CMS-1392-P-554 **Medicare**

Submitter : Ms. Louise McCleery **09/10/2007**

Organization : Upper Connecticut Valley Hospital
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

see attached

#5514

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1392-P-555 **Medicare**

Submitter : Dennis Kemp **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMSys proposal to bundle the payment rate to hospitals for physician-injected drugs.y I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms.y Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.y

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me.y The guidance service is critically important for this treatment to be effective.y
Thank you for allowing me to provide these comments.
Sincerely,
Dennis Kemp

CMS-1392-P-556 **Medicare**

Submitter : Mrs. Joan Buettner **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with cervical dystonia, (dystonia is a movement disorder resulting from sustained involuntary muscle spasms). I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia. I have to continue to work full-time, and while the pain associated with cervical dystonia bothers me at work, I have no choice BUT to work. My family relies on me for our health insurance.
I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective. Thank you for allowing me to provide these comments.
Sincerely,
Joan M. Buettner
Harrisburg, PA 17111

CMS-1392-P-557 **Medicare**

Submitter : Ms. Louise McCleery **09/10/2007**

Organization : Upper Connecticut Valley Hospital
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

see attached

#557

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1392-P-558 **Medicare**

Submitter : Raman Patel **09/10/2007**

Organization : I am a Patient with Dystoniia
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services.
However, as a patient with Torticollis (a type of dystonic movement disorder resulting in 24/7 pain in the neck and, sustained involuntary muscle spasms), I am very concerned about CMS proposal to bundle the payment rate to hospitals for physician-injected drugs.
I routinely receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to live life as best as I can, with manageable neck pain and pulling.
I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change will result in continuous deterioration of quality CARE from the speciality doctors. Madicare and Medicaid is already squeezing the speciality doctors with less and less payment!
Sincerely,
Raman S Patel
811 E Sage Road
West Chester, PA 19382

CMS-1392-P-559 **Medicare**

Submitter : Mrs. Rita Novak **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding CMS-1392-P
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with spasmodic torticollis, (a movement disorder resulting from sustained involuntary muscle spasms), I have concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally. I respectfullly request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve spasms. Also this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
As a person who has had this disorder for 30 years, I know first hand how it affects your quality of life.
Thank you for allowing me to provide these comments.

Sincerely,

CMS-1392-P-560 **Medicare**

Submitter : **09/10/2007**

Organization :
Nurse

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I maintain that the guiding principles of APC reimburesment were stated April 7, 2000, and your straying from a fundamental rule is a radical departure . Please stick to the original guidelines for expensive items, such as fluorodeoxyglucose and any item over $100 in real cost :

Federal Register / Vol. 65, No. 68 / Friday, April 7, 2000 / Rules and Regulations 18447

Response: We are persuaded by commenters arguments that packaging payment for certain expensive items and services into an APC group rate could have such a potentially negative impact as to jeopardize beneficiary access to these items and services in the hospital outpatient setting. Therefore, in response to comments, we are not packaging within an APC payment rate the costs associated with certain

specified items and services. Instead, we will make a separate APC payment for these particular items and services under the outpatient PPS.

CMS-1392-P-561 Medicare

Submitter : Ms. Linda Knadler **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

The Letter #1:

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with cervical dystonia, (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. When receiving the botulinum injections, an emg machine is used in order to determine which muscles are experiencing these symptoms. Both the emg machine service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring

doctors not to utilize this equipment which could result in the injections becoming less effective. Obviously, knowing the right muscles in which to inject the botulinum toxin is critically important for this treatment to be effective.

Thank you for allowing me to provide these comments.

Sincerely,

Linda Knadler

CMS-1392-P-562 **Medicare**

Submitter : Ms. Grace Elinsway **09/10/2007**

Organization : Ms. Grace Elinsway
Other Health Care Professional

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
Thank you for allowing me to provide these comments.

Sincerely,
Grace Elinsway

CMS-1392-P-563 **Medicare**

Submitter : **09/10/2007**

Organization :
Health Care Professional or Association

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-563-Attach-1.PDF

#563

CYBERKNIFE
CKC
COALITION

September 10, 2007

Submitted electronically via attachment to
http://www.cms.hhs.gov/eRulemaking

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: File Code: CMS-1392-P

Dear Administrator Weems:

The CyberKnife® Coalition is a non-profit association of thirty-seven (37) institutions across the United States committed to improving patient access to radiosurgery that can be performed throughout the body. We appreciate the opportunity to comment to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule for the hospital outpatient prospective payment system for calendar year (CY) 2008, CMS-1392-P "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates."

