

**Hayes, Yolanda K. (CMS/OSORA)**

1-0  
(459)

**From:** Tracy Orwig [tracy.orwig@lls.org]  
**Sent:** Thursday, December 06, 2007 12:02 PM  
**To:** Weems, Kerry (CMS/OA)  
**Subject:** Please reconsider the payment levels for the radioimmunotherapies.

December 6, 2007  
Kerry Weems

Dear Kerry Weems,

As a Patient Services Manager with the Leukemia and Lymphoma Society, I am writing to to express my 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). Specifically, I would like you to implement the three recommendations in a letter to you from George Dahlman, Senior Vice President for Public Policy at the Leukemia and Lymphoma Society.

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 those in the lymphoma community who live with this disease and recognize that this form of treatment may truly be a life saving one. I urge you to please support this request to reconsider the payment levels for the radioimmunotherapies.

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

Sincerely

Tracy Orwig  
501 Hawk Ridge Lane  
Sykesville, MD 21784-7651

**From:** DANIEL C BAGWELL [mailto:danbag@msn.com]  
**Sent:** Monday, November 19, 2007 9:08 PM  
**To:** Weems, Kerry (CMS/OA)  
**Subject:** Re: Radioimmunotherapy (RIT)

*Mr. Weems,*

*Your position and power can either deny cancer patients possible lifesaving treatment using drugs like Zevalin and Bexxar or can promote drugs known to be effective treatments. It's not just about money, it's about people and how you can help. Change these policies and allow people that might need these drugs access to them. Please don't tie the doctors hands and the hospitals as well. Thank you.*

*Sincerely,  
Dan Bagwell*

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**From:** susan3190@bellsouth.net [mailto:susan3190@bellsouth.net]  
**Sent:** Monday, November 19, 2007 4:50 PM  
**To:** Weems, Kerry (CMS/OA)  
**Subject:** RIT

Dear Mr. Weems:

I have a close friend suffering from non-Hodgkins lymphoma and was dismayed over the recent article that appeared in Newsweek. I would like to say that I think RIT should be supported like any other proven chemo drug. We cannot standby if a cure is in sight and let our friends and family suffer. I hope that you will take this to heart and support RIT.

Sincerely,

Susan Boling

11/21/2007

**From:** John Cauffiel [mailto:jscauffiel@comcast.net]  
**Sent:** Monday, November 19, 2007 10:01 PM  
**To:** Kuhn, Herb B. (CMS/OA); Weems, Kerry (CMS/OA)  
**Subject:** CMS Ruling, please reverse

Dear Mr. Kuhn,

I urgently need your help, with my fellow Lymphoma survivors, the below ruling will actually cost the Gov't more money in the long run, if not reversed.

I am a patient with non hodgkins lymphoma . My Doctor is Mark Kaminski of the Univ. of Michigan, the father of the below drug Bexxar. He has saved my life, I have been in remission for 3 years, 8 year total cancer survivor.

I am contacting you regarding a CMS ruling that will have a devastating effect on the survival of patients with lymphomas. The ruling is contained in CMS-1392-FC as it relates to Bexxar and Zevalin

If this ruling is not reversed, patients in need will be denied access to a life saving therapy, and future patients will be denied access to Bexxar or Zevalin and similar targeted drugs.

Also as ASH (The American Society of Hematology) has written: the CMS ruling will have "a chilling effect on the development of future drugs and radiopharmaceuticals for treating other forms of cancer and other diseases."

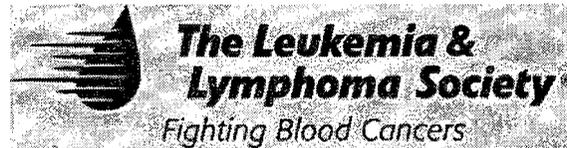
**ACTION NEEDED**

I respectfully request that you take all necessary actions to reverse CMS-1392-FC as it relates to Bexxar and Zevalin.

For background on the consequences of this ruling to patients, please see the Newsweek article of Nov 14: <http://www.newsweek.com/id/70301>

John S. Cauffiel  
46780 Timberlane  
Northville, MI 48167

11/21/2007



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

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**From:** Ronald Danzig [mailto:rdanzig@sbcglobal.net]  
**Sent:** Sunday, November 18, 2007 2:08 PM  
**To:** Weems, Kerry (CMS/OA)  
**Subject:** RIT

Dear Mr. Weems,

As a retired physician I was appalled to read the article in Newsweek about the CMS decision which will result in the loss of Bexxar and Zevalin from the therapeutic armamentarium for NHL. The comment that these are diagnostic tools must be a misquote. These drugs do not diagnose anything. They are therapeutic agents and are recognized as such by the FDA. Fortunately these drugs have been available for many patients who have failed other therapies and are not transplant candidates.

Credibility must be a mandate for agencies such as CMS and FDA. If you refuse to pay for these agents because of the expense then say so. Don't misrepresent these drugs which are life-saving for many people as diagnostic agents.

Ronald Danzig MD FACC FACP  
4619 Westchester Drive  
Woodland Hills, CA 91364  
rdanzig@sbcglobal.net

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**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

**From:** Brnzbabe1@aol.com [mailto:Brnzbabe1@aol.com]  
**Sent:** Friday, November 16, 2007 1:37 PM  
**To:** Weems, Kerry (CMS/OA)  
**Subject:** RIT

Sir...As the mother of a patient with a form of lymphoma, I am not only angry but disgusted with the ruling from CMS against RIT, a treatment that has proven to be a huge step in cancer treatment. Please do whatever you can to support and encourage doctors and hospitals to move ahead with RIT. Perhaps if some of these "beancounters" had cancer they might not be so blind to the suffering of others.

