The
National
Association
for **Proton**
Therapy

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September 29, 2006

Honorable Mark B. McCellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Proton Therapy Payment Rates

Dear Dr. McClellan:

The National Association for Proton Therapy (NAPT), founded in 1990, has great respect for the complexities of your mission and the challenges faced by CMS in the past several years under your effective leadership.

With that in mind, we are writing to you on matters of vast importance to the proton therapy community and cancer patients around the nation. In the past 16 years, about 16,000 patients have successfully battled cancer in the U.S. with proton beam radiation therapy. Worldwide, more than 50,000 patients have been treated. Proton therapy is a precise form of non-invasive treatment that targets cancer without harming healthy tissue surrounding the tumor site. Physicians are able to administer high levels of proton beams to the target site with minimum to no serious side effects or morbidity, compared to traditional radiation treatment. A factor that has caught the attention of the mainstream medical community.

Therefore, we offer our strong support for the proposed **CY'07 Hospital Outpatient Prospective Payment System** (OPPS) **Payment Rules for proton beam therapy.** They are **APC 0664** for simple proton therapies **(77520 and 77522)** and **APC 0667** for immediate/complex therapies **(77523 and 77525).**

This action will continue to ensure that the nation's proton centers will have the capability to provide full patient services and meet increasing demand for proton treatment.

We believe the opening of additional proton facilities in the U.S. will enable more multi-institutional and cooperative research – and will ultimately lead to more innovations in the field. We also believe the potential of protons is only beginning to be realized. New technological advances and collaborative trials will reveal more applications for proton therapy such as treatment of non-cancerous diseases like Parkinson's disease and epilepsy.

continued>

1301 HIGHLAND DRIVE SILVER SPRING, MD 20910 TEL 301 587 6100 FAX 301 565 0747 www.proton-therapy.org

Freestanding Proton Therapy Centers

On another equally as important matter, we want to express our concern for the manner in which the CMS has given significant latitude to its contracted Carriers, but ***limited guidance*** when it comes to determining payment rates for proton therapy. Our concern involves the freestanding proton facilities in the states of Texas, Florida, and Indiana and the rate inconsistency by Carriers in each locale. Therefore, we strongly recommend that:

CMS direct its Carriers on issues of payment for proton therapy for Freestanding Centers so that CMS contracted Carriers' determinations regarding proton therapy payment rates are in keeping with National Payment policy decisions currently in effect for HOPD facilities.

In conclusion, we want to thank you for your attention to these important matters and for your continuing support of proton therapy during your tenure at the CMS. Thank you also for your important contributions to the nation's health and well being. We wish you all the best in your next career move.

Sincerely yours,

Leonard J. Arzt
Executive Director
NAPT

lenarzt@proton-therapy.org

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tyco / Healthcare / Valleylab

October 4, 2006

Submitted via Federal Express

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P
Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

Valleylab, a division of Tyco Healthcare Group LP, is submitting these comments in response to the August 23, 2006 proposed rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates. Valleylab is the world leader in the innovation and manufacture of advanced energy based medical systems including devices for the radiofrequency ablation of lesions and tumors. Valleylab is submitting comments specific to **"Device-Dependent APCs."**

Efforts to Address Radiofrequency Ablation (RFA) Reimbursement
Over the past year and a half Valleylab has actively engaged CMS's assistance in remedying various RFA reimbursement issues:

- In the prior year's rulemaking period Valleylab commented and CMS agreed to reassign two laparoscopic RFA procedures (CPTs 47370 and 50542) to a resource appropriate APC based on the two times rule;
- Valleylab worked with Pat Brooks of the Division of Acute Care to secure twelve ablation specific ICD-9-CM Procedure codes effective October 1, 2006;
- Valleylab submitted to the Division of Outpatient Care an application for an additional device category code to help hospitals bill for the RF device appropriately and thereby provide more accurate paid claims data to CMS for future rate-setting purposes; and

- In the current year's proposed rule CMS is proposing to place three integral imaging guidance codes (CPTs 76362, 73294, and 76940) onto the bypass list, an action that Valleylab supported in our comments to the prior year's proposed rule.

