

2007 DEC 18 PM 6:33

December 17, 2007

VIA OVER NIGHT AND ELECTRONIC MAIL
www.cms.hhs.gov/regulations/eRulemaking

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**RE: [CMS-1392-FC] Medicare Program: Changes to the Hospital
Outpatient Prospective Payment System and CY 2008 Payment Rates**

Dear Acting Administrator Weems:

GlaxoSmithKline (GSK) appreciates the opportunity to comment on the Final Rule, entitled "*Changes to the Hospital Outpatient Prospective Payment System (OPPS) and CY 2008 Payment Rates*" (Final Rule).¹ GSK is a world-leading, research-based pharmaceutical company dedicated to improving the quality of human life by enabling people to do more, feel better, and live longer. The company is an industry leader, with significant products in several therapeutic areas, such as anti-infectives, HIV, central nervous system (CNS), respiratory, gastrointestinal, metabolic, cardiovascular, and oncology.

GSK understands the ongoing challenges the Centers for Medicare and Medicaid Services (CMS) face in advancing the healthcare system for Medicare beneficiaries so that they continue to receive high-quality goods and services at an appropriate cost. In an effort to help ensure fair drug reimbursement practices, we ask CMS to consider our comments regarding the treatment of radioimmunotherapeutics, particularly as applied to GSK's important non-Hodgkin's lymphoma (NHL) treatment, BEXXAR[®] (Tositumomab and Iodine I 131 Tositumomab). The payment rate outlined in the Final Rule results in a reimbursement rate that is approximately 50 percent below hospitals' actual acquisition cost for the therapy (including preparation and handling). It is already recognized in the patient care arena that the BEXXAR[®] Therapeutic Regimen is currently under-utilized, with the current reimbursement environment cited as a major

¹ 72 Fed. Reg. 66580 (November 27, 2007).

contributing factor.² CMS's payment methodology for 2008 can only exacerbate this serious problem, to the detriment of patients with NHL.

In the Final Rule, CMS specifically asks for comments as to whether the average sale price (ASP) methodology currently used for the payment of separately payable drugs and biologicals under OPSS is appropriate for radiopharmaceuticals in ratesetting. As is clear in our September 11, 2007 comments to the Proposed Rule, GSK believes ASP is an appropriate methodology for radioimmunotherapies, particularly BEXXAR[®]. That said, CMS's request for comments in the Final Rule is focused on "separately payable therapeutic radiopharmaceuticals" which, in the case of BEXXAR[®], CMS has incorrectly classified as only one of the four components of the BEXXAR[®] Therapeutic Regimen. To address the issue of payment methodology appropriately, the underlying assumptions upon which it is based must also be addressed. We request that CMS consider our comments on the specific payment classification and subsequent payment amount assigned to the BEXXAR[®] Therapeutic Regimen. Our comments are summarized below:

- For CY 2008 and beyond, CMS should properly classify the overall BEXXAR[®] Therapeutic Regimen. At this time, CMS does not properly reflect that the drug components comprising BEXXAR[®] are approved by the Food and Drug Administration (FDA) as a single therapeutic regimen, and each component meets the Medicare law definition of specified covered outpatient drugs (SCODs), as has been previously recognized by CMS. Further, no single component of the BEXXAR[®] Therapeutic Regimen is approved for use by itself; rather, the entire regimen must be administered to a patient in order to achieve the desired clinical outcome.
- For CY 2008 and beyond, consistent with payment policies for other SCODs, GSK requests that CMS accept and reimburse the BEXXAR[®] Therapeutic Regimen using the ASP methodology. As of this writing, GSK has voluntarily submitted two quarters of ASP data for the BEXXAR[®] Therapeutic Regimen. These data illustrate the significant payment shortfall for hospitals under CMS's current chosen methodology of using hospital claims data as a proxy for actual acquisition costs. In addition, the CY2006 claims data used by CMS vary widely. For example, the minimum unit cost for the "hot dose" (HCPCS Code A9545) reported was \$4.32 with a maximum unit cost of \$61,156.85. In addition, the number of claims represents a relatively small sample size, with a total of 342 units reported in CY2006. The wide variance and small number of claims submitted make it clear that the CY2006 claims data are both an inaccurate and inappropriate proxy for acquisition costs. These discrepancies provide a sound basis for CMS to act immediately on our ASP request.

² Garber K. Journal of the National Cancer Institute. Vol 99. Issue 7. April 4, 2007 and The New York Times. July 14, 2007.

- In addition, the payments to hospitals should also include the costs incurred by hospitals for the compounding of the product by a radiopharmacy, a necessary step required to prepare the product for patient administration.

Non-Hodgkin's Lymphoma and the BEXXAR® Therapeutic Regimen

Each year, about 54,000 Americans are diagnosed with NHL.³ The National Cancer Institute estimates that, in 2007 alone, there will be 63,190 new cases of NHL and that 18,660 people will die from this disease. Although NHL can occur at any age, most people with this disease are older than age 60.⁴

The BEXXAR® Therapeutic Regimen differs from conventional chemotherapy in that the entire treatment takes place over seven to fourteen days, and is approved by the FDA as a single, one-time therapeutic intervention, as opposed to the multiple cycles of therapy required when a patient receives chemotherapy. The BEXXAR® Therapeutic Regimen is a second-line therapy used for those patients for whom first-line therapies have not achieved a good clinical outcome. The disease course of follicular/low-grade NHL is such that patients usually initially respond (*i.e.*, their tumors shrink) to chemotherapy. Their disease, however, invariably returns and they will then need to receive additional treatment. Many patients treated with the BEXXAR® Therapeutic Regimen have experienced disease remissions that have lasted several years with a single one time intervention completed within days.

The BEXXAR® Therapeutic Regimen consists of four different drug doses, each described with a unique National Drug Code (NDC) number (thus demonstrating their status as drugs), as follows:

- 1) dosimetric dose of Tositumomab (NDC 00007-3260-31),
- 2) dosimetric dose of Iodine I-131 Tositumomab (NDC 00007-3261-01),
- 3) therapeutic dose of Tositumomab (NDC 00007-3260-36), and
- 4) therapeutic dose of Iodine I-131 Tositumomab (NDC 00007-3262-01).

The dosing regimens of BEXXAR® include a "cold dose," "warm dose," and a "hot dose." The "cold dose" is reflected by numbers 1 and 3 above, while the "warm dose" is number 2. Number 4 describes the "hot dose," and this radiolabeled version of Tositumomab is currently coded with HCPCS code A9545. We have attached the dosing schedule from the prescribing information guide for BEXXAR® for your review (Attachment A).

³ Non-Hodgkin's Lymphoma, National Institutes of Health (NIH) Publication No. 05-1567.

⁴ *Id.*

For general reference purposes, the table below outlines, for the hospital outpatient setting i) the payment rate for the BEXXAR[®] Therapeutic Regimen in CY2007, ii) the payment rate for BEXXAR[®] in CY2008 under the Final Rule, and iii) for contrast, GSK's reported ASP for BEXXAR[®] for 3Q2007.

Table 1. Payment History and 3Q07 ASP

HCCPS Code	Description	CY 2007 Payment Rate	CY 2008 Payment Rate	GSK Reported ASP for drug component only 3Q2007
G3001* "Cold dose"	Supply and administration of Tositumomab, 450 mg	\$1,374.83	\$1,747.11	\$2,144.98
G3001* "Cold dose"	Supply and administration of Tositumomab, 450 mg	\$1,374.83	\$1,747.11	\$2,144.98
A9544 "Warm dose"	I131 Tositumomab, dx	Charges adjusted to cost (cost-based)**	No separate payment	\$2,271.15
A9545 "Hot dose"	I131 Tositumomab, tx	Charges adjusted to cost (cost-based)**	\$11,264.25	\$19,683.30
New code Needed	Radiopharmacy Compounding Fee***	Charges adjusted to cost (cost-based)**	No separate payment	N/A****

* G3001 is billed twice (administered prior to the dosimetric dose and prior to the therapeutic dose).

