CMS-1392-P-673 **Medicare**

Submitter : Mrs. Sandra Luttrell **09/11/2007**

Organization : D.A.P.A.
Individual

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please reconsider your decision to cut funds for the DAPA program!! This program is very much needed to help people with severe mental illness and/or substance abuse!! I have a friend whose daughter is finally learning to cope with her problems after many, many years of destructive behavior!! She and her family have tried numerous avenues of help for her, but this is the first one that has been able to get through to her and to make a wonderful amount of progress in her behavior, attitude and outlook on life!! Please keep funding the DAPA program and make cuts in other areas that are not as critical and are not having the success that DAPA is having with their patients!!
Thank you for your time and consideration in this very important matter!! May the Lord bless you and give you wisdom in this very detrimental decision!!

CMS-1392-P-674 **Medicare**

Submitter : Dr. Lynn Frame **09/11/2007**

Organization : Dr. Lynn Frame
Physician

Category :

Issue Areas/Comments

New Technology APCs

New Technology APCs

September 11, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P. O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Kuhn:

As a practicing gynecologist I am pleased that the CMS has offered the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians offering this technology to patients. We believe that this technology has tremendous potential to improve health outcomes and the uterine

fibroid application is only the first of many to come.

I welcome CMS□s proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

1) Treatment objective is non-invasive tumor destruction
2) The surgery is conducted using an external source of energy which penetrates into the body to reach the tumor
3) Imaging technology is required
4) Extensive treatment planning is involved with continuous monitoring during treatment
5) Expensive capital equipment in dedicated specialized treatment rooms
6) Lengthy procedure time ranging from 2-5 hours

However, the payment rate for this procedure continues to be far below the costs incurred to provide this service and does not reflect the treatment planning component that is required to perform the MRgFUS procedure.

I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to

be classified into an APC with similar clinical and resource homogeneity.

The MRgFUS procedure provides excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals and outpatient center to offer this less invasive procedure option to patients with uterine fibroids. We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127, which more accurately reflects the clinical and economic resources utilized.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 23008.

Respectfully,

Lynn E. Frame, M.D.
LEFMD

CMS-1392-P-675 **Medicare**

Submitter : Mr. Robert Gessele **09/11/2007**

Organization : Middle Fork Surgery Center
Ambulatory Surgical Center

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

CMS-1392-P-676 **Medicare**

Submitter : Mrs. Margaret Acree **09/11/2007**

Organization : Pain Consultants of Oregon
Ambulatory Surgical Center

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, □Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and CY 2008 Payment Rates□ (the Proposed Rule) published in the Federal Register on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.
I. ASC Procedures

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

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography □ lumbar - radiological

supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

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

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

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

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

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device.
Sincerely,

Maggie Acree,
Director of Patient Services

CMS-1392-P-677 **Medicare**

Submitter : Mrs. Lisa Paoni **09/11/2007**

Organization : Boulder City Hospital PHP Hospital

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

I am a licensed clinical social worker. I am writing to help ensure that the Partial Hospitalization level of care remains available to persons with mental illness. This is a crucial level of care to help individuals function better while remaining in the community. Mental health benefits are already too scarce and there needs to be access to mental health care for all of our citizens. We work mostly with disabled adults who require this intensive level of psychiatric treatment to prevent inpatient hospitalization. I am concerned that cuts in these benefits would harm our mentally ill who are an at risk population without the means to help themselves. Our program is the only PHP in all of Southern Nevada, other programs have closed and others have been unable to successfully open. Please keeep this crucial benefit intact as it benefits the entire community.
Thanks for your consideration,
Lisa Paoni, LCSW
PHP Manager
Boulder City Hospital
901 Adams Blvd.
Boulder City, Nevada
702-217-7767

CMS-1392-P-678 **Medicare**

Submitter : **09/11/2007**

Organization : Bengin Essential Blepharospasm Research Foundation
Other Association

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:

On behalf of the Benign Essential Blepharospasm Research Foundation, Inc., we are writing to express our concern about CMS proposal to package the payment rate to hospitals into a single payment for items and services that CMS considers are always or most often furnished together.

The patients we represent live with various types of dystonia, a neurological condition resulting in sustained, involuntary muscle spasms. The treatment of choice for these patients is injections of botulinum toxin. Those who have only blepharospasm (chronic, involuntary, forcible closure of the eyelids) do not require use of electromyography (EMG) to receive their treatments. However, many of them have multiple forms of dystonia such as facial spasms (Meige) or cervical dystonia that may require it. Their physicians may need help placing and directing the needle by using EMG and electrical stimulation guidance in conjunction with the botulinum toxin injections.

Under CMS proposal, a hospital would be paid the same amount whether or not the treatment required guidance equipment to inject. This would result in doctors receiving payment for a service they did not perform. In cases where the EMG and electrical stimulation guidance are necessary, the combined payment amount would be less than the total amount presently available when these services are paid separately. The proposed change may result in hospitals pressuring doctors not to utilize guidance and the injections being ineffective because the botulinum toxin did not get to the right muscles to benefit the patient. I respectfully request that CMS not package the payment of these services together but continue to pay for them separately.