Valleylab is committed to working with CMS to gather more accurate paid claims data. It is evident from paid claims reviews completed for Valleylab by the Moran Company that hospitals around the country need assistance and guidance in billing appropriately for the use of RF devices in RFA procedures. It is our hope that CMS and Valleylab can work together again to improve the accuracy of paid claims data through the establishment of an additional device category code with device dependent status for APCs containing RFA procedure codes.

In light of these efforts we respectfully submit the following comment to CMS:

Comment

Valleylab appreciates the opportunity to comment on CMS's proposed Outpatient Prospective Payment System rule for 2007. Furthermore, Valleylab supports mandatory device reporting and the use of coding edits in device dependent APCs by CMS.

Valleylab respectfully requests that CMS assign device dependent status to the APCs found below and apply coding edits to radiofrequency ablation procedures. Valleylab further requests that CMS establish an additional device category code for pass through status titled "Electrode for the Radiofrequency Ablation of Lesion(s) or Tumor(s)." (Valleylab submitted an application dated May 26, 2006 for an additional device category code to the Division of Outpatient Care.)

- **APC 0423 – Level II Percutaneous Abdominal and Biliary Procedures**
- **APC 0132 – Level III Laparoscopy**
- **APC 0050 – Level II Musculoskeletal Procedures Except Hand and Foot**
- **APC ???? – For the anticipated Lung radiofrequency ablation code**

What is Radiofrequency Ablation?
Radiofrequency ablation involves the percutaneous, laparoscopic, or intraoperative insertion of a radiofrequency energy emitting electrode into a lesion or tumor with the assistance of imaging guidance. Radiofrequency (RF) energy is used to rapidly heat and destroy diseased tissue, leaving the surrounding healthy tissue unharmed. Protein denaturation and coagulation are the ultimate cause of cell death. This is an important new tool for clinicians to treat various forms of cancer and has been shown to significantly improve net health outcomes in patients who are not appropriate candidates for conventional surgery.

Device Dependent APC
The proposed rule states that "device dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure." Radiofrequency ablation procedures are always performed with the use of a

radiofrequency electrode. The radiofrequency electrode once inserted into the human body and directed to the lesion or tumor is used to deliver the radiofrequency energy to heat and ablate the diseased tissue.

Radiofrequency ablation procedures currently reside within APC 423, APC 132, one is proposed to be assigned to APC 050 in 2007, and it is currently unknown which APC CMS will assign the anticipated lung RFA code.

APC 0423	**Level II Percutaneous Abdominal and Biliary Procedures**
CPT 47382	Ablation, one or more liver tumor(s), percutaneous, radiofrequency
CPT 50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
APC 0132	**Level III Laparoscopy**
CPT 47370	Laparoscopy, surgical, ablation of one or more liver tumors, radiofrequency
CPT 50542	Laparoscopy, surgical, ablation or renal mass lesion(s)
APC 0050	**Level II Musculoskeletal Procedures Except Hand and Foot (Proposed)**
CPT 20982	Ablation, bone tumor(s) (eg, Osteoid osteoma, metastasis) radiofrequency, percutaneous, including computed tomography guidance
APC ????	**Proposed grouping for anticipated Lung RFA code**
CPT xxxxx	Anticipated Lung RFA code
CPT 2005 is a registered trademark of the American Medical Association. All rights reserved	

Both RFA procedures of APC 423 require the use of the RFA device to perform the procedure. In addition to the RFA procedures of APC 423 CMS is proposing to accept an APC Panel recommendation to add CPT 0135T (Ablation renal tumor(s), unilateral, percutaneous, cryotherapy) to APC 423. The APC Panel suggested and CMS is proposing to accept the clinical and resource use similarities of cryotherapy procedures and radiofrequency ablation procedures represented by CPT 47382. Devices used to cryo-ablate lesions and tumors are represented in the HCPCS coding system with C2618 (Probe, cryoablation). The criteria used to justify the establishment of C2618 are clinically and financially comparable to an application for a radiofrequency electrode for the ablation of lesions and tumors. The proposed addition of this code to APC 423 further supports our request for CMS to establish a radiofrequency electrode device category code and assign the identified APCs as device dependent.

