 2006	CY2007
APC Payment	$21,435	$25,307	$23,431	$25,040
Invoice Price	$21,844	$22,350	$21,827	$24,342

Access to cochlear implants by Medicare beneficiaries has been disproportionately low vis a vis other medical devices, and inadequate Medicare payment policy has played a significant role in this. As long as the methodology to determine device costs is reliant on overall cost-to-charge ratios, hospitals will be reluctant to provide services to Medicare beneficiaries when the APC payment does not cover the cost of the device.

Conclusion

Through a thorough review of the available resources on charge compression of high-cost devices and the impact the discounted pricing has on CMS payment to hospitals, The Lewin Group concludes the following:

1. The issue of charge compression is as important in the outpatient setting as in the inpatient, and warrants further study, as current CMS methodology does not recognize hospitals' variability in setting charges.

2. The hospital invoice price for cochlear implants is $24,342, which is 97% of the proposed APC payment of $25,040. For the approximately seven APCs wherein the device comprises over 80% of the cost of the device, it seems prudent to continue to consider information beyond that contained in the claims when setting rates.

3. Cochlear implant device costs have risen since 2004, yet the proposed APC CY2007 payment of $25,040 is lower than the CY2005 payment of $25,307.

Appendix A:

Device Related Percentages of Ambulatory Payment Classification Costs for 2005

APC	DESCRIPTION	APC percent attributed to devices (1)	2005 Device-related portions
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	93.92%	$22,655.11
0259	Level VI ENT Procedures	85.24%	$21,572.04
0107	Insertion of Cardioverter-Defibrillator	92.57%	$16,629.01
0222	Implantation of Neurological Device	86.19%	$10,664.04
0039	Level I Implantation of Neurostimulator	79.71%	$9,989.03
0225	Level I Implementation of Neurostimulator Electrodes	79.43%	$9,528.45
0227	Implantation of Drug Infusion Device	82.12%	$7,037.70
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	81.55%	$6,280.21
0119	Implantation of Infusion Pump	81.25%	$5,832.46
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	78.41%	$4,896.19
0654	Insertion/Replacement of a permanent dual chamber pacemaker	81.07%	$4,868.17
0090	Insertion/Replacement of Pacemaker Pulse Generator	79.34%	$4,093.48
0386	Level II Prosthetic Urological Procedures	62.02%	$4,028.23
0674	Prostate Cryoablation	59.47%	$3,801.73
0681	Knee Arthroplasty	64.31%	$3,363.70
0082	Coronary Atherectomy	53.34%	$3,132.64
0680	Insertion of Patient Activated Event Recorders	79.39%	$2,892.96
0385	Level I Prosthetic Urological Procedures	61.65%	$2,448.02
0104	Transcatheter Placement of Intracoronary Stents	51.09%	$2,361.55
0226	Implantation of Drug Infusion Reservoir	85.09%	$2,104.35
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	61.05%	$1,918.36
0229	Transcatherter Placement of Intravascular Shunts	48.74%	$1,725.73
0040	Level II Implantation of Neurostimulator Electrodes	57.33%	$1,609.70
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	43.41%	$1,369.45
0648	Breast Reconstruction with Prosthesis	40.10%	$1,154.17
0086	Ablate Heart Dysrhythm Focus	34.77%	$892.56
0670	Level II Intravenous and Intracardiac Ultrasound	48.09%	$832.55
0202	Level X Female Reproductive Proc	32.78%	$740.95
0167	Level III Urethral Procedures	43.19%	$699.69
0048	Level I Arthroplasty with Prosthesis	28.36%	$652.84
0087	Cardiac Electrophysiologic Recording/Mapping	30.05%	$637.53
0384	GI Procedures with Stents	36.72%	$566.69
0085	Level II Electrophysiologic Evaluation	25.61%	$507.11
0081	Non-Coronary Angioplasty or Atherectomy	21.59%	$402.97
0115	Cannula/Access Device Procedures	26.83%	$392.34
0653	Vascular Reconstruction/Fistula Repair with Device	13.54%	$216.68
0080	Diagnostic Cardiac Catheterization	9.52%	$196.74
0032	Insertion of Central Venous/Arterial Catheter	23.98%	$146.82
0652	Insertion of Intraperitoneal Catheters	9.18%	$145.28
0122	Level II Tube changes and Repositioning	26.63%	$125.75

(1) Based on Device Related Percentages of Ambulatory Payment Classification costs used for 2004

Sorted by highest cost to lowest cost device

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(1) Based on Device Related Percentages of Ambulatory Payment Classification costs used for 2004

Sorted by highest percentage device related portion

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