Thank you for considering our comments.

Nilda Rendino
BEBRF Eastern District Director

CMS-1392-P-679 **Medicare**

Submitter : Dr. Erik Dahl **09/11/2007**

Organization : Parkway Neuroscience and Spine Institute
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-679-Attach-1.DOC

#679

September 10, 2007

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

Re: CMS-1392-P

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient P rospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

I. ASC Procedures

My request is that CMS to reviews and addresses the procedures addressed below. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). These procedures have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are safely performed in ASCs and are not routinely performed in physicians' offices. There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

Additionally, two procedures, 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. As these services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the t ransition period will be $295, a payment of $178, representing a 40% cut in reimbursement, is excessively low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

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

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925

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

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

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

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

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

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from

the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

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

***

Thank you for your consideration of my comments.

Sincerely,

Erik A. Dahl MD MBA
Interventional Pain Specialist
Parkway Neuroscience and Spine Institute
Hagerstown, MD 21740

CMS-1392-P-680 **Medicare**

Submitter : Ms. Sally Lawlor **09/11/2007**

Organization : GE Healthcare
Critical Access Hospital

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I have been in the echo business for 30 years and have seen what happens when products get bundled for reimbursement. Often a product, like a contrast agent, that needs to be used for the benefit of the patient, is not used. This can be very detrimental to the patient, especially when it comes to diagnosis and treatment.

CMS-1392-P-681 **Medicare**

Submitter : Ms. Mischelle Oslin **09/11/2007**

Organization : Ms. Mischelle Oslin
Individual

Category :

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

RE: ACP Code 0033 CY2008
To whom it may concern;
I have been involved in the mental health field for over fifteen years. I have seen first hand the tremendous progress of patients involved in daily outpatient psychiatric services provided by Psychiatric Partial Hospitalization Programs. Services provided by outpatient treatment programs are an integral part of community programs which, in the long run, save the community, the state and federal government financial expenses they would otherwise incur without these services. Psychiatric Partial Hospitalization programs are the key to success in psychiatric treatment outcomes. Reductions in reimbursement for these programs will jeopardize the spectrum of care available to the mentally ill population. Any further cuts in reimbursement to these programs could diminish the very important services of many effective community programs. Please consider the problems further budget cuts may cause your community and ours.

Sincerely,
Mischelle Oslin

CMS-1392-P-682 **Medicare**

Submitter : Mrs. Marilyn Smith **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
While I appreciate the efforts of CMS to provide quality medical care and their effort to control the costs of services provided, I do have serious concerns that the impact of CMS proposals to reduce payments to hospital physicans. Many physicians can inject Botox for cosmetic purposes, however, a small number of physicians are qualified to inject me with the Botox required for my Blepharospasm and Meige Syndrome. These injections are critically important to my ability to function normally. My primary concern with CMS-1392-P is that the reduction in compensation will result in the loss of these highly skilled physicians and/or the addition of new members to cover the current shortages.
I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008 but maintain the current payment formula.

CMS-1392-P-683 **Medicare**

Submitter : Mr. Roger Hunter **09/11/2007**

Organization : GlaxoSmithKline
Drug Industry

Category :

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1392-P-683-Attach-1.PDF

#683

GlaxoSmithKline
Three Franklin Plaza
1600 Vine Street
Philadelphia, PA 19102

215 751 4000
www.gsk.com

September 11, 2007

BY HAND DELIVERY 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–P] Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Acting Administrator Weems:

GlaxoSmithKline (GSK) appreciates the opportunity to comment on the proposed rule, dated August 2, 2007, entitled "*Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates*" (Proposed 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. We are pleased to submit our comments to the Centers for Medicare and Medicaid Services (CMS) to ensure Medicare beneficiaries continue to have access to our life-saving technologies.

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[1] 72 Fed. Reg. 42628 (August 2, 2007).

GSK understands the ongoing challenges CMS faces in advancing the healthcare system for Medicare beneficiaries so that they continue to receive high-quality services at an appropriate cost. While we generally support most of the efforts that CMS has proposed to promote fair drug reimbursement practices, we ask CMS to consider our comments regarding the proposed treatment of radiopharmaceuticals, particularly as applied to GSK's important Non-Hodgkin's Lymphoma (NHL) drug, BEXXAR®. The payment rate outlined in the Proposed Rule, if implemented, would result in a reimbursement rate that is more than 50 percent below the acquisition cost for the therapy. Consequently, Medicare beneficiary access to this important therapy would be severely impeded. It is already recognized that the BEXXAR® therapeutic regimen is currently under-utilized, with the current reimbursement environment cited as a major contributing factor.[2] The payment rates in the Proposed Rule would exacerbate this already critical situation by effectively making it difficult (if not impossible) for hospitals to offer this highly efficacious therapy to their NHL patients.