** Payment varies by hospital. Hospital charges for radiopharmaceuticals with Status Indicator H are based on all costs associated with the acquisition, preparation, and handling in order for payments to accurately reflect all actual costs.

***\$3000 represents the approximate cost charged by commercial radiopharmacies for preparing BEXXAR[®].

****Not Applicable as this cost is invoiced to hospitals by radio pharmacies independent of GSK.

The Finalized OPPS Payment Methodology Misclassifies Integral Drug Components of the BEXXAR[®] Therapeutic Regimen as Diagnostic and as Supplies

CMS has finalized a payment methodology that inappropriately treats the various components of the BEXXAR[®] Therapeutic Regimen differently, thus understating the total payment amount to hospitals that administer it, relative to their acquisition costs. Currently, two of the components, Tositumomab dosimetric and Tositumomab therapeutic (referred to as the two "cold" doses--numbers 1 and 3 above) are incorrectly classified as supplies and assigned a temporary G-code (G3001), while the other two

radiolabeled components (referred to as the “warm” and “hot” doses, respectively-- numbers 2 and 4 above) are assigned A-codes (A9544 and A9545, respectively). Unfortunately, CMS finalized its intention to incorrectly treat the radiolabeled drug administered in the dosimetric step in the regimen, the “dosimetric warm” dose (number 2 above), as “diagnostic,” now subject to packaging into the associated procedure payment, and the “cold dose” as a supply, therefore receiving no additional payment. GSK again urges CMS to re-evaluate the “cold” and “warm” doses, and properly to re-classify those doses as drugs, consequently eligible to receive separate J-codes, and paid as separately billable drugs.

These doses are an integral part of the FDA-approved BEXXAR[®] Therapeutic Regimen. Further, the dosimetric “warm dose” leads to a determination of the amount of radiolabeled monoclonal antibody required for the final therapeutic dose – the “hot dose”. This unique radioimmunotherapeutic regimen is distinct from the broader class of radiopharmaceuticals, which are generally used for medical diagnostic purposes. The primary purpose of every component and step of the BEXXAR[®] Therapeutic Regimen is to treat, not diagnose, disease. In the Final Rule, CMS acknowledges that the “warm dose” of BEXXAR (HCPCS code A9544) is not used to diagnose disease, however CMS argues that this “warm dose” is used to determine whether future therapeutic services would be beneficial to the patient. CMS uses the analogy of positron emission tomography (PET) scanning for staging purposes when there has already been a diagnosis of disease but the physician is seeking information to use in planning a course of therapy. This analogy is not appropriate. While PET scanning is used to stage patients, unlike the “warm dose” of BEXXAR[®], PET scanning is not part of an overall therapeutic regimen. Furthermore, the data from a PET scan can be used to plan a variety of different treatments for a given patient. The purpose of the “warm dose” of BEXXAR[®], however, is solely to calculate the final “hot dose” required for each patient and not to plan for other treatments. The hot dose cannot be administered without administration of the “warm dose”. Again, it should be noted that no single component of the BEXXAR[®] Therapeutic Regimen is approved for use alone, rather the entire regimen must be administered to a patient in order to achieve the desired clinical outcome. It is for this reason that the FDA has approved the BEXXAR[®] Therapeutic Regimen as a single therapeutic regimen.

In addition, the methodology utilized by CMS to determine the CY2008 payment rate during the process of packaging the “warm dose” (HCPCS code A9544) into HCPCS code 78804 is unclear. In the Final Rule, CY2006 claims data are referenced as a source for determining payment rates in the packaging of diagnostic radiopharmaceuticals with the associated nuclear medicine procedures, however again the hospital claims data are a poor proxy for acquisition costs as demonstrated by the significant shortfall between the CY2006 mean unit cost and ASP for A9544. Furthermore, the CY2006 claims data for A9544 vary widely with a minimum unit cost reported of \$16.57 and a maximum unit cost of \$18,143.14. In addition, the number of claims represents a relatively small sample size, with a total of 246 units reported for A9544 in CY2006. Finally, the fact that there is approximately 100 less units for the dosimetric dose (A9544: 246 units) versus the therapeutic dose (A9545: 342 units) in

the CY2006 claims data highlights another potential flaw in these data given that patients should not receive the therapeutic dose without the preceding dosimetric dose.

We are deeply concerned that CMS's under-reimbursement and misclassification of parts of the BEXXAR[®] Therapeutic Regimen will result in reduced access to this important therapy – not only for Medicare beneficiaries, but for all patients. If hospitals do not offer BEXXAR[®] to Medicare patients, they are unlikely to offer BEXXAR[®] to patients with private insurance, thus eliminating all patient access to BEXXAR[®]. In the Final Rule, CMS declares that it “may terminate the provider agreement of any hospital that furnishes this or any other service to its patients but fails to also furnish it to Medicare patients who need it.” This provides cold comfort for patients that are in need of appropriate treatment. Given the current reimbursement under the Final Rule for 2008, hospitals are unlikely to offer BEXXAR[®] to any patient.

In order to accurately reflect actual acquisition costs incurred by hospitals when administering BEXXAR[®], the payments to hospitals should also include the costs incurred by hospitals for the compounding of the product by a radiopharmacy, a necessary step required to prepare the product for patient administration. In fact, the Medicare statute directs that overhead and related expenses, such as pharmacy and handling costs, be factored into the ambulatory payment classifications for specified covered outpatient drugs.⁵ It is important to note that the compounding costs are service costs, and are provided by entities independent of GSK, including in a few instances, by hospital pharmacies that have specialized internal capability. Compounding costs are not GSK-incurred drug costs and are not reflected in the ASP reports prepared and submitted by GSK to CMS.

Data Available for Setting CY 2008 Payment Rates for BEXXAR[®] “Hot Dose”

GSK is disappointed by CMS's decision to reimburse the BEXXAR[®] “hot dose” (HCPCS code A9545) based on mean per unit cost, as outlined in the Final Rule. CMS has correctly noted on several occasions since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), that the BEXXAR[®] Therapeutic Regimen is a “specified covered outpatient drug” (SCOD) as that term is defined in § 1833(t)(14)(B)(i) of the Social Security Act (the Act). Most recently, in the preamble to the Final Rule, CMS confirmed that: “In accordance with section 1833(t)(14)(B)(i)(I) of the Act, radiopharmaceuticals are classified under the OPPIs as SCODs.”⁶

Medicare Statutory Payment Requirements -- The Medicare statute directs that CMS must pay for SCODs at either the “average acquisition cost for the drug for that year” or “if hospital acquisition cost data are not available, the average price for the

⁵ SSA § 1833(t)(14)(E).

⁶ 72 Fed. Reg. 66765 (November 27, 2007).

drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.” These citations reference the ASP, special AWP-based reimbursement rates, or the Part B Competitive Acquisition Program (CAP) payment rate approaches, not a “mean cost per unit” based on a CMS-developed alternative methodology.⁷ Therefore, the Medicare statute mandates that SCODs, such as BEXXAR[®], must be paid according to one of these alternative payment methods, and under the circumstances presented does not authorize CMS to substitute hospital charges or other proxies for the payment options specified in the statute, including for hospital acquisition costs. In fact, there are aspects of the “mean per unit cost” method that, by definition, lead to artificial comparisons of the values relative to actual acquisition cost.

Nevertheless, for therapeutic radiopharmaceuticals, CMS has established that the CY 2008 payment rates be “... based on the mean unit costs from [the Agency’s] CY 2007 OPSS claims data.”⁸ CMS believes that the hospital claims data that are currently available for rate-setting purposes are reliable and accurate.⁹ GSK respectfully disagrees. Payment based on historical hospital claims data are not appropriate for therapeutic radioimmunotherapeutics because the methodology is not consistent with the statutory requirement, as discussed above, and the data chosen by CMS do not serve as an accurate measure of the average hospital acquisition and associated handling cost of separately payable radioimmunotherapy regimen products. This point is well illustrated by the CMS reported CY2006 claims data. As stated previously, these data vary widely with a minimum unit cost for the “hot dose” (HCPCS Code A9545) reported of \$4.32 and a maximum unit cost of \$61,156.85. In addition, the number of claims represents a relatively small sample size, with a total of 342 units reported in CY2006. The wide variance and small number of claims submitted make it clear that the CY2006 claims data are both an inaccurate and inappropriate proxy for acquisition costs.