DORIS J. KRAMER .

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From: Julie Liell [mailto:julie\_liell@hotmail.com]

**Sent:** Tuesday, November 20, 2007 12:11 PM

**To:** LeavittVT, Mike (HHS/OS); Weems, Kerry (CMS/OA)

**Cc:** senator@stabenow.senate.gov

**Subject:** Radioimmunotherapies for lymphoma patients

Dear Secretary Leavitt,

My brother is a 42 year old mechanic supporting his wife and two children, ages 11 and 13. He has follicular non-Hodgkins lymphoma. He was diagnosed about five years ago and has undergone a variety of treatments for his cancer, which has manifested itself as tumors in his groin, neck, lungs, and tongue (a great portion of which had to be removed). So far Bexxar has been his most effective treatment. Our family is terrified at the potentially tragic implications of reduced coverage for RIT.

We implore you to intervene and to help ensure all lymphoma patients are able to continue to receive affordable RIT treatments.

Sincerely  
Julie Liell Hurst

November 19, 2007  
The Honorable Michael Leavitt  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

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Dear Secretary Leavitt:

The Lymphoma Research Foundation (LRF) is a voluntary health agency dedicated to improving the quality of health care and quality of life for those with lymphoma. LRF is writing to express grave concerns about the payment levels for radioimmunotherapies that are set in the calendar year 2008 hospital outpatient prospective payment system (HOPPS). Unless extraordinary action

is taken to modify these reimbursement rates before they go into effect on January 1, 2008, we fear that patient access to these life-saving therapies may be significantly limited, if not eliminated.

Radioimmunotherapies – tositumomab (Bexxar) and ibritumomab tiuxetan (Zevalin) – represent an important treatment option for individuals with non-Hodgkin lymphoma, including patients who have undergone another treatment that is no longer providing a therapeutic benefit. For some of these patients, the radioimmunotherapies may truly be the only effective option remaining. It is also important to note that these therapies are only given to patients for a single course of therapy and are not given in successive cycles of treatment, so the overall cost of treatment is the cost of a single course.

Administration of the radioimmunotherapies is somewhat complex and must be undertaken in major cancer centers or other health care facilities that are properly equipped for their administration. This fact presents an initial challenge to patient access, but the proposed payment rates for 2008 represent a much more serious barrier to access. It is our understanding that the payment rates for 2008 will be significantly less than the cost of acquisition, preparation, and handling of radioimmunotherapies. If this payment situation is not resolved, hospital outpatient departments will be unable to stock these therapies, and this treatment option will be effectively eliminated for non-Hodgkin lymphoma patients.

We recommend that several specific steps be taken to rectify this situation:

- The Centers for Medicare & Medicaid Services (CMS) should consider the radioimmunotherapy regimen a specified covered outpatient drug, or SCOD. In the 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.
- 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.
- 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 is a matter of public health that demands your personal intervention. We fear that these radioimmunotherapies will simply not be available for treatment of non-Hodgkin lymphoma patients after the new year if the payment rates for these products are not adjusted. The payment structure proposed for 2008 will not produce savings to the Medicare program in the long run, and it will certainly not ensure access to health care for lymphoma patients.

We look forward to your immediate response.

Sincerely,

Leonard Rosen  
Chair  
Public Policy Committee  
Lymphoma Research Foundation

cc: Kerry Weems  
Administrator  
Centers for Medicare & Medicaid Services

**From:** VV925@aol.com  
**Sent:** Sunday, November 25, 2007 5:11 PM  
**To:** LeavittVT, Mike (HHS/OS)  
**Cc:** Weems, Kerry (CMS/OA)  
**Subject:** Radioimmunotherapies payment levels

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Dear Mr. Leavitt:

I am a non-Hodgkin's lymphoma survivor, having had six regimens of treatments in the past 12 years. I fully expect to need a future treatment with either Zevalin or Bexxar, radioimmunotherapies which have proved to be successful when more traditional chemotherapy and radiation are no longer effective.

I am writing you to express my concern over the recent CMS determination about the payment levels for radioimmunotherapies that are in the 2008 hospital outpatient prospective payment system. I am asking you to support the recommendations contained in a November 19th letter to you from Mr. Leonard Rosen, Chairman of the Lymphoma Research Foundation's Public Policy Committee.

Briefly, these recommendations are: 1) CMS should consider the radioimmunotherapy regimen a specified covered outpatient drug. 2) CMS should cover the cost of compounding radioimmunotherapies. 3) The agency should consider setting payment for radioimmunotherapies that would reflect the entire cost of the radioimmunotherapy regimen.

Mr. Rosen, this is a serious matter for persons like myself who need to know these life-saving treatments of radioimmunotherapies will be available when needed. If the payment rates for these products are not adjusted before January 1, 2008, they will not be affordable for most of us.

Thank you for considering these requests.