Background

Medical linear accelerators (LINACs) were developed in the 1960's and allowed physicians to deliver isocentric radiation treatments to tumors over several weeks while sparing normal tissue. Advancements in computer and linear accelerator technology in the 1980's led to 3-dimensional conformal radiation (3D-CRT) and image-guided radiation therapy (IGRT), which combined computed tomography (CT) imaging with LINAC technology to identify the location of a lesion before and after a treatment session. In the 1990's, intensity modulated radiation therapy (IMRT) further customized the shape of the radiation field to better conform to the lesion.

In the 1950's and 1960's, frame-based stereotactic radiosurgery (SRS) was developed to deliver radiation with a high degree of accuracy to the brain and skull base. This intracranial treatment relies on placement and adjustment of an external head frame and manual positioning of the patient. The accuracy afforded by this technology allows delivery of large, single, ablative doses of radiation. Then, in the late 1990's, image-guided robotic stereotactic radiosurgery (r-SRS) was developed; this technology provides two significant advantages over traditional radiosurgery : (1) no head or body frames are required, and (2) the flexibility of non-isocentric treatments allows for highly conformal treatments throughout the body together with a significant decrease in the amount of radiation delivered to normal tissue.

Proposed Treatment of Image-guided Stereotactic Radiosurgery

At present, the OPPS payment system groups SRS in three ambulatory payment classifications (APCs). For CY 2008, however, the Centers for Medicare & Medicaid Services (CMS) has proposed to include two disparate technologies together with r-SRS in these APCs. The CyberKnife Coalition strongly disagrees with this proposal, because we believe that it does not maintain the degree of coherence in clinical and resource terms that CMS usually maintains and that is exhibited by other APCs. The two technologies are ultrasound ablation of uterine fibroids with magnetic resonance guidance (MRgFUS) and magnetoencephalography (MEG). Neither of these technologies is similar to SRS, and we urge CMS to move them to APCs more in accord with their clinical characteristics and resource uses.

Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

MRgFUS is not similar to SRS. MRgFUS is a system by which high intensity focused ultrasound heats and destroys uterine fibroid tissue using sound waves. The mechanism of treatment for MRgFUS is most similar to that of Radiofrequency Ablation (RFA). Both MRgFUS and RFA ablate tissue by raising the temperature high enough to lead to cell death. By contrast, stereotactic radiosurgery utilizes precisely targeted, large doses of radiation to destroy tumors and treat other select disorders anywhere in the body (for instance, in brain, lung, or spine). Because of the longer duration of treatment, the requirements for monitoring and adjusting to patient movement are much greater.

Furthermore, the two technologies differ significantly in resource utilization. Unfortunately, claims information provides little reliable guidance on this point. MRgFUS is performed on very few Medicare patients and, therefore, very few claims are available. In CY 2005, for example, only two claims were submitted with a HCPCS code associated with MRgFUS.

The nature of the two treatments,h owever, provides a strong indication of resource differences. When using MRgFUS,t he treatment table containing the ultrasound transducer used to perform MRgFUS is rolled into conventional MRI equipment and the table is docked directly onto an existing MR scanner. The same MRI machine used to provide MRgFUS is also used to perform conventional MRI procedures and, therefore, does not represent an additional capital expense for the hospital. Moreover, no separate build-out is needed to house the equipment, since an existing diagnostic suite is used to perform MRgFUS. In comparison, stereotactic radiosurgery requires a lead-shielded vault, complete with special weighted mounting. SRS systems are dedicated to the treatment of tumors and select disorders with high dose radiation; they are not used to perform other procedures that could mitigate resource requirements. Additionally, SRS treatment times are longer. Therefore, both operating and capital expenses are commensurately larger.

We therefore urge reconsideration of the proposal to move MRgFUS into stereotactic radiosurgery APCs. We agree with the agency's assessment in the CY 2007 OPPS final rule that retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

Magnetoencephalography (MEG)

Similarly, MEG is also substantially dissimilar to SRS. MEG is a diagnostic imaging technique used to measure magnetic fields produced by electricalac tivity in the brain. MEG, also known as Magnetic Source Imaging (MSI), is much like Magnetic Resonance Imaging (MRI). Both MEG/MSI and MRI produce internal images by recording magnetic signals and are used to provide information to aid in diagnosis. Their use is limited to obtaining information about the brain for diagnostic purposes. SRS, on the other hand, is a therapeutic medical procedure that utilizes large, precisely targeted doses of radiation to destroy tumors and treat select disorders anywhere in the body.

