#104

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : **Mr. sean jennings** **Date: 08/15/2007**

Organization : **Berkshire Medical Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS Impact

OPPS Impact

Center for Wound Care
and Hyperbaric Medicine at Berkshire Medical Center
BERKSHIRE HEALTH SYSTEMS, INC.

August 15th, 2007

Mr. Kerry Weems
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

ATTN: CMS-1392-P
Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective
Payment System and CY 2008 Payment Rates; Skin Repair Procedures
Dear Administrator Weems:
Berkshire Medical Center appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Berkshire Medical Center is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.
We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.
In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf s CPT procedure codes do not account for the actual clinical resource use in our experience.
We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.
Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf. We have reviewed our charges for skin repair procedures and have updated/plan to update the charges for CPT codes 15340 and 15341 to include cost into for the surgical site preparation which was previously billed under CPT code 15000.
We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.
Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Seam Jennings at (413) 496-6832.
Sincerely,
Scan Jennings, MA CHT
Berkshire Medical Center
777 North St., Pittsfield MA 01201

#106

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

#107

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : Betsy de Parry **Date:** 08/16/2007

Organization : Betsy de Parry

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

RE: CMS-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to vehemently protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

Five years ago, I was rescued by RIT after all else failed, and so from a very personal standpoint, I know how effective it is. But more important than my personal experience, scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

It is highly doubtful that I would be alive today had RIT not become available in the nick of time. All patients deserve the same chance of a successful outcome, but they will not have that chance if the proposed change is adopted. And so it is that I urge you in fact, I beg you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Sincerely,

Betsy de Parry
Ann Arbor, Michigan

Submitter : Dr. Joan Geiger-Dow **Date:** 08/16/2007

Organization : Dr. Joan Geiger-Dow

Category : Physician

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I am writing to protest the change in reimbursement proposal for I-131 tositumomab (Bexxar) and Y90 ibritumomab (Zevalin). I write as a physician and as a Non-Hodgkin's Lymphoma (NHL) patient.

It has become more apparent in recent years that NHL is a chronic disease that requires multiple treatments. It does not continue to repond to the same treatments repeatedly, which is one of the factors that until more recently, meant NHL patients had less than a 10 year life expectancy. That may seem a long time if diagnosed at age 75, but consider my case where I was diagnosed at age 47, with 3 school aged children.

I have not yet been treated with radioimmunotherapy, although I have not yet had complete remission in the 3 years since being diagnosed. I have hoped to save it for a later time when drugs like Rituxan are no longer able to keep the disease suppressed. Now I am watching this political process unfold with alarm as it appears I may soon not have access to this treatment, since it is most likely that hospitals will not be able to subsidize the use of these very effective drugs.

Let me remind you that the side effect profile of Bexxar and Zevalin is very favorable, especially when compared with current standard treatments, which must be given over a longer period of time (radioimmunotherapy is given as a single dose). The increased number of side effects, in the end, increase the cost of standard therapy. Also, the medical literature is currently showing that these treatments are more likely to produce a lasting remission when used early in the course of disease, rather than as a 'last ditch' treatment when no other therapy is effective.

Please reconsider this proposal as it will effectively remove very promising therapy from the market, which will discourage scientists from the expensive and necessarily lengthy testing required to bring innovative treatments forward.
Thank you.

Joan Geiger-Dow, MD
Austin, Texas

Submitter : Elizabeth McConville **Date:** 08/16/2007

Organization : Masspro

Category : Nurse

Issue Areas/Comments

Quality Data

Quality Data

1. Regarding validation of outpatient measures data. It is proposed that 5 charts from Jan 2008 data submission be validated for APU. This is the first month the hospitals will be abstracting on these new measures and therefore the most likely to err and / or produce flawed data. I believe validating that one month will be an obstacle to obtaining full CY 2009 APU for OPPS.
2. I have been unable to locate a clear, concise, definitive definition of "Hospital Outpatient Services". Can you provide one? We will need to communicate clearly to Hospital Quality Departments which patient populations are effected by this data submission.
3. OPPS data submission appears to have a 1st of the month submission deadline, while inpatient measures have a 15th of the month submission deadline. In the interest of alignment to avoid confusion and error will you consider changing the rule to align the data submission deadlines for both outpatient and inpatient measures?
Thank you

Submitter : **Kenneth Lacko** **Date: 08/16/2007**

Organization : **Kenneth Lacko**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to vehemently protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

I was diagnosed with Non Hodgkin s Lymphoma(NHL) in 2000. I have received two cycles of chemotherapy treatments. Due to the nature of this disease, I have adopted a watch and wait approach, but expect to see the disease again. Through my own research and the advice of renown doctors throughout the country, I believe that RIT is the best treatment for me and it is the treatment that I plan on using when this ugly disease resurfaces. But more important than my personal experience, scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

All patients deserve the same chance of a successful outcome, but they will not have that chance if the proposed change is adopted. And so it is that I urge you in fact, I beg you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Sincerely,

Kenneth Lacko
Lake Havasu City, AZ

Submitter : Mr. Karl Schwartz **Date:** 08/16/2007

Organization : Patients Against Lymphoma

Category : Consumer Group

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear Sir or Madam:

I am writing to share my deep concern for the proposed deep cuts in reimbursement for radioimmunotherapy (RIT).

Through our non-profit organization, Patients Against Lymphoma, I represent patients and caregivers with lymphoma. I also serve as a patient consultant to FDA (ODAC). My spouse, Joanne, was diagnosed in 1996 with an incurable type of indolent lymphoma: follicular center cell.

Her response to CHOP in 1997 was short-lived lasting less than 8 months. Following each relapse the lymphoma progressed relentlessly, requiring numerous courses of chemotherapy to keep the lymphoma from getting too advanced. Subsequent treatments never achieved a remission, and the lymphoma was evident quickly following therapy each time, often before her hair grew back fully.

In February of 2005 following a single course of Bexxar RIT the disease is no longer detectable today more than 2 years later. Her weight has returned to normal, as are her blood counts and her life.

I feel certain that without the availability of RIT, Joanne would have required a stem cell transplant, which, as you know, involves high dose chemotherapy, radiation, extensive hospitalization, and significant mortality risks.

Importantly, a review the literature will show that Joanne s experience with RIT is not unique. Many patients with advanced disease and many prior therapies RIT can and often do achieve durable complete remissions. See http://www.lymphomation.org/treatment-rit.htm#about

I feel that the policy change will devastate lymphoma patients and their families, present and future.

* It s likely to change prescribing practices, which already favor using chemotherapy and Rituxan over RIT.

* It will make RIT too expensive for many patients to afford.

* It will move the sponsors of Zevalin and Bexxar to discontinue them, as it is widely known that each are not yet profitable.

Finally, cutting reimbursements for RIT will be a disincentive for companies to develop new therapies, which are still urgently needed. We need to adopt policies that will make companies more willing to take these financial risks of developing new treatments, not less willing, if we are to make significant progress in treating the victims of cancer.

Submitter : Ms. susan hagoog **Date:** 08/16/2007

Organization : Ms. susan hagoog

Category : Nurse

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

The considered changes are unaeceptqble. Many people, mysister included will not be able to afford treatment is her disease proesses to the point where she will need this option. Please reconsidcr. Think of the many people who are not wealthy. Do the right thing.

#114

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : **Dr. William Jacobs** **Date: 08/16/2007**

Organization : **Dr. William Jacobs**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I am writing to you to oppose your change in scheduled reimbusements for RIT NHL therapies (such as Bexxar and Zevalin).

As a recent New York Times article discussed, there is considerable evidence of the efficacy of both of these treatments. Yet for a variety reasons both drugs are underused. As things currently stand, neither is profitable to their producers. Reducing reimbursement fees will make the RIT therapy option too expensive for many patients. This will further endanger the viability of both of these radiopharmaceuticals. What we ought be doing is increasing reimbursement for this novel therapeutic approach, thereby encouraging the development of other RIT drugs.

Therefore, I strongly urge you not to reduce the reimbursement for RIT.

Submitter : **Mrs. Daneen Zureich** **Date: 08/17/2007**

Organization : **Mrs. Daneen Zureich**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to vehemently protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

Five years ago, I was rescued by RIT after all else failed, and so from a very personal standpoint, I know how effective it is. But more important than my personal experience, scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

It is highly doubtful that I would be alive today had RIT not become available in the nick of time. All patients deserve the same chance of a successful outcome, but they will not have that chance if the proposed change is adopted. And so it is that I urge you in fact, I beg you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Sincerely,

Daneen Zureich
Ypsilanti, MI

Submitter : Jamie dylenski **Date:** 08/17/2007

Organization : Jamie dylenski

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I am against the proposed change for a drug that has proven effectiveness with a deadly disease.

Submitter : **Date: 08/17/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I recently participated in a clinical trial for Bexxar usage with aggressive lymphomas. I am 43 and I have non hodgkins lymphoma. Hopefully Bexxar helped save my life. I strongly disagree with the proposal to change payments on this drug. It is a step backward and a disincentive for drug companies to proceed in developing new drugs.

Submitter : Mr. Eric Meier **Date:** 08/17/2007

Organization : Calypso Medical Technologies, Inc.

Category : Device Industry

Issue Areas/Comments

Packaged Services

Packaged Services

Calypso Medical appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment System Proposed Rule (the Proposed Rule) for Calendar Year 2008. We currently market the Calypso 4D Localization System (the Calypso System), a system that allows radiation oncologists to minimize the likelihood of unnecessary radiation damage to healthy tissue by providing accurate, objective, and continuous target localization throughout the delivery of radiation. This comment letter addresses CMS's proposal to package payment for guidance services. Calypso Medical is concerned that the Proposed rule will hinder patient access to critical new technology for patients undergoing radiation therapy, including the Calypso System.

Please see our attached comment for more information.

CMS-1392-P-119-Attach-1.PDF

#119

CALYPSO

www.calypsomedical.com

August 10, 2007

Carol Bazell, M.D.
Director, Division of Outpatient Care
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.

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **OPPS: Packaged Services**

Calypso Medical appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment System Proposed Rule (the Proposed Rule) for Calendar Year 2008. We currently market the Calypso® 4D Localization System (the Calypso System), a system that allows radiation oncologists to minimize the likelihood of unnecessary radiation damage to healthy tissue by providing accurate, objective, and continuous target localization throughout the delivery of radiation. This comment letter addresses CMS's proposal to package payment for guidance services. Calypso Medical is concerned that the Proposed Rule will hinder patient access to critical new technology for patients undergoing radiation therapy, including the Calypso System.

Background On Calypso 4D Localization System

The Calypso System provides continuous, real-time alignment and monitoring of tumor positions through the use of small devices (Beacon Transponders) permanently implanted in or adjacent to the tumor receiving radiation, in conjunction with a proprietary electronic system that generates and records

Calypso Medical Technologies, Inc. 2101 4th Avenue, Suite 500 | Seattle, WA 98121 206.254.0600 | fax 206.254.0606

continuous electromagnetic signals from the transponders. As a result, the technology ensures continuous sub-millimeter level accuracy and precise tumor position information during radiation treatment. By allowing physicians to more confidently deliver radiation to the tumor, this product can provide increased clinical benefits to patients in terms of improved treatment of the tumor and less radiation to healthy tissue, resulting in an expected reduction in co-morbidities.

The Calypso System was cleared by the FDA in 2006 for its initial indication in patients undergoing external beam radiation treatment for prostate cancer. It is presently in use at 15 radiation therapy centers in the United States including MD Anderson Cancer Center Orlando, University of Michigan, University of Pennsylvania, Oregon Health Sciences University, and University of Nebraska, and will expand to a total of approximately 35 leading radiation therapy centers by the end of 2007.

The Calypso 4D Localization System represents a significant clinical improvement over existing methods for patient positioning and is the only method to monitor organ motion during actual treatment. The key health benefits for Medicare beneficiaries undergoing external beam radiation therapy for prostate cancer include:

- the elimination of unnecessary, non-therapeutic, ionizing radiation from x-ray and CT based patient positioning systems, as the Calypso System replaces the use of x-ray based patient positioning systems,
- the potential for the reduction of radiation-induced complications such as acute and chronic urinary and rectal incontinence, rectal bleeding, and impotence often associated with radiation treatment for prostate cancer; and
- the potential for improved tumor control by ensuring that the tumor target always receives the full course of radiation.

Recently published clinical studies demonstrate the clinical benefits of the Calypso 4D Localization System compared to existing methods for treatment setup. Existing guidance methods only provide a subjective snap-shot position of the tumor prior to the delivery of radiation. Therefore, with existing technology,

the clinician is unable to objectively determine the position of the tumor at the start of treatment and cannot monitor target tissue motion during treatment, thereby raising the likelihood of irradiating healthy tissue adjacent to the tumor. Furthermore with existing x-ray based patient positioning systems, the patient is exposed to daily doses of unnecessary, non-therapeutic, ionizing radiation when the clinician x-rays the patient before treatment sessions to locate the tumor.

New Technology APC Application

In August 2006, Calypso Medical submitted:

- an application for a New Technology APC for the daily treatment setup and monitoring necessary for the Calypso 4D Localization System, and
- an application for a Transitional Pass-Through Payment for the permanently implanted Beacon electromagnetic transponders.

Both applications were submitted with extensive supporting clinical and economic data.

In the Proposed Rule, CMS notes that these two special payment programs are designed "to provide appropriate and consistent payment for designated new procedures that are not yet reflected in [CMS] claims data." Calypso Medical appreciates the availability of these programs, which provide necessary incentives for the adoption of new technology that may lead to better clinical experiences and lower total costs for Medicare beneficiaries.

Calypso Medical, along with outside clinical experts from the University of Nebraska and Swedish Cancer Medical Center, met with CMS in May 2007 to review the recent clinical data and answer any additional questions that CMS had regarding the applications and associated information.

To date, CMS has not ruled on these two applications. We respectfully request that CMS grant the New Tech APC and Pass-Through applications and assign temporary HCPCS codes and payment rates for these services.

Packing For Guidance Services

In the Proposed Rule, CMS proposes to package payment for HCPCS codes for supportive guidance services, such as ultrasound, fluoroscopic, and stereotactic navigation services, into the payment for the associated primary diagnostic or therapeutic modalities in which they are used. Specifically, CMS proposes packaging the guidance codes because it believes that these services "are typically ancillary and supportive" to the associated modality, and, "in those cases, are an integral part of the primary service they support."

Accordingly, most of these HCPCS codes would be identified as "always integral to the performance of the primary modality" and the associated costs would be packaged into the costs of the separately paid primary services with which they are billed. Under this proposal, hospitals may no longer receive a separate payment for guidance procedures for radiation treatment for disease states such as prostate cancer, and reimbursement would be packaged in the payment rate for the radiation treatment procedure codes.