The causes for the underpayment of BEXXAR® under the approach in the Proposed Rule are two-fold:

1) the use of inadequate and inaccurate claims data by CMS to set reimbursement rates, and

2) the overall classification of the BEXXAR® Therapeutic Regimen by CMS does not properly reflect that the drugs composing the BEXXAR® radioimmunotherapeutic regimen are approved by the Food and Drug Administration (FDA) and meet the Medicare law definition of specified covered outpatient drugs (as has been recognized by CMS), and thus, must be paid on the basis of average acquisition cost or other statutorily specified methods discussed below.

In the sections that follow, we will summarize the statutory requirements with respect to payment for this radioimmunotherapeutic regimen; we will provide a detailed description of the regimen to ensure it is clearly understood and thus can be properly classified; and we will offer some suggestions about how best to achieve a legally supported and equitable payment result to address the disincentives in the current and proposed payment system so that this technology will be appropriately available to Medicare patients who need it. Proper treatment of, and payment for, this important regimen will be extremely important to ensure the availability of radioimmunotherapies for Medicare patients in the future.

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

Overview and Summary of Recommendations

As described below, BEXXAR® is a comprehensive therapeutic regimen administered in multiple steps over the course of a two-week period. Although the Food and Drug Administration (FDA) has approved BEXXAR® as a single therapeutic regimen, the Proposed Rule purports to separate the regimen into multiple parts -- treating the radiolabeled dosimetric intervention as "diagnostic" and radioactive final intervention as therapeutic. Furthermore, CMS continues to misclassify the non-radiolabeled dose administered prior to the dosimetric radiolabeled and final radiolabeled intervention as a "supply," rather than as a single drug that is an intrinsic part of the FDA-approved therapeutic regimen.

The approach that CMS has proposed is neither clinically nor legally supported, will result in inadequate reimbursement to hospitals, and literally could result in patients not receiving this potentially life-saving treatment. GSK strongly urges CMS to modify its approach in the CY 2008 Final Rule. As described below, GSK recommends that CMS treat the full BEXXAR® therapeutic regimen (all four doses) as specified covered outpatient drugs, and that CMS establish a payment methodology based on actual, average acquisition costs for each and every drug component within the FDA-approved regimen.

As with other drugs and biologicals, payment could be based on the prevailing Average Sales Price (ASP)-based methodology for the BEXXAR® therapeutic regimen. 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.[3] 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 would not be reflected within any ASP reports prepared by GSK.

Any of the suggested approaches would require modifications to the existing coding of the drugs in the BEXXAR® therapeutic regimen, and would also differ significantly from the policies proposed by CMS for reasons we believe are supported clinically and in law. The following sections will describe the regimen in detail, illustrate the problem areas that we respectfully request that CMS address, and provide some suggestions for how CMS might better proceed to achieve an equitable recognition of this therapy within the OPPS legal and policy framework.

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[3] The Medicare statute directs that overhead and related expenses, such as pharmacy and handling costs, should be factored into the ambulatory payment classifications for specified covered outpatient drugs. SSA § 1833(t)(14)(E).

For general reference purposes, we have provided a table outlining payment history for the BEXXAR® therapeutic regimen in the hospital outpatient setting.

HCPCS Code	Description	CY 2005 Payment Rate (Final)	CY 2006 Payment Rate (Final)	CY 2007 Payment Rate (Final)	CY 2008 Payment Rate (Proposed)
G3001*	Supply and administration of tositumomab, 450 mg	$2,250.00	$2,250.00	$1,374.83	$1,925.11
G3001*	Supply and administration of tositumomab, 450 mg	$2,250.00	$2,250.00	$1,374.83	$1,925.11
A9544***	I131 tositumomab, dx	$2,241.00	Cost-Based**	Cost-Based**	No separate payment
A9545***	I131 tositumomab, tx	$19,422.00	Cost-Based**	Cost-Based**	$8,283.41
	TOTAL	$26,163.00	$4,500.00 + Cost-Based**	$2,749.66 + Cost-Based**	$12,133.63

* 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.
*** A9544 was formerly C1080; A9545 was formerly C1081.

Proper Payment For BEXXAR® Should Treat the Drugs Comprising the Therapeutic Regimen as Specified Covered Outpatient Drugs

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 (SSA). For example, in 2004, CMS concluded that, "Zevalin and Bexxar are radiopharmaceuticals, and the MMA includes them as 'specified covered outpatient drugs' for OPPS payment purposes."[4] Most recently, in the preamble to the CY 2008 HOPPS Proposed 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."[5]

4 69 Fed. Reg. 65682, 65787.

5 72 Fed. Reg. 42628, 42737.

Medicare Statutory Payment Options--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 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+6 percent, special AWP-based reimbursement rates, or the Part B Competitive Acquisition Program (CAP) payment rate approaches.[6] Therefore, the Medicare statute mandates that SCODs 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.