ASP-Based Methodology -- In the Final Rule, CMS notes that it is willing to consider the acceptance of ASP data for rate-setting purposes, and requests comments from the public regarding that approach on how radiopharmaceutical ASP information could be used for setting OPSS payment rates. GSK firmly endorses applying the ASP methodology for CY2008 to radioimmunotherapies, like the BEXXAR[®] Therapeutic Regimen. We believe that using this methodology is much more accurate than the mean unit cost obtained through OPSS claims data because ASP enables payments to reflect, to the greatest extent possible, the actual market transaction prices for these types of drugs. The ASP data provided by GSK clearly show that an ASP-based methodology serves as a much more accurate proxy for actual acquisition costs

⁷ SSA § 1833(t)(14)(A)(iii).

⁸ 72 Fed. Reg. 66772 (November 27, 2007).

⁹ *Id* at 66772.

compared to the CY2006 hospital claims data reported by CMS. Further, ASP based reimbursement is already utilized by CMS for other SCODs under the OPPS.

GSK strongly believes that all SCODs should be treated equally and reliance on ASP will also lead to a more uniform payment policy for radioimmunotherapeutics across sites of care. Therefore, beginning in CY 2008, we urge that CMS accept and reimburse for the BEXXAR® Therapeutic Regimen (all four doses) using the established ASP methodology. As mentioned above, GSK has voluntarily submitted ASP data for the BEXXAR® Therapeutic Regimen to CMS for the last two quarters, and it is prepared to continue to submit these data

Conclusion

In closing, GSK supports the goals of the OPPS to promote fair drug reimbursement practices. If, however, the CY 2008 payment policy is implemented for the BEXXAR® Therapeutic Regimen, this action could severely restrict access to one of the few treatment options available for certain patients with non-Hodgkin's lymphoma. This, in turn, could have a devastating effect on the development of future drugs and radioimmunotherapies for treating other forms of cancer and other diseases. It is critical that CMS properly classify all of the components of the BEXXAR® Therapeutic Regimen, provide reimbursement for the associated compounding fees, and adopt the ASP methodology for radioimmunotherapeutics. Taking these steps would substantially improve the payment levels, and thus allow patients continued access to appropriate cancer treatment.

If you have any questions, or would like to discuss this matter in further detail, please contact Roger Hunter at 215-751-7470. We appreciate CMS's consideration of this important matter.

Respectfully submitted,



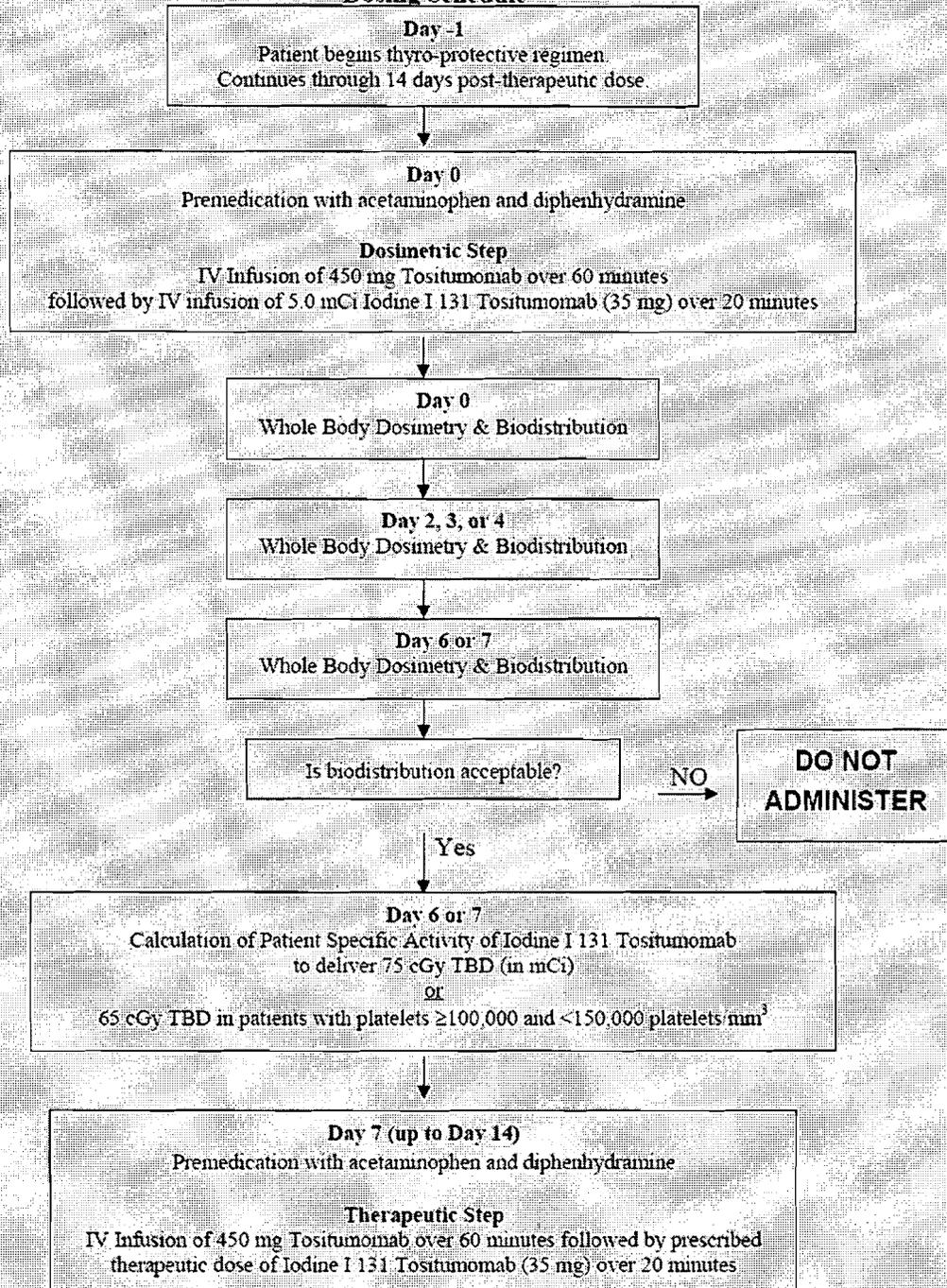
Roger A. Hunter
Executive Director
New Product Planning and Policy
GlaxoSmithKline Oncology/Critical &
Supportive Care

cc: Mr. Herb Kuhn
Ms. Liz Ritcher
Dr. Carol Bazell

ATTACHMENT A
Dosing Schedule from BEXXAR® Prescribing Information

Figure 1

Dosing Schedule



FUI - Reg Staff
37

~~638~~
639876

JAN 11 2008

RECEIVED

DEC 26 2007

OSORA DIVISION
OF CORRESPONDENCE
MANAGEMENT

December 18, 2007.