Packaging Of Guidance Technology Will Discourage Use Of Novel And Clinically Effective Technology

Under the proposal, hospitals would receive the same payment for radiation treatment regardless of the type of guidance technology used to align the radiation beam. Calypso Medical is concerned that the proposed packaging creates a disincentive for hospitals to use potentially more costly technology even when it offers important clinical advantages over existing guidance alternatives such as ultrasound or x-ray based solutions.

In the Proposed Rule, CMS acknowledges that hospitals have several options regarding the performance and types of guidance services they use, and stated that it does not want to create payment incentives for hospitals to prefer one form of guidance instead of another, yet this is precisely what the packaging approach will do. According to the proposed rule, packaging will encourage hospitals "to utilize the most cost effective and clinically advantageous method of guidance that is appropriate in each system." However, the proposed packaging does not

provide an incentive for hospitals to use clinically superior devices, particularly when less effective devices represent sunk costs and lower expenses.

Existing payment levels for guidance devices such as cone-beam CT, stereoscopic kV x-ray, or ultrasound do not adequately represent costs and resource use of Calypso Medical beacon transponders and daily electromagnetic localization. If hospitals are discouraged from using new technology due to insufficient reimbursement levels, the cost and charge data will be slow to reflect the appropriate level of adoption of clinically effective new technology. This reinforcing cycle will present a barrier to beneficiary access for even longer than the typical two to three years that New Tech APC and Pass-Through payments are designed to be available.

Although CMS intends to adjust payments for packaged HCPCS as described in the Proposed Rule, these adjustments will not take into account the costs of new technologies such as beacon transponders. As a result it may limit implementation of new and more effective means to deliver radiation therapy, including the continuous, real-time monitoring possible with the Calypso System that allows clinicians to deliver more effective, more accurate doses of radiation directly to the tumor and eliminate the necessity of using existing x-ray based patient positioning systems. Despite the advent of new and more effective technologies, it is our belief that hospitals tend to delay using new technologies without separate reimbursement.

Electromagnetic localization tracking is an emerging technology and should not be included in packaged payments. CMS should phase in the packaging approach and should not apply it to new technologies. We appreciate and support CMS's current commitment to pay appropriately for new technologies through the Pass-Through payments and New Technology APCs. A separate payment for new technologies will appropriately reduce the incentive for hospitals to substitute lower cost guidance technologies when a new technology is more clinically effective. Unless these special payments continue to be readily available for new technologies that would otherwise be packaged, the payment under the package APC will not appropriately reflect the cost of the new technology.

Conclusion

To ensure patients receive the most effective medical care for prostate cancer, Calypso Medical respectfully requests that in the Final Rule the agency delay packaging guidance services and continues to set separate payment for new guidance technologies.

Calypso Medical respectfully requests that CMS provide separate payment for Calypso 4D Localization and Beacon Transponders for guidance services through a New Tech APC assignment and Transitional Pass-Through Payment. Without separate reimbursement, hospitals will delay using new technologies, forcing providers to rely on less clinically effective methods of tumor positioning and localization, thereby resulting in less cost-effective solutions.

Respectfully,

Eric R. Meier
CEO, President
Calypso Medical Technologies, Inc.

Submitter : **Sherry Hall** **Date: 08/17/2007**

Organization : **University of Michigan**

Category : **Individual**

Issue Areas/Comments

Payment for Diagnostic Radiopharmaceuticals

Payment for Diagnostic Radiopharmaceuticals

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to vehemently protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

Five years ago, I was rescued by RIT after all else failed, and so from a very personal standpoint, I know how effective it is. But more important than my personal experience, scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

It is highly doubtful that I would be alive today had RIT not become available in the nick of time. All patients deserve the same chance of a successful outcome, but they will not have that chance if the proposed change is adopted. And so it is that I urge you in fact, I beg you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Sincerely,
Sherry S. Hall

Submitter : Ms. Susan Cook **Date:** 08/17/2007

Organization : Ms. Susan Cook

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Re: PAYMENT for Therapeutic AND Diagnostic radiopharmaceuticals.
One of my colleagues at the University of Michigan has non-Hodgkin's lymphoma (NHL) and may require Bexxar or Zevalin in the future. The slashing of reimbursement for both the diagnostic and the therapeutic doses of these radioimmunotherapeutic (RIT) compounds will cause treatment centers to stop using these things altogether. RIT will then not be available for people with NHL who have failed other treatments; some will die without the option of this targeted RIT. Slashing Medicare reimbursement is the first step towards stopping production of the compounds altogether. Please reconsider this decision which will certainly cause lives to be lost if it is kept in the final rule. Thank you.

Submitter : **Mr. Neal Dofelmier** **Date: 08/17/2007**

Organization : **Mr. Neal Dofelmier**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear SIr or Madam:
I am writing in connection to your review of proposed cuts in reimbursment for radioimmunltherapy (RIT) primarily I believe affecting Zevalin and Bexxar. I am a patient with NHL and have alrcady undergone chemotherapy and considering my next course of treatment as my lymphoma has returned. With my cancer it is all about staging various treatment protocols in a manner that you hope will givc you a long term survival. It seems all clinical trials with RIT have provided long term remissions with no more serious side effects than other treatments and have come after treatments such as chemo and have given impressive results. Already duc to the high cost of these treatments the companies that produce them are cutting back and if you further reduce your contributions, the companies will cancel their manufacturing contributing to a significant loss in a cancer patients treatment alternatives when other treatments have failed. Yes it is expensive but as they say you are getting alot of bang for your buck with such long term remissions. Please do not cut these reimbursments for RIT. Thank you

Submitter : Sue Heinze **Date:** 08/17/2007

Organization : Sue Heinze

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

To whom it may concern,
As a non-Hodgkin's Lymphoma survivor, who has twice battled this disease, I am concerned with the possiblity of cutbacks involving Bexxar (or any other radiotherapy). When I was first diagnosed in 2002 I was told that upon relapse the option was stem cell transplant or zevalin. Each year since then, more targeted options have appeared on the horizon--each which is more satisfactory to me than stem cell transplant (a last ditch, costly and serious option in my mind). I was treated with Velcade 3 years ago and am alive and well to this day--no evidence of disease--and have in the back of my head the possibilities of Bexxar or Zevalin at another relapse. I have an incurable cancer, I am 48 years old, I am not pleased to hear that medically sound options for my disease might disappear because they are not profitable enough----tell that to my children should I lose the battle some day partially because legitimate treatments were pulled.
I do hope you reconsider this part of your proposal.
Sincerely,
Sue Heinze

Submitter : **Christine La Forge** **Date: 08/17/2007**

Organization : **Community Access Center**

Category : **Psychiatric Hospital**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

I want a CHANGE to the medicare 190 mental health days to stay in a psychiatric hospital to unlimited.
If a person is diagnosed with a mental illness of various kinds as we know exist, then they will need "Maintenance" throughout their entire life. This can only be done in a psychiatric setting. Example: A person with Bipolar disorder will need medication adjustments and services within this setting all their life. Medications don't always have a long term affect and need adjusting, a person has an "Episode". Only a psychiatric setting is appropriate.
We with mental illness need unlimited in hospitalization days. 190 just doesn't cut it!

Submitter : Gail Campanella **Date:** 08/17/2007

Organization : Gail Campanella

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I oppose the proposed changes in reimbursement for I-131 tositumomab, known as Bexxar, and Y90 ibritumomab,known as Zevalin, both classed as radioimmunotherapy or RIT. The proposed reimbursement changes will reduce the amount of reimbursement for all treatment to one-half of the cost of the medications. This proposed change will result in the denial of treatment to patients by hospitals who will remain unreimbursed for the other half of the cost of the drugs.

I know three people who owe their lives to RIT. Please don't let them, and others who so desparately need this treatment, die.

Submitter : Mrs. Sylvia Caldwell **Date:** 08/17/2007

Organization : Mrs. Sylvia Caldwell

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear Sir or Madam:

I am very concerned regarding the proposed cuts in the payment reimbursement for radioimmunotherapy (RIT).

I am a patient under treatment for follicular lymphoma. My current treatment has put me in remission, but my type of lymphoma is a chronic type with a high relapse rate. RIT is currently the best option for me should my lymphoma relapse. I am not on Medicaid nor Medicare, but the insurance community tends to move with decisions made by those angencies.

It is very disturbing that at a time when I face enough anxiety I also have to deal with the fact that the best treatment for me when I relapse may be out of reach.

I also fear that a cut in reimbursements such as the proposed one may cause drug companies to not take the risks to develop new drugs and treatments. Please do not cut these reimbursements.

Sincerely,
Sylvia Caldwell

Submitter : Dr. Linda Gerstley **Date:** 08/17/2007

Organization : Patients Against Lymphoma

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express my concern for the proposed cuts in reimbursement for radioimmunotherapy (RIT), specifically Zevalin and Bexxar.

I have several friends who have not responded well to other lymphoma treatments and have had significant responses and longterm remissions using these. One, was not responding to any traditional treatments and, after receiving Bexxar, she has been in remission eight years.

Cutting reimbursment for these medications will, in all likelihood reduce patient options. And, as a lymphoma patient, I would hope to have these medications available in the future.

* It s likely to change prescribing practices, which already favor using chemotherapy and Rituxan over RIT.

* It will make RIT too expensive for many patients to afford.

* It will move the sponsors of Zevalin and Bexxar to discontinue them, as it is widely known that each are not yet profitable.

Finally, cutting reimbursements for RIT will be a disincentive for companies to develop new therapies, which are still urgently needed. We need to adopt policies that will make companies more willing to take these financial risks, not less willing, if we are to make significant progress in treating the victims of cancer.

Sincerely,

Linda Gerstley, Ph.D.
Licensed Psychologist

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I am writing to express my concern for the proposed cuts in reimbursement for radioimmunotherapy (RIT), specifically Zevalin and Bexxar.

I have several friends who have not responded well to other lymphoma treatments and have had significant responses and longterm remissions using these. One, was not responding to any traditional treatments and, after receiving Bexxar, she has been in remission eight years.

Cutting reimbursment for these medications will, in all likelihood reduce patient options. And, as a lymphoma patient, I would hope to have these medications available in the future.

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* It will move the sponsors of Zevalin and Bexxar to discontinue them, as it is widely known that each are not yet profitable.

Finally, cutting reimbursements for RIT will be a disincentive for companies to develop new therapies, which are still urgently needed. We need to adopt policies that will make companies more willing to take these financial risks, not less willing, if we are to make significant progress in treating the victims of cancer.

Sincerely,

Linda Gerstley, Ph.D.
Licensed Psychologist

Submitter : **Michael Romuald** **Date: 08/17/2007**

Organization : **Michael Romuald**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear Sir or Madam:

I am writing in regard to proposed changes in coverage for Radioimmunotherapy drugs. This issue is very important to me as I am battling follicular NHL and I have benefited greatly from RIT already. I was diagnosed in September of 2006 and treated with Zevalin (similar to Bexxar) in October as part of a clinical trial. The results of my treatment were dramatic, and I was declared to be in complete remission within 5 weeks with very few side effects. The alternative to this trial would have been a chemotherapy regimen called R-CHOP, which is extremely hard on the entire body - it can only be taken once in a lifetime due to the damage it does to the heart.

My fear is that economic issues are causing exciting new breakthroughs like Bexxar and Zevalin to be underutilized. As a result of this issue, the maker of Zevalin recently sold off the drug to another company.

We who are battling this form of cancer need every tool at our disposal to stay alive and healthy. For us this IS a matter of life and death.

Sincerely,

Michael E. Romuald

#129

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : Dr. Peter Kosek **Date:** 08/17/2007

Organization : Middle Fork SUrgery Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

As a surgery center that specalizes in pain management, we implant spinal neurostimulators for chronic nerve pain. Pain relief can be dramatic, with patients often no longer requiring narcotic analgesics when these devices are implanted.

Rechargeable devices have revolutionized the ability of my patients to benefit from this therapy, as they are no longer limited by their ability to use the device due to fear of depleting the battery. Prior to rechargeable devices, many patients could deplete a device in under 12 months, making this therapy both intensive and much more expensive. New rechargeable devices have all but eleiminated the need for device replacement, and the associated morbidity and costs.

The proposed payment for the implantation of neurostimulators is less thatn the cost of the rechargeable device to my center. My center would be forced to only used fixed cell devices, and this will result in a need for additional replacement surgeries when these devices fail.

Rechargeable stimulators deserve a seperate reimbursement code that is above that of fixed cell devices so that payment for these devices can reflect device cost. Overall, this will reduce costs by markedly lowering the need for replacement devices.

Submitter : Mr. Paul Michael **Date:** 08/17/2007

Organization : St. Paul Heart Clinic

Category : Other Technician

Issue Areas/Comments

Impact

Impact

I am the manager of an ultrasound department. I can say without a doubt that useage of ultrasound contrast will definitely drop off if not reimbursed, thusly keeping a very necessary and helpful product away from patients in need, causing poorer quality studies to be submitted for reading. This can result in misdiagnosing, or more expensive tests being ordered if the ultrasound is technically difficult.

Submitter : Mr. Walter Caldwell **Date:** 08/17/2007

Organization : Mr. Walter Caldwell

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

This letter is on behalf of my wife Sylvia, She has small cell folicular non hodgkins lymphoma and this would be the next course of theatment for her. If funding is cut, then the cost of the treatments might be out of our reach as the insurance will not cover it.

Submitter : John Arnold **Date:** 08/18/2007

Organization : John Arnold

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear CMS,

I am writing because of deep concern regarding proposed funding cuts for radioimmunotherapy (RIT). As a patient with follicular non-Hodgkin's lymphoma who has received both chemotherapy (4 cycles of CHOP+Rituxin) and RIT (Zevalin) I find it exceedingly troubling to imagine a future that deprives a cancer patient of insured coverage to perhaps the most potent and convenient therapy for non-Hodgkin's lymphoma. The clinical trial data to date show RIT to be unparalleled in its ability to produce complete responses to treatment. It is cost-effective: the one-week RIT treatment does not aproach the cost of a standard six-cycle, 18-week, CHOP+R chemotherapy treatment. It is dramatically kinder in the toll it takes in side effects on the patient's body. The target specificity of RIT is a blessing compared to chemotherapy's toxic shotgun approach to killing fast-dividing cells in a patient's body. Believe me, I know from personal experience. Please reconsider any action to reduce coverage of such a potent, cost-effective, and kind therapy.

Submitter : **Mr. Paul Stivers** **Date: 08/18/2007**

Organization : **Mr. Paul Stivers**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I understand that there is a proposal to cut reimbursement for radioimmunotherapy (RIT) and am writing to express my concern that that not happen.