Furthermore, other APCs that house cryotherapy procedures have been assigned device dependent status. Endometrial cryotherapy ablation (CPT58356) in APC 202 and Prostate cryoablation (CPT 55873) in APC 674 are assigned device dependent status using C2618 as their device code. Radiofrequency and cryotherapy tumor ablation are similar to endometrial and prostate cryoablation because all procedures require the use of a device to perform the procedures.

Finally, laparoscopic RFA procedures within APC 132, the bone RFA procedure proposed for APC 050, and the anticipated lung RFA procedure also require an RF device be used to perform the procedures.

Additional Device Category Application Summary
Valleylab submitted an application dated May 26, 2006 for the establishment of an additional device category code entitled "Electrode for the Radiofrequency Ablation of Lesion(s) or Tumor(s)". Valleylab's application provided a detailed background on the technology, the coding history of RFA procedures, an explanation on why these procedures offer a treatment option to Medicare beneficiaries who are ineligible for or unresponsive to current treatments, and demonstrated the cost of RF electrode devices are not insignificant.

The following is an excerpt from Valleylab's May 26, 2006 application:

SUMMARY OF DEVICE CATEGORY APPLICATION

Tyco Healthcare Valleylab requests that CMS create a device category code for transitional pass through status for radiofrequency electrodes for the ablation of lesions and tumors as this proposed device category meets all CMS criteria for status as summarized below:

1. The radiofrequency ablation electrode has received FDA approval;

2. The device is reasonable and necessary for the treatment of beneficiaries with lesions and tumors;

3. The device, which is inserted into the human tissue of only one patient, is an integral part of the service;

4. The device is not capital equipment, is not an incidental supply, and does not replace human skin;

5. The device substantially improves the treatment of an illness for a patient population that is unresponsive to or ineligible for traditional treatment modalities; and

6. The reasonable average cost of the radiofrequency electrode is not insignificant relative to applicable APC payment rates. The average reasonable cost of radiofrequency electrodes used in procedures for all models on the market ranges from $1,500 to $2,000.

The Moran Company Analysis
Please find attached to this comment a two-page memorandum and a graph from Rachel Feldman and Mary Jo Braid-Forbes of The Moran Company regarding their analysis of 2005 and 2004 Medicare claims data regarding how hospitals are accounting for the cost of RF electrodes in RFA procedures. The following is a brief sample of the memorandum findings:

Nearly half of the single claims used for rate setting in 2005 do not contain any charges that could be attributed to the RF ablation electrode. On the half that do contain charges that could be an RF electrode, hospitals in many cases are using incorrect device HCPCS codes.

- In 2005, 40 single claims (9%) have incorrect devices on the claim that may represent charges for the RF ablation electrode. This is an increase over 2004 when 9 of the single claims (3%) had incorrect devices
- In 2005, only 180 out of 422 single claims (43%) have revenue lines containing charges high enough to include the RF ablation electrode.
- In 2005, 202 single claims (48%) appear not to have charges that capture the cost of the RF ablation electrode.

Please see the attached Moran Company memorandum for the remainder of their findings.

The attached graph shows the average charge for hospitals performing percutaneous liver RFA procedures (CPT 47382). An average charge of less than $6,000 in light of applicable cost to charge ratios is insufficient to cover the cost of the procedure and the device when RF devices cost at least $900 though most are $1,500 or more. Therefore it is unlikely that hospitals are packaging the cost of the RF device into their charges for RFA procedures.

Conclusion

Valleylab respectfully requests that CMS establish a radiofrequency electrode category code for pass through status and assign APCs 423, 132, and 050 as device dependent with appropriate coding edits. We appreciate the opportunity to offer our comments to CMS on its proposed 2007 Outpatient Prospective Payment System rule.