MEG is also performed on very few Medicare beneficiaries. Between CY 2002 and 2005, no more than 23 claims were submitted for one MEG CPT code. The other two MEG CPT codes together accounted for only eight claims during those years

In light of the significant differences between a diagnostic tool such as MEG/MSI and a therapeutic medical procedure such as SRS, we request CMS reconsider its proposal to assign MEG/MSI to the stereotactic radiosurgery APCs. Moreover, we agree with the agency's previous comments indicating that resource and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

SRS Treatment Delivery Services

We support CMS's proposal to continue use of HCPCS codes G0173, G0251, G0339, and G0340. We agree with the assessment that these codes are more specific in their descriptors than available CPT codes, and that hospital claims data continue to reflect significantly different use of hospital resources. Adoption of a smaller set of CPT codes with less specific descriptors would not appropriately reflect the resource costs of these procedures to hospitals and would result in violations of the two times rule.

For CY 2004, CMS created two HCPCS codes, G0339 and G0340, in order to accurately distinguish image-guided robotic SRS systems from other forms of linear accelerator-based SRS systems and to account for the cost variation in delivering these services (CMS-1392-P). And, while there is now three years of hospital claims data, examination of the data reveals that ongoing confusion among hospital providers about appropriate coding, resulting in cost and utilization data for SRS systems of all types being captured in the image-guided robotic SRS codes.

Since the agency's intent for CY 2008 is to continue using the G-codes for reporting LINAC-based SRS treatment delivery services under the OPPS, and to ensure appropriate payment to hospitals for the different facility resources associated with providing these services , we respectfully suggest minor revisions be made to the coding descriptors for clarification purposes. We believe that coding confusion and thus inappropriate payments relate to the concept of 'image-guided robotics.' The Coalition believes that clarification of the descriptors is

necessary in order to achieve the results intended by the agency's 2004 revisions, and we would be grateful for the opportunity to work together to accomplish these goals.

Conclusion

In summary, we urge CMS to:

- Not adopt its proposal to assign MRgFUS to the APCs for SRS. As indicated in the CY 2007 OPPS finalr ule, retaining MRgFUS procedures in clinicalA PCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

- Not adopt its proposal to assign MEG to the APCs for SRS. As recommended by CMS in the August 2005 APC Panel Meeting, resources and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Levell V Nerve and Muscle Tests.

- Retain the SRS HCPCS codes, G0173, G0251, G0339, and G0340. Further, we request that CMS clarify the associated code descriptors to achieve the agency's goal of distinguishing image-guided robotic stereotactic radiosurgery (r-SRS) systems from other LINAC systems.

Sincerely,

Linda F. Winger
President, CyberKnife® Coalition

CMS-1392-P-564 **Medicare**

Submitter : Dr. George Rizk **09/10/2007**

Organization : Cedars Cardiovascular, PC
Physician

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

To Whom It May Concern:

The Medicare cuts are heavily out of balance with the increased cost of living.

It has come to my attention that Medicare had proposed to bundle the Color Flow Doppler CPT code 93325 into all echocardiography services.

The color doppler information is critical for the decision making process in patients with suspicion of heart valve disease, as well as appropriate selection of patients for valve surgery, or medical management. In addition, a color flow doppler is important in the accurate diagnosis of many other cardiac conditions.

When a color doppler is performed, extra time is necessary by both the Physician and the Technician over and above the general echo study process.

Physicians like myself are being forced out of quality practice with the ongoing Medicare cuts. It has become increasingly difficult to satisfy staff salary and to cover overhead expense.

Please do not bundle code 93325 with all echocardiography.

Respectfully,

George T. Rizk MD FACC

CMS-1392-P-565 **Medicare**

Submitter : **09/10/2007**

Organization :
Device Industry

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-565-Attach-1.PDF

#565

ACCURAY

September 10, 2007

Submitted electronically via attachment to
http://www.cms.hhs.gov/eRulemaking

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments to Proposed Rule [File Code: CMS-1392-P]

Dear Administrator Weems:

Accuray Incorporated is a producer of image-guided robotic stereotactic radiosurgery (r-SRS) equipment used around the world to treat malignant and benign tumors and other select disorders with high dose,p recisely targeted radiation. On behalf of Accuray, I thank you for the opportunity to comment to the Centers for Medicare and Medicaid Services (CMS) on CMS-1392-P,M edicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates.