My wife was diagnosed with follicular Non-Hodgkins Lymphoma (fNHL) in May, 2007 and is currently undergoing chemotherapy (R-CHOP). fNHL is currently an incurable cancer. The goal of treatment is to achieve remission, then wait for relapse and treat again. Unfortunately, R-CHOP can only be used once. Each relapse is generally more difficult to treat, and the treatment options decrease over time.

I have done extensive research on the potential therapies that might be available if the cancer does not go into remission or returns at a later date. The nature of my wife's lymphoma makes radiation risky and difficult. RIT is one of the most promising therapies, not only because of its effectiveness, but also because it does not have as severe toxicity of some other treatments. In addition, according to a recent study RIT is very cost-effective compared to other regimens for NHL. See Abstract 8089 from the Journal of Clinical Oncology, 2007 ASCO Annual Meeting Proceeding Part I. Vol. 25, No. 18S (June 20 Supplement), 2007: 8089 authored by C.R.Flowers and others.

It is extremely important to a cancer patient with a life-threatening illness to have available treatment options. Unfortunately, those options tend to be quite limited for fNHL. Reducing reimbursement rates for RIT therapy will likely limit or eliminate the availability of one of the few effective treatments available to fNHL patients facing relapse. Zevalin and Bexxar are the two RIT drugs that have been successful for fNHL. The manufacturers of those drugs cannot be expected to continue the expense of producing them if they are not profitable because of low usage. Even more disturbing, drug companies will have little incentive to continue to search for improved drugs if there is a lack of support when such a drug is found. It would be tragic to have reimbursement policies that effectively stop the use of effective therapies such as these. There is every reason to encourage the development of new drugs for better treatment for cancers in general and an incurable cancer like fNHL in particular.

At this time there are no "good" treatments for fNHL. The choice is among the least bad given the collateral damage to the body of the patient, and the prospect of further treatments at each relapse. RIT offers the hope of bringing more durable remissions and possible cure, with minimal side effects, and at a cost that is lower than the costs associated with chemotherapy, taking into account the cost of the drugs, lab tests, monitoring , adverse events, and earlier relapse.

I urge you to do what you can to encourage the use of RIT and other regimens that give hope to NHL patients. Please do not decrease the reimbursement for RIT.

Submitter : **Ms. Constance Hester** **Date: 08/19/2007**

Organization : **Ms. Constance Hester**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

To whom this may concern.

Bexxar and Zevalin are emerging as treatments that promote long term remissions of indolent lymphomas and for the first time possibly a cure for these types.

In the ongoing trials few people are relapsing after a single dose after multiple years of follow up.

At this point, these drugs are not yet profitable and the manufacturers are considering discontinuing them. Because they are so effective, the potential savings to medicare and medicaid are huge. Therefore, the reimbursement schedule must be designed to encourage their use.

When a person uses these drugs, their remission is greatly extended and may turn out to be a permanent cure. It takes years to prove this, but multiple years of data are indicating it. If use of these drugs are encouraged, it will save medicare and medicaid many times the cost of the drug. Other, expensive treatments (long term mabs, chemotherapy, stem cell transplants, ...) and the cost of their complications which are extensive will be saved.

For these two drugs, the reimbursement should be increased to encourage their use now which will save medicare and medicaid many many times this initial cost.

The cost of ongoing cancer treatment is staggering. If a drug can minimize or eliminate the need for future treatment for a patient, it will save a tremendous amount of money. It will also greatly improve the quality and quantity of life for the patients.

Please increase reimbursement rates for these incredibly effective radiopharmaceuticals. It will decrease cost and increase quality and quantity of life.

Thank you, for considering this very important issue.

Submitter : **Michelle Hylton** **Date: 08/19/2007**

Organization : **Michelle Hylton**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I am the mother of three young children with an incurable type of lymphoma NHL (at this point) RIT would be something that I would want to use when I have to battle again. Please allow this treatment for me and others who follow behind me. Lymphoma is a beast, but knowing that people are getting Complete Remissions from RIT and not having to use conventional chemo therapy offers so much HOPE to so many of us. I want to be here to watch my children grow, learn, graduate high school, college, marriage and possibly see grandchildren one day. RIT is NEEDED don't let it go. It is a lifesaver to many.

I appreciate you taking the time to hear my voice and please please, RIT is needed so much don't stop it now. Please hear our cries.

Sincerely,
Michelle Hylton

Submitter : **Dr. Andrew Michael** **Date: 08/19/2007**

Organization : **Dr. Andrew Michael**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

The proposed reduction in the amount paid for drugs such as Zevalin and Bexxar is alarming. With their great promise for the treatment of currently incurable cancers such as indolent forms of non-Hodgkins Lymphoma, they are still finding their proper place in clinical practice as doctors attempt to figure out if they are best used early in the disease cycle or at later relapses. But because integrating a new treatment into clinical practice for these diseases is an extremely difficult process, the drugs are currently underutilized and could fail economically even as they turn out to be effective ways to extend the lives of patients such as myself. By threatening the economic survival of these drugs, I feel like this rule is actually threatening my survival. While I am currently undergoing treatment with a combination of chemotherapy and the monoclonal antibody Rituxan, these therapeutic radiopharmaceuticals are a strong option to use for my next relapse. I just hope they still exist at that time. Please do not threaten their economic survival at this critical juncture.

Submitter : **Date: 08/19/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dcar Sir or Madam:

I am writing to share my deep concern for the proposed deep cuts in reimbursement for radioimmunotherapy (RIT).

I feel that the policy change will devastate lymphoma patients and their families, present and future.

* It s likely to change prescribing practices, which already favor using chemotherapy and Rituxan over RIT.

* It will make RIT too expensive for many patients to afford.

* It will move the sponsors of Zevalin and Bexxar to discontinue them, as it is widely known that each are not yet profitable.

Finally, cutting reimbursements for RIT will be a disincentive for companies to develop new therapies, which are still urgently needed. We need to adopt policies that will make companies more willing to take these financial risks, not less willing, if we are to make significant progress in treating the victims of cancer.

Submitter : **Mrs. Sandra Richards** **Date: 08/19/2007**

Organization : **Mrs. Sandra Richards**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Iam writing to ask you to please reconsider cutting reimbursement for therapeutic Radiopharmaceuticals and Diagnositic Radiopharmaceuticals. I wasdiagnosed with Non-Hodgkins Lymphoma in 2003. I have not yet had to have treatment with RIT, but know that some time in the future I will need such treatment. If you follow through with the proposed funding cut, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

I beg you, and my family begs you, to please reconsider this decision.

Thank you.

Sandra Richards

Submitter : **Ms. Heidi Bollinger** **Date: 08/19/2007**

Organization : **Ms. Heidi Bollinger**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear Sir or Madam:

I am writing in regards to the proposed changes in coverage for radioimmunotherapy drugs, Zevalin and Bexxar. I have a personal interest in keeping these drugs available to all who need them. I was diagnosed with follicular, low-grade Non-Hodgkins lymphoma in April 2007. I may need to be treated with Zevalin or Bexxar in the future. These drugs have been shown to provide great results with long remissions. They have much fewer side effects than chemotherapy. Those of us with this disease need radioimmunotherapy drugs to be available when we need them. It could mean the difference between life and death.

Sincerely,

Heidi Bollinger

Submitter : **Mr. Donald Richards** **Date: 08/19/2007**

Organization : **Mr. Donald Richards**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I am writing to beg you to reconsider your decision to cut reimbursements for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs. My wife was diagnosed with Non-Hodgkins Lymphoma in 2003. Although she has not yet had to have RIT treatment, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

I beg you, my adughter begs you, my grandchildren beg you to reconsider this decision. We want our wife, mother, grandmother to be around for a long time. Without the possibility of RIT treatment, this may not be possible.

Thank you for your consideration.

Donald Richards

Submitter : **Mr. Paul Ernzen** **Date: 08/19/2007**

Organization : **Individual**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to vehemently protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

Scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

As a former cancer patient, I firmly believe that all patients deserve the same chance of a successful outcome, but they will not have that chance if the proposed change is adopted. And so it is that I urge you in fact, I beg you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Sincerely,

Paul M. Ernzen
1740 Cliffs Landing
Ypsilanti, MI 48198

Submitter : Mr. John Lischak **Date:** 08/20/2007

Organization : Union Hospital Association

Category : Hospital

Issue Areas/Comments

Quality Data

Quality Data

For the HOP QDRP, it would be quite helpful for hospitals to have had the opportunity to review the detailed specifications on the 10 measures proposed for commenting. After conducting some limited research - including through our QIO - I could not find information to help our organization understand the numerators, denominators, & inclusion or exclusion criteria.

These details are rather critical for hospitals, for 2 reasons. First are the implications related to the burden & cost of producing the data for submission & public consumption. Intellectually, healthcare leaders may not debate the clinical relevance & value of the measures in patient care & the need for transparency and public accountability. But, operationally these initiatives are not "free." Hospitals must identify sources for the data, labor resources to abstract the data, & information technology solutions to process the data. Original ORYX/Core Measures estimates were for 20 minutes to abstract data from a chart. Extend that out by the hourly wage equivalent of your labor commitment & the number of applicable cases & you arrive at a substantial "unfunded mandate."

Second is the appropriateness of these measures for hospital outpatient care. Although the receipt of full OPPS payment is attached only to submission of the data & not the actual performance of the data, community perception may not concur. Let's consider, for example, PQRI #1: A1c control in diabetes. As the parent of a diabetic child, I clearly understand the value in managing my child's A1c & appreciate the long-term consequences of poor control. But as a hospital quality professional, I ascribe the responsibility of that management to the physician who attends to his care, not the hospital that performs the testing.

In summary, my 2 most relevant concerns are the costs that will be imposed on an already burdened healthcare system & the appropriateness of who will be perceived as responsible & accountable for the care.

Submitter : **Ms. Katharene Schoof** **Date: 08/20/2007**

Organization : **University of Michigan**

Category : **Social Worker**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to vehemently protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

Scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

As a clinical social worker, I have a strong commitment to seeing that all patients deserve the chance of a successful outcome, but they will not have that chance if the proposed change is adopted. I see firsthand the devastating impact of a life threatening illness on my own family members, my patients, and my colleagues. And so it is that I urge you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Katharene Schoof, LMSW, ACSW
Clinical Social Worker

Submitter : Ms. K. Corsmeier **Date:** 08/20/2007

Organization : Ms. K. Corsmeier

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

For the group of patients with non-Hodgkins lymphoma for whom treatment with Zevalin or Bexxar may well be their best treatment option (most notably, those with refractory disease), the CMS reimbursement proposal for CY2008 is profoundly disturbing, disheartening and of grave concern. As the daughter of such a patient, I plead with CMS to make patient access to care the primary factor in determining the reimbursement methodology for these drugs for CY2008, not inconsistency with the overall prospective basis of the OPPS. Indeed, reimbursement based on a hospital's charges reduced to cost using the hospital's CCR would be consistent with reimbursement for CY2007, as CMS itself notes in the proposed rule. [1] When CMS proposed changes to reimbursement for these drugs for CY2007, Dr. Mark Kaminski, one of the chief developers of these therapies, noted that these therapies are two of the few treatments that can dramatically extend a follicular lymphoma patient's life and the quality of that life through complete remissions of more than 10 years. [2] These drugs have shown great promise for treatment of patients with additional forms of lymphoma, including, for example, mantle cell. Dr. Kaminski goes on to note that reimbursement changes that result in hospital disincentives to use these drugs would be 'devastating.' This remains the case. For CY2008, CMS proposes reimbursement based on mean unit cost as reported in 2006 OPPS claims data. One critical problem for the affected patients is that reimbursement for these drugs under APCs is significantly low-priced and all diagnostic uses would now be packaged into the APC rate. In both the therapeutic and diagnostic setting, the proposed methodology is stated by multiple reliable industry sources to be likely to result in substantial reimbursement reductions, resulting in reduced or eliminated patient access to life-saving cancer treatment. [3] A well established body of literature notes that these drugs are already effective yet under-utilized. [4] Please reconsider this methodology to keep these life-extending treatment options open to those in need.

Thank you for your consideration.

[1] Federal Register: August 2, 2007 (Volume 72, Number 148, pg. 42738)
[2] Letter to CMS from Dr. Mark Kaminski dated 10/10/2006
[3] See, e.g., http://www.aer.org/HomePageCategories/News/ACRNewsCenter/ACRsummaryofHOPPS2008Changes.aspx;
[4] See, e.g., http://www.lymphoma.org/site/apps/nl/content2.asp?c=chKOI6PEImE&b=1573635&ct=3846091

Submitter : Mr. Jeff Daniels **Date:** 08/20/2007

Organization : Bingham Memorial Hospital

Category : Critical Access Hospital

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

I am attaching a word document

CMS-1392-P-146-Attach-1.DOC

#146

BINGHAM MEMORIAL HOSPITAL

Your Health, Your Community, Your Hospital

August 20, 2007 **VIA E-MAIL**

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-P
P. O. Box 8011
Baltimore, MD 21244-1850

RE: Comments regarding proposed changes to CAH off-campus facilities:

To Whom It May Concern:

I am writing to express my concerns with the proposed changes to off-campus facilities. Bingham Memorial is a Critical Access Hospital and is essentially land locked for future growth. If we were to try and find office space for a physician or service that would be hospital based it would be more than the current 250 yards given street addresses. The only remaining option would be to build on remaining vacant land which would take away from any future expansion of hospital services. If measured from corners of property there are a few more options, however there are not many. This would severely restrict the hospitals ability to provide the quality services required by the community.

I understand not allowing facilities to expand into metropolitan areas competing with other facilities however, given the short distance for on campus qualifications; this will virtually limit any future growth for the needs of our community. I suspect that would be the case for many other Critical Access Hospital providers.

I would strongly urge consideration be given to not implementing this provision as presently written. At the very least I would request amending it such that a greater allowance for qualification of on-campus (e.g. 500 - 750 yards) facilities would be available.

Thank you for allowing us to comment on the proposed regulations.

Sincerely,

D. Jeffery Daniels
Chief Financial Officer

Submitter : Ms. Kathleen Rosendahl-Garcia **Date:** 08/20/2007

Organization : Methodist DeBakey Heart Center

Category : Other Health Care Professional

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

I am an Echocardiographer and work with patients on a daily basis. I understand that the government needs to reduce costs as much as possible. However combining contrast agent and echocardiography as a single charge is note promoting efficiency and will eventually become harmful.
Contrast is a completely separate entity from echocardiographic imaging. Contrast is a useful diagnostic tool and a specific tool; it needs to be used only when necessary. I see that combining imaging and contrast will be harmful in two ways. Number one, by not separating imaging and contrast agents eventually the outcome will reduce the access of contrast to the general public. The manufacture of contrast will stop as reimbursement drops and it s the necessity drops. Number two, by requiring contrast the operator is obligated to use contrast on each patient. Contrast requires an intravenous catheter or IV. Inserting an IV requires extra time, skill and supplies and exposes the patient to a needle stick. All of this is fine when the patient actually needs contrast as contrast can be a life saving imaging tool. But if the patient does not need contrast this is an unnecessary cost and the government is not saving any money at all. I think this will cause practitioners to over use contrast. I can see lawyers suing because contrast was not used on each patient and more IV complications when the contrast is used unnecessarily. Contrast is a tool is needed occasionally and for specific purposes this packaging of the two diminishes the actual usefulness of contrast. Contrast needs to be reimbursed separately.