Sincerely,

Gary V. Delhougne JD, MHA
Tyco Healthcare Valleylab
675 McDonnell Blvd, 10-3-C
St. Louis, MO 63134
314-654-7238
314-654-3099 fax
Gary.Delhougne@tycohealthcare.com

Attachments

CC:

Carol Bazell	(Carol.Bazell@cms.hhs.gov)
Edith Hambrick	(Edith.Hambrick@cms.hhs.gov)
Joan Sanow	(Joan.Sanow@cms.hhs.gov)
Barry Levi	(Barry.Levi@cms.hhs.gov)

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

Memorandum (September 14, 2006)

TO: Lisa Saake
Gary Delhougne
Tyco / Healthcare / Valleylab

FROM: Rachel Feldman & Mary Jo Braid-Forbes
The Moran Company

SUBJECT: Analysis of Radiofrequency Ablation Electrode Costs as Captured in Setting Rates for 47382 and Analysis of Hospital Billing for Related Procedures

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You asked us to examine hospital outpatient claims submitted in 2004 and 2005, and to investigate the extent to which the claims used in setting rates for radiofrequency ablation procedures include the costs associated with the Cool-Tip™ RF Electrode which does not currently have a separate HCPCS code. The procedure that we are examining for the presence of costs is CPT®[1] code 47382 [Ablation, one or more liver tumor(s), percutaneous, radiofrequency]. This memorandum provides a summary of our findings.

Nearly half of the single claims used for rate setting in 2005 do not contain any charges that could be attributed to the RF ablation electrode. On the half that do contain charges that could be an RF electrode, hospitals in many cases are using incorrect device HCPCS codes.

- In 2005, 40 single claims (9%) have incorrect devices on the claim that may represent charges for the RF ablation electrode. This is an increase over 2004 when 9 of the single claims (3%) had incorrect devices
- In 2005, only 180 out of 422 single claims (43%) have revenue lines containing charges high enough to include the RF ablation electrode.
- In 2005, 202 single claims (48%) appear not to have charges that capture the cost of the RF ablation electrode.

Methods

We utilized the Medicare 2004 OPPS claims data released with the 2006 final rule, and the 2005 data released with the 2007 proposed rule for this analysis. We matched the CMS count of single claims within "one" of the count of single claims in the 2005 data, and our simulated median was 3% lower than CMS' median. CMS is using only 59% of the occurrences of this code for setting the payment weight for 2007.

TMC		CMS		Percent Difference		Total Frequency	% Used in Rate-setting
Singles Freq-uency	Median Cost	Singles Freq-uency	Median Cost	Singles Frequency	Median Cost		
422	$2,333.55	423	$2,410.33	0%	-3%	715	59%