Background

Medical linear accelerators (LINACs) were developed in the 1960's and allowed physicians to deliver isocentric radiation treatments to tumors over several weeks while sparing normal tissue. Advancements in computer and linear accelerator technology in the 1980's led to 3-dimensional conformal radiation (3D-CRT) and image-guided radiation therapy (IGRT) which combined computed tomography (CT) imaging with LINAC technology to identify the location of a lesion before and after a treatment session. In the 1990's, intensity modulated radiation therapy (IMRT) further customized the shape of the radiation field to better conform to the lesion.

In the 1950 and 1960's frame-based stereotactic radiosurgery (SRS) was developed to deliver radiation with a high degree of accuracy to the brain and skull base. This intracranial treatment relies on placement and adjustment of an external head frame and manual adjustment of the patient. The accuracy afforded by this technology allows delivery of large, single, ablative doses of radiation. Then, in the late 1990's, image-guided robotic stereotactic radiosurgery (r-SRS) proved significantly different from traditional radiosurgery in two ways: 1) no head or body frames are required, and 2) the flexibility of non-isocentric treatments allows for highly conformal treatments throughout the body together with a significant decrease in normal tissue radiation.

At present, the OPPS groups SRS into three ambulatory payment classifications (APCs). For

CY 2008, however, CMS has proposed including two disparate technologies together with SRS in these APCs. Accuray strongly disagrees with this proposal, because we believe that it does not maintain the clinical and resource-related coherence that CMS usually maintains and that is exhibited by other APCs. The two technologies are ultrasound ablation of uterine fibroids with magnetic resonance guidance (MRgFUS) and magnetoencephalography (MEG). Neither of these technologies is similar to SRS and we urge CMS to move them to APCs more in accord with their clinical characteristics and resource uses.

Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

MRgFUS is not clinically similar to SRS. MRgFUS, a system by which high intensity focused ultrasound heats and destroys uterine fibroid tissue using sound waves. The mechanism of treatment for MRgFUS is most similar to that of Radiofrequency Ablation (RFA). Both MRgFUS and RFA ablate tissue by raising the temperature high enough to lead to cell death. By contrast, stereotactic radiosurgery utilizes precisely targeted, large doses of radiation to destroy tumors and treat other select disorders anywhere in the body (e.g., brain, lung, or spine).

Furthermore, the two technologies differ significantly in resource utilization. Unfortunately, claims information provides little reliable guidance on this point. MRgFUS is performed on very few Medicare patients and, therefore, very few claims are available. In CY 2005, for example, only two claims were submitted with a HCPCS code associated with MRgFUS.

The nature of the two treatments,h owever, provides a strong indication of resource differences. During MRgFUS, the treatment table containing the ultrasound transducer used to perform the procedure is rolled into conventional MRI equipment and the table is docked directly onto an existing MR scanner. The same MRI machine used to provide MRgFUS is also used to perform conventional MRI procedures and, therefore, does not represent an additional capital expense for the hospital. Moreover, no separate build out is needed to house the equipment, since an existing diagnostic suite is used to perform MRgFUS. In comparison, stereotactic radiosurgery requires the build out or retrofit of a lead-shielded vault, complete with special weighted mounting. Aside from the need for custom site construction, SRS systems are dedicated to the treatment of tumors and select disorders with high dose radiation; they are not used to perform other procedures that could mitigate resource requirements. Additionally, SRS treatment times are longer. Therefore, both operating and capital expenses are commensurately larger.

Accordingly, we urge reconsideration of the proposal to move MRgFUS into stereotactic radiosurgery APCs. We agree with the agency's assessment in the CY 2007 OPPS final rule that retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

Table A. Overview of Clinical and Resource-Related Differences Between SRS and MRgFUS

Clinical/Resource Consideration	Stereotactic Radiosurgery	MRgFUS
Treatment Indication(s)	Treatment of benign and malignant tumors; other select disorders	Treatment of fibroids
Area(s) Treated	Anywhere in the body (e.g., brain, spine, lung, and liver)	Uterus

Patient Population	Men and women; Medicare and non-Medicare beneficiaries	Women under 65; Commercial insurance patients
Mechanism of Treatment	Precise, high-dose radiation	Focused ultrasound
Clinically Comparable Treatment(s)	Open surgery; radiation therapy	Radiofrequency ablation
Build-Out Requirements	Separate lead-shielded vault with special weighted mounting	No build-out required; diagnostic suite used
Additional Uses for Equipment	None; dedicated to radiosurgery	MRI equipment used for traditional imaging services
Claims Data Available (2005)	6,751 claims submitted[1]	2 claims submitted

Magnetoencephalography (MEG)

Public comments were not solicited regarding the reassignment of Magnetoencephalography (MEG) to Level I, II, and III Stereotactic Radiosurgery APCs. However, since the descriptor in the proposed rule for this series of payment classifications includes a change to incorporate MEG, and since this change is inconsistent with the agency's policy of homogeneity within payment groups, we believe that public input is warranted.