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMS's new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Code 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

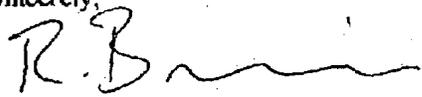
The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,



Ramsin Benyamin, MD
President, Millennium Pain Center, Bloomington, Illinois



Ophthalmology and
Ophthalmic Surgery

- James S. Allen, M.D.
- Scott R. McKee, M.D.
- Richard P. Stanek, M.D.
- Alan S. Weingarden, M.D.
- Dan A. Nichols, M.D.
- Honora E. Kennedy, M.D.
- Thomas J. Rice, M.D.
- James E. George, M.D.
- Phillip T. Sheridan, M.D.
- Aaron W. Tsai, M.D.
- Todd M. Watanabe, M.D.
- Scott A. Uttley, M.D.
- Susan J. Quick, M.D.
- Eric A. Steffen, M.D.
- Erik S. Bachmeier, O.D.
- H. Joseph Drannen,
Administrator

December 6, 2007

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

RE: Lacri Cath

To Whom It May Concern:

Downtown
 Wells Fargo Place
 30 East 7th Street
 St. Paul, MN 55101
 (651) 227-6634
 fax: (651) 228-9398

Maplewood
 100 Beam Professional Bldg.
 1675 Beam Avenue
 Maplewood, MN 55109
 (651) 770-1371
 fax: (651) 770-5746

Midway
 861 Central Medical Bldg.
 393 N. Dunlap Street
 St. Paul, MN 55104
 (651) 641-0457
 fax: (651) 641-0704

Eagan
 3440 O'Leary Lane
 Eagan, MN 55123
 (651) 454-2526
 fax: (651) 994-8867

Woodbury
 230 Midwest Eye & Ear Institute
 2080 Woodwinds Drive
 Woodbury, MN 55125
 (651) 578-6949
 fax: (651) 578-3074

West St. Paul
 200 Thompson Avenue East
 West St. Paul, MN 55118
 (651) 451-3963
 fax: (651) 451-0351

Roseville
 1330 W. County Road B
 Roseville, MN 55113
 (651) 631-2922
 fax: (651) 631-0355

Laser Vision Center
 210 Midwest Eye & Ear Institute
 2080 Woodwinds Drive
 Woodbury, MN 55125
 (651) 770-0023 or
 (888) 756-0023
 fax: (651) 770-0427

Administrative Office
 110 Midwest Eye & Ear Institute
 2080 Woodwinds Drive
 Woodbury, MN 55125
 (651) 738-6800
 fax (651) 714-6997

This letter is in regard to the Lacri Cath catheter. It is my understanding that there has been a new CPT code, 68816, established for this procedure. Please be aware that as a pediatric ophthalmologist, I have never performed this surgery in the clinic. All of my surgeries have been done under anesthesia. In addition to doing this type of surgery, I frequently do simple nasolacrimal duct surgeries using CPT code 68815. The Lacri Cath catheter takes considerably more skill and much more time to perform. The catheter itself has to be left within the lacrimal system for minutes. In addition, it is much more difficult to get the catheter into the lacrimal system than a simple probing. It is my understanding that the reimbursement rate is going down significantly and that it is felt that this is usually done in the clinic.

With regards to performing this procedure on adults, I have never done it on an adult and cannot comment.

Again, the two main points I would like to re-emphasize are: (1) This is a procedure that is not done in the office setting, but in my practice is done entirely under anesthesia. (2) In addition, there is no way that it is quicker to do this type of surgery than a simple tear duct probing since there are many more steps involved and it is a more complicated surgery to perform.

Should you have any questions or concerns regarding my feedback regarding CPT code 68816, please do not hesitate to contact me or call me.

Sincerely,

Todd Watanabe, M.D.
 Pediatric Ophthalmologist/Adult Strabismus
 TW:EM149/SP0399

cc: Sue Reynolds
 Ophthalmology Sales and Marketing Manager
 Quest Medical

January 23, 2008



Mr. Kerry Weems
Acting Administrator
Mr. Herb Kuhn
Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1392-FC
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1392-FC
Comments on Tumor Imaging procedure APC's and the
radiopharmaceutical In-111 Pentetretotide (HCPCS code A9565 in
2007, A9572 in 2008)

Dear Acting Administrator Weems and Mr. Kuhn:

Covidien Imaging Solutions (formerly Tyco Healthcare/Mallinckrodt), a manufacturer and marketer of radiopharmaceutical products, is submitting these comments in follow-up to a January 7, 2008 meeting with Mr. Herb Kuhn and to the Centers for Medicare and Medicaid Services (CMS) in response to the 2008 Medicare Hospital Outpatient Prospective Payment System (HOPPS) Final Rule.

We manufacture and market Indium In-111 Pentetretotide, an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors¹. "Neuroendocrine tumors (previously referred to as carcinoids) are ill-understood, enigmatic malignancies that, although slow-growing compared with adenocarcinomas, can behave aggressively. In 2004, they comprised 1.25% of all malignancies; their incidence is increasing by approximately 6% per year"². The National Comprehensive Cancer Network (NCCN) has published clinical practice guidelines for neuroendocrine tumors which provide an overview of the clinical role that Indium In-111 Pentetretotide plays in the diagnosis of these tumors³.

CMS has implemented a new reimbursement methodology for diagnostic radiopharmaceuticals for 2008 moving away from separate payment. The 2008 methodology classifies diagnostic radiopharmaceuticals as dependent "supplies" and packages payment, regardless of the clinical indication and acquisition cost, into the payment for the nuclear medicine procedure. This new payment methodology results in a significant financial burden for hospital outpatient providers of neuroendocrine tumor imaging services.

¹ Indium In-111 Pentetretotide package insert

² Björn Gustafsson, Mark Kidd, Irvin Modlin, Neuroendocrine tumors of the diffuse neuroendocrine system. *Current Opinion in Oncology* 2008, 20:1-12. page 1

³ NCCN Clinical Practice Guidelines in Oncology™ Neuroendocrine Tumors V.1. 2007 www.nccn.org

We understand and support CMS's initiatives to develop a prospective payment system that provides hospitals with the greatest administrative simplicity and enables hospitals to manage their resources with maximum flexibility⁴. We also perceive however, through public comments that it is CMS's intent to balance packaging initiatives with appropriate payment for medically necessary services.

Packaging of payment for Indium In-111 Pentetretotide into the payment for tumor imaging procedures has created significant financial disincentives for hospitals and designated hospital-based cancer centers to provide clinically appropriate tumor imaging procedures to patients with a potential or confirmed neuroendocrine tumor diagnosis. This burden will not necessarily be offset by other tumor imaging procedures as it appears from analysis of paid claims files for tumor imaging procedures that many tumor specific (i.e. neuroendocrine tumor, prostate tumor, Nonhodgkin's Lymphoma) imaging services will be significantly underpaid. (See attachment 1)

We believe in the case of high cost tumor imaging agents, (per dose cost greater than \$750) CMS has made a methodological error by packaging and should be willing in interest of appropriate patient care to revise the methodology for 2008.

CMS's publicly available 2006 paid claims files (claims utilized to establish 2008 payment) for Indium In-111 Pentetretotide (2006 HCPCS code A9565) document a mean cost per dose for the radiopharmaceutical drug alone of \$1065. Under the 2008 final rule, the likely payment for a dose of Indium In-111 Pentotretotide has been predominantly packaged into one of 3 APC groupings:

- a. APC 408 - 2008 payment rate of \$981
- b. APC 414 - 2008 payment rate of \$536
- c. APC 406 - 2008 payment rate of \$323

These payment rates result in a significant financial burden for hospital outpatient providers who choose to provide imaging procedures for the diagnosis of neuroendocrine tumors.

We respectfully request that CMS change the methodology utilized to establish payment for Indium In-111 Pentetretotide (2008 HCPCS code A9572) and tumor imaging procedures and propose one of the following methodologies to establish appropriate payment

A. Change the status indicator for A9572 from "N" packaged service to "K" non-pass through drug and biological and allow for separate payment for this neuroendocrine tumor imaging agent or

B. Utilize CMS's authority to define what constitutes a "Neuroendocrine tumor imaging service" for purposes of payment under HOPPS and create an APC configuration for Indium In-111 Pentetretotide tumor imaging services. This APC configuration would be developed based on correctly coded combinations of HCPCS code A9572 and tumor imaging procedure code 78800, 78801, 78802, 78803 and 78804.