Sincerely,

Vivian Virden  
16714 E. Gunsight Dr. #137  
Fountain Hills, AZ 85268  
480-837-3650  
e-mail: VV925@aol.com

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December 17, 2007

VIA OVER NIGHT AND ELECTRONIC MAIL  
[www.cms.hhs.gov/regulations/eRulemaking](http://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).<sup>1</sup> 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<sup>®</sup> (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<sup>®</sup> Therapeutic Regimen is currently under-utilized, with the current reimbursement environment cited as a major

<sup>1</sup> 72 Fed. Reg. 66580 (November 27, 2007).

contributing factor.<sup>2</sup> 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<sup>®</sup>. That said, CMS's request for comments in the Final Rule is focused on "separately payable therapeutic radiopharmaceuticals" which, in the case of BEXXAR<sup>®</sup>, CMS has incorrectly classified as only one of the four components of the BEXXAR<sup>®</sup> 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<sup>®</sup> Therapeutic Regimen. Our comments are summarized below:

- For CY 2008 and beyond, CMS should properly classify the overall BEXXAR<sup>®</sup> Therapeutic Regimen. At this time, CMS does not properly reflect that the drug components comprising BEXXAR<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Therapeutic Regimen using the ASP methodology. As of this writing, GSK has voluntarily submitted two quarters of ASP data for the BEXXAR<sup>®</sup> 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.

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<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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).

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

<sup>4</sup> *Id.*

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

**Table 1. Payment History and 3Q07 ASP**

HCPCS 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<sup>®</sup>.

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

### **The Finalized OPSS Payment Methodology Misclassifies Integral Drug Components of the BEXXAR<sup>®</sup> Therapeutic Regimen as Diagnostic and as Supplies**

CMS has finalized a payment methodology that inappropriately treats the various components of the BEXXAR<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> to Medicare patients, they are unlikely to offer BEXXAR<sup>®</sup> to patients with private insurance, thus eliminating all patient access to BEXXAR<sup>®</sup>. 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<sup>®</sup> to any patient.

In order to accurately reflect actual acquisition costs incurred by hospitals when administering BEXXAR<sup>®</sup>, 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.<sup>5</sup> 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<sup>®</sup> “Hot Dose”**

GSK is disappointed by CMS's decision to reimburse the BEXXAR<sup>®</sup> “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<sup>®</sup> 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 OPPS as SCODs.”<sup>6</sup>

**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

<sup>5</sup> SSA § 1833(t)(14)(E).

<sup>6</sup> 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.<sup>7</sup> Therefore, the Medicare statute mandates that SCODs, such as BEXXAR<sup>®</sup>, 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 OPPS claims data.”<sup>8</sup> CMS believes that the hospital claims data that are currently available for rate-setting purposes are reliable and accurate.<sup>9</sup> 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 OPPS payment rates. GSK firmly endorses applying the ASP methodology for CY2008 to radioimmunotherapies, like the BEXXAR<sup>®</sup> Therapeutic Regimen. We believe that using this methodology is much more accurate than the mean unit cost obtained through OPPS 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.

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<sup>7</sup> SSA § 1833(t)(14)(A)(iii).

<sup>8</sup> 72 Fed. Reg. 66772 (November 27, 2007).

<sup>9</sup> *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,



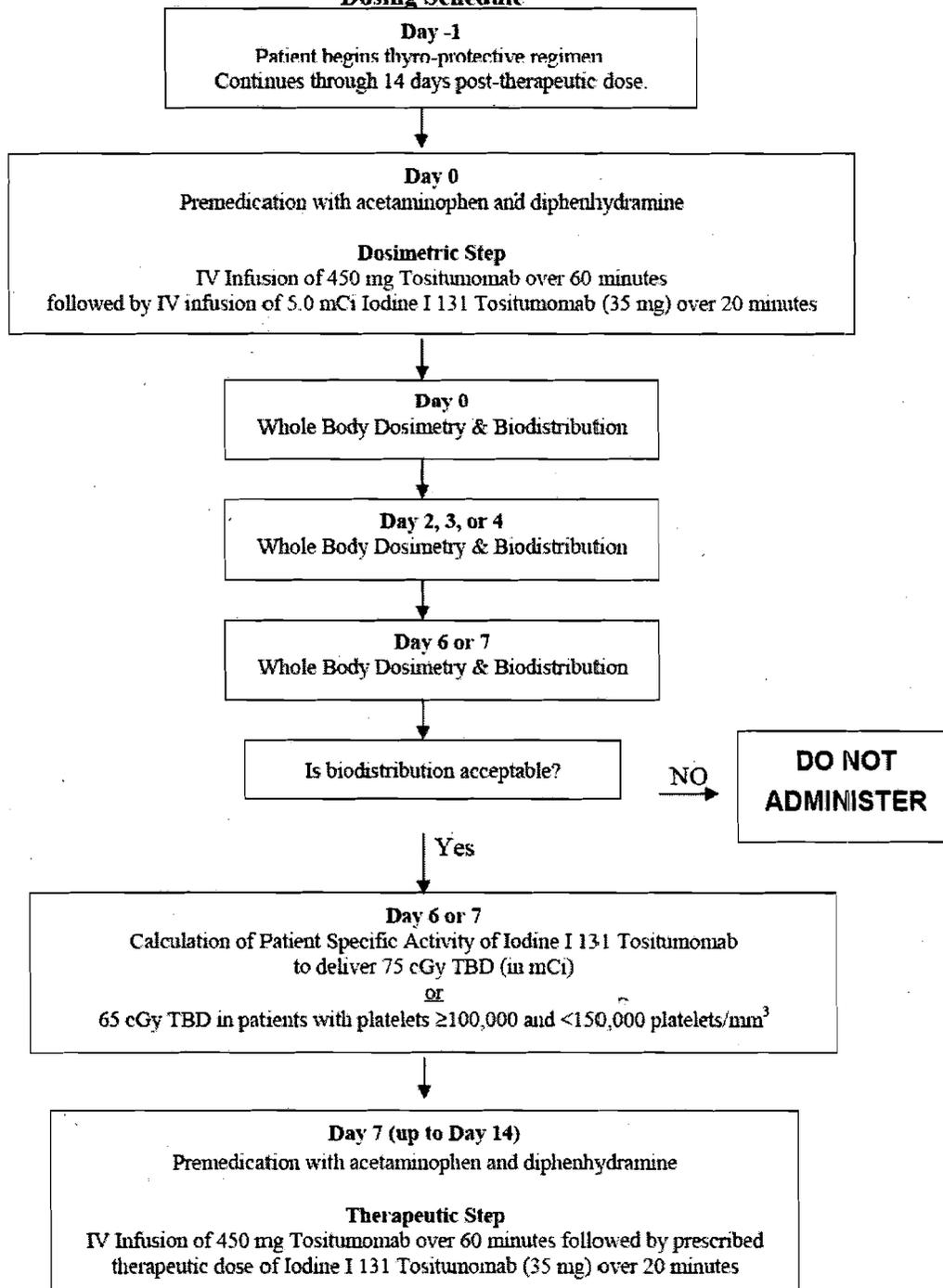
Roger A. Hunter  
Executive Director  
New Product Planning and Policy  
GlaxoSmithKline Oncology/Critical &  
Supportive Care