MEG is also substantially dissimilar to SRS. It is an imaging technique used to measure magnetic fields produced by electrical activity in the brain. MEG, a diagnostic tool also known as Magnetic Source Imaging (MSI), is much like Magnetic Resonance Imaging (MRI). Both MEG and MRI produce internal images by recording magnetic signals and are used to provide information to aid in diagnosis. Their use is limited to obtaining information about the brain for diagnostic purposes. SRS, on the other hand is a therapeutic medical procedure that utilizes precisely targeted, large doses of radiation to destroy tumors and treat other select disorders anywhere in the body. SRS is clinically comparable to open surgery or, in some cases, other forms of radiation treatment.

Like MRgFUS, MEG is also performed on very few Medicare beneficiaries and, therefore, very few claims exist for comparative purposes. Between CY 2002 and 2005, no more than 23 claims were submitted for one of the three MEG CPT codes. The other two MEG CPT codes were reported on only eight claims combined during those years. Without sufficient claims data, a justification for resource similarity is difficult to make.

In light of the significant differences between a diagnostic tool such as MEG and a therapeutic medical procedure such as SRS, we request CMS reconsider its proposal to assign MEG to the stereotactic radiosurgery APCs. Moreover, we agree with the agency's previous comments indicating that resource and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

[1] Number reflects single claims (used in rate setting) submitted in 2005 with a SRS or r-SRS HCPCS code: G0173, G0251, G0339, or G0340.

Table B. Overview of Clinical and Resource-Related Differences Between SRS and MEG

Clinical/Resource Consideration	Stereotactic Radiosurgery	MEG
Reason for Use	Therapeutic medical procedure	Diagnostic tool
Indications	Treatment of benign and malignant tumors; other select disorders	Measure electrical signals to aid in diagnosis
Area(s) Treated	Anywhere in the body (e.g., brain, spine, lung, and liver)	Brain
Mechanism of Treatment	Precise, high-dose radiation treats lesions and select disorders	Not a therapeutic treatment; used in conjunction with other diagnostic data in neurosurgical planning
Clinically Comparable Treatment(s)	Open surgery; radiation therapy	Not a therapeutic treatment
Claims Data Available (2005)	6,751 claims submitted[2]	31 claims submitted (CY 2002 – 2005)[3]

SRS Treatment Delivery Services

We support CMS in its proposalt o continue use of HCPCS codes G0173, G0251, G0339, and G0340. We agree with the assessment that these codes are more specific in their descriptors than available CPT codes, and that hospital claims data continue to reflect significantly different hospital resources which would lead to violations of the 2 times rule if the codes were crosswalked to CPT codes with less specific descriptors.

For CY 2004, CMS created two new Level II HCPCS codes, G0339 and G0340, in order to accurately distinguish image-guided robotic SRS systems from other forms of linear accelerator-based SRS systems and to account for the cost variation in delivering these services (CMS-1392-P). And, while there is now three years of hospital claims data, examination of the data reveals that there has been ongoing confusion among hospital providers resulting in cost and utilization data for SRS systems of all types being captured in the image-guided robotic SRS codes.

Since the agency's intent for CY 2008 is to continue using the G-codes for reporting LINAC-based SRS treatment delivery services under the OPPS, and to ensure appropriate payment to hospitals for the different facility resources associated with providing these complex services (CMS-1392-P), we respectfully suggest minor revisions be made to the coding descriptors for clarification purposes. We believe that coding confusion and thus inappropriate payments relate to the concept of 'image-guided robotics.' We believe that clarification of the descriptors is necessary in order to achieve the results intended by the agency's 2004 revisions, and we would be grateful for the opportunity to work together to accomplish these goals.