Submitter : Ms. Donna Sobrak **Date:** 08/20/2007

Organization : private citizen

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

So when CMS does not pay, or refuses to pay for services because of hospital preventable errors ... who pays?

Submitter : Dr. William McRoberts **Date:** 08/20/2007

Organization : Dr. William McRoberts

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

Cutting reimbursements for spinal cord and peripheral nerve stimulators as well as other pain procedures will, in effect decapitate an entire specialty devoted to the care and comfort of patients. PLEASE DO NOT PASS THESE CUTS, you may as well not pay for them at all because the cuts are so severe that the practice of pain management will no longer exist. I pray some influential members of this decision making process be afflicted with chronic pain- only to then fully understand the impact and necessity of pain management abd neuromodulation.

Submitter : Dr. Ignacio Rodriguez **Date:** 08/20/2007

Organization : South Miami Pain Center

Category : Physician

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

The proposed changes in reimbursement for rechargeable spinal neurostimulators to outpatient hospital and amubulatory surgical center is absurd. Spinal neurostimulators are an important part of chronic pain patient management. With the removal of "pass through payment" in the hospital outpatient setting and reimbursing at 65% of the hospital outpatient reimbursement in ambulatory surgical centers, Medicare is forcing pain physicians to perform these procedures in the hospital inpatient setting costing Medicare thousands of dollars more. It is unimagineable that Medicare continues to punish physicians who do ambulatory surgery saving Medicare thousands of dollars over the same services provided in the inpatient setting. By eliminating the L codes for these stimulators not only is Medicare going to limit these procedures to its beneficiaries, but it is also going to cost US healthcare more in the long run as these procedures will simply shift into the inpatient setting.

Submitter : Dr. Anthony Hall **Date:** 08/21/2007

Organization : South Florida Neurosurgical Institute, Inc

Category : Physician

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Sir/Madam: I have implanted neurostimulators for 18 years and many patients are critically in need of this therapy to get off high-dose drugs. A reduction in payment to the facilities, who already cover much cost, would impair the scope of availability of this procedure. Only rich people will be able to receive this care with cash payment. Average Americans will have to remain as drug addicted dependents without access to this technology. I implore your committee to consider those Americans who cannot afford cash-payment surgery and continue the payment schedule for these devices for the future. Thanking you in advance.

Submitter : Dr. Michael Levine **Date:** 08/21/2007

Organization : Lake Medical Imaging/Radiology Associates of Centr

Category : Physician

Issue Areas/Comments

PET/CT Scans

PET/CT Scans

August 21, 2007
Re: Docket #CMS-1392-P (Proposed Changes to HOPPS)

Dear Committee Members:

We are Managing Physicians with Lake Medical Imaging, which encompasses three outpatient diagnostic imaging centers serving Central Florida for 35 years. We are writing to express concern with regard to Medicare s proposed payment for FDG PET procedures under the Hospital Outpatient Prospective Payment System for Calendar Year 2008. Lake Medical Imaging has been providing Positron Emission Tomography services since early 2003.

We appreciate the hard work and careful consideration CMS put into developing the proposed rule and are aware of the rate and payment method for PET services that CMS has set forth in the Federal Register. In response to the agency s request for public comments on this issue, we would like to urge CMS to retain current Medicare payment for these critical services as a separate payment for the radiopharmaceutical and for the technical component. The proposed payment reductions for PET radiopharmaceuticals will have limiting effects on beneficiary access to PET services.

Proposed bundling of RP into the technical payment would drastically reduce the reimbursement rate for PET scans for patients with cancer and these reductions would significantly diminish access to PET for Medicare patients. We are very concerned that our PET program simply cannot sustain such a substantial reduction in Medicare payment again in a single year and still continue to provide high quality services. The potential result would be a significant reduction in access to PET for Medicare beneficiaries.

PET Imaging has the unique ability to provide physicians with information about the body s chemistry, cell function, and location of disease can eliminate unnecessary surgeries, reduce the number of diagnostic procedures and otherwise demonstrate to physicians the most effective mode of treatment. PET can evaluate tissue metabolism to determine the presence or absence of malignancy whereas anatomic imaging depends on size and location of lesions to determine likelihood of malignancy.

The clinical benefits of this technology are enormous, as are the costs of continuing to offer this service, including the medical equipment and highly trained and specialized staff. The radiopharmaceutical FDG has a very short half-life and PET centers need to purchase sufficient quantities to administer to patients. The proposed bundling of RP into the technical component would represent a significant decrease in total reimbursement for FDG PET.

We believe that the Cost to Charge Ratio has only this year begun to accurately reflect the cost of supplying PET radiopharmaceuticals. Thank you for your consideration; we appreciate the opportunity to submit and discuss these comments with you.

Sincerely yours,
MICHAEL S. LEVINE, M.D. CATHRINE E. KELLER, M.D
Senior Partner Managing Physician.

Submitter : **Mr.** **Date: 08/21/2007**

Organization : **Mr.**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Sirs,

I am a current Indolent Non-Hodgins Lymphoma patient. Please do not take away the option for me to undergo radioimmunotherapy (RIT) in the future. If cuts are approved then I fear that this proven successful treatment option will not be available when I need it and it may be the only hope left for me to survive longer from this incurable disease. Please do not take this option away from me.

Thank you,

John Trevino
Indolent Non Hodkins Lymphoma Patient

Submitter : **Amanda Bettag** **Date: 08/21/2007**

Organization : **Amanda Bettag**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear Sir or Madam:

I am writing to share my deep concern for the proposed deep cuts in reimbursement for radioimmunotherapy (RIT).

My husband, Brian, was diagnosed in Feb 2007 with an incurable follicular indolent Non-Hodgkin's lymphoma. He is just 32 years old and we have two children under the age of 2.

Although Brian is currently in good health and has not required treatment, we live in constant fear that he will not be alive to see our children graduate from high school, get married, have children of their own, or enjoy our retirement.

Bexxar and Zevalin are two incredibly promising therapies that may one day save my husband's life. It is my sincerest hope that they are available at a reasonable cost to us when we need them. THERE IS NO DOUBT IN MY MIND THAT THE INCURABLE NATURE OF MY HUSBAND'S CANCER WILL NECESSITATE THE USE OF THESE DRUGS AT SOME POINT IN HIS BATTLE WITH CANCER.

There are other people much more knowledgeable than me that can tell you the detrimental effects that a change in this policy will have on lymphoma patients and their families. We are two-working parent family and have a small savings, yet large medical bills would cause us to lose our home and everything we ve worked for.

Cancer has already taken away our peace of mind, dreams of a long happy life, hopes of having more children, and threatened our financial future. Please don t jeopardize my children s future by limiting the treatments available to their father by allowing this policy to change.

Thank you for your time.
Amanda Bettag

Submitter : **Sandra Richards** **Date: 08/21/2007**

Organization : **Sandra Richards**

Category : **Individual**

Issue Areas/Comments

Payment for Diagnostic Radiopharmaceuticals

Payment for Diagnostic Radiopharmaceuticals

Please don't drop the funding for this medicine. What if you had a family member whose life this medicine would save, what would you do? Think about that!!!!

#156

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : **Date: 08/21/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Outpatient surgery centers have higher patient satisfaction rates and lower complication rates than hospital based operating rooms. Reducing reimbursement to outpatient surgery centers will further limit patient access to more efficient, effective, and pleasing care. Please do not do this.

Submitter : Dr. Joseph Jasper **Date:** 08/21/2007

Organization : WA Society of Interventional Pain Physicians

Category : Ambulatory Surgical Center

Issue Areas/Comments

Expiring Device Pass-Through Payments

Expiring Device Pass-Through Payments

separate facility payment rates for rechargeable vs. non-rechargeable neurostimulators - need to preserve in the ASC. Rechargeable systems should save CMS the cost of IPG replacements in some patients.

Submitter : **Dr. Joseph Jasper** **Date: 08/21/2007**

Organization : **WA Society of Interventional Pain Physicians**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Impact

ASC Impact

Please, consider for ASC coverage the following procedures that are currently routinely provided in ASCs safely without need for overnight hospitalization or prolonged stay: IDET 22526-7, lumbar discography 62290, cervical/thoracic discography 62291, hip injection 27093. Such procedures are best performed in the sterile OR environment and are ideally suited to outpatient ASC. Private carriers already cover them in ASCs. Disposable device costs should be considered in the comutation of rates or carved out for pass through coverage. Thank you

Submitter : Leslie Phillips **Date:** 08/22/2007

Organization : Gottlieb Memorial Hospital

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-160-Attach-1.DOC

#160

August 22, 2007

Mr. Kerry Weems
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

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **Skin Repair Procedures**

Dear Administrator Weems:

Gottlieb Memorial Hospital Wound Healing & Hyperbaric Medicine Center appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Gottlieb Memorial Hospital Wound Healing & Hyperbaric Medicine Center is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf®. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 — a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.

In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf's CPT procedure codes do not account for the actual clinical resource use in our experience.

We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.

Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf. We have reviewed our charges for skin repair procedures and have updated the charges for CPT codes 15340 and 15341 to include cost into for the surgical site preparation which was previously billed under CPT code 15000.

We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.

Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact me at (708) 681-7373.

Sincerely,

Leslie Phillips
Program Director
Gottlieb Wound Healing & Hyperbaric Medicine Center
708-681-7373
708-681-7366 fax

Submitter : Ms. Lynn Myers **Date:** 08/22/2007

Organization : Ms. Lynn Myers

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

As a patient diagnosed with follicular Non-Hodgkins Lymphoma (fNHL), I am writing to share my deep concern for the proposed cuts in reimbursement for radioimmunotherapy (RIT).

As you know, FNHL is an incurable cancer. There are various treatments (mostly chemotherapy) that will beat back the cancer for awhile, but it always returns and always results in death.

Now, with the availability of RIT, we patients have a real chance at a life-saving treatment that has minimal life-affecting side effects. I know of many patients who have had radio-immunutherapy (Bexxar and Zevelin) with excellent results. While it is too early to tell if they are "cured," they are enjoying very long remissions and are leading productive lives. These types of relatively low-toxic treatments and remissions are critical for the treatment of this devastating disease.

Due to the radio-labeled antibodies, radio-immunotherapy (RIT) doctors frequently do not offer RIT to patients. This is extremely unfortunate, given its high success rate. Too few doctors are experienced with this treatment and do not want to invest in being able to administer RIT. Please do not further burden these important drugs from patients with decreased funding. In the long run, RIT will prove to be far more effective and less expensive than the chemotherapy drugs that are now used. RIT, and similar targeted treatments, are the future for lymphoma.

This policy change will devastate lymphoma patients and their families, present and future.

Cutting reimbursements for RIT will be a disincentive for companies to develop new therapies, which are still urgently needed. We need to adopt policies that will make companies more willing to take these financial risks, not less willing, if we are to make significant progress in treating the victims of cancer.

Submitter : **Dr. Ralph Millsaps** **Date: 08/22/2007**

Organization : **Western Baptist Hospial**

Category : **Physician**

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

Definity costs 125.00 per vial and you expect the hospital to eat this cost? Here is what will happen: we'll stop using it BUT we will do a lot more TEE's, MUGA's and CT angiograms to get the information we could have gotten IF it was not prohibitively expensive to use Definity.
Your choice: don't pay for Defnity separately at 125 OR pay for lots of other studies at >500.00.

Submitter : Mrs. Sue Maisey **Date:** 08/22/2007

Organization : St. Luke's Episcopal Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing sonographer at St. Luke's Episcopal Hospital and I use contrast agents. If separate payment for echo contrast agents is eliminated for hospital outpatients...I believe it will reduce patient access to echo contrast agents. Not all patients are required contrast agents.

Submitter : Dr. Anjan Gupta **Date:** 08/22/2007

Organization : St. Lukes medical center

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

If separate payment for echo contrast agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents. It will actually increase the overall cost for Medicare because physicians may be ordering for unnecessary tests because of poor quality studies.

Submitter : **Date: 08/23/2007**

Organization :

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

The proposal to include outpatient quality indicators is a sound one. But, unfortunately for hospitals, there are no additional resources to complete these tasks. There is NO objection to the fact that pts. need quality care whether as an inpt. or outpt. My major concern is financially driven. How do we keep finding qualified staff and finding the resources to pay them a competitive salary to fulfill these regulations?

My other concern is that we are expected to implement these Jan. 1, 2008 and the regulations defining them are not available for our vendors to program them into their quality systems. The turn-around time from the regulations to programming to implementation is WAY too short.

Submitter : **Mr. Joe Horstman** **Date: 08/23/2007**

Organization : **Faith Regional Health Services**

Category : **Other Technician**

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

To:Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Attention:CMS-1392-P

Dear Leslie,
I am a practicing sonographer at Faith Regional Health Services and I use Echo contrast on a daily basis. Echo contrasts greatly improve image quality. I believe eliminating separate payment for echo contrast used on hospital outpatients will reduce it's availability in many institutions. This would be a great disservice to many of our patients.
Regards,
Joe Horstman RVT, RDCS

Submitter : **Mrs. Kandi Alvarado** **Date: 08/23/2007**

Organization : **Newman Regional Health Wound Care Clinic**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Skin Substitute

August 23, 2007

Mr. Kerry Weems
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

ATTN: CMS-1392-P
Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective
Payment System and CY 2008 Payment Rates; Skin Repair Procedures
Dear Administrator Weems:
Newman Regional Health Wound Care Clinic appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Newman Regional Health Wound Care Clinic is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.
We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.
In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf s CPT procedure codes do not account for the actual clinical resource use in our experience.
We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.
Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf. We have reviewed our charges for skin repair procedures and have updated/plan to update the charges for CPT codes 15340 and 15341 to include cost into for the surgical site preparation which was previously billed under CPT code 15000.
We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.
Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Kandi Alvarado at (620) 340-6174.
Sincerely,

Kandi Alvarado, RN

Submitter : Dr. Mark Wallace **Date:** 08/23/2007

Organization : Univ of California - San Diego

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-P-168-Attach-1.DOC

#168

Issue Identifier: Implantation of Spinal Neurostimulators

Dear Sir or Madam:

As the Director of the Center for Pain Medicine at the University of California-San Diego, I am writing to encourage Medicare to create a separate APC payment category for rechargeable neurostimulators to recognize the significant clinical and cost differences between rechargeable and non-rechargeable neurostimulators.