Nevertheless, for therapeutic radiopharmaceuticals, CMS is now "proposing to establish CY 2008 payment rates based on their mean units costs from our CY 2006 OPPS claims data."[7] Although CMS acknowledges in the Proposed Rule that "section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs be set prospectively based on a measure of average acquisition cost," CMS "believe[s] [its] claims data offer an acceptable proxy for average hospital acquisition cost and associated handling and preparation costs for radiopharmaceuticals."[8] GSK respectfully disagrees. Prospective payment based on historical hospital claims data is not, in our view, appropriate for therapeutic radioimmunotherapies because it is not consistent with the statutory requirement 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. Further, § 1833(t)(14)(D)(ii)-(iv) of the Act also clearly anticipates that the Secretary (authority delegated to CMS) would carry out ongoing and statistically valid surveys of hospitals' actual acquisition costs in order to establish appropriate payment levels, under this payment option. The statute does not contemplate failure to carry out this data collection requirement and substituting a proxy for average acquisition cost. To our knowledge, no government entity has conducted a survey of hospitals' actual acquisition costs for the BEXXAR® therapeutic regimen for Medicare payment purposes. CMS has indicated that such surveys are burdensome for the Agency, hospitals, and/or manufacturers. Therefore, we suggest that CMS consider our recommendation to adopt one of the other options permitted in this setting, namely the ASP approach, which would rectify these issues.

Separately, as CMS has acknowledged, charge compression issues in how hospital cost-to-charge ratios are calculated for payment purposes can result in an underestimation of costs for high-cost radiopharmaceuticals (and hence an

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6 SSA § 1833(t)(14)(A)(iii).

7 Id. at 42738.

8 Id.

inadequate payment rate). CMS in fact confirms in the Proposed Rule that it "received anecdotal reports from some industry stakeholders asserting that the mean costs for the most expensive radiopharmaceuticals are understated in our claims data."[9] For this reason, among others described in this letter, the data that CMS proposes to use result in payment rates that amount to only half of the BEXXAR® acquisition cost.

ASP Payment Alternative--As discussed above, § 1833(t)(14)(A)(3) of the Act specifies an alternative to acquisition cost in the event that adequate information is unavailable -- the ASP methodology. Although GSK believes that CMS should rely upon data that reflect the actual acquisition cost of radiopharmaceuticals to hospitals in setting payment rates (and not poor proxies), an appropriate and statutorily supported alternative approach would be the ASP-based methodology that is used for drugs and biologicals reimbursed under Medicare Part B. Although GSK is not required, and therefore, currently does not report ASPs for the drugs comprising the BEXXAR® therapeutic regimen, GSK intends to submit 2Q 2007 ASPs to CMS and would initiate routine, quarterly ASP reporting promptly if CMS were to adopt this approach in the Final Rule. This approach would be consistent with the approach that CMS proposed for CY 2006[10] and would be within CMS's authority for radioimmunotherapies.[11] We note that in CMS's referenced discussions in the 2006 rulemaking process, that CMS stated in part:

> "As we do not have ASPs for radiopharmaceuticals that best represent market prices, we are proposing as a temporary 1-year policy for CY 2006 to pay for radiopharmaceutical agents that are separately payable in CY 2006 based on the hospital's charge for each radiopharmaceutical agent adjusted to cost...Section 303(h) of Pub. L. 108–173 exempted radiopharmaceuticals from ASP pricing in the physician office setting where the fewer numbers (relative to the hospital outpatient setting) of radio-pharmaceuticals are priced locally by Medicare contractors. However, radiopharmaceuticals are subject to ASP reporting. We currently do not require reporting for radiopharmaceuticals because we do not pay for any of the radiopharmaceuticals using the ASP methodology. However, for CY 2006, we are proposing to begin collecting ASP data on all radiopharmaceutical agents

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9 72 Fed. Reg. 42740 (August 2, 2007).

10 70 Fed. Reg. 42674, 42727-28 (July 25, 2005).

11 MMA, § 303(h); *see also*, 70 Fed. Reg. 42674, 42727 ("radiopharmaceuticals are subject to ASP reporting").

for purposes of ASP-based payment of radiopharmaceuticals beginning in CY 2007."[12]

Although CMS ultimately decided to postpone adoption of the ASP method, GSK notes that CMS has been receptive to this option, such thinking could be applied to radioimmunotherapies (all drugs in the regimen), and it presents many advantages by bringing those drugs properly into the framework of other SCODs in the outpatient hospital setting.

Finally, in addition to the payment for the BEXXAR® therapeutic regimen, hospital payments also must include the costs incurred for the compounding of the product by a radiopharmacy, a necessary step required to prepare the product for patient administration.[13] This cost is independent of the drug costs charged by GSK for the four components of the BEXXAR® therapeutic regimen. Following is detailed information on the regimen itself.

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

Each year, about 54,000 Americans are diagnosed with NHL.[14] The National Cancer Institute (NCI) 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.[15]

Our NHL product, BEXXAR® (tositumomab and Iodine I 131 tositumomab), 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 do initially respond (i.e., their tumors shrink) to chemotherapy. However, their disease 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 that is complete within 7 to 14 days. More patients experience these types of disease remissions when BEXXAR® is used early in the course of their disease.

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12 70 Fed. Reg. 42727 (July 25, 2005).