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

**ATTACHMENT A**  
**Dosing Schedule from BEXXAR® Prescribing Information**

**Figure 1**

**Dosing Schedule**





**THE EYE CARE GROUP**

**ROBERT L. LESSER, MD**  
*Neuro-Ophthalmology  
Cataract & Lens Implant Surgery*

**STANLEY B. HERSH, MD**  
*Glaucoma  
Cataract & Lens Implant Surgery*

**DAVID E. SILVERSTONE, MD**  
*Glaucoma  
Cataract & Lens Implant Surgery*

**ANDREW J. LEVADA, MD**  
*Pediatric Eye Care  
Adult Eye Muscle Disorders*

**CRAIG A. SKLAR, MD**  
*Diseases & Surgery of the  
Retina & Vitreous  
Diabetic Eye Disease*

**ARON D. ROSE, MD**  
*Glaucoma  
Cataract & Lens Implant Surgery*

**PETER J. BRANDEN, MD**  
*Glaucoma  
Cataract & Lens Implant Surgery*

**STEPHANIE L. SUGIN, MD**  
*Diseases & Surgery of the  
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Diabetic Eye Disease*

**YANINA KOSTINA-O'NEIL, MD**  
*Neuro-Ophthalmology  
Comprehensive Ophthalmology  
Cataract & Lens Implant Surgery*

**JOEL A. GEFFIN, MD**  
*Cornea, Refractive  
& Cataract Surgery*

**JONATHAN E. SILBERT, MD**  
*Ophthalmic Plastic  
& Reconstructive Surgery*

December 11, 2007

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

I am writing to comment on the ASC payment level and the physician payment for CPT code 68816.

I would like to comment that balloon dacryoplasty is generally done 100 percent of the time on children in my practice since I am a pediatric ophthalmologist. One hundred percent of the time, this is done under general anesthesia, usually in an ASC setting and rarely in a hospital outpatient setting, and never in the office. This is also true for irrigation and probing as well as insertion of stents. An ASC setting, of course, is clinical to monitoring young children who are undergoing treatment for nasolacrimal duct obstruction.

In addition, I would like to comment that balloon dacryoplasty takes significantly more time than just a simple probing. In most cases, a probing precedes the insertion of the LacriCATH. In addition, there is a significant time for the inflation/deflation procedures for the LacriCATH, and all of these times are in addition to the standard steps in probing. I would estimate that on average, a LacriCATH procedure takes two and a half times the amount of time required to do a simple probing. I do not understand why the reimbursement in an ASC setting is so much lower than in a hospital outpatient setting since, given the cost of the balloon catheter, the ASC will be unable to perform a procedure profitably. This will drive treatment into a hospital outpatient setting where, in my experience, anesthesia times are significantly longer since the hospital outpatient setting is not used to doing children rapidly in my area. Of course, since the balloon dacryoplasty requires more work than CPT code 68815, I do not see why this should be paid at a lower physician payment also.

- 1201 WEST MAIN STREET SUITE 100 WATERBURY, CT 06708 TEL: 203-597-9100 FAX: 203-596-4758
- 40 TEMPLE STREET SUITE 5-B NEW-HAVEN, CT 06510 TEL: 203-789-2020 FAX: 203-562-6028
- 22 OLD WATERBURY ROAD SUITE 202 SOUTHURY, CT 06488 TEL: 203-262-1600 FAX: 203-262-8506
- 6 BUSINESS PARK DRIVE SUITE 102 BRANFORD, CT 06405 TEL: 203-488-5411 FAX: 203-488-5390

I would be happy to discuss this with you further if necessary.

Sincerely,

A handwritten signature in cursive script, appearing to read "Levada". The signature is written in dark ink on a white background.