My experience with spinal neurostimulators for chronic pain dates to 1992. Since that time, I have prescribed both non-rechargeable and rechargeable neurostimulators for Medicare patients to relieve their severe intractable pain. I have found rechargeable neurostimulators to be an important advancement that improves treatment for chronic neuropathic pain by providing long-term relief for chronic pain patients who require high power settings, while potentially avoiding costly surgeries and potential complications associated with a surgery to simply replace a non-rechargeable neurostimulator due to battery depletion.

I have observed an average battery life of about 4 years for non-rechargeable neurostimulators. The frequent replacement of non-rechargeable neurostimulators will ultimately increase long-term costs to both the M edicare p rogram and M edicare b eneficiaries (who will f ace h igher c oinsurance du e t o multiple surgeries). From a clinical perspective, non-rechargeable neurostimulators can compromise my ability to achieve optimal pain relief due to concerns about preserving battery life.

Alternatively, rechargeable neurostimulators allow for continuous stimulation at high settings that can optimize patient pain relief without rapid battery depletion. Rechargeable neurostimulators will last several times longer than non-rechargeable devices and also feature advanced technology such as that ability to precisely target the stimulation that is only possible with high-power rechargeable systems.

In 2006, Medicare approved rechargeable neurostimulators as a new technology pass-through device because these devices represented a clinical improvement for Medicare patients Medicare's 2008 proposed OPPS rules would reduce reimbursement for a rechargeable neurostimulator in our facility from approximately $22,500 in 2007 (APC + Pass-Through) to only $12,300 in 2008. This 55% payment cut could significantly impact UCSD Medical Center's ability to offer rechargeable neurostimulators due to hospital administration concerns about cost versus reimbursement.

Again, I encourage Medicare to consider these comments and create a separate payment category for insertion of rechargeable neurostimulators. Please feel free to contact me at mswallace@ucsd.edu with any questions.

Sincerely,

Mark Wallace, M.D.
Professor of Clinical Anesthesiology
Director, Center for Pain and Palliative Medicine
University of California – San Diego

Submitter : **Dr. Giancarlo Barolat** **Date: 08/23/2007**

Organization : **The Barolat Institute**

Category : **Physician**

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Dear Sir or Madam:

I am a neurosurgeon with 30 year experience with implantable neurostimulators. My practice is currently dedicated exclsively to neurostimulation.

As you know, rechargeable neurostimulators have received transitional pass-through payment under Medicare s hospital outpatient prospective payment system (OPPS) since January 1, 2006, and their pass-through status will expire on January 1, 2008. Transitional pass-through payment was granted to rechargeable neurostimulators on the basis that these devices demonstrated substantial clinical improvement and that the technology would be inadequately paid under APC 0222, to which implantation of neurostimulator devices is assigned. Pass-through payment made rechargeable technology available to patients in the hospital outpatient setting. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would deny patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222, despite very significant differences in the cost of the two devices. I am concerned that the proposed payment for APC 0222 of $12,313.94 thousands less than the average cost of rechargeable neurostimulators will create a strong financial disincentive for the use of rechargeable neurostimulators. CMS own data shows the median cost for implanting rechargeable neurostimulators is $18,088.71, while the median cost for non-rechargeable neurostimulators is $11,607.75, a difference of $6,480.96.

"Chronic pain patients requiring higher power needs to achieve pain relief can use their rechargeable system without concern for premature battery depletion.

"The increased battery life of rechargeable neurostimulators results in a reduction in the number of device replacement surgeries and other associated medical interventions. The reduced number of surgeries and other medical interventions results in less patient trauma and a substantial cost savings to the healthcare system over time.

I am urging CMS to create separate APCs for the implantation of rechargeable and non-rechargeable neurostimulators, which should adequately recognize the cost of both devices and allow the patient population indicated for rechargeable neurostimulators continued access under the hospital outpatient prospective payment system
Thanks for your attention to this matter.
Giancarlo Barolat MD

Submitter : **Mr. Ernest Schmid** **Date: 08/24/2007**

Organization : **Texas Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

see attachment

Submitter : **Dr. John Braun** **Date: 08/24/2007**

Organization : **Meridian Anesthesiology P.A**

Category : **Physician**

Issue Areas/Comments

OPPS: Conversion Factor

OPPS: Conversion Factor

RE: Medicare Pay Increases for Anesthesia Services

Dear Sir:

I would very much like to thank you, in advance, for the planned increase in 2008 reimbursement for anesthesia services! The 32% work undervaluation and underpayment for anesthesia services, due to the flawed conversion factor formula, along with the across-the-board yearly reductions in Medicare/Medicaid payments, has been exceedingly painful for all anesthesia providers. It seems particularly unfair and ironic that Medicare recipients get annual COLAs (cost of living adjustments), while their Doctors get annual pay cuts.

If I may, I would like to make one last comment. I understand that it is planned to give the CRNAs (Certified Registered Nurse Anesthetists) a 12% pay increase, while giving the Anesthesiologists only a 4% increase. This is a 300% larger pay increase to the nurse that the doctor. Since the anesthesiologist has gone to medical school for 4 years and completed a 4 year Anesthesiology/Critical Care/Pain Management residency, and the CRNA has never attended medical school and has only two years of anesthesia training, there seems to be no basis for this discrimination. Doctors are always held to a higher standard of care than nurses, have higher malpractice premiums, and of course have higher malpractice judgments against them than nurses. It seems only fair that the anesthesiologist should get the 12% increase, not the nurse anesthetists, to help defray
these additional expenses.

I know that you will give careful consideration to these genuine concerns. Let me thank you once again for any and all help in rectifying the inequities in anesthesia reimbursement.

Respectfully,

John C. Braun, DDS, MD

Submitter : Dr. Stephen Pyles **Date:** 08/24/2007

Organization : Florida Pain Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I've been placing spinal cord stimulators since 1987. I have seen these devices improve considerably during the years. The most dramatic improvement made in spinal cord stimulation to date has been the introduction of the rechargeable batteries used to power the electrodes. This technology more than doubles the effective life of each stimulator system and therefore in my opinion deserves a significantly higher pass through payment. On behalf of our patients please give this your most serious consideration. Thank you. Stephen T. Pyles M.D.

Submitter : **Ms. Marcella Galvan** **Date: 08/24/2007**

Organization : **Illinois Masonic Wound Care Resources**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-173-Attach-1.RTF

CMS-1392-P-173-Attach-2.RTF

CMS-1392-P-173-Attach-3.RTF

#173

Advocate Illinois Masonic Medical Center
Hyperbaric & Wound Care Resources
836 W. Wellington Avenue
Chicago IL 60657

August 24, 2007

Mr. Kerry Weems
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

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **Skin Repair Procedures**

Dear Administrator Weems:

Advocate Illinois Wound Healing Center appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Advocate Illinois Wound Healing Center is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf®. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 — a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.

In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf's CPT procedure codes do not account for the actual clinical resource use in our experience.

We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.

Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf

We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.

Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Marcella at (773) 296 - 8360.

Sincerely,

Marcella Galvan
Program Director
Advocate Illinois Wound Healing Center

Submitter : **Dr. Vance Johnson** **Date: 08/25/2007**

Organization : **Inland Physiatry Medical Group, Inc.**

Category : **Physician**

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Re: CMS-1392-P: 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

Issue Identifier: Implantation of Spinal Neurostimulators

Dear Sir or Madam:

I am a Physician with specialty training in Physical Medicine & Rehabilitation (1999 board cert) and subspecialization in Interventional Spine Pain Medicine. I have been using Spinal Cord Stimulators for 6 years to help my patients suffering from intractable neuropathic pain. I am impressed with the magnitude of relief they can get and the intensity of knowledge, technical ability, and experience physicians must have to perform this service. Since this therapy can dramatically improve the lives of so many, its' availability must grow.

As you know, rechargeable neurostimulators have received transitional pass-through payment under Medicare s hospital outpatient prospective payment system (OPPS) since January 1, 2006, and their pass-through status will expire on January 1, 2008. Transitional pass-through payment was granted to rechargeable neurostimulators on the basis that these devices demonstrated substantial clinical improvement and that the technology would be inadequately paid under APC 0222, to which implantation of neurostimulator devices is assigned. Pass-through payment made rechargeable technology available to patients in the hospital outpatient setting. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would deny patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222, despite very significant differences in the cost of the two devices. I am concerned that the proposed payment for APC 0222 of $12,313.94 thousands less than the average cost of rechargeable neurostimulators will create a strong financial disincentive for the use of rechargeable neurostimulators. CMS own data shows the median cost for implanting rechargeable neurostimulators is $18,088.71, while the median cost for non-rechargeable neurostimulators is $11,607.75, a difference of $6,480.96.

" Chronic pain patients requiring higher power needs to achieve pain relief can use their rechargeable system without concern for premature battery depletion.

" The increased battery life of rechargeable neurostimulators results in a reduction in the number of device replacement surgeries and other associated medical interventions. The reduced number of surgeries and other medical interventions results in less patient trauma and a substantial cost savings to the healthcare system over time.

" Increased control and wider array of electrode programs is more satisfying for patients.

I am urging CMS to create separate APCs for the implantation of rechargeable and non-rechargeable neurostimulators, which should adequately recognize the cost of both devices and allow the patient population indicated for rechargeable neurostimulators continued access under the hospital outpatient prospective payment system.

I appreciate CMS s past recognition of the clinical benefits offered by rechargeable technology for Medicare beneficiaries, and I hope that you will carefully consider these comments. Should you have any questions or need additional information, please feel free to contact me at vjohnson@yourpaincare.com

Sincerely,

Vance Johnson, MD

Submitter : **Ms. Betty M Robinson** **Date: 08/25/2007**

Organization : **Ms. Betty M Robinson**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I beg you to reconsider your changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). . The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. There can be no question as to the consequences of these reduced costs to the hospitals and ultimately to the patients. This action will effectively deny treatment for patients with follicular lymphoma, which currently is considered incurable.
I am particularly interested in your actions in this matter as I was diagnosed with Follicular Lymphoma last year. The unintended consequences of reducing the payment for this proven, effective treatment for lymphoma will essentially deny those of us with lymphoma a chance for a longer life.
Thank you for your reconsideration to this matter.

Submitter : **Mr. Fred Osterwisch** **Date: 08/25/2007**

Organization : **Mr. Fred Osterwisch**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

RE: CM-1392-P
Comments regarding proposed changes to diagnostic and therapeutic radiopharmaceuticals

Gentlemen:

I am writing to protest the proposed changes in reimbursement for I-131 tositumomab, commonly known as Bexxar, and Y90 ibritumomab, commonly known as Zevalin. These two drugs belong to a class of medicine known as radioimmunotherapy (RIT). Although the drugs are given as a single treatment, the proposed reimbursement separates their components for payment under both diagnostic and therapeutic radiopharmaceuticals. The total amount of reimbursement for all components of the treatment amounts to approximately one half their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.

Scientific studies consistently show that RIT is the most effective single agent available for the treatment of some forms of lymphoma. It has few side effects, and because it is given in a period of only one week, patients are able to return to work almost immediately. Traditional treatments such as chemotherapy and transplants require much longer treatment periods and cause significantly more side effects which add to both the cost of treatment and the reduction in patient productivity. Worse, these traditional treatments are known to be less effective than RIT.

If the proposed reimbursement change is adopted, hospitals will not subsidize this treatment and patients will no longer have access to it. In fact, if it is approved, the change will effectively sound the death knoll for this important and effective treatment. This begs several questions: How can the war on cancer ever be won if newer and better FDA-approved treatments are allowed to disappear because the system of reimbursement fails to recognize their value to human life? How many millions of dollars will have been wasted on their development? And how many patients will die?

All patients deserve the best chance of a successful outcome, but they will not have that chance if the proposed change is adopted. And so I urge you to consider patients first and to deny the proposed changes in reimbursement to these drugs. Thank you for your consideration.

Sincerely,

Fred Osterwisch
Ann Arbor, Michigan

Submitter : **Dr. Yeshvant Navalgund** **Date: 08/26/2007**

Organization : **DNA Health Systems**

Category : **Physician**

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

I am attatching my letter to these comments.

CMS-1392-P-177-Attach-1.DOC

CMS-1392-P-177-Attach-2.DOC

#177

August 21, 2007

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: 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

Issue Identifier: Implantation of Spinal Neurostimulators

Dear Sir or Madam:

My name is Dr. Yeshvant A. Navalgund. I provide pain management services in the Western PA region. I am a physician who specializes in the implantation of spinal cord stimulators. My practice consists of 4 physicians including Dr. Rodney B. Dayo, Dr. Brinda K. Navalgund, and Dr. Louis T. Olegario. We are very active in the management of neuropathic pain and the use of spinal cord stimulation to achieve this goal. We are all very disturbed by the thought that a proposition to combine rechargeable and non-rechargeable devices into one payment for reimbursement is even being contemplated. This will no doubt alter the decisions made by hospitals we practice in regards to what devices would be recommended to use. The long term consequence will be increased costs to all parties including the federal government. Rechargeable devices cost more to make but save thousands of dollars per patient in the long run, by preventing repeated surgery and O.R. Costs as well as other hospital costs.

In summary:

- ***Chronic pain patients requiring higher power needs to achieve pain relief can use their rechargeable system without concern for premature battery depletion.***
- ***The increased battery life of rechargeable neurostimulators results in a reduction in the number of device replacement surgeries and other associated medical interventions. The reduced number of surgeries and other medical interventions results in less patient trauma and a substantial cost savings to the healthcare system over time.***

I hope the following information helps you make the best choice for our patients as well as the huge burden already being placed on our healthcare system:

As you know, rechargeable neurostimulators have received transitional pass-through payment under Medicare's hospital outpatient prospective payment system (OPPS) since January 1, 2006, and their pass-through status will expire on January 1, 2008. Transitional pass-through payment was granted to rechargeable neurostimulators on the basis that these devices demonstrated "substantial clinical improvement" and that the technology would be inadequately paid under APC 0222, to which implantation of neurostimulator devices is assigned. Pass-through payment made rechargeable technology available to patients in the hospital outpatient setting. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would deny patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222, despite very significant differences in the cost of the two devices. I am concerned that the proposed payment for APC 0222 of $12,313.94—thousands less than the average cost of rechargeable neurostimulators—will create a strong financial disincentive for the use of rechargeable neurostimulators. CMS' own data shows the median cost for implanting rechargeable neurostimulators is $18,088.71, while the median cost for non-rechargeable neurostimulators is $11,607.75, a difference of $6,480.96.

I am urging CMS to create separate APCs for the implantation of rechargeable and non-rechargeable neurostimulators, which should adequately recognize the cost of both devices and allow the patient population indicated for rechargeable neurostimulators continued access under the hospital outpatient prospective payment system.