13 SSA, § 1833(t)(14)(E).

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

15 Id.

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) a dosimetric dose of tositumomab (NDC 00007-3260-31),

2) a dosimetric dose of Iodine I-131 tositumomab (NDC 00007-3261-01),

3) a therapeutic dose of tositumomab (NDC 00007-3260-36), and

4) a therapeutic dose of Iodine I-131 tositumomab (NDC 00007-3262-01).

CMS has consistently treated dose numbers 1 and 3 above incorrectly as medical supplies, rather than as separate drugs, even though they have their own unique NDCs. CMS also proposes to treat the radioactive dose described in number 2 above as a "diagnostic" to be packaged. This dose, in fact, is not diagnostic, but rather, together with dose number 1 above, represents the initiation of the radioimmunotherapeutic regimen. Prior to receiving BEXXAR®, the patient already has been diagnosed with NHL and has failed some type of treatment (i.e., conventional chemotherapy, or combined immunochemotherapy). In short, each drug is part of the therapeutic intervention, and the drug dosing in this regimen should not be confused with numerous other radiopharmaceutical products that serve diagnostic purposes in medical care. Because proper coding and payment depends on fully understanding the BEXXAR® therapeutic regimen, we have outlined the infusion process below in some detail.

Step 1: Dosimetric Dosing

The non-radioactive monoclonal antibody (tositumomab), hereinafter referred to as the "dosimetric cold" dose, is administered initially to the patient. This infusion helps prepare the previously-diagnosed NHL patient, who has failed conventional chemotherapy, or combined immunochemotherapy, to receive a subsequent radioactive component. This cold dose is administered to ensure that the radioactive dose is directed towards the tumor cells and not areas where normal B-cells reside, e.g., the liver. After administration of the "dosimetric cold" dose, the same monoclonal antibody is administered with a trace amount of radioactive isotope (Iodine I 131 tositumomab) attached. This radiolabeled monoclonal antibody is referred to as the "dosimetric warm" dose.

The purpose of the dosimetric step, both the "cold" dose and the "warm" dose, is to both initiate therapy and to enable physicians to administer the appropriate *total* amount of radiolabeled monoclonal antibody specific to an individual patient's needs to achieve the prescribed necessary dose of radiation. After the "dosimetric warm" dose is administered, three total-body scans are performed over the course of several days. In effect, therapy has begun with the administration of these doses, but is not completed until information from the scans permit calculation of the specific *final* amount of the radioactive product to include in the patient-specific *final* therapeutic dose under the BEXXAR®

therapeutic regimen. The amount of radioactivity required for the prescribed total-body dose over the complete course of the BEXXAR® therapeutic regimen is variable across patients, and is dependent upon the assessment of each patient's reaction to the dosimetric steps in the regimen.

Step 2: Final Dosing

After completion of the dosimetric steps, the "cold" dose is again administered. This infusion helps prepare the patient to receive the subsequent radioactive dose. Next, a "hot" dose, containing the patient-specific *final* amount of radiolabeled monoclonal antibody, is administered, thus completing the regimen. The BEXXAR® therapeutic regimen involves infusion of all four of the separate drug components to provide the single course of therapy to the patient.

For example, a typical regimen may be outlined as:

Day 0: A 450 mg "dosimetric cold" dose is administered intravenously (IV) to a patient over a 60 minute period, followed by a "dosimetric warm" dose (5mCi) over a 20 minute period. The first of three total-body scans is performed on the patient for determination of the appropriate total-body dose of radiation for utmost effectiveness through dosimetry following the third scan.

Day 2, 3, or 4: The second of three total-body scans is performed on the patient for determination of the appropriate total-body dose of radiation for utmost effectiveness through dosimetry following the third scan.

Day 6-7: The third of three total-body scans is performed on the patient and the dosimetry is calculated separately to determine appropriate total-body dose of radiation for utmost effectiveness.

Day 7 (or any subsequent day up to Day 14): A 450 mg "cold" dose is administered, followed by an intravenous infusion of the "hot" dose—the specific amount unique to each patient based on reactions to and data from the "dosimetric warm" dose, administered on Day 0.

* * * *

As described below, GSK believes that the payment rules for BEXXAR® should be corrected in a number of respects to ensure that hospitals are reimbursed for their true average acquisition costs for the entire BEXXAR® therapeutic regimen.

The Proposed HOPPS Payment Methodology Misclassifies Integral Drug Components of the BEXXAR® Therapeutic Regimen as Diagnostic

CMS has proposed a payment methodology that 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 above 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). The "cold" doses should be classified as drugs, assigned J-codes, and paid as such. This is addressed further in the next section. In addition, CMS has proposed to treat the radiolabeled drug administered in the dosimetric step in the regimen, the "dosimetric warm" dose (number 2 above), as "diagnostic" and subject to packaging into the associated procedure payment.