Andrew J. Levada, M.D., F.A.C.S.  
Associate Clinical Professor  
Department of Ophthalmology & Visual Science  
Yale University School of Medicine

AJL/si

T:12/12/07



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December 12, 2007

NOEL D. SAKS, M.D.  
Ophthalmic Plastic &  
Reconstructive Surgery  
Orbital Surgery  
Ophthalmology

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

To Whom it May Concern:

This letter is to discuss specific concerns that I have regarding the ASC payment level and physician payment for CPT68816 balloon dilation of the nasal lacrimal duct.

A stenotic nasolacrimal duct is often seen in some adults and often in children as a causative factor explaining a failed probing. My current course of action as an oculoplastic and lacrimal duct surgeon in these patients who have continued tearing is a balloon dilation of the nasolacrimal duct. I typically perform almost 100% of these procedures in an ambulatory surgical center (ASC) and I perform 100% of these procedures under general anesthesia, as this simply is mandatory in order to prevent pain and to have control should there be any intraoperative bleeding, etc. My understanding is that part of the decision for the level of reimbursement for CPT68816 is based on an office setting. This is simply not an office procedure in any way, shape, or form, and I certainly would not want it performed on myself in anyone's office. In the office setting, there is potential for complications including bleeding, pain, and problems with the airway if there is not general anesthesia. An ambulatory surgical center provides better preoperative work-up, better intraoperative patient monitoring and care postoperatively. It should be noted that a standard probing typically takes only a few minutes to probe down the nasolacrimal duct, whereas a typical balloon dilation involves a probing of the nasolacrimal duct followed by insertion of the tube followed by inflation, deflation, moving of the tube, followed by repeat inflation and deflation, and often a check with irrigation through the ballooned duct in order to ascertain its patency. This procedure is often combined with an infraction of the inferior turbinate, and I often combine it with placement of silicone intubation to keep the ballooned duct open, as well. None of these surgeries are possible without general anesthesia in an ambulatory surgical care setting.

The ambulatory surgical center is clearly the model for performing these in a reduced cost setting, as these are typically privately run businesses that are interested in maintaining proper overhead and the proposed lower ASC payment is actually a financial deterrent to treat patients in a hospital setting which greatly elevates the healthcare costs rather than decrease them. It should be noted that the cost of the balloon catheter is \$306.00, and the payment of \$434.00 for the CPT code in the ASC setting would not allow for any of these patients to be treated economically in the ambulatory setting.

December 12, 2007  
RE: ASC payment level  
Page Two

The physician payment amount decreasing in 2008 from \$205.00 for 68815 to \$193.00 under 68816 is certainly also a concern because 68815 refers to simple probing and possibly placing a tube into the duct, whereas 68816 as outlined above is a much more complicated and time consuming procedure. Therefore, introducing this as a code with lower reimbursement does not seem to make clinical sense.

Please feel free to contact my office as above if you desire to speak with me directly. Please note that I feel very strongly about this matter, as balloon dilation of the nasolacrimal duct has become an integral portion of my practice.

Sincerely,



Noel D. Saks, M.D.  
Ophthalmology  
Ophthalmologic Plastic and Reconstructive Surgery

NDS:dc

15



P.O. Box 6002  
Grand Forks, ND  
58206-6002  
(701) 780-5000 phone  
www.altru.org web

December 11, 2007

Center for Medicare & Medicaid Services  
Department of Health & Human Services  
Attn: CMS-1392-FC Mail stop C42605  
7500 Security Blvd  
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing in regard to the ASC payments level and physician payment for CPT 68816. This interim payment for an ASC is not in the contact of reality. I do many balloon dilations of the nasal lacrimal duct, but only after there has been a failure with conventional probing or if there has been a long period of time that they never had a probe at all. This is mainly for those 12-24 months old and older. These things can never be done in an office since 100% of them require general anesthesia. Without general anesthesia, doing these in the office would either be a sham or be accompanied by a huge amount of complications. This is not the preferred setting for these procedures. 100% of these are done on children under the age of four and I could not think of any indication for these to be done in an adult. These take more time than a simple probing, almost 3-5 times more time for the probing depending on how many sides are being done. I think if there were any indication for any watchdog activity here, it would be on the fact if a practice were suddenly doing more balloon duct dilations than they had in the past.

In my opinion, there are only a limited number of indications for this; but it is all done in the hospital and it is never done in a physician's office, and 100% require general anesthesia. At the present time I probably do a dozen of these a year.

Sincerely,

Norman T. Byers, MD, FACS

equal opportunity employer



December 17, 2007

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

**Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates and Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Final Rule with Comment**

Dear Mr. Weems:

The American Society for Therapeutic Radiology and Oncology (ASTRO)<sup>1</sup> appreciates the opportunity to provide written comments on the "Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates and Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates" published in the *Federal Register* as a final rule on November 27, 2007. Our comments focus on the following issues which are presented in the order in which they appear in the final rule: (1) APC relative weights and the bypass list; (2) packaging of guidance services; (3) packaging of diagnostic radiopharmaceuticals; (4) composite APCs - prostate low dose rate (LDR) brachytherapy; (5) electronic brachytherapy; (6) proton beam therapy; (7) OPPTS payment for brachytherapy sources; and, (8) quality data.