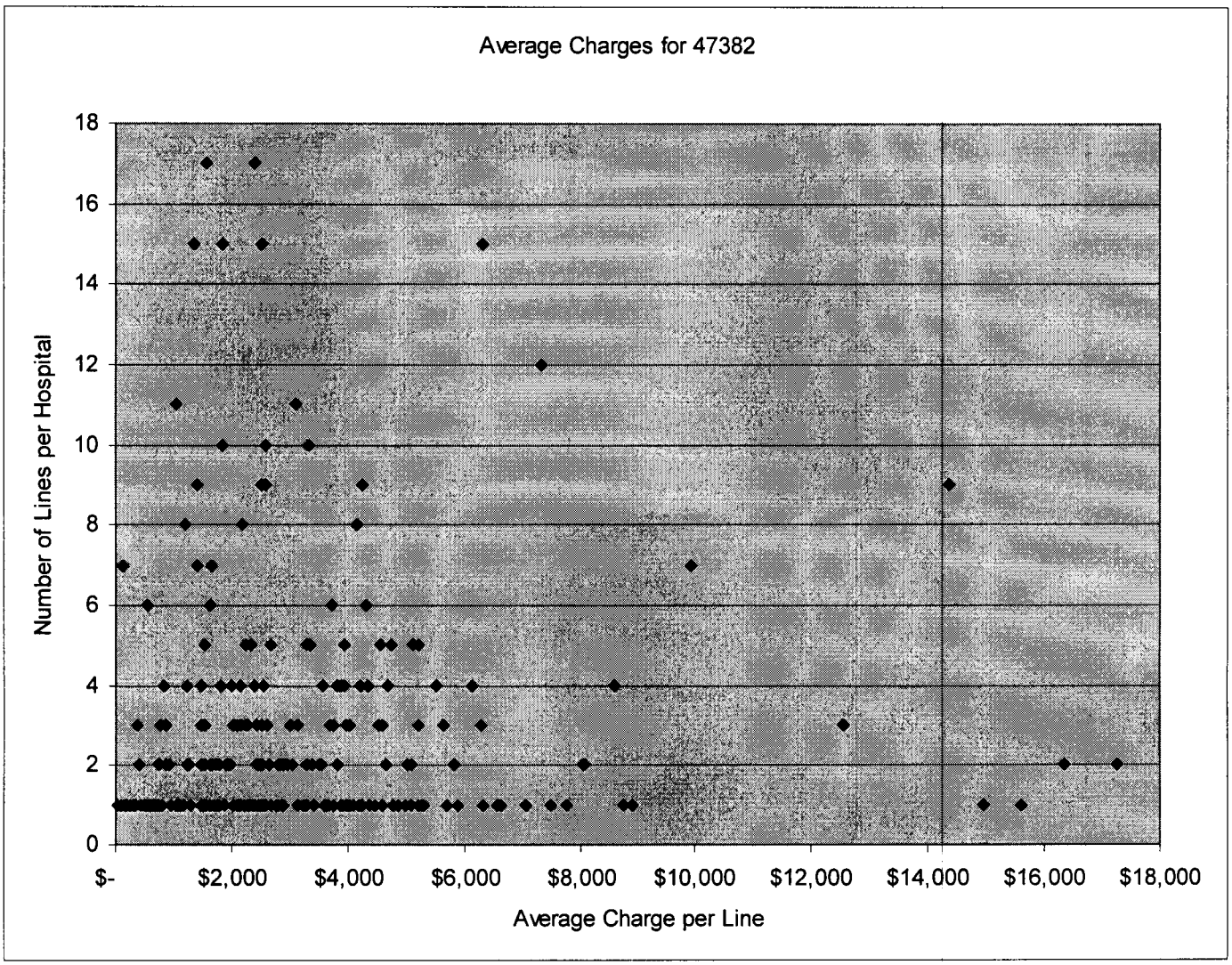
[1] Current Procedural Terminology (CPT) is copyright 2004 and 2005 American Medical Association. All rights reserved.

To identify the claims with charges high enough to account for the RF ablation electrode, we looked for medical supply revenue code lines with charges and units that would be in excess of the acquisition cost you indicated of between $800 and $1,200 per probe. Multiple probes can be used based on the clinical needs of the case. The specific charge and unit criteria are shown in the table below along with the counts of claims in each category and the associated revenue code. We only included codes that appeared on the same date as the procedure. Charges high enough to indicate a probe most often occurred in revenue code 0272 'Medical/Surgical Supplies-Sterile Supply'. However, this level of charges also frequently occurred with revenue code 0270 'Medical/Surgical Supplies-General Classification.' The table below also shows the incorrect device C-codes billed with this procedure and their frequency.