Under the BEXXAR® therapeutic regimen, however, the "dosimetric warm" dose and subsequent patient evaluation are not diagnostic. Instead, they are an integral part of the FDA-approved BEXXAR® therapeutic regimen; they represent the initiation of therapy, not diagnosis of disease, and lead to a determination of the amount of radiolabeled monoclonal antibody required for the final therapeutic dose – the "hot" dose. The "hot" dose is patient-specific and administered subsequent to the dosimetry and evaluation of the biodistribution of the initial "dosimetric warm" dose in the patient, using three total-body scans to ensure that, in the aggregate, the patient receives the total-body dose of radiation demonstrated as efficacious. 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 therapeutic, not diagnostic. Indeed, patients who receive the initial "dosimetric cold" and "dosimetric warm" doses have already been diagnosed with NHL, and have relapsed or failed prior treatment regimen(s).

While we understand the CMS intent to encourage efficiency in the outpatient setting, incorrectly packaging the "dosimetric warm" dose with the patient evaluation would not promote hospital efficiencies by selecting the most clinically appropriate diagnostic approach as described in the Proposed Rule. In the case of the BEXXAR® therapeutic regimen, it would be clinically inappropriate and infeasible to use any other agent. As explained above, the purpose of dosimetric I-131 tositumomab is to allow physicians the ability to administer the appropriate amount of radioactivity specific to an individual patient's needs to achieve the prescribed total body dose of radiation. The amount of radioactivity needed to be administered in the final "hot" dose, in order to gain the therapeutic effect of the product without being exposed to unnecessary radiation, is calculated based on the characteristics and clinical responses of each specific patient to the "dosimetric warm" dose. This can only be accomplished in a clinically appropriate manner if I-131 tositumomab, specifically, is administered to the patient. Therefore, hospitals cannot select another substitute for dosimetric I-131 tositumomab.

The Cold Doses Are Misclassified as Supplies When They Are In Fact Drugs

CMS repeatedly has asserted in the Proposed Rule that it considers "unlabeled tositumomab"[16] (i.e., the "cold" doses) as a supply and not as a drug or biological, stating "unlabeled tositumomab is not approved as either a drug or a radiopharmacetical, but is a supply that is required as part of the Bexxar treatment regimen."[17] Contrary to CMS's proposal, however, the FDA has approved these drugs as part of the therapeutic regimen, and these doses are also recognized as drugs in approved compendia listings.

For example, in the June 2003 letter approving BEXXAR®, the FDA noted that:

> "Tositumomab and Iodine I 131 Tositumomab, administered as a therapeutic regimen, are indicated for the treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to Rituximab and has relapsed following [conventional] chemotherapy (emphasis added)."[18]

Similarly, the **DESCRIPTION** section of the BEXXAR® FDA label provides:

> "The **BEXXAR** therapeutic regimen (Tositumomab and Iodine I 131 Tositumomab) is an anti-neoplastic radioimmunotherapeutic monoclonal antibody-based regimen composed of the monoclonal antibody, Tositumomab, and the radiolabeled monoclonal antibody, Iodine I 131 Tositumomab (emphasis added)."[19]

The FDA label confirms that the "cold" doses are part of the approved regimen and thus are drugs and not supplies.

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[16] Characterization of the "cold dose" as "unlabeled" refers to the fact that it is not associated with a radioactive isotope (i.e., it is not radioactive). This term should not be misconstrued as meaning the cold doses are not within labeling or otherwise not approved by the FDA for the stated uses - the cold doses are included in the FDA-approved label for the BEXXAR® therapeutic regimen.

[17] See 68 Fed. Reg. 63443 (2003); See 70 Fed. Reg. 68654 (2005); See 71 Fed. Reg. 68034 (2006).

[18] This FDA letter may be found at: http://www.fda.gov/cder/foi/appletter/2003/tosicor062703L.htm (accessed August 29, 2007).

[19] This FDA label may be found at: http://www.fda.gov/cder/foi/label/2004/125011_0024lbl.pdf (accessed August 31, 2007).

The Medicare statute and related sub-regulatory guidance compel the same conclusion. For instance, SSA § 1861(t)(1) defines drugs and biologicals as follows:

> The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.[20]

The Medicare Benefit Policy Manual similarly provides:

> Drugs or biologicals must be determined to meet the statutory definition. Under the statute § 1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USP-DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. . . Inclusion in such a reference . . . is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above compendia.[21]

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[20] SSA § 1861(t)(1).

[21] Medicare Benefit Policy Manual, Chapter 15, § 50.1 Definition of Drug or Biological.

The heading of the USP-DI BEXXAR® listing is: "Tositumomab and I 131 Tositumomab." In fact, this description is used throughout the USP-DI listing for BEXXAR®. The BEXXAR® therapeutic regimen thus consists of the two cold doses, and the warm and hot doses. All of these doses -- "cold," "warm," and "hot" -- are encompassed in the Medicare definition of drugs as a combination drug (Section 50.1 of Chapter 15 of the Medicare Benefit Policy Manual, quoted above) because "the combination itself or all of the therapeutic ingredients of the combination are included . . . in [the USP-DI]." Because the FDA approved tositumomab as one of the drugs in the BEXXAR® therapeutic regimen and because that regimen is included in the USP-DI, BEXXAR® is a drug under the definition in the Medicare statute. Furthermore, the BEXXAR® therapeutic regimen cannot be administered without the cold doses. Indeed, the therapy cannot be delivered without any of the individual components that comprise the therapeutic regimen. For these reasons, we urge CMS to recognize the cold dose as a drug for payment purposes and all of the doses should be coded accordingly.