**I. APC Relative Weights - Bypass List (72 Fed. Reg., 66590)**

For CY 2008, CMS proposed to continue using the codes on the CY 2007 OPPTS bypass list but to remove codes that were proposed for packaging for CY 2008. CMS also proposed to remove codes that were on the CY 2007 bypass list that "ceased to meet the empirical criteria under the proposed packaging changes when clinical review confirmed that their removal would be appropriate in the context of the full proposal for the CY 2008 OPPTS." (Page# 66590)

Eight radiation oncology codes were among the codes proposed for deletion from the bypass list. In our comments on the proposed rule, we argued that removing these codes from the bypass list would result in fewer claims for use in rate-setting since more claims would remain multiple

<sup>1</sup> ASTRO is the largest radiation oncology society in the world, with more than 9,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing healthcare environment.

procedure claims. We also argued that there is minimal associated packaging with these codes. In the final rule, CMS accepted our comments for all codes, with the exception of CPT<sup>®</sup> code 77417 *Therapeutic radiology port film(s)* which was not retained on the bypass list because CMS decided to assign this code a status of unconditionally packaged. Such codes are never separately paid and their presence on a claim does not make that claim a multiple procedure bill.

ASTRO appreciates CMS's decision to retain seven of the eight radiation oncology codes identified in our comments on the bypass list. This decision will help to maintain the stability and accuracy of the APC payments as more single claims will be available for rate-setting. However, we are disappointed by the decision related to code 77417. The CMS decision appears to have been based on a conclusion that code 77417 should be unconditionally packaged. We will address our concerns with this decision in the next section of our comments.

## II. Packaging of Guidance Services (72 Fed. Reg., 66614)

As an initial step toward creating larger payment groups for hospital outpatient care, CMS proposed to package payment for items and services in seven categories into the payment for the primary diagnostic or therapeutic modality to which CMS believes these items and services are typically ancillary and supportive. One of the seven categories proposed for packaging was guidance services, including the following 5 radiation oncology codes that are used in Image Guided Radiation Therapy (IGRT):

- 76950 Ultrasonic guidance for placement of radiation therapy fields
- 76965 Ultrasonic guidance for interstitial radioelement application
- 77417 Therapeutic radiology port film(s)
- 77421 Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
- 77014 Computed tomography guidance for placement of radiation therapy fields

In our comments, we opposed this proposal because we were extremely concerned that the packaging of IGRT would hamper the adoption and continued use of this valuable service and that the proposal could create payment incentives to avoid the use of quality-enhancing services for financial reasons. In addition, we were concerned that the proposed payments for radiation oncology services might not reflect the full costs of the packaged services. As an illustration of our concern, we noted that the payment for APC 0313 *Brachytherapy* was proposed to be reduced from \$789.70 to \$739.46. It made no sense to us to preclude separate payment for IGRT and then decrease payments for the services to which they are packaged.

In the final rule, our comments and the recommendation of the APC Panel to not package these services were rejected. CMS stated "We believe that packaging will create incentives for hospitals and their physician partners to work together to establish appropriate protocols that will eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently" (Page# 66619). We continue to believe that this rationale

for packaging does not apply in the case of IGRT. In addition, our concerns about APC 0313 were realized by a final payment rate in 2008 of \$743.81, a six percent reduction from the 2007 payment rate.

We understand that the CMS decision is considered final but we are compelled to re-state our concerns that the packaging of radiation oncology codes used in IGRT could be detrimental to continued access to high quality care. We ask that the decision be reversed.

At a minimum, we ask that CMS monitor the provision of IGRT services. In the proposed rule, CMS stated that it expects to "carefully monitor any changes in billing practices on a service-specific and hospital-specific basis to determine whether there is reason to request that Quality Improvement Organizations (QIOs) review the quality of care furnished or to request that Program Safeguard Contractors review the claims against the medical record" (Page# 42657). This expectation was not re-stated in the final rule and we are concerned that it will be forgotten or simply set aside. ASTRO requests that this monitoring be a priority during 2008 if the decision to package these codes is not reversed.

### **III. Packaging of Diagnostic Radiopharmaceuticals (72 Fed. Reg., 66635)**

CMS proposed to package payment for diagnostic radiopharmaceuticals into the payment for diagnostic nuclear medicine procedures for CY 2008. In our comments, we noted that CMS inappropriately included in the definition of diagnostic radiopharmaceuticals the following two codes that describe critical components of radioimmunotherapy:

A9542 Indium IN-111 ibritumomab tiuxetan, diagnostic, per study dose, up to 5 millicuries  
A9544 Iodine I-131 tositumomab, diagnostic, per study dose

We pointed out that radioimmunotherapy is completely distinct from the broader class of radiopharmaceuticals which are generally used for medical diagnostic purposes. Radioimmunotherapy involves the combination of a monoclonal antibody and a radiation emitting molecule or isotope. The monoclonal antibody attaches to a specific molecule on the cancer cells and the isotope emits radiation to kill the cells to which the monoclonal antibody has attached. This revolutionary and underutilized therapy results in the killing of cancer cells while sparing normal tissue cells.

Codes A9542 and A9544 are integral parts of the FDA-approved therapeutic regimens Zevalin and Bexxar. Their use represents the initiation of therapy, not the diagnosis of disease. We also noted that regardless of how the products were classified, the proposed packaging of this component of Zevalin and Bexxar therapies would result in grossly inadequate payment for these products.

We urged CMS to make an exception to its proposed payment policy for therapeutic radiopharmaceuticals and to continue in 2008 the current methodology of paying for Zevalin and Bexxar based on individual case charges reduced to costs using hospital-specific overall Cost-to-

Charge Ratios (CCR). This would buy time until the prices become publicly available either late in 2008 or early in 2009. We also suggested the use of Average Sales Price (ASP) data if manufacturers agree to share this data publicly.