I appreciate CMS's past recognition of the clinical benefits offered by rechargeable technology for Medicare beneficiaries, and I hope that you will carefully consider these comments. Should you have any questions or need additional information, please feel free to contact me at [insert contact information].

Sincerely,

Yeshvant A. Navalgund, M.D.

Diplomate American Board of Anesthesiology
Diplomate ABA Pain Medicine

Submitter : **Robert Hesse** **Date: 08/26/2007**

Organization : **Patients Against Lymphoma**

Category : **Individual**

Issue Areas/Comments

Payment for Diagnostic Radiopharmaceuticals

Payment for Diagnostic Radiopharmaceuticals

Dear Sir or Madam:

I am writing to share my deep concern for the proposed deep cuts in reimbursement for radioimmunotherapy (RIT).

Importantly, a review the literature will show that many patients with advanced disease and many prior therapies RIT can and often do achieve durable complete remissions. See http://www.lymphomation.org/treatment-rit.htm#about

I feel that the policy change will devastate lymphoma patients and their families, present and future.

* It s likely to change prescribing practices, which already favor using chemotherapy and Rituxan over RIT.

* It will make RIT too expensive for many patients to afford.

* It will move the sponsors of Zevalin and Bexxar to discontinue them, as it is widely known that each are not yet profitable.

Finally, cutting reimbursements for RIT will be a disincentive for companies to develop new therapies, which are still urgently needed. We need to adopt policies that will make companies more willing to take these financial risks, not less willing, if we are to make significant progress in treating the victims of cancer.

Robert Hesse

Submitter : **Dr. Robert Hullander** **Date: 08/26/2007**

Organization : **Pacific Pain Physician**

Category : **Physician**

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

26 August 2007

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: 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

Issue Identifier: Implantation of Spinal Neurostimulators

Dear Sir or Madam:

Pacific Pain Physicians is a pain management practice that cares for the majority of patients in the Santa Barbara county area for both acute and chronic pain. We currently implant 4-6 neurostimulators a month. The rechargeable stimulators have made a huge difference in the functionality of the equiptment and the range of patients we can care for.

As you know, rechargeable neurostimulators have received transitional pass-through payment under Medicare s hospital outpatient prospective payment system (OPPS) since January 1, 2006, and their pass-through status will expire on January 1, 2008. Transitional pass-through payment was granted to rechargeable neurostimulators on the basis that these devices demonstrated substantial clinical improvement and that the technology would be inadequately paid under APC 0222, to which implantation of neurostimulator devices is assigned. Pass-through payment made rechargeable technology available to patients in the hospital outpatient setting. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would deny patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222, despite very significant differences in the cost of the two devices. I am concerned that the proposed payment for APC 0222 of $12,313.94 thousands less than the average cost of rechargeable neurostimulators will create a strong financial disincentive for the use of rechargeable neurostimulators. CMS own data shows the median cost for implanting rechargeable neurostimulators is $18,088.71, while the median cost for non-rechargeable neurostimulators is $11,607.75, a difference of $6,480.96.

[In this area, you can articulate why the development of rechargeable neurostimulators represents a substantial advancement over non-rechargeable stimulators and the patient benefits offered by this new technology. The following is an example.]:

? Chronic pain patients requiring higher power needs to achieve pain relief can use their rechargeable system without concern for premature battery depletion.

? The increased battery life of rechargeable neurostimulators results in a reduction in the number of device replacement surgeries and other associated medical interventions. The reduced number of surgeries and other medical interventions results in less patient trauma and a substantial cost savings to the healthcare system over time.

I am urging CMS to create separate APCs for the implantation of rechargeable and non-rechargeable neurostimulators, which should adequately recognize the cost of both devices and allow the patient population indicated for rechargeable neurostimulators continued access under the hospital outpatient prospective payment system.

I appreciate CMS s past recognition of the clinical benefits offered by rechargeable technology for Medicare beneficiaries, and I hope that you will carefully consider these comments. Should you have any questions or need additional information, please feel free to contact me at [insert contact information].

Sincerely,

R Mihael Hullander, MD
President, Pacific Pain Physicians

#180

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

#181

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : John Manter **Date:** 08/27/2007

Organization : John Manter

Category : Nurse

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I suggest that CMS should do further study before making blanket changes to the packaging rules that have been established since the inception of OPPS. Specifically, many radiological guidance codes already are packaged, and those that are not, presumably have significant costs, so are paid separately.

My rationale for suggesting further study is that the published proposed rule contains coding errors, incomplete analysis, and coding classification errors. For example, page 42655, you state that fluoroscopy CPT 76001 may be used with the ERCP procedure, CPT 43260. This is incorrect and is a coding error. You appear to be making packaging assumptions without expert coding guidance or editing. Radiological guidance for ERCP 43260, as stated in the CPT book, is reported with 74328, 74329, or 74330, but never with 76001. The ERCP radiological guidance codes always include fluoroscopy. This established coding rule wasn't used.

The example in Table 7, p 42656, addresses packaging of 76940 (which you define as ultrasound guidance for spinal ablation rather than liver ablation) with liver tumor ablation, 47382. The table implies that you are packaging the ultrasound procedure paid $73, but the price for the primary procedure increases over $400. Did you factor in the fact that liver ablations can also use specific HCPCS codes for CT or MRI guidance rather than ultrasound? You don't mention this in your discussion, and seem to OK with packaging a $73 procedure and paying $400 more. You need, in my opinion, more analysis when proposed payments that you cite as examples in the Federal Register defy common sense. Were CT and MRI costs considered in the proposed payment? You state that ultrasound was done 19% of the time with liver ablation.

Finally, I suggest further study for blanket, sweeping changes, because you apparently make packaging decisions based on some misclassification of CPT codes. Table 8, page 42657, for example lists code 19295 as a radiological guidance code to be packaged, but in fact this code represents a surgical breast procedure which by definition already includes the dependent radiology service. Your lack of differentiating surgical from radiology coding, again suggests the need for further study.

While in theory I do support your move to more comprehensive packaging, I suggest a more gradual change, with more study.
I also question the fairness of packaging payment, for example, where 20% of providers might use an add on code (a coding sub classification you blanket for 100 % packaging), but now the payment will be redistributed to all providers.

Submitter : Dr. Thomas Ryan **Date:** 08/27/2007

Organization : American Society of Echocardiagraphy

Category : Health Care Professional or Association

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

See Attached Letter and Attachments

CMS-1392-P-183-Attach-1.DOC

CMS-1392-P-183-Attach-2.DOC

CMS-1392-P-183-Attach-3.PDF

CMS-1392-P-183-Attach-4.PDF

#183

American Society of Echocardiography

August 27, 2007

Herbert B. Kuhn, Acting Administrator
Centers for Medicare and Medicaid Administration
Department of Health and Human Services
CMS 1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1392-P; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates**

Dear Mr. Kuhn:

On behalf of the American Society of Echocardiography (ASE), I am writing to comment on the proposed changes to the Hospital Outpatient Prospective Payment System ("HOPPS") for CY 2008 set forth in the August 2, 2007 *Federal Register* (the "CY 2008 HOPPS Proposed Rule"). The ASE is a professional society consisting of over 13,000 professionals committed to excellence in cardiovascular ultrasound and its application to patient care.

CMS is proposing a number of significant changes to the APC methodology and rates for echocardiography ("echo") services. In particular, CMS is proposing to bundle" Medicare payment for spectral Doppler (CPT 93320) and color Doppler (CPT 93325) into the APC(s) for the principal procedure(s) with which these Doppler studies are billed (hereafter "base" services). In addition, CMS is proposing to bundle Medicare payment for contrast agents used in the provision of echo services into the "base" echo services. Under the CMS proposal, separate Medicare payment would be unavailable under HOPPS for spectral or color Doppler, or for echo contrast agents, effective on January 1, 2008.

Preliminarily, we note that, at this stage, the cardiology community is faced with no fewer than three proposals for bundling Doppler studies into "base" echo codes:

- **Proposed HOPPS Approach**. Under this proposal, *both spectral and Doppler* are bundled into *all* echo base codes, and *APC rates for base codes are increased proportionately.*

- **Proposed PFS Approach**. This approach, which was proposed by CMS in the July 12 *Federal Re*gister as part of the notice of proposed rulemaking for the CY 2008 Physician Fee Sc*hedule (the "PFS Proposed Rule") singles out color Doppler only* and "bundles" it into *all* echo base codes, *without providing additional payment* on the grounds that color Doppler is an "inherent" part of all echocardiography studies. For the reason set forth in the attached comments (Attachment A), which were filed with CMS in response to the PFS Proposed Rule, ASE strenuously disagrees with this approach and the underlying rationale.

- **RUC Approach**. At the urging of CMS representatives and others, the American College of Cardiology recently submitted, and the CPT Editorial Panel recently approved, a CPT code request for a *new* CPT code for the commonly performed combination of adult transthoracic echocardiography (TTE) (93307) with color Doppler and spectral Doppler. The new code is to become effective in January, 2009. This approach differs from the PFS and the HOPPS approach since it would bundle *both spectral and color Doppler only when these services are performed in conjunction with adult TTE* (CPT 93307), *and the current Doppler codes would remain available for separate reporting and payment when provided with other echo "base" services.* Recommended valuation under the PFS would be provided by the RUC, and payment under HOPPS for the new code would be determined in the interim final HOPPS rule for CY 2009.

Under these circumstances, we cannot help but conclude that CMS's approach to bundling of echo and other services is in need of additional study and coordination. Our more specific comments regarding the elimination of separate payment for Doppler studies and contrast agents, as set forth in the HOPPS Proposed Rule, follow.

* * * * *

Bundling of Spectral and Color Doppler

We have a number of concerns about CMS's proposal to bundle color and spectral Doppler into the APC rates for echo "base" services. First, CMS's proposal reflects a real misunderstanding of color Doppler, characterizing color Doppler as an "image processing" service.[1] The clinical utility and resources involved in the provision of color Doppler are described in some detail in

[1] We also believe that the characterization of spectral Doppler into the category of "intraoperative" services is misleading. While the HOPPS Proposed Rule makes it clear that the term "intraoperative" in this context includes services that are "supportive dependent services" related to a non-surgical "independent" service, the use of the term "intraoperative" for this category of bundled services is misleading. We would suggest that CMS revise this terminology to read "supportive dependent services."

our comments to CMS on the PFS Proposed Notice, provided as Attachment A to these comments. The ASE's Guideline entitled, "Recommendations for Evaluation of the Severity of Native Valvular Regurgitation with Two-dimensional and Doppler echocardiography," (www.asecho.org/freepdf/vavularregurg.pdf) details the physician work involved in color Doppler for the assessment of valvular disease, which includes performance of a number of important measurements. Likewise, the sonographer time and skill involved in providing color Doppler is not insubstantial. The protocol for data acquisition for color Doppler requires the cardiac sonographer to perform numerous tasks and obtain a number of measurements, as reflected in the ASE's valvular regurgitation standard cited above and the ASE standard, "Recommendations for Quantification of Doppler Echocardiography" at www.asecho.org/freepdf/RecommendationsforQuantificationofDopplerEcho.pdf. Thus, characterizing color Doppler as simply "data processing" does a grave injustice to the knowledge and skill required of both the interpreting physician and the cardiac sonographer.

Second, we are troubled by the fact that, under the HOPPS Proposed Rule, Doppler studies would be bundled not only into "base" echo services with which Doppler is performed as the "standard of care," but also into "base" echo codes that are rarely performed with Doppler. The chart set forth at Attachment B indicates the proportion of echo "base" codes that include spectral and color Doppler, and, as that chart illustrates, only adult TTE (CPT 93307) and congenital TTE (93303) are generally performed with both spectral and color Doppler. Where (as for the remaining echo "base" codes) the performance of Doppler is not the "standard of practice," CMS's bundling proposal may provide an inappropriate disincentive to perform Doppler studies, which is not in the best interests of our patients.

In this regard, we note that the CPT Editorial Panel has recently approved a new code (which was submitted by the ACC at the urging of the RUC, including the CMS RUC representative), which includes adult TTE (CPT 93307), spectral Doppler (93320) and color Doppler (93325). The new code is scheduled to become effective in CY 2009. If the Doppler services are bundled into all echo base codes in 2008, the introduction of this new code in CY 2009 is likely to result in substantial confusion among hospitals. In order to assure that both color Doppler and spectral Doppler services are bundled into all "base" echo codes in the correct proportion, we request that, if CMS does decide to proceed with the approach set forth in the PFS Proposed Rule, it should instruct hospitals to continue to use current coding nomenclature when adult TTE is performed with spectral and color Doppler, rather than using the new CPT code that will become effective in CY 2009. In that way, reporting of spectral and color Doppler services will be uniform regardless of which echo "base" code is performed, and Doppler charges can be built into the APCs for all echo base codes in a similar manner.

Third, we have a number of concerns about whether the HOPPS data base accurately reflects the correct distribution of Doppler services across echo "base" services and whether CMS's proposed methodology will allocate Doppler charges appropriately to the correct echo "base" codes. For example, we understand that CMS is proposing to bundle the Doppler codes and echo contrast agents with whatever "base" code is billed on the same claim. So if a hospital fails to bill for a Doppler procedure or for a contrast agent on the same claim as the echocardiography

"base" procedure involved, and then bills later or on a separate claim, the cost of the bundled item or service may be built into the APC rate of an entirely unrelated service that happens to be on the same claim (*e.g.*, an E&M service).

The discussion at pp.42658-42659 of the HOPPS Proposed Rule illustrates another problem with CMS's proposed bundling policy, which may occur when a Doppler service is reported on the same claim as more than one "base" service. That discussion indicates that color Doppler is to be bundled into the APC rates for both stress echo (CPT 93350) and for stress tests (CPT 93017), since both of these principal services are found on the same claims as color Doppler. Yet, it is entirely inappropriate to allocate any of the color Doppler claims or associated charges with stress tests. The large majority of stress tests are performed either alone or in conjunction with myocardial perfusion (SPECT) studies, rather than with stress echo; it is appropriate to bundle color Doppler only with those stress imaging studies that are performed in conjunction with stress echo. Thus, all of the color Doppler charges billed with both stress tests and stress echos should be built into the stress echo APC data base.

Likewise, it is unclear to us how the HOPPS Proposed Rule's bundling proposal would address spectral or color Doppler claims that, for whatever reason, are not billed with any echo "base" service. It is our understanding that, at least when the HOPPS was initially instituted, there were a not-insignificant number of Doppler studies that were in fact billed alone, likely as the result of hospital billing errors. It is unclear how these claims are to be factored into the APC rates for the principal procedures under CMS's proposal, but it is clear that, if they are ignored, the APC rates for the principal procedures will not accurately reflect the performance of Doppler studies.