Recommendations

To ensure that patients have appropriate access to the BEXXAR® therapeutic regimen and to satisfy the statutory requirement that payment rates for these products be measured by average acquisition cost, GSK recommends that CMS consider the approach described below to ensure adequate payment for a course of the BEXXAR® therapeutic regimen:

1. Recognize tositumomab (the two "cold" doses) as a drug by creating a J-code for it and setting a payment rate using ASP or another recognized measure of average acquisition cost.

2. As addressed above, because both doses of tositumomab have their own NDC numbers and the FDA has recognized these doses as part of the approved BEXXAR® regimen, tositumomab should be paid separately as a drug. The administration of the two separate doses of tositumomab should be allowed for the two 60 minute infusions (according to the dosing schedule outlined from the Prescribing Information in Attachment A), according to usual practice.

3. An alternative to actions 1 and 2 above would be to retain the G3001 code for the cold doses but to set the payment rate for those drugs equal to ASP+6 percent (or another recognized measure of acquisition cost) for tositumomab plus the payment rate for a 60 minute infusion of tositumomab, according to usual practice.

4. CMS should not separate the component parts of the BEXXAR® therapeutic regimen by isolating the "dosimetric warm" dose from the therapeutic regimen and treating it as a diagnostic procedure for payment purposes.

5. CMS should use ASP data to set the payment rates for dosimetric I-131 tositumomab (A9544) and therapeutic I-131 tositumomab (A9545) (the "warm" and "hot" doses, respectively).

6. CMS should include the radiopharmacy compounding cost in the payment rates for the drugs or create new G codes for reporting these costs.

Consideration of Composite APC for the BEXXAR® Therapeutic Regimen

GSK recommends that CMS exercise caution if considering the BEXXAR® therapeutic regimen as a candidate for a Composite APC. For a variety of circumstances, a small percentage of patients do not receive all of the four drug components in the BEXXAR® therapeutic regimen. Therefore, a composite APC could inappropriately result in overpayment by CMS, in some cases.

However, if CMS proceeds with such an evaluation, there are a number of components that we believe CMS would need to properly identify, evaluate, and value for potential inclusion in such an APC, which we provide in Attachment B. Most importantly, the drug product coding, classification and payment issues must be addressed prior to moving forward on an even more complex proposal layering in other services and costs. Further, CMS would need to address the "multi-episode" aspect of the BEXXAR® regimen, as services and products are administered over approximately a 7-14 day period in the hospital outpatient setting. This presents numerous hospital billing challenges that would need to be addressed at a Medicare operational level before such a concept could proceed.

Due to the complexities touched on above, if CMS were to propose a composite APC affecting radioimmunotherapy regimens, we strongly recommend that CMS publish in the OPPS Notice of Proposed Rulemaking in 2008 or 2009, any such proposed methodology. This will provide affected hospitals, physicians, and other stakeholders an opportunity to evaluate and publicly comment upon the specific elements and impact of the proposal, consistent with the purposes and requirements of the Administrative Procedures Act.

If such changes were developed and implemented, we recommend they be accompanied by a robust educational program for hospitals regarding proper billing and coding.

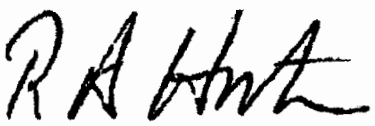
Conclusion

Radioimmunotherapeutic regimens are relatively new and developing therapeutic interventions. Medicare payment policy will have a material impact upon the future availability of this important technology. Appropriate recognition in payment systems of the unique labeling and structure of these interventions is essential to ensure the availability of this highly complex, but efficacious technology. Evidence suggests this therapy is being used by only a small number

of patients for whom it is indicated and beneficial, with a major cause being the current reimbursement environment. Proper recognition and valuation of the components of the first regimens of this scientific platform to enter into patient care will permit hospitals to offer these regimens to patients who can truly benefit from these innovative therapies, without reimbursement rates negatively impacting their ability to deliver and offer these therapies. In addition, it will create an appropriate precedent for future radioimmunotherapeutic regimens that that FDA may approve.

We acknowledge that this is an unusual circumstance and thank you for your thoughtful and close attention to this matter to ensure that the healthcare needs of Medicare beneficiaries are properly met. If you have any questions, or would like to discuss this matter in further detail, please contact Roger Hunter at 215-751-7470 or roger.a.hunter@gsk.com.