In the final rule CMS disregarded ASTRO's recommendations, classified Codes A9542 and A9544 as diagnostic radiopharmaceuticals and packaged the payment of both codes into the nuclear medicine procedures with which they are reported. In response to our suggestion that ASP data be used, CMS noted that when they proposed to acquire ASP data for radiopharmaceuticals for purposes of paying for them separately under the CY 2006 OPSS, commenters were virtually unanimous that the industry could not report valid sales price data on radiopharmaceuticals. We question whether the manufacturers of Zevalin and Bexxar hold this position when it comes to these unique products.

We believe a serious error has been made by CMS. A nuclear medicine procedure used in the assessment of the biodistribution of Zevalin or in the calculation of the dose of Bexxar is 78804 *Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging*. The 2008 final payment for code 78804 is \$981.10. However, the estimated hospital acquisition cost for the Zevalin code A9542 is approximately \$2,800; for the Bexxar code A9544 it is approximately \$2,600. Although packaging is intended to encourage hospitals to use the most cost efficient diagnostic radiopharmaceutical product that is clinically appropriate, for this patient population there are no other products available. With payment rates that will not cover even half the cost of the products, patient access to radioimmunotherapy will be impeded, as hospitals may no longer be able to make this therapy available to Medicare beneficiaries.

When the discrepancy between payments and costs become so large, we believe that CMS should be willing to make exceptions to its policies that will ensure continued access to important therapies. An exception was made in the past for oral anti-emetics, an important component of cancer care. We ask that the same be done for radioimmunotherapies. Please continue in 2008 the current methodology of paying for Zevalin and Bexxar based on individual case charges reduced to costs using hospital-specific overall CCRs.

#### **IV. Composite APCs - Prostate Low Dose Rate (LDR) Brachytherapy (72 Fed. Reg., 66654)**

For CY 2008, CMS proposed to create a composite APC 8001, titled "LDR Prostate Brachytherapy Composite," that would provide one bundled payment for LDR prostate brachytherapy when a hospital bills the following two CPT<sup>®</sup> codes as component services provided during the same hospital encounter:

- 55875 *Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy; and*
- 77778 *Interstitial radiation source application; complex.*

Hospitals that furnish LDR prostate brachytherapy would report CPT<sup>®</sup> codes 55875 and 77778 and the codes for the applicable brachytherapy sources in the same manner that they currently report these items and services (in addition to reporting any other services provided), using the same HCPCS codes and reporting the same charges. CMS would require that hospitals report both CPT<sup>®</sup> codes resulting in the composite APC payment on the same claim when they are furnished to a single Medicare beneficiary in the same facility on the same date of service.

ASTRO was cautiously supportive of this proposal with the exception of the packaging of image guidance as discussed in the previous section of our comments. In the final rule, the proposal to create a composite APC for prostate brachytherapy was made final. While we do not oppose this decision, we continue to believe this major change in the APCs must be closely monitored to be certain that access to this important therapy is not compromised by this change in payment policy. We recommend that CMS report back on this specific issue in the future.

#### **V. Electronic Brachytherapy Services (New Technology APC 1519) (72 Fed. Reg., 66691)**

For CY 2008, CMS proposed to continue with the mid-year proposed payment rate of \$1,750 for electronic brachytherapy (CPT<sup>®</sup> Code 0182T, APC 1519). This code and its APC assignment had been released in July 2007 through the OPSS quarterly update process. In our comments, we applauded CMS for promptly incorporating new technologies into the OPSS but we noted that the payment rate of \$1,750 was significantly higher than the payment rates for other brachytherapy services in APCs 0313 and 0651. The payment rates for these two APCs were \$739.46 and \$981.88 respectively, in CY 2007. We expressed our concern that the discrepancy in payment rates between electronic brachytherapy and other brachytherapy services would encourage the adoption of an emerging technology where the risks and benefits have not been clearly established. We recommended a payment rate more in line with the other brachytherapy codes.

In the final rule, CMS rejected our recommendations and finalized its proposal to assign CPT<sup>®</sup> code 0182T to APC 1519 with a payment rate of \$1,750. We remain concerned that this payment rate will encourage the adoption of an emerging technology where the risks and benefits have not been clearly established and we ask that CMS reconsider its decision next year when developing the proposed rule for CY 2009.

#### **VI. Proton Beam Therapy (APCs 0664 and 0667) (72 Fed. Reg., 66719)**

For CY 2007, CMS proposed an exception to the 2 times rule for APC 0664 (*Level I Proton Beam Radiation Therapy*) since this therapy is offered in only two facilities in the country. In addition, CMS proposed a 27 percent reduction in payments for this APC and for 0667 (*Level II Proton Beam Radiation Therapy*). We supported CMS's decision to make an exception to the 2 times rule for APC 0664 but objected to the significant reductions in payment that we believed would discourage - if not eliminate - the further adoption of this complex and important cancer-treating technology. We recommended that CMS maintain the current rates for APCs 0664 and 0667 for two to three years, pending the collection of additional charge data from other hospitals that are expected to adopt this technology in the future.