In light of these potential sources of inaccuracy, if, **contrary to our strenuous objections**, CMS decides to adopt its Doppler bundling policy in the HOPPS Final Rule, we request that the agency utilize the data on Attachment B, which sets forth an accurate distribution of Doppler services among echo "base" codes, to ensure that the final bundled APC rates are accurate.

Bundling of Echo Contrast

Used appropriately, echo contrast has the potential to improve the accuracy of diagnosis of cardiac disease and to save downstream costs resulting from repeat or more costly testing. However, due in part to the cost of echo contrast and the lack of any Medicare payment for its administration, we believe that echo contrast agents likely are underutilized in the current practice of echocardiography.

Under the HOPPS Proposed Rule, hospitals will receive the same amount regardless of whether contrast is used, creating an additional disincentive to use echo contrast. We understand that it may be appropriate to bundle some contrast agents where, for example, the cost of the contrast agent is relatively minimal and Medicare payment for its administration is available because the applicable CPT codes distinguish imaging studies performed with contrast from those performed without contrast. However, this is not the case for echo contrast, since there is no CPT code that

distinguishes echo studies performed with contrast from those performed without it and the cost of the agent is relatively high.

However, if CMS does decide to bundle echo contrast, the Medicare Act requires CMS to establish a separate APC for contrast-enhanced echo services. Specifically, Section 1833(t)(2)(G) of the Medicare Act states:

> (G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not;

Because there is no separate CPT code for contrast-enhanced echo services, bundling echo contrast would require the creation of separate HCPCS codes for adult TTE and stress echo services performed with contrast.

Thus:

- Bundling echo contrast likely would further decrease use of contrast agents, which are underutilized already. Underutilization of contrast agents increases downstream costs for more invasive and more expensive follow up testing.

- The cost of echo contrast is substantial relative to the proposed APC rate for the echo procedure with which it is most often used (approximately $120 (Q9957)(contrast); $306 (CPT 93350) (stress echo)).

- The only echo contrast agent that remains on the market (Q9957)(Inj. perflutren lip micros, ml) substantially exceeds the $60 threshold historically used by CMS to determine which drugs should be bundled, and also significantly exceeds the cost of most other contrast agents – for example, those generally used with CT and MRI procedures.

- There is no separate CPT code for contrast-enhanced echocardiography procedures at this time and no separate APC for contrast-enhanced procedures. Bundling contrast agents is significantly more straightforward for modalities, like CT and MRI, where there are separate CPT codes and separate APCs for contrast-enhanced procedures.

- If, despite our strong opposition, CMS decides to bundle echo contrast into the underlying APC rates, the Medicare Act requires that CMS establish a separate APC for contrast-enhanced echo procedures, which will require the establishment of separate HCPCS codes for contrast-enhanced adult TTE and stress echo procedures.

APC Reclassification of Stress Echo

The current and proposed APC classification and rates for echo procedures are set forth at Attachment C. As that Attachment makes clear, CMS is proposing to reclassify stress echo into

an APC that includes **limited** adult and congenital studies, rather than leaving it in the same APC that includes adult TTE.

We strenuously object to this reclassification of stress echo. The performance of a stress echo necessarily requires the performance of a full echocardiogram when the patient is at rest and repetition of the study when the patient is under stress. The time and resources involved in the provision of a stress echo often exceed the time and resources involved in the performance of adult TTE and far exceed the time and resources involved in the performance of the type of limited echo studies with which stress echo is classified under the HOPPS Proposed Rule. Specifically, the performance of a stress echo requires the use of a high quality echo machine with stress echo capabilities and transducers; space for both the echo machine and a treadmill or other stress test equipment; a CVT or RN to run the treadmill and obtain the treadmill data; a physician on site to provide direct supervision; a sonographer to perform the images pre, peak, and post stress; code carts with ER drugs and associated staff; and dictating equipment and staff for the completion of a full report. Moreover, approximately 35% of stress echos are performed with color Doppler, and contrast agents are most often used in conjunction with stress echo. It is clearly inappropriate to provide payment of only approximately $306 for stress echo services, when current Medicare payment for echo contrast alone is over $200 and current payment for color Doppler alone is approximately $98.

Recommendations

For the reasons set forth above, we urge CMS to adopt the following policies in the HOPPS Final Rule:

Bundling of Doppler Studies

- We urge CMS not to bundle spectral or color Doppler this year, but to retain separate payment at least until 2009, when there will be a new CPT code that includes adult TTE, color Doppler, and spectral Doppler. At that time, we urge CMS to bundle spectral and Doppler only when these services are performed with adult TTE; to instruct hospitals to continue to use current coding (separate charges for CPT 93307, 93320 and 93325) rather than the new combined code; and to establish the APC rate for this code combination using the methodology described in the HOPPS Proposed Rule.

- If, **despite our strong opposition**, CMS decides to bundle Doppler services this year, CMS should do so only when Doppler services are performed in conjunction with adult TTE and should continue to allow separate billing for color and spectral Doppler performed with other "base" echo services.

- If, **despite our strong opposition**, CMS decides to bundle Doppler services with **all** echo "base" services this year, it should (a) refrain from bundling any color Doppler services (93325) into the allowance for stress tests (93017); and (b) ensure that all Doppler services are bundled into some echo "base" service – even if hospitals have failed to bill

these services with any other code or have billed these services which includes another "major procedure" code along with an echo "base" code. To the extent that the resulting distribution of Doppler services among echo "base" codes deviates from the data submitted on Attachment B, the data on Attachment B should be used to effectuate the accurate bundling of Doppler services.

- If, **despite our strong opposition**, CMS decides to proceed with its bundling proposal for Doppler this year, CMS should issue instructions to hospitals directing them to continue to use the Doppler codes (and any other bundled codes), since the frequency of utilization of these services will be used for future APC rate-setting purposes.

Bundling of Echo Contrast

- CMS should not bundle contrast agents into the APCs, since this exacerbates current disincentives to provide contrast.

- If, **despite our strong opposition**, CMS does decide to bundle contrast agents, CMS is *required by the governing statute* to establish a separate APC for contrast-enhanced echo studies. This would require the establishment of a number of new Level III HCPCS codes for contrast-enhanced resting and stress echo studies.

APC Classification of Stress Echo

- Regardless of whether and to what extent CMS adopts its bundling proposals in the Final Rule, CMS should continue to classify stress echo (CPT 93350) into the same APC as adult TTE (93307), rather than classifying this service into the APC that includes "limited" adult and congenital TTE.

We appreciate the opportunity to submit these comments, and look forward to meeting with you to discuss these issues at further length.

Sincerely yours,

/s/ *Thomas Ryan, MD/by DSM*

Thomas Ryan, MD
President

Attachment A

ASE Comments on the CY 2008 Physician Fee Schedule Proposed Rule
(Transmitted under separate cover).

Attachment B

Distribution of Doppler Claims among Echo "Base" Codes
(Transmitted under separate cover)

American Society of Echocardiography

August 6, 2007

Herb Kuhn, Acting Administrator
Centers for Medicare and Medicaid Administration
Department of Health and Human Services
CMS 1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD. 21244-1850

Re: CMS-1385-P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008. **CODING – ADDITIONAL CODES FROM 5-YEAR REVIEW.**

Dear Mr. Kuhn:

On behalf of the American Society of Echocardiography (ASE), I am writing to comment on the proposed changes in the Physician Fee Schedule (PFS) for CY 2008, published in the July 12, 2007 *Federal Register* (the "CY 2008 PFS Proposed Rule").

The ASE strenuously objects to CMS's proposal to "bundle" Medicare payment for color Doppler (CPT Code 93325) into all echocardiography ("echo") "base" services, effective January 1, 2008. This proposal:

- Is inconsistent with the approach to the "bundling" of color Doppler taken by the Relative Value Update Committee (RUC) – an approach that was taken at the urging of CMS;

- Is based on the faulty assumption that color Doppler is "intrinsic" to the performance of <u>all</u> echo services – an assumption that CMS has made despite ASE's prior transmittal of an analysis of Medicare claims that demonstrates that this assertion is incorrect; and

- Ignores the very real physician work and intra-service practice expenses associated with color Doppler – neither of which are reflected in any echo "base" services.

I. Background

A. Background: The Clinical Utility of Color Doppler

Color Doppler is performed in conjunction with one of the echo "base" imaging codes (transthoracic (TTE), transesophageal, congenital, fetal, or stress) to identify and quantify the severity of valvular malfunction, congenital lesions, myocardial dysfunction and other structural abnormalities. It is used to evaluate hemodynamic status, to select therapy, and to follow the results of treatment. Interpretation of the findings requires a systematic analysis of the color Doppler images, quantitation and integration of the data, and incorporation of this information into the echocardiographic report.

Careful review of color Doppler information is essential for decision making and patient management in a variety of clinical situations. This modality is typically the primary diagnostic technique used in determining optimum therapy for many conditions. For example, color Doppler provides quantitative diagnostic information on the severity of valve regurgitation and, therefore, is essential to identify patients with mitral or aortic regurgitation (in whom murmurs are not always audible and may be unimpressive) to optimize their treatment, and especially to identify those who are candidates for surgical repair.

In similar fashion, color Doppler is necessary for evaluating patients with more common clinical conditions, such as heart failure and acute myocardial infarction, to assess valvular, myocardial and hemodynamic status quantitatively. Color Doppler information is critical to the decision-making process in determining appropriate treatment and following up on the results of treatment. For example in these patients it is used to select patients for medical management versus surgical repair/replacement of valves and is used to assess myocardial synchrony to determine who does and does not need cardiac resynchronization therapy for heart failure.

B. Background: Valuation and "Bundling" of Color Doppler

CMS initially requested inclusion of CPT code 93325 in the five-year review because this service had not been subject to RUC review previously. Accordingly, in 2005 the ACC conducted a survey of the physician work associated with this code in accordance with established RUC survey procedures. Instead of considering the survey results, and based primarily on the fact that the number of claims for color Doppler approximated the number of claims for TTE, the RUC requested ACC to consider submitting a CPT code request that "bundled" color Doppler (but not spectral Doppler) into CPT code 93307.

Shortly thereafter, the ACC and ASE attempted to engage CMS in a dialogue on the issue, and sent an in-depth analysis to CMS setting forth numerous reasons to maintain current coding for color Doppler (the "2005 Position Paper") (Attachment A), including an independent consultant's study detailing the distribution of color Doppler services across echo base codes (the

"2005 Direct Research Analysis) [1] CMS did not respond until March 2, 2006, shortly before the Editorial Panel meeting.. At that time, CMS indicated in e-mail correspondence that: ***"If we decide to review this code {93325}, it will be as part of our usual rule-making process."*** (Emphasis added.) However, CMS did not convey to the CPT Editorial Panel any plan to handle the color Doppler issue in the context of the 2007 PFS, and the Editorial Panel referred the color Doppler back to the RUC "for valuation."

Prior to the next RUC meeting, attempts were made to confirm with the RUC and with CMS that the meeting would address color Doppler valuation – not bundling – and oral assurances were received from RUC sources. Despite these assurances, the RUC meeting once again focused on "bundling" of color Doppler. Subsequently, at the urging of the RUC and CMS, ACC submitted a request for a NEW CPT code for TTEs performed with **both** color and spectral Doppler (i.e., the combination of CPT codes 93307, 93325, and 93320). RUC staff confirmed in writing that this approach was consistent with the RUC's directive. The code request was approved by the Editorial Panel on June 7-10, 2007 and is scheduled for valuation by the RUC at its upcoming September meeting.

II. Comments

A. CMS's Color Doppler Proposal Is Inconsistent with the RUC Process

As discussed above, the RUC, with the full participation of CMS and based in part on what was understood as CMS's position, has already approved a new comprehensive transthoracic CPT code that bundles color Doppler (along with spectral Doppler) into a new CPT code for TTE (933xx). The new CPT code, which is slated for valuation by the RUC in September, 2007 and for implementation in 2009, addresses both spectral and color Doppler, and bundles Doppler services only with TTEs currently reported using CPT code 93307 – since 93% of color Doppler and 94% of spectral Doppler services are performed in conjunction with this base code. An estimated 400,000 Medicare claims (based on the 2005 Direct Research Report) and a substantial number of spectral Doppler services performed in conjunction with other echo "base" procedures remain separately reportable and separately payable. By contrast, CMS's proposal (a) bundles color Doppler with **all** echo base codes; and (b) does not address spectral Doppler.

It is unclear to us why CMS modified its view on this issue at this late date. However, we respectfully urge CMS to refrain from pre-empting all of the time and effort put into this matter by affected professional groups, the RUC, and the Editorial Panel by now adopting a completely different bundling policy which (as discussed below) does not reflect clinical practice insofar as it "bundles" color Doppler into "base" echo services with which color Doppler is not routinely performed.

[1] As discussed below, the 2005 Direct Research is analysis, which was also provided to the CPT Editorial Panel and the RUC (both of which include CMS representation), demonstrates that color Doppler is not an "intrinsic part" of all echo base codes.

B. Color Doppler Is Not "Intrinsic" to the Performance of **all** Echo "Base" Codes

Contrary to CMS's assumption (and as supported by the 2005 Direct Research Analysis), color Doppler is not "intrinsic" to the performance of all echo base services. In fact, the 2005 Direct Research Analysis that accompanied the 2005 Position Statement – which was provided previously to the RUC and Editorial Panel (including CMS) – demonstrates that the only echo "base" code with which color Doppler is billed more than 57% of the time (other than CPT code 93307) is the code for congenital echo (CPT 93303), which generally is not performed for Medicare beneficiaries. More recent data (Attachment C) drawn from the 5% Physician/Supplier Standard Analytic File for 2005 and analyzed by Direct Research (the 2007 Direct Research Report) confirms that this pattern has remained essentially unchanged: Of the 13 echo "base" codes, seven include color Doppler less than 50% of the time. Thus, CMS's own data demonstrate that the performance of color Doppler is not, in fact, "intrinsic" to all echocardiography services.

C. CMS's Color Doppler Proposal Ignores the Physician Work and Practice Expenses Involved in Color Doppler

CMS's proposal to "bundle" (and thereby eliminate payment for) color Doppler completely ignores the practice expenses and physician work involved in performance and interpretation of color Doppler studies. Thus the proposal ignores RUC valuations that were previously accepted, without providing any explanation.

Preliminarily, please note that, as the result of CMS's recent modifications of its Practice Expense Relative Value Unit (PE-RVU) methodology, Medicare payment for color Doppler is already slated to decline by **over 60%.** Therefore, if CMS's interest in bundling color Doppler arises from the unstated assumption that this service is overpriced, significant reductions are already scheduled to occur.