⁴ CMS Final OPSS rule with comment period. Federal Register Vol 72, No. 227 Nov. 27, 2007 page 66635

Detailed Analysis

CMS guidelines on APC Groupings

Per CMS 2008 OPSS final rule "all services and items within an APC group are comparable clinically and with respect to resource use (section 1833 (t) (2) (B) of the Act). In accordance with section 1833(t) (2) of the Act, subject to certain exceptions, services and items within an APC group cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost for an item or service within the same APC group (referred to as the "2 times rule"). In implementing this provision, we generally use the median cost of the item or service assigned to an APC group.⁵

Data Analysis 2008 Tumor/Infection Imaging APC Groupings

In depth data analysis of CMS 2006 paid claims files and simulation of CMS's APC groupings for tumor imaging radiopharmaceuticals and tumor imaging procedures conducted by an outside consultant (Susan White PhD, Cleverly and Associates) clearly demonstrates that packaging of tumor diagnostic radiopharmaceuticals without regard to the indication, clinical utility and cost threshold into one of three APC groupings results in a significant disruption of the clinical and resource use comparability standards associated with the OPSS program.

1. APC 406-Level 1 Tumor/Infection Imaging-Within this APC the range of median costs per procedure for the various tumor imaging diagnostic radiopharmaceuticals varies five-fold (\$258-\$1318). Tumor imaging procedures using I-131 and Tc99m Sestamibi dominate this APC grouping resulting in a weighted payment rate of \$333. (See Attachment 1)
2. APC 414-Level II Tumor/Infection Imaging- Within this APC the range of median costs varies approximately five-fold (\$332-\$1533). This APC also combines infection imaging procedures with tumor imaging procedures. Infection imaging procedures performed with one of three diagnostic radiopharmaceuticals, Tc99m Examatazine, In-111 oxyquinoline, and Gallium dominate this APC grouping resulting in a weighted payment rate of \$536. (See Attachment 1)
3. APC 408- Level III Tumor/Infection Imaging- Within this APC the range of median costs varies approximately five-fold (\$411-\$2130). Tumor imaging procedures using Indium In-111 Pentetretotide(neuroendocrine tumors) and In-111 capromab pendetide (prostate tumors) dominate this APC grouping with a Median cost of \$1200. The payment rate is diluted by the combination with agents with lower median costs resulting in an APC payment rate of \$981. (See Attachment 1)

⁵ Federal Register Vol. 72, No. 227 Nov. 27, 2007 page 66585

This data analysis clearly demonstrates that for tumor imaging procedures specifically, CMS could implement its packaging methodology and assure more appropriate payment levels by utilizing the diagnostic tumor imaging radiopharmaceuticals as independent variables and the tumor imaging procedures as dependent variables.

We reiterate our request that for 2008 CMS should:

- Change the status indicator for A9572 from "N" packaged service to "K" non-pass through drug and biological and allow for separate payment for this neuroendocrine tumor imaging agent or
- CMS should utilize their authority to define what constitutes a "service" for purposes of payment under OPPS and create an APC configuration for Indium In-111 Pentetretotide tumor imaging services. This APC configuration would be developed based on correctly coded combinations of HCPCS code A9572 and tumor imaging procedure code 78800, 78801, 78802, 78803 and 78804.

Thank you for taking the time to meet with us on January 7, 2008. We appreciate the opportunity to share this important information with CMS with the hope that CMS will recognize the need to make immediate changes to assure continued Medicare beneficiary access to Indium In-111 Pentetretotide neuroendocrine tumor imaging services. We also respectfully request that CMS continue to work throughout 2008 with stakeholders to develop more accurate, transparent, data analysis and payment methodologies for these important specified covered outpatient drugs and their associated procedures for implementation in 2009.

Sincerely,


Robert F. Carretta MD
Vice President Medical Affairs
Covidien
Imaging Solutions
Phone 314-654-3447
E-mail robert.carretta@covidien.com


Lisa Saake RN, MSN, MBA
Global Director, HCE
Covidien
Imaging Solutions
Phone 314-654-3071
E-mail lisa.saake@covidien.com

Attachments

Cc: Carol Bazell M. D.
Director, Division of Outpatient Services
Center for Medicare Management

Attachment #1



APC 406 408 414 Analysis by Diagnostic Radiopharmaceutical

© Copyright 2008 Cleverley + Associates. All Rights Reserved.
 Note 1: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.
 Note 2: This analysis uses the CMS single/multiple logic, but does not include any trimming of cost values.

APC	Definition	2008 Payment				
APC 0406	Level I Tumor/Infection Imaging	\$ 322.81				
Diagnostic Radiopharm	Definition	Single /Pseudo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A9500	Tc-99m sestamibi, up to 40 mCi	565	338.46	51.19	3,092.93	257.81
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	53	532.60	147.24	1,910.18	284.01
A9544	I-131 tositumomab, dx, per dose	13	426.40	264.51	833.49	286.80
A9556	Ga-67 gallium citrate, per mCi	163	342.26	91.14	1,375.19	288.04
A9528	I-131 sodium iodide capsule(s) per mCi	1,572	501.46	53.09	6,164.50	369.29
A9521	Technetium Tc-99m exametazine, up to 25 mCi	27	523.73	406.87	1,550.35	408.52
A4641	Diagnostic imaging agent	186	631.46	86.69	3,482.38	504.24
A9565	In-111 pentetretotide, per mCi	145	1,261.58	115.41	4,755.37	946.31
A9507	In-111 capromab pendetide, up to 10 mCi	12	1,571.92	507.67	3,256.58	1,317.73

APC	Definition	2008 Payment				
0408	Level III Tumor/Infection Imaging	\$ 981.10				
Diagnostic Radiopharm	Definition	Single /Pseudo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A9500	Tc-99m sestamibi, up to 40 mCi	193	479.20	148.24	1,455.92	410.97
A9556	Ga-67 gallium citrate, per mCi	187	547.98	128.68	2,223.11	443.44
A9547	In-111 oxyquinoline, dx, per 0.5 mCi	18	560.94	354.20	1,117.69	518.56
A9528	I-131 sodium iodide capsule(s) per mCi	22	587.45	177.16	1,455.96	562.60
A4641	Diagnostic imaging agent	99	1,302.34	103.36	8,023.57	1,085.74
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	105	1,338.45	49.20	5,452.58	1,158.39
A9565	In-111 pentetretotide, per mCi	938	2,044.69	148.06	16,309.12	1,196.44
A9507	In-111 capromab pendetide, up to 10 mCi	501	1,467.66	377.43	10,270.48	1,210.42
A9544	I-131 tositumomab, dx, per dose	46	1,896.19	960.92	6,059.95	1,513.25
A9542	In-111 ibritumomab, dx, up to 5 mCi	150	3,354.55	309.97	28,165.30	2,129.75

APC	Definition	2008 Payment				
0414	Level II Tumor/Infection Imaging	\$ 536.15				
Diagnostic Radiopharm	Definition	Single /Pseudo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A9556	Ga-67 gallium citrate, per mCi	1,354	399.60	66.78	6,624.03	332.33
A9500	Tc-99m sestamibi, up to 40 mCi	19	356.26	140.06	606.44	332.37
A9528	I-131 sodium iodide capsule(s) per mCi	23	393.44	206.33	705.45	392.57
A9521	Technetium Tc-99m exametazine, up to 25 mCi	3,499	663.79	93.85	11,795.14	553.03
A9547	In-111 oxyquinoline, dx, per 0.5 mCi	2,704	670.80	102.54	6,362.30	564.48
A4641	Diagnostic imaging agent	691	733.21	145.10	3,627.52	637.80
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	97	1,262.12	284.47	7,368.64	877.12
A9565	In-111 pentetretotide, per mCi	600	1,401.61	62.74	13,071.21	1,048.47
A9507	In-111 capromab pendetide, up to 10 mCi	156	1,358.62	309.71	3,599.77	1,233.65
A9542	In-111 ibritumomab, dx, up to 5 mCi	106	2,303.86	259.92	11,330.49	1,533.46



**The Leukemia &
Lymphoma Society®**
Fighting Blood Cancers

November 26, 2007

The Honorable Michael Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Leavitt:

The Leukemia & Lymphoma Society (LLS) urges you to take immediate action to promote and protect the public health by establishing 2008 Medicare payment rates for radioimmunotherapy products that are adequate and appropriate. The reimbursement levels for these products defined in the calendar year 2008 hospital outpatient prospective payment system (HOPPS) will create unreasonable obstacles to access to these life-saving therapies, and those payment rates should be adjusted before their effective date of January 1, 2008.