Total Single claims	**422**	
Devices appear to be billed in place of the rf ablation electrode		
	Claims	
C1888 catheter ablation non-cardiac endovascular	26	
C2618 cryoablation probe	8	
C1769 guidewire	6	
Total	40	9%
Revenue code charges indicating RF Ablation Probe		
Revenue codes $1000-2000 <=2 units		
0270	2	
0271	1	
0272	14	
0279		
0621	10	
Revenue codes $2000-5000 1-5 units		
0270	17	
0271		
0272	73	
0279		
0621	18	
Revenue codes $5000+ 1-8 units		
0270	8	
0271	1	
0272	31	
0279		
0621	5	
Total	180	43%

THE MORAN COMPANY

Hospital Average Charges by Frequency for 47382 in 2005
Prepared for: Tyco Valleylab
Source: 2005 Medicare OPPS Claims accompanying Proposed 2007 Rule
September 2006



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Submitter : Dr. Kelly Carson

Date: 10/02/2006

Organization : Metro Atlanta Endoscopy, LLC

Category : Physician

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

I am a gastroenterologist in Atlanta. The largest portion of my practice and largest number of patients seen in my endoscopy center are Medicare patients. The proposed change to the ASC payment system in regards to a further reduction in ASC payment rates would actually result in an increase in program expenditures. My specialty of Gastroenterology would no longer be able to keep their ASC doors open to Medicare beneficiaries. It's a clear case of "false savings" as patients would then have to have their colorectal cancer screenings, as well as their diagnostic colonoscopies and endoscopies, at HOPD's resulting in an increase instead of a decrease in expenditures.

tyco
Healthcare

Mallinckrodt

675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

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October 3, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington DC 20201

Re: CMS-1506-P
Medicare Program: Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule
Section V (B) "OPPS: Nonpass-Through Drugs, Biologicals and Radiopharmaceuticals

Dear Dr. McClellan:

Mallinckrodt Inc., an affiliate of Tyco Healthcare, LP, is submitting these comments in response to the August 23rd 2006 proposed rule: Medicare Program: Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates. Mallinckrodt, through its Imaging division, is a developer, manufacturer, marketer and distributor of radiopharmaceuticals provided to hospitals for the diagnosis and treatment of Medicare and other patients in the hospital outpatient setting.

Mallinckrodt is submitting comments specific to Section V B of the proposed rule Drugs, Biologicals and Radiopharmaceuticals without Pass-through Status

Summary
The Medicare Statute requires that payment for drugs under HOPPS be based on the drugs "average acquisition cost" and subject to any adjustment for overhead costs and other adjustments determined to be necessary by the Secretary of Health and Human Services (see Social Security Act, section 1833 (t) (14). We support CMS' efforts to preserve Medicare beneficiary access to high quality Radiopharmaceuticals however we are concerned that CMS' proposal to set fixed payment in 2007 for radiopharmaceutical products has resulted in severe reductions in proposed payment for select radiopharmaceutical products. We are concerned that the proposed payment rates for OctreoScan (In-111 Pentetreotide) will result in significant underpayment to providers

which may impact beneficiary access. We are also concerned that the proposed payment rate for NeutroSpec (Tc99m Fanolesomab) represents a reimbursement rate that was significantly less than the providers' acquisition costs.

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The proposed change in payment methodology for 2007 (payment rates for Radiopharmaceutical products developed based on 2005 charges for radiopharmaceutical products reduced by department specific costs) does not capture key changes that CMS instructed hospitals to make in Radiopharmaceutical charges for 2006. In early 2006 we conducted extensive education to our hospital customers regarding changes in HCPCS coding as well as payment methodology for Octreoscan. We believe that hospitals utilized this education and made appropriate adjustments to their chargemasters for OctreoScan.

We respectfully request that CMS retain the CCR methodology throughout 2007 based on the belief that one more year is critical to stabilize hospital data and achieve a reliable data source to "calculate average acquisition cost".

Analysis/Discussion

OctreoScan® Background Information-(2006 HCPCS code A9565 with a description of In-111 Pentetreotide diagnostic per mCi)