Respectfully submitted,



Roger A. Hunter
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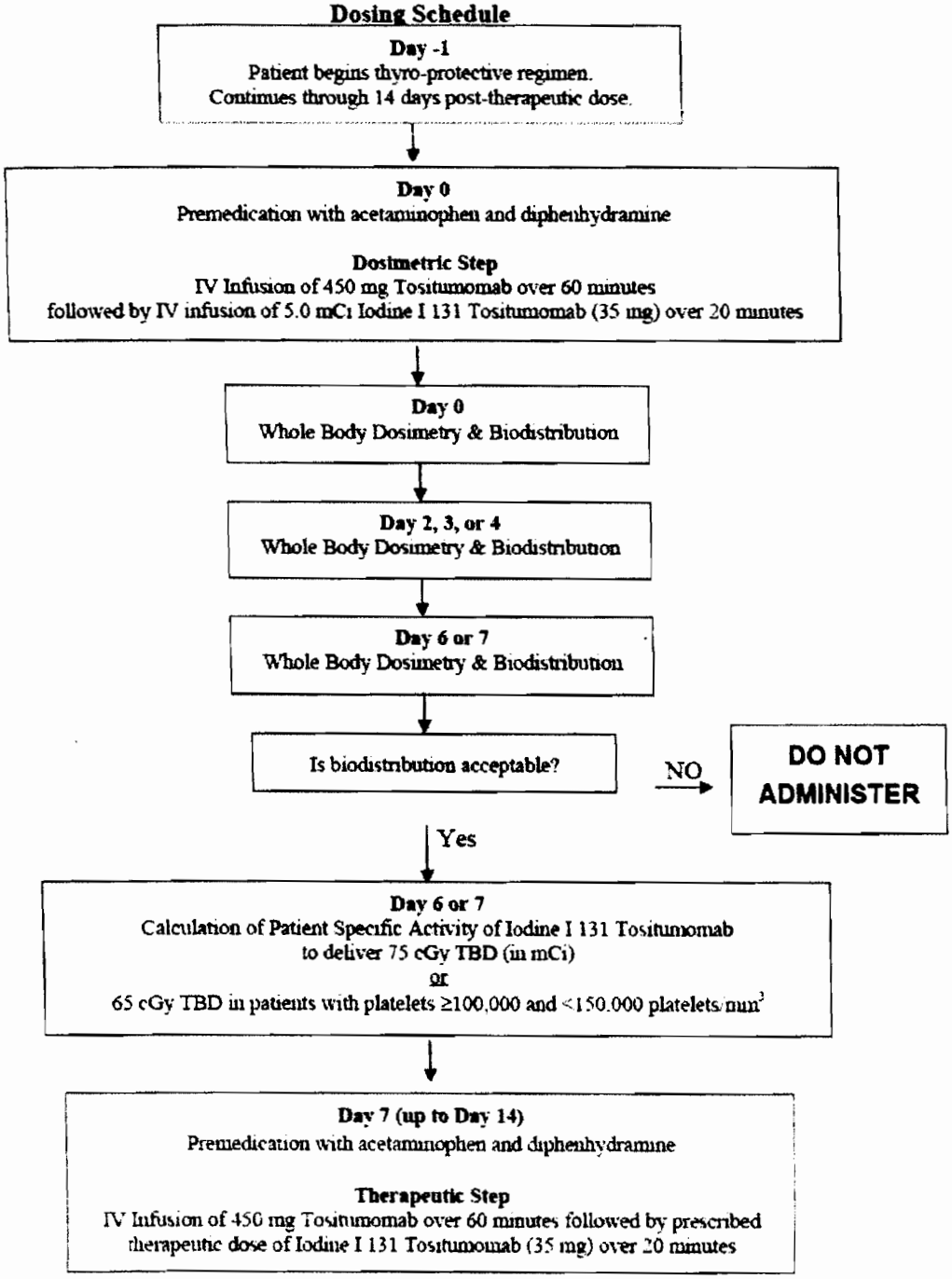
ATTACHMENT A
Dosing Schedule (Figure 1) from BEXXAR® Prescribing Information

Figure 1

Dosing Schedule



ATTACHMENT B

Code	Descriptor	Basis for Rate-Setting
New Service/ New Code	Tositumomab for Dosimetric Step (NDC 00007-3260-31)	ASP (or WAC): update quarterly
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug (Infusion for tositumomab prior to A9544)	Median costs from claims data and update annually
A9544	Iodine I-131 tositumomab, diagnostic, per study dose (NDC 00007-3261-01)	ASP (or WAC): update quarterly
79403	Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion (administration of A9544)	Median costs from claims data and update annually
78804	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging.	Median costs from claims data and update annually
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician	Median costs from claims data and update annually
New Service/ New Code	Tositumomab for Therapeutic Step (NDC 00007-3260-36)	ASP (or WAC): update quarterly
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug (Infusion for tositumomab prior to A9545)	Median costs from claims data and update annually
A9545	Iodine I-131 tositumomab, therapeutic, per treatment dose (NDC 00007-3262-01)	ASP (or WAC): update quarterly
79403	Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion (administration of A9545)	Median costs from claims data and update annually
New Service/ New Code	Radiopharmacy Compounding Fee for A9544 and A9545	Hospital invoices
Numerous	All other packaged items and services	Median costs from claims data and update annually