LLS is the world's largest voluntary health agency dedicated to the blood cancers. This year, we will commit some \$70 million to blood cancer research and provide a wide range of patient education and support services to patients with blood cancers and their friends and families. The well-being of lymphoma survivors is a core concern for LLS.

The radioimmunotherapies – tositumomab (Bexxar) and ibritumomab tiuxetan (Zevalin) – are critically important treatment options for individuals with non-Hodgkin lymphoma. When other treatments for non-Hodgkin lymphoma are no longer providing a therapeutic benefit, the radioimmunotherapies may be the best treatment option. The 2008 HOPPS payments may create an insurmountable barrier to those products for Medicare patients. Because these products are accompanied by specific requirements for storage and administration, only a limited number of health care institutions -- cancer centers and large hospitals -- currently stock them. That number may dwindle in the face of inadequate payment, seriously affecting access to care and quality of care for lymphoma patients.

The Honorable Michael Leavitt
November 26, 2007
Page Two

In setting payment rates for 2008, the Centers for Medicare & Medicaid Services (CMS) eliminated the compounding fee and also classified the initial doses of the radioimmunotherapies as diagnostic instead of therapeutic doses. The first action ignores the significant cost to institutions associated with compounding, and the second action is at odds with the Food and Drug Administration (FDA) labeling for the drug and is inconsistent with current clinical practice. CMS also changed the methodology for payment in a manner that significantly reduces reimbursement. The result is a payment rate that will adversely affect quality of care for lymphoma patients.

The Leukemia & Lymphoma Society urges the following:

- CMS should classify the radioimmunotherapy regimen a specified covered outpatient drug, or SCOD. In the CY 2008 rule, the agency improperly considers the initial doses of radioimmunotherapies to be diagnostic rather than therapeutic doses. This is not consistent with FDA labeling or with current practice.
- CMS should cover the cost of compounding radioimmunotherapies. Institutions should be paid fairly for the costs associated with compounding these products.
- The agency should consider setting payment for radioimmunotherapies on the basis of 106 percent of average sales price (ASP) or a composite ambulatory payment classification (APC) that would reflect the entire cost of the radioimmunotherapy regimen. We understand that the APC Advisory Panel reviewed these options at a recent meeting, and we urge CMS to consider these proposals. Because the effective date of the payment system is imminent, an ASP-based system may represent the most feasible alternative.

We are asking you to take extraordinary action to adjust the 2008 payment rates for radioimmunotherapies. This situation requires special action to protect the ability of patients with a life-threatening disease to obtain a possibly life-saving therapy.

We look forward to your reply.

Sincerely,

George Dahlman
Senior Vice President, Public Policy
The Leukemia & Lymphoma Society

cc: Kerry Weems
Administrator
Centers for Medicare & Medicaid Services

41

Swann, Renee L. (CMS/OSORA)

From: Randy Druitt [randy@tucsonlegalnurse.com]
Sent: Thursday, November 29, 2007 3:22 PM
To: Weems, Kerry (CMS/OA)
Subject: Please reconsider the payment levels for the radioimmunotherapies.

November 29, 2007
Kerry Weems

Dear Kerry Weems,

As an active Registered Hospice Nurse in Tucson, AZ and a qualified practicing legal nurse consultant, I am writing to to express my deep concern over the recent CMS determination about the payment levels for radioimmunotherapies that are set in the calendar year 2008 hospital outpatient prospective payment system (HOPPS).

These recommendations are:

- "(1) The Centers for Medicare & Medicaid Services (CMS) should consider the radioimmunotherapy regimen a specified covered outpatient drug, or SCOD. In CY 2008 rule, the agency improperly splits the radioimmunotherapy regimen into separate elements and considers the initial doses to be diagnostic rather than therapeutic doses. This is at odds with the Food and Drug Administration labeling of the products and with current practice.
- (2) CMS should cover the cost of compounding radioimmunotherapies. Elimination of the compounding fee creates another obstacle to the willingness of institutions to make this therapy available to their patients, because these institutions find the payment inadequate to meet their costs.
- (3) The agency should consider setting payment for radioimmunotherapies on the basis of 106 percent of average sales price (ASP) or a composite ambulatory payment classification (APC) that would reflect the entire cost of the radioimmunotherapy regimen. We understand that the APC Advisory Panel reviewed these options at a recent meeting, and we urge CMS to consider these proposals. Because the effective date of the payment system is imminent, an ASP-based system may represent the most feasible alternative."

Mr. Secretary, this issue is of critical importance to me not only to my inner community of friends and family whose lives are forever interrupted by this terrible disease thus being affected by this decision, but also the greater public community I serve as an RN. This decision weighs heavily on our political powers that be to understand and FEEL the depth of importance their health care decisions have.

This form of treatment may truly be a life saving one. I do not want another lymphoma patient dying in my Hospice unit who may have had a fighting chance to live!!! I urge you to please support this request to reconsider the payment levels for the radioimmunotherapies.

Most Sincerely,

Randy J. Druitt RN BSN CLNC
Tucson, AZ
520-247-6715

cc: Kerry Weems, Administrator
Centers for Medicare & Medicaid Services

Sincerely

Randy J. Druitt RN BSN CLNC
1280 E. Calle Mariposa
Tucson, AZ 85718-2954

Johnson, Sharon B. (CMS/OSORA)

From: Wade Foster [wadefoster1@yahoo.com]
Sent: Sunday, December 23, 2007 7:35 PM
To: Weems, Kerry (CMS/OA)
Cc: rmoy@ucla.edu
Subject: email from Dr. Wade Foster, Mohs surgery fellow in Los Angeles

Mr. Weems,

I am a Mohs surgery fellow and board certified dermatologist in Los Angeles, CA. As such I see a great number ~2000 Medicare patients each year with a variety of skin cancers. I am concerned about the proposed cuts for Medicare reimbursements for Mohs surgery and their potential effects on physicians and my patients. Here are a couple of points that I would ask you to consider before these changes are enacted.

1. Mohs surgery is 99% effective in removing the most common skin cancers. The Mohs procedures were first placed on the Multiple Procedure reduction rule exemption list in 1992 and there have been no new technologies or techniques since then that allow the surgeon to perform the procedure in less time than it took in 1992.
2. The proposed reductions will result in reimbursement that does not cover the cost of performing the procedure. As you know, CMS's new rule for 2008 will reduce Medicare payments to Mohs surgeons by 50% if they perform multiple procedures (i.e., Mohs surgeries and/or reconstructions) on the same patient on the same day. Medicare payments will also be reduced when done with a large repair such as a flap or graft-thus paid at less than the cost of performing the service.
3. The proposed cuts are not justified since the procedure has not changed in efficiency. There are no economies or efficiencies in performing multiple procedures because the Mohs surgeon must start the process for each surgery from the beginning and then microscopically examine each tissue sample from each surgery separately. Reducing the payment for multiple procedures by 50% will not cover the surgeon's expenses.
4. This CMS change will affect many of my patients who have more than one skin cancer, particularly those who are elderly and immunosuppressed. In the past we have typically treated all the tumors on a single day. If reconstructive surgery must be performed, the Mohs surgeon performs that on the same day also, thus saving the patients many return trips to the office. If the proposed cuts are enacted, patients may have to make multiple office trips to have each cancer addressed in series and on separate days to avoid soaring and unmanageable overhead for the physician. Alternatively, the patients may have to go to a physician of another specialty (plastic surgery) who will admit them to an ambulatory surgical center or hospital for the same procedure that we would perform much more economically in our office on an outpatient basis. This will inconvenience patients by making them travel to a distant site with a large wound in their skin and will result in soaring expenses from hospital admission or accompanying surgical center fees.