1. Per the package insert, "Indium 111 pentetreotide (OctreoScan®) is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.
2. The billing code assignment for OctreoScan® has experienced numerous HCPCS coding changes over the past several years with changes in both the HCPCS code assignment (Q code 2005 to A code for 2006) along with the HCPCS code description (variation in code description of per mCi to per 3 mCi back to per mCi for 2006 despite request for per dose descriptors).
3. GAO study on Hospital Radiopharmaceutical prices reported an average purchase price in 2004 for a "dose" of OctreoScan to be $1280 ($213/mCi) with a Median purchase price $1424 ($237 per mCi). The GAO study also stated that their data demonstrated relatively little variation in the purchase price of a 3 mCi dose versus a 6 mCi dose. We would suggest that the GAO survey from 2004 reflect 2006 average acquisition prices for this product.
4. CMS proposes to reimburse providers $185.65 per mCi ($1114 for a 6 mCi dose) which represents a rate that significantly under compensates Medicare Hospital outpatient providers based on historical benchmarks provided by the GAO.
5. Moran analysis of the 2005 claims data for Q3008 (A9565 for 2006) demonstrates:
    a. OctreoScan volume is spread over many hospitals in small amounts. No one hospital dominates.
    b. 356 hospitals (21% of units) billed 1 unit/line (1014 units) at a mean $575.84/unit or $191.95/mci.
    c. 288 hospitals billed 2 units/line.

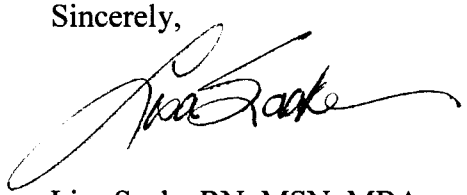
d. 84 hospitals billed between 1 and 2 units/line.
e. 87 hospitals billed more than 2 units/line, with 15 hospitals billing 6 units/line. (we would suggest that these would not represent correctly coded claims for OctreoScan)

Based on CMS' instructions to hospitals regarding their charge practices, we anticipate that a more reliable data set may emerge for possible rate setting in 2008. We will be approaching the HCPCS panel again to request the HCPCS code descriptor be revised to read "per dose up to 6 mCi" as we believe the ongoing changes in the descriptor have been problematic for OctreoScan providers and may have an impact on cost calculations.

Mallinckrodt agrees with the APC Panel (recommendations Nos. 18 and 20) that CMS is premature in moving to a new payment methodology for radiopharmaceuticals for FY2007. We urge CMS to continue with the current CCR payment methodology for one more year (CY2007) in order to establish reliable data and explore alternative methods for capturing hospital costs for radiopharmaceuticals.

We appreciate the opportunity to offer our comments and provide additional data to assist CMS in refining the OPPS system.

Sincerely,



Lisa Saake RN, MSN, MBA
Director, Healthcare Economics
Tyco Healthcare/Mallinckrodt
675 McDonnell Boulevard
St. Louis, MO 63134
Phone- 314-654-3071
E-mail- lisa.saake@tycohealthcare.com

Cc : via e-mail
Carol Bazell

Attachments
GAO-05-733R Hospital Radiopharmaceutical Prices

Table 1: Purchase Prices for Radiopharmaceuticals Accounting for 9 Percent of Medicare Spending on SCODs

Rank in Medicare spending on radio-pharmaceutical SCODs	HCPCS code	Description	Medicare spending on SCOD, 2004[a] ($ in millions)	% of Medicare spending on SCODs, 2004[a]	Number of hospitals in sample	Total number of hospitals[b]	CMS payment rate for 2005[c] ($)	Average purchase price[d] ($)	95% confidence interval of the average purchase price[e] ($)	Median purchase price[f] ($)	95% confidence interval of the median purchase price[e] ($)
1	A9500	Technetium Tc 99m Sestamibi, per dose	66.5	3.4	405	2,477	106.32	75.15	73.24 - 77.06	76.47	75.58 - 77.85
2	A9502	Technetium Tc 99m Tetrofosmin, per dose	38.8	2.0	174	964	104.58	70.70	67.92 - 73.48	67.59	66.23 - 70.98
3	C1775	Fluorodeoxyglucose (FDG) F18, per dose (4-40 mCi/ml)	32.1	1.6	71	687	221.11	287.90	263.24 - 312.55	272.80	261.83 - 308.52
4	C1083	Yttrium 90 Ibritumomab Tiuxetan, per dose	7.1	0.4	80	130	20,948.25	19,614.96	19,498.98 - 19,730.95	19,516.70	19,459.55 - 19,565.02
5	A9505	Thallous Chloride TL 201, per mCi	6.7	0.3	292	1,199	18.29	17.18	16.32 - 18.05	15.49	15.06 - 17.06
6	Q3005	Technetium Tc 99m Mertiatide, per mCi[g]	6.2	0.3	292	1,655	31.13	27.40	26.47 - 28.34	27.58	27.56 - 27.60
7	A9507	Indium In 111 Capromab Pendetide, per dose	4.8	0.2	56	262	1,915.23	1,801.12	1,760.80 - 1,841.43	1,841.23	1,703.46 - 1,860.22
8	Q3008	Indium In 111 Pentetreotide, per 3 mCi[h]	4.5	0.2	193	666	1,079.00	1,279.55	1,198.35 - 1,360.76	1,423.87	1,395.49 - 1,437.61
9	A9521	Technetium Tc 99m Exametazime, per dose	3.8	0.2	180	773	778.13	455.59	358.29 - 552.89	456.30	379.90 - 523.95