Regardless of the value assigned to color Doppler, providing this service unquestionably does involve real work. While the current work-RVUs associated with color Doppler are minimal, the physician work is real – and growing. (Currently, .07 work RVUs are assigned to this service, which equates to approximately $2.66, assuming the current conversion factor.) The ASE's Guideline entitled, "Recommendations for Evaluation of the Severity of Native Valvular Regurgitation with Two-dimensional and Doppler echocardiography," (www.asecho.org/freepdf/vavularregurg.pdf) details the physician work involved in color Doppler for the assessment of valvular disease:

> This technique [color Doppler] provides visualization of the origin of the regurgitation jet and its width (vena contracta), the spatial orientation of the regurgitant jet area in the receiving chamber and, in cases of significant regurgitation, flow convergence into the regurgitant orifice. The size of the regurgitation jet by color Doppler and its temporal resolution however, are

> significantly affected by transducer frequency and instrument settings such as gain, output power, Nyquist limit, size and depth of the image sector. Thus, full knowledge by the sonographer and interpreting echocardiographer of these issues is necessary for optimal image acquisition and accuracy of interpretation.

This document requires the interpreting physician to perform a number of measurements. Yet, CMS's proposal ignores the physician work involved, assuming (without basis or explanation) that the additional value of this work is 0.

Likewise, CMS's proposal utterly ignores the practice expenses involved in performing color Doppler studies. It appears that CMS believes that because echo equipment now universally incorporates color Doppler capability, and because color Doppler is often performed concurrently with the imaging and spectral Doppler components of echo studies, there are no practice expenses involved. In fact, however, the provision of color Doppler adds sonographer and equipment time to the study, both of which are recognized under CMS's PE methodology.

More specifically, the practice expenses recognized by the PEAC when this code was valued set forth in detail the resources required, and establish quite clearly that there was no "double counting" of the color Doppler and the base code practice expenses. Attachment E. To the contrary, the **total** practice expenses involved in color Doppler (CPT code 93325), spectral Doppler (CPT 93320) and transthoracic echo (CPT 93307) were valued **together,** in reference to two other ultrasound codes – Duplex scan of extracranial arteries; complete bilateral study (CPT 93880) and Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study (CPT 93975). The presenter argued, and the PEAC agreed, that the total clinical labor time involved in the provision of 93307, 93325, and 93320 (93 minutes), considered together, was greater than the clinical labor time for a duplex scan (82 minutes) and less than the clinical labor time for an abdominal arterial and venous study (108 minutes). Of the total combined 93 minutes of clinical labor time, 13 minutes was accorded to color Doppler (11 minutes of intraservice time was approved for data acquisition, and two minutes for processing, analyzing, and recording the results). Because color Doppler is always performed in the same session as an echo "base" code, no pre- or post service time was requested by the presenter or approved by the PEAC: To avoid double counting, all pre and post-service time – which should be allowed only once for the entire session – was associated with the "base" code.

The direct practice expense data published on the CMS website appears to reflect only 11 (rather than 13) minutes of staff time, and presumably direct expenses for the necessary echo equipment were estimated on the basis of staff time. There are no supply costs associated with color Doppler.

The sonographer time and skill involved in providing color Doppler is not insubstantial. The protocol for data acquisition for color Doppler requires the cardiac sonographer to perform numerous tasks and obtain a number of measurements, as reflected in the ASE standard entitled,

"Recommendations for Quantification of Doppler Echocardiography" at www.asecho.org/freepdf/RecommendationsforQuantificationofDopplerEcho.pdf , as well as in the vavular regurgitation standard at www.asecho.org/freepdf/vavularregurg.pdf). Thus, allocating 11 minutes of time for the cardiac sonographer to acquire, process, and record the preliminary results of a color Doppler study is, if anything, conservative. CMS's proposal to pay nothing for the cardiac sonographer's time, the equipment time, and associated overhead is entirely unsupportable. In fact, if CMS's proposal were adopted, the practice expenses involved in the performance of a complete TTE examination, including spectral and color Doppler services, would be less than the practice expenses involved in performing a duplex study, which clearly was not the intent of the PEAC.[2]

Moreover, the Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for CY 2008 includes an entirely different proposal for "bundling" color Doppler into echo base codes. Under this proposal, the practice expenses associated with **both color and spectral** Doppler are bundled: However, the Ambulatory Payment Classification (APC) rates of the associated "base" echo services are increased to account for the additional costs. While we have not yet fully analyzed the HOPPS color Doppler "bundling" proposal and we clearly disagree with the "bundling" rationale used in the HOPPS Proposed Rule for both spectral and color Doppler, the HOPPS "bundling" proposal at least does recognize the very real resources involved in the provision of color Doppler.

III. Our Request.

At this stage, the cardiology community is faced with no fewer than three proposals for "bundling" color Doppler into base echo codes:

- **Proposed PFS Approach**. This approach singles out *color Doppler* and "bundles" it into all echo codes, *without providing additional payment* on the grounds that color Doppler is an "inherent" part of echo. We disagree strongly with this approach and the underlying rationale.

- **Proposed HOPPS Approach**. This approach bundles Medicare payment for numerous add-on codes and other "ancillary support" services into the APC payment amounts for the associated principal procedures, and *increases APC rates* applicable to principal procedures proportionately. Under this proposal, *both spectral and Doppler* are bundled into all echo base codes, the former on the grounds that it is an "intra-operative procedure" and the latter on the grounds that it is an "image processing" service. In point of fact, neither of these rationales reflects an accurate understanding of cardiac Doppler services

[2] In fact, if this proposal is adopted, we believe that it would be appropriate to re-value the practice expenses accorded to both the carotid duplex and the AAA reference codes.

- **RUC Approach**. The RUC approach (taken with the apparent concurrence of CMS) would create a *new code* for the commonly performed combination of (resting) TTE (93307) with *color Doppler and spectral Doppler*, without bundling either spectral or color Doppler into any other echo base code. *Recommended valuation under the PFS would be provided by the RUC*, and payment under HOPPS for the new code would be determined in the interim final HOPPS rule for CY 2009.

Under these circumstances, we cannot help but conclude that CMS's approach to "bundling" of echo and other services is in need of additional study and coordination. **For this reason, we request a meeting that includes not only CMS personnel with authority over the CY 2008 PFS Proposed Rule but also those with authority over the CY 2008 HOPPS Proposed Rule, as soon as practicable.**

We appreciate the opportunity to comment on this proposal, and look forward to meeting with you to discuss the possibility of a more unified and well-reasoned approach to this issue.

Sincerely yours,

/s/ *Thomas Ryan, MD/by DSM*

Thomas Ryan, MD
President
ASE

Medicare 5% Sample LDS SAF Physician/Supplier File 2005.
All Claims Lines with the Indicated CPT Codes -- Crosstab Showing Add-on Codes Appearing With Base Codes

		Count of Claims With Add-on Codes					Percent of Base Code Claims Having Add-On Code					Percent of all Add-On Code Occurrences				
Base Codes	All Claims	93320	93321	93325	92978	92979	93320	93321	93325	92978	92979	93320	93321	93325	92978	92979
Total all claims	422,018	379,204	4,280	376,567	1,587	178						100%	100%	100%	100%	100%
No base code on claim	10,454	4,678	252	6,936	1,576	176						2%	1%	6%	2%	99%
76825	40	-	-	18	-	-	0%	0%	45%	0%	0%	0%	0%	0%	0%	0%
76826	5	-	-	3	-	-	0%	0%	60%	0%	0%	0%	0%	0%	0%	0%
76827	31	-	-	6	-	-	0%	0%	19%	0%	0%	0%	0%	0%	0%	0%
76828	22	-	-	6	-	-	0%	0%	27%	0%	0%	0%	0%	0%	0%	0%
93303	293	249		253	-	-	85%	0%	86%	0%	0%	0%	0%	0%	0%	0%
93304	44		16	28	-	-	0%	36%	64%	0%	0%	0%	0%	0%	0%	0%
93307	369,139	357,750	669	349,376	11		97%	0%	95%	0%	0%	87%	94%	16%	93%	1%
93308	5,327	654	2,262	2,115	-	-	12%	42%	40%	0%	0%	1%	0%	53%	1%	0%
93312	10,997	6,469	292	7,423	-	-	59%	3%	68%	0%	0%	3%	2%	7%	2%	0%
93314	1,008	431	65	531	-	-	43%	6%	53%	0%	0%	0%	0%	2%	0%	0%
93315	102	58		61	-	-	57%	0%	60%	0%	0%	0%	0%	0%	0%	0%
93317	64	48	-	15	-	-	75%	0%	23%	0%	0%	0%	0%	0%	0%	0%
93350	24,492	8,861	716	9,796	-	-	36%	3%	40%	0%	0%	6%	2%	17%	3%	0%

Note: Totals reflect 5% sample data. Multiply by 20 to get estimated US totals. Data blanked if fewer than ten claims.

CY 2007

CPT/ HCPCS	Description	CI	SI	APC	Relative weight	Payment rate	*Indicates a Change
93308	Echo exam of heart		S	0697	1.60	98.18	
93304	Echo transthoracic		S	0697	1.60	98.18	
93320	Doppler echo exam, h	CH	S	0697	1.60	98.18	
93321	Doppler echo exam, heart		S	0697	1.60	98.18	
93325	Doppler color flow add-on		S	0697	1.60	98.18	
93303	Echo transthoracic		S	0269	3.22	197.64	
93350	Echo transthoracic		S	0269	3.22	197.64	
93307	Echo exam of heart		S	0269	3.22	197.64	
93312	Echo transesophageal		S	0270	6.25	384.21	
93313	Echo transesophageal		S	0270	6.25	384.21	
93314	Echo transesophageal		N				
93315	Echo transesophageal		S	0270	6.25	384.21	
93316	Echo transesophageal		S	0270	6.25	384.21	
93317	Echo transesophageal		N				
93318	Echo transesophageal intraop		S	0270	6.25	384.21	

Proposed 2008

93350	Echo transthoracic	CH	S	0697	4.8072	306.18	
93308	Echo exam of heart		S	0697	4.8072	306.18	
93304	Echo transthoracic		S	0697	4.8072	306.18	
93303	Echo transthoracic		S	0269	6.5908	419.79	
93307	Echo exam of heart		S	0269	6.5908	419.79	
93312	Echo transesophageal		S	0270	8.42	536.30	
93313	Echo transesophageal		S	0270	8.42	536.30	
93314	Echo transesophageal		N				
93315	Echo transesophageal		S	0270	8.42	536.30	
93316	Echo transesophageal		S	0270	8.42	536.30	
93317	Echo transesophageal		N				
93318	Echo transesophageal intraop		S	0270	8.42	536.30	
93320	Doppler echo exam, h	CH	N				
93321	Doppler echo exam, h	CH	N				
93325	Doppler color flow add	CH	N				

Submitter : Dr. Roger Schechter **Date:** 08/27/2007

Organization : Palomar Wound Care Center - San Marcos

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Skin Substitute.
To Whom It May Concern,
I am concerned about the reimbursement rate for the Apligraf, skin substitute. This product has been able to heal patients with chronic difficult to treat/heal venous leg ulcers and diabetic foot ulcers. I have utilized this product with great success and the fear of losing reimbursement extends to patient care. I am concerned patients that need the product and benefit from its efficacy will not have access to the product. It is important that all patients regardless of coverage should have access to the advanced therapies that are offered in wound care, specifically Apligraf. Please reconsider the decision and continue your support for Apligraf and the continued support of my efforts for healing patients in a timely manner, which not only saves limbs but also effieiently treats patients by lowering incidence of infection or amputation, therefore leading to more expensive treatment. Thank you.
Roger Schechter, MD., FACEP, FCCWS

Submitter : Dr. Gerit Mulder **Date:** 08/27/2007

Organization : University of California, San Diego Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Skin Substitute
August 27, 2007

Mr. Kerry Weems
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

ATTN: CMS-1392-P
Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Skin Repair Procedures

Dear Administrator Weems:
University of San Diego, Wound Care appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. University of San Diego is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.
We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.
In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogencity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf s CPT procedure codes do not account for the actual clinical resource use in our experience.
We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.
Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf
We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.
Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Gerit Mulder at (619) 543-7276.
Sincerely,
Gerit Mulder, DPM, MS
Director, Wound Treatment & Research Center
Associate Professor of Surgery & Orthopedics

Submitter : **Dr. Joseph Curletta** **Date: 08/27/2007**

Organization : **Dr. Joseph Curletta**

Category : **Physician**

Issue Areas/Comments

New Technology APCs

New Technology APCs

Implantation of Spinal Neurostimulators.

I recently learned the CMS is recommending that rechargeable neurostimulators be grouped with non-rechargeable neurostimulators in Ambulatory Payment Classification 0222, despite a significant cost differential between the types of products (approximately $6500). For the reasons I will outline below, this proposal appears to defy any modicum of logic.

Patients with non-rechargeable impulse generators, in my practice, would typically require 4 impulse generators in a 10-year period of time versus one rechargeable impulse generator over that same 10-year period. This obviously represents a large cost savings to Medicare and an undeniable clinical benefit to the patient, who would require three less impulse generators and disrupting surgical interventions. For obvious reasons, the rechargeable generators can also be made smaller and there therefore much more comfortable and less intrusive to the patient.

I would therefore only recommend implementing APC 0222 if your intent was to spend larger sums of money on lesser medical care, since clinicians would have no choice but to revert to non-rechargeable systems. Thank you for this opportunity to comment on proposed healthcare changes. Please feel free to contact me if I can provide you with any further information.

Submitter : **Mr. John Shliapa** **Date: 08/27/2007**

Organization : **South County Physical Therapy**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is John Shliapa and I am employed by South County Physical Therapy in Auburn, MA. I do clinical work in the clinic for approximately 15-20 hours a week and work in a secondary school for approximately 20-25. I attended Northeastern University where my education consisted of cooperative education, clinical rotations, as well as a intense curriculum. I earned a Bachelor of Science in Athletic Training and am now certified by the National Athletic Trainers Association Board of Certification.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

John Shliapa, ATC

Submitter : **Dr. Julio Paez** **Date: 08/28/2007**

Organization : **South Lake Pain Institute**

Category : **Physician**

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Rc: Implantation of Spinal Neurostimulators.
I urge you to to create a separate APC for rechargeable neurostimulators to ensure continued patient access to this vital therapy.
Rechargable and non rechargable ARE NOT the same thing. If anything you could lower non rechargable since it has an added cost to be replaced.
Thanks for allowing my imput
Julio Paez MD

#189

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : **Ms. Donna Bennett** **Date: 08/28/2007**

Organization : **Boston College Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a certified athletic trainer who has worked in the area of sports medicine for the past 30 years. I feel that the high school athlete can be adversely affected if there are restrictions to outpatient rehabilitation services as to how athletic trainers can be utilized in the clinical/secondary school work setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that these regulations NOT be passed.
Donna Bennett, MS, LAT, ATC