Mr. Weems, the proposed changes to the Mohs surgery reimbursement will adversely affect my patients and limits the quality of care that I can deliver. I would ask you to speak with Dr. David Brodland ((800) 500-7224 / (414) 347-1103), President of the Mohs College more about these issues and to heed the numerous patient letters requesting a stay of these proposed changes.

Sincerely,
Wade Foster

K. Wade Foster, M.D., Ph.D.
Procedural Dermatology Fellow
Moy-Fincher Medical Group
100 UCLA Medical Plaza, Suite 590
Los Angeles, CA 90024

From: STEVENBS@aol.com [mailto:STEVENBS@aol.com]

Sent: Friday, November 09, 2007 1:53 PM

To: Weems, Kerry (CMS/OA)

Subject: THANK GOD FOR BEXXAR

GENTLEMEN;

I WAS ON W&W FOR 7 YEARS AND THEN MY ONC SAID IT WAS TIME FOR CHEMO. I REFUSED CHEMO, BECAUSE AT 79 I DID NOT WANT MY IMMUNE SYSTEM DESTROYED WITH CERTAINLY NO GUARANTEE OF A CURE. (DX, F NHL, LOW GRADE)

MY ONC WAS FURIOUS WITH ME, AND I LEFT TO FIND A BEXXAR CLINICAL TRIAL ...AND I DID !!!

IT HAS BEEN A YEAR NOW IN "CR" WITHOUT THE SIDE EFFECTS I'VE SEEN MY FRIENDS GO THROUGH. GRANTED I WAS A PERFECT CANDIDATE, BUT THERE ARE SO MANY OTHERS LIKE ME, THAT CAN BE TREATED BEFORE "TRANSFORMATION" OR VERY HEAVY TUMOR BURDEN..... BEXXAR AND DONE !!!

I FEAR FOR MY CHILDREN AND GRANDCHILDREN IF BEXXAR AND ZEVALIN SHOULD NOT BE AVAILABLE FOR THEM.

PLEASE HELP US, CHEMO 5 AND 6 TIMES IS FAR MORE EXPENSIVE THAN THESE FANTASTIC DRUGS COULD EVER BE.

THANK YOU FROM A VERY GRATEFUL PATIENT...

BETTY STEVEN

See what's new at <http://www.aol.com>

11/29/2007

From: LMROSEN@wlrk.com [mailto:LMROSEN@wlrk.com]
Sent: Sunday, November 11, 2007 4:28 PM
To: niederhj@mail.nih.com.; kerry.weems@CMS.hhs.gov.; Kuhn, Herb B. (CMS/OA)
Subject: CMS-1392-FC, Payment for Radioimmunotherapies(RIT)

I am a 9 year survivor of Non-Hodgkin's lymphoma. I am a 77 year old retired attorney and have been active in my attempt to understand my disease and the treatment thereof and to do what I can to help those afflicted in any way that I can. In that regard I am, and have been for many years, a member of the Board of Directors of the Lymphoma Research Foundation and Chairman of its Public Policy Committee. I served as a Patient Advocate for 6 years on the Lymphoma Committee of CALGB, one of the Cooperative Groups funded by the NCI. I also served as a participant in the NCI Progress Review Group for Blood Cancers. Although my disease has thus far not required medical treatment, it does require careful monitoring.

I closely follow the medical advances that have been made in the treatment of lymphoma knowing that my time for needing treatment can come at any time. To me as a lay person the most significant advances made in the last 9 years for those affected by Lymphoma have been the development and availability of Rituxan, Bexxar and Zevalin. These are targeted remedies substantially superior to untargeted chemotherapies in many ways and may yet prove to cure indolent lymphoma (which is so far incurable) or to make it a chronic disease. Bexxar and Zevalin have clearly demonstrated in many clinical trials that they are important soldiers in the battle to subdue lymphoma. They are often an effective last resort when other

11/29/2007

treatments cease to work.

CMS-1392-FC should not be adopted if there is substantial uncertainty that hospitals will be willing or able to provide Bexxar or Zevalin without losing money. This is not simply an academic question. Lives are at stake. If further study is needed, then it should be done before reimbursement rules are changed. We should not risk destroying the market for drugs that have proven themselves to be effective.

Sincerely,
Leonard Rosen

Any tax advice contained in this communication is not intended or written to be used, and cannot be used, for the purpose of avoiding tax penalties and is not intended to be used or referred to in promoting, marketing or recommending a partnership or other entity, investment plan or arrangement.

Please be advised that this transmittal may be a confidential attorney-client communication or may otherwise be privileged or confidential. If you are not the intended recipient, please do not read, copy or re-transmit this communication. If you have received this communication in error, please notify us by e-mail (helpdesk@wlrk.com) or by telephone (call us collect at 212-403-4357) and delete this message and any attachments. Thank you in advance for your cooperation and assistance.

www.wlrk.com

>>

>>>-----Original Message-----

>>>From: Betsy de Parry [mailto:betsy@annarborbuilders.com]

>>>Sent: Thursday, November 08, 2007 1:03 PM

>>>To: Weems, Kerry (CMS/OA)

>>>Subject: Fw: CMS-1392-FC

>>>

>>>RE: CMS-1392-FC, Payment for Radiopharmaceuticals

>>> BEXXAR® Therapeutic Regimen (Tositumomab + Iodine 131

>>>Tositumomab) and

>>> ZEVALIN® Therapeutic Regimen (Ibritumomab Tiuxetan)

>>>

>>>Dear Mr. Weems,

>>>

>>> I am writing as an individual who was diagnosed with follicular
>>>non-Hodgkins lymphoma nearly six years ago. I was initially treated
>>>with two different types of chemotherapy, but never completed a full
>>>course of either because my disease resisted both.

>Radioimmunotherapy

>>>became available in the nick of time and I have now been healthy for
>>>five full years.

>>>

>>> Since my recovery, my husband and I have closely followed the
>>>progress of radioimmunotherapy. While we recognize that these
>>>radiopharmaceuticals
>>have

>>>presented challenges since they do not fit neatly into existing
>>categories,

>>>it is also disappointing that reimbursement rates have already
>>>negatively impacted hospitals' ability to offer and deliver these
>>>treatments. In fact, several publications, including the Journal of
>>>the National Cancer Institute (Volume 99, Issue 7, April 4,
>2007) and

>>>the New York Times (July 14,
>>2007),

>>>have reported that between 5% and 10% of patients who are
>eligible for

>>>it have actually received it, citing the reimbursement
>environment as

>>>a major contributing factor of this underutilization.

>>>
>>>I am deeply concerned that the payment rates as set forth in
>the Final
>>>Ruling for CY 2008 will make it impossible for patients to receive
>>>this highly effective treatment. Specifically, the
>reimbursement rate
>>>for all the components of the BEXXAR® Therapeutic Regimen is
>>>approximately one
>>half
>>> its cost, a fact which will leave hospitals in the position of
>>> choosing
>>to
>>>subsidize or abandon the treatment. The latter is most likely, as
>>>both
>>the
>>> American Society of Hematology and the American Society of Clinical
>>>Oncologists have pointed out in letters to CMS during the comment
>>>period prior to the final ruling.
>>>
>>> CMS, in its final ruling, disputes this fear, saying that
>"given that
>>>the Medicare population is such a dominant portion of the population
>>>to which these services are targeted, we do not believe that
>>>hospitals will cease to provide the service." With all due respect,
>>>how does CMS expect hospitals to provide any service for which they
>>>will lose money?
>>>
>>> Additionally, CMS warns that "under 42 CFR 489.53(a)(2), CMS may
>>terminate
>>>the provider agreement of any hospital that furnishes this or any
>>>other service to its patients but fails to also furnish it
>to Medicare
>>>patients who need it." Surely no hospital will jeopardize
>its provider agreement.
>>> Thus, if these treatments are unavailable to Medicare
>patients, they
>>>will also be unavailable to anyone else.
>>>
>>>As I understand it, the final reimbursement rate is based on
>previous
>>>hospital claims. CMS acknowledges that many claims were
>"incorrectly
>>>submitted" and "some represented unusually low costs." The agency
>>>also acknowledges that some claims were "incorrectly coded" and thus
>>>"unlikely to represent claims for treatment with the products
>>>described as A9543 and A9545" (Zevalin and Bexxar respectively).
>>>Although CMS removed these "likely incorrectly coded claims in the
>>>ratesetting process," CMS cannot
>>be
>>>sure which claims were coded correctly and which were not.
>Using data
>>that
>>>was known to be flawed, the new rate could not have been set
>accurately.
>>>
>>> Furthermore, under the Medicare Prescription Drug, Improvement and
>>>Modernization Act of 2003 (MMA), the BEXXAR® Therapeutic Regimen was
>>>classified as a "specified covered outpatient drug" (SCOD) and the
>>>statute directs that CMS must pay for SCOD's at either "the average
>>>acquisition cost for the drug for that year" or "if hospital
>>>acquisition cost data are not available, the average price for the
>>>drug in the year established." I am not an attorney, but
>the statute
>>>does not seem to authorize CMS to set rates based on an average of
>>>claims, much less ones that are known to be inaccurate. The
>>>methodology used to set this rate was flawed, incorrect,
>irresponsible