Sources: GAO survey and CMS.

Notes: mCi = millicurie, ml = milliliter

[a]Medicare spending is for the period January 1, 2004, through September 30, 2004. The percentage of Medicare spending is based on all SCODs—both drugs and radiopharmaceuticals.

[b]This estimate of the total number of hospitals in the population is based on our sample.

[c]This is the payment rate specified for each HCPCS for 2005. It incorporates CMS's April 2005 update.

[d]This price is based on data provided by the hospitals in our survey and does not reflect delivery fees or any other ancillary costs associated with purchasing or administering this product. We asked hospitals to report prices for drugs purchased from July 1, 2003, through June 30, 2004. We weighted the prices by the volume purchased as well as by the sample weights.

[e]The confidence interval measures the precision of the estimate. The narrower the interval, the greater the precision.

[f]The median purchase price is the midpoint of all prices reported by hospitals in our sample. This price does not reflect delivery fees or any other ancillary costs associated with purchasing or administering this product. Half of the prices reported by hospitals are above the median and half are below. The median is weighted by volume purchased and by hospital sample weights.

[g]The billing unit of measure for Q3005, Technetium Tc 99m Mertiatide, is per mCi. The per mCi purchase price reported is based on purchase prices for two commonly reported dose sizes, 5 mCi and 10 mCi. Since in our data the 5 mCi dose is more common than the 10 mCi dose and the purchase price of a 5 mCi dose and of a 10 mCi dose were similar, we treated a 10 mCi dose as if it were a 5 mCi dose.

[h]The billing unit of measure for Q3008, Indium In 111 Pentetreotide, is per 3 mCi. The per mCi purchase price reported is based on purchase prices for two commonly reported dose sizes, 3 mCi and 6 mCi. Since a 3 mCi dose is the billing unit specified by CMS for Q3008 and since in our data the purchase price of a 3 mCi dose and of a 6 mCi dose varied relatively little, we treated a 6 mCi dose as if it were a 3 mCi dose.

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OPPS

NT

Bruce M. Kaplan, MD
St. Francis Hospital Cancer Center
94 Woodland Street
Hartford, CT 06105

Marjorie (2)
Joan
Carol
Alberta

October 4, 2006

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

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

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

New Technology APCs

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

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

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

CY 2002

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

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

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

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

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

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

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

CY 2003

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

CY 2004

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

CY 2005

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

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

CY 2006

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

Proposed CY 2007 APC Changes

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

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

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

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

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

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

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

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

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

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

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

Historical Precedent – Gamma Knife New Technology Codes

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

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

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

CY 2004 and CY 2005 Data Variability Summary

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

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

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

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

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

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

Conclusion

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

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

Recommendations

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

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

Sincerely,

Bruce M. Kaplan, MD
St. Francis Hospital Cancer Center
94 Woodland Street
Hartford, CT 06105

Phone: 860-714-4568

E-mail: bkaplan@stfranciscare.org