At our request, CMS re-checked its calculations, concluded they were correct and, as shown in the table below, published even lower payment rates for 2008 than had been proposed:

APC	Group Title	Payment rate 2007	Payment Rate 2008	% Change in Payment
0664	Level I Proton Beam Radiation Therapy	\$1,161.29	\$816.59	-29.7%
0667	Level II Proton Beam Radiation Therapy	\$1,389.37	\$977.09	-29.7%

Ironically, CMS stated "As more hospitals adopt this technology, we expect that the fluctuation in payment for APCs 0664 and 0667 will be moderated by the increased number of observations for similar services and the incorporation of claims from a larger number of hospitals in the ratesetting process"(Page# 66719). Clearly, CMS misunderstood our concern that inadequate payments would stifle further adoption of this therapy by other hospitals. Again, we ask CMS to maintain the current rates for APCs 0664 and 0667 for two to three years, pending the collection of additional charge data from other hospitals that will adopt this technology in the future if the payment rates are reasonable.

## VII. OPSS Payment for Brachytherapy Sources (72 Fed. Reg., 66780)

Section 1833(t)(2)(H) of the Act, as amended by section 107(b)(1) of the TRHCA, requires separate payment groups based on stranded and non-stranded devices on or after July 1, 2007. To implement this requirement, CMS created six new HCPCS codes to differentiate the stranded and non-stranded versions of iodine, palladium and cesium sources. These six new HCPCS codes replaced the three prior brachytherapy source HCPCS codes for iodine, palladium and cesium (C1718, C1720, and C2633), all of which were deleted as of July 1, 2007.

Because CMS is required to create separate APC groups for stranded and non-stranded sources and because the CY 2006 billing codes did not differentiate stranded and non-stranded sources, CMS proposed to make certain assumptions when they estimated the median costs for stranded and non-stranded (low activity) iodine-125, palladium-103, and cesium-131 based on the CY 2006 aggregate claims data. CMS proposed to calculate median costs for stranded sources based on the 60<sup>th</sup> percentile of the aggregate data and the 40<sup>th</sup> percentile of the aggregate data for non-stranded sources.

In our comments, we acknowledged the statutory requirement to create separate APC groups for stranded and non-stranded brachytherapy sources but expressed our concern that the differential in payment might encourage utilization of stranded sources for other than clinical reasons and create perverse incentives in the marketplace. We recommended a revision of the proposal so that payment rates in CY 2008 would not create such drastic payment differentials for brachytherapy sources. Our recommendation was not accepted and for CY 2008, CMS calculated median costs for stranded sources based on the 60<sup>th</sup> percentile of the aggregate data and the 40<sup>th</sup> percentile of the aggregate data for non-stranded sources. We continue to believe this will create inappropriate incentives and we ask CMS to reconsider its decision.

### **VIII. Quality Data (72 Fed. Reg., 66865)**

Under amendments to the Social Security Act made by section 109(a) of the MIEA-TRHCA, CMS is required to establish a program under which hospitals will report data on the quality of hospital outpatient care using standardized measures of care to receive the full annual update to the OPSS payment rate, effective for payments beginning in CY 2009. CMS refers to the program established under these amendments as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). These amendments are consistent with CMS plans described in the CY 2007 OPSS/ASC final rule.

In the proposed rule for CY 2008, CMS identified 10 quality measures that are both applicable to care provided in hospital outpatient settings and likely to be sufficiently developed to permit data collection consistent with the timeframes defined by statute. In addition, CMS sought public comment on 30 additional measures, which have been identified as hospital outpatient-appropriate measures that are under consideration for inclusion in the HOP QDRP measure set for CY 2010 or subsequent calendar years. One of the potential indicators is "Radiation therapy is administered within 1 year of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer" (Page# 66868).

ASTRO strongly supported inclusion of this radiation oncology measure. We noted it is consistent with well-established National Comprehensive Cancer Network clinical practice guidelines for oncology that recognize the benefit of postoperative radiation in lowering local recurrence rates. This measure was endorsed by the National Quality Forum (NQF) on May 9, 2007.

We were extremely disappointed that this measure was not adopted in the final rule because it is one of the few measures that accounts for effective care coordination, which is vital in caring for cancer patients. It also would address a significant number of Medicare beneficiaries with breast cancer and narrow the gaps in care for minority women. Finally, since this measure is used by physicians under the PQRI, including it as a measure under the HOP QDRP would help achieve CMS's stated goal of harmonization which is "to assure that comparable care in different care settings can be evaluated in similar ways, which further assures that quality measurement and improvement can focus more on the needs of a patient with a particular condition than on the specific program or policy attributes of the setting at which the care is provided." (Page# 66865)

We ask that CMS reconsider its decision and include this radiation oncology measure in the Hospital Outpatient Quality Data Reporting Program measure set as soon as possible.

December 17, 2007

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### Conclusion

Thank you for the opportunity to comment on this final rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Marsha Kaufman, MSW, ASTRO Assistant Director of Health Policy at (703) 839-7300.

Respectfully,



Laura I. Thevenot

Chief Executive Officer

cc: Herb Kuhn  
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December 12, 2007

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To Whom It May Concern:

I have been made aware of a proposed payment in the Ambulatory Surgery Center setting for a CPT code 68816. Whereas this procedure payment code is \$433.69, in the hospital setting, I understand this procedure code pays \$1,193.03.

I specialize in children's eye disease and, although I can perform this procedure for these patients in Ambulatory Surgery Center, I generally perform them in a hospitalized setting. Were it to be done in an Ambulatory Surgery Center, it would be just as great of difficulty and time consuming procedure for me as done in the hospital setting.

I recommend that the payment levels be set the same in the Ambulatory Surgery Center, as it is the case in the hospital settings.

Sincerely,



T. Otis Paul, M.D.

TOP/mlc