>>>and may not even comply with the statute.
>>>
>>>One thing is certain. The new rate will have long term and
>>>devastating consequences. It will undoubtedly condemn these drugs to
>>>medical history, which will set a disturbing precedent and
>>>disincentive for the
>>development
>>>of future innovative therapies. Furthermore, it will deprive many
>>patients
>>>of a valuable treatment option and worse, surely condemn
>some patients
>>>to death. I say that with some authority since I would not be alive
>>>today
>>had
>>>this treatment not been available - and there are many
>success stories
>>like
>>>mine. It is within your power to give others the same
>chance - or to
>>>deny it, as this final ruling, if allowed to take effect, will do.
>>>
>>> I recognize that the panel has invested a significant
>amount of time
>>>and effort reviewing the many drugs and procedures that this ruling
>>>covers,
>>but
>>> I respectfully beg CMS to revisit and reverse its position on
>>>radiopharmaceuticals. Please allow patients to benefit from all the
>>>treatments that scientists have worked so hard to develop.
>And please
>>>don't condemn a single cancer patient to death by allowing
>this ruling
>>>to take effect.
>>>
>>>I respectfully request a meeting with you at your earliest
>convenience
>>>to discuss this matter further.
>>>
>>>Sincerely,
>>>
>>>Betsy de Parry
>>>6310 Sandy Creek Court
>>>Ann Arbor, Michigan 48103
>>>(734) 216-5872
>>>
>
>

From: Jim Forsberg [mailto:jimfloisf@comcast.net]
Sent: Saturday, November 10, 2007 12:55 PM
To: Weems, Kerry (CMS/OA)
Subject: CMS-1392-FC

Dear Mr. Weems,

I am writing to you to add my voice to the thousands who are crying out for your help. My sister Betty has NHL. We are asking that you do what you can to reverse the decision made by CMS in regards to the payment rates to hospitals.

If a treatment option like this is withheld from those who so desperately need it what does that say about the society we live in.

Sincerely,

11/29/2007

From: JFox1065@aol.com [mailto:JFox1065@aol.com]
Sent: Wednesday, November 14, 2007 10:32 AM
To: Weems, Kerry (CMS/OA)
Subject: CMS-1392-FC

I am writing to ask for your help in reversing a cancer treatment ruling, CMS-1392-FC.

This week, a Newsweek story by Jonathan Alter, one of the most respected and experienced journalists in the country, featured the negative ruling by Congress on the drugs Zevalin and Bexxar. These drugs have saved people's lives. Patients are going to die without them.

Jonathan writes about the ruling and how present government policies will create a huge disincentive for the development of innovative therapies for all kinds of cancers and other illnesses.

Several of us with Non-Hodgkin's Lymphoma are fighting vigorously to turn the CMS-1392-FC ruling around, but we have very little time. I am asking for your help in doing this. Other people with different cancers can also benefit from the reversal. I am also concerned about the ruling on radioimmunotherapy, a very effective target therapy.

I am asking that a "legislative fix" be written into the Appropriations Bill that would maintain the 2007 reimbursement rates for Bexxar and Zevalin. This will give CMS the necessary time to correct its methods prior to setting rates for 2009.

PLEASE support this revision so that these important treatments will continue to be available to patients.

Thank you,

11/29/2007

From: Paula Winkler [mailto:jrseygirl22@yahoo.com]
Sent: Sunday, November 11, 2007 8:25 PM
To: Weems, Kerry (CMS/OA)
Subject: Payment for radio pharmaceuticals

Dear Mr. Weems:

RE: CMS-1392-FC, Payment for Radio pharmaceuticals
BEXXAR® Therapeutic Regimen (Tositumomab + Iodine 131 Tositumomab)
and
ZEVALIN® Therapeutic Regimen (Ibritumomab Tiuxetan)

Several publications, including the Journal of the National Cancer Institute (Volume 99, Issue 7, April 4, 2007) and the New York Times (July 14, 2007), have reported that between 5% and 10% of patients who are eligible for radio pharmaceutical therapy have actually received it, citing the reimbursement environment as a major contributing factor of this under utilization.

I am deeply concerned that the payment rates as set forth in the Final Ruling for CY 2008 will make it impossible for patients to receive this highly effective treatment. Specifically, the reimbursement rate for all the components of the BEXXAR® Therapeutic Regimen is approximately one half its cost, a fact which will leave hospitals in the position of choosing to subsidize or abandon the treatment. The latter is most likely, as both the American Society of Hematology and the American Society of Clinical Oncologists have pointed out in letters to CMS during the comment period prior to the final ruling.

11/29/2007

CMS, in its final ruling, disputes this fear, saying that "given that the Medicare population is such a dominant portion of the population to which these services are targeted, we do not believe that hospitals will cease to provide the service." With all due respect, how does CMS expect hospitals to provide any service for which they will lose money?

Additionally, CMS warns that "under 42 CFR 489.53(a)(2) , CMS may terminate the provider agreement of any hospital that furnishes this or any other service to its patients but fails to also furnish it to Medicare patients who need it." Surely no hospital will jeopardize its provider agreement. Thus, if these treatments are unavailable to Medicare patients, they will also be unavailable to anyone else.

As I understand it, the final reimbursement rate is based on previous hospital claims. CMS acknowledges that many claims were "incorrectly submitted" and "some represented unusually low costs." The agency also acknowledges that some claims were "incorrectly coded" and thus "unlikely to represent claims for treatment with the products described as A9543 and A9545" (Zevalin and Bexxar respectively) .

Although CMS removed these "likely incorrectly coded claims in the rate setting process," CMS cannot be sure which claims were coded correctly and which were not. Using data that was known to be flawed, the new rate could not have been set accurately.

Furthermore, under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), the BEXXAR® Therapeutic Regimen was classified as a "specified covered outpatient drug" (SCOD) and the statute directs that CMS must pay for SCOD's at either "the average acquisition cost for the drug for that year" or "if hospital acquisition cost data are not available, the average price for the drug in the year established. " The statute does not seem to authorize CMS to set rates based on an average of claims, much less ones that are known to be inaccurate. The methodology used to set this rate was flawed, incorrect, irresponsible and may not even comply with the statute.

One thing is certain. The new rate will have long term and devastating consequences. It will undoubtedly condemn these drugs to medical history, which will set a disturbing precedent and disincentive for the development of future innovative therapies.

Furthermore, it will deprive many patients of a valuable treatment option and worse, surely condemn some patients to death.

I recognize that the panel has invested a significant amount of time and effort reviewing the many drugs and procedures that this ruling covers, but I respectfully beg CMS to revisit and reverse its position on radio pharmaceuticals. Please allow patients to benefit from all the treatments that scientists have worked so hard to develop.

Please don't condemn a single cancer patient to death by allowing this ruling to take effect.
Thank you very much for your consideration.

Very truly yours,

Paula H. Winkler
1175B Valley Road
Wayne, NJ 07470-7969