[2] Number reflects single claims (used in rate setting) for claims submitted in 2005 with a SRS or r-SRS HCPCS code: G0173, G0251, G0339, or G0340.
[3] Number reflects all claims submitted between CY 2002 and 2005. No breakdown specific to 2005 available.

Conclusion

In summary, we appreciate the opportunity to comment and urge the agency to implement the following recommendations:

- MRgFUS is unlike SRS based on clinical coherence and resource utilization and, therefore, should not be moved into SRS APCs. As indicated in the CY 2007 OPPS final rule, retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

- MEG, a diagnostic tool akin to MRI and used to measure magnetic fields produced by electrical activity in the brain, is in no way clinically similar to SRS, a radiation-based therapeutic medical procedure for the treatment of tumors and other disorders. Therefore, MEG should not be moved into APCs for SRS. As recommended by CMS in the August 2005 APC Panel Meeting,r esources and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

- Level II HCPCS codes,G 0173, G0251,G 0339,and G0340 should be retained. Further, we request clarification of the code descriptors in order for the agency to achieve its goals of distinguishing image-guided robotic stereotactic radiosurgery (r-SRS) systems from other LINAC systems, and accounting for the cost variation in delivering these complex services.

Sincerely,

Wendy Wifler
Sr. Director, Health Policy and Payment
wwifler@accuray.com
Tel (949) 246-7970

CMS-1392-P-566 **Medicare**

Submitter : Mr. Timothy Wick **09/10/2007**

Organization : Burnett Medical Center
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

Dear Deputy Administrator Kuhn,

I am writting in response to the proposed rule referenced above,specifically in regards to proposals made affecting the Critical Access Hospital(CAH) program. I am the CEO at Burnett Medical Center in Grantsburg,WI.

We have been a CAH since October of 2003 and have been operating a provider-based rural health clinic since 2002. We are interested in expanding our clinic locations in Burnett County which is a medically underserved area. We are concerned that the above proposal would limit our ability to continue to extend our services out to rural seniors and meet their needs as close to their homes as possible.

Due to these concerns, I respectively request that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAH's. Suh a provision would limit our abiliy to extend ourselves into the underserved communities we serve. We believe this is not the intention of the CAH program which is to provide financial stability for small rural hospitals to serve their communities.

Thank you for considering these comments. Feel free to contact me(715-463-5353) if you have any questions.

Cordially,

Timothy J. Wick
CEO-Burnett Medical Center
Grantsburg,WI 54840

CMS-1392-P-567 **Medicare**

Submitter : Mrs. Ilona Horton **09/10/2007**

Organization : Adventist Health/Redbud Community Hospital
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1392-P-568 **Medicare**

Submitter : Mr. allen overlander **09/10/2007**

Organization : Mr. allen overlander
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with ST Dystonia, I have serious conserns about CMS's proposal to reduce the payment rate to hospital for patient-injected drugs. I receive injections of botulinum toxin to alleviate the debiliting dystonic symptoms. These injections are critically important to my ability to function normally.

1. I RESPECTFULLY REQUEST THAT CMS NOT CHANGE THE PAYMENT FOR PHYSCIAN-INJECTABLE DRUGS FOR 2008, AND INSTEAD MAINTAIN THE CURRENT PAYMENT FORMULA. Any reductions in reimbursement will lead to fewer injecters in an area where we have too few knowledgeable injecters in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalities to providers, depending on where the injections are given.

2. Thank you for allowing me to provide these comments.
3. Sincerely,

CMS-1392-P-569 **Medicare**

Submitter : Dr. eric marcus **09/10/2007**

Organization : private practice
Physician

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with spasmodic torticolis, I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.

Thank you for allowing me to provide these comments.

Sincerely,

Eric H. Marcus, MD

CMS-1392-P-570 **Medicare**

Submitter : Michele Yann **09/10/2007**

Organization : Michele Yann
Health Care Professional or Association

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Not all echocardiograms need echo contrast only those with suboptimal visualization of the endocardium. In some instances it is essential to have good endocardial definition while in other instances evaluating function is not the priority. Using contrast takes added time, personel and cost and should therefore be an additional cost as compared to a routine echocardiogram.
Michele Yann,RN,RDCS

CMS-1392-P-571 **Medicare**

Submitter : Ms. Shanna Forman **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear CMS, Please do not change the payment formula for doctor-injectable drugs for 2008. Please maintain the current payment formula. I have spasmodic torticollis and Botox has given me back my life. Any changes in the system could affect my treatment and take away my quality of life.

Thank you for giving me the opportunity to make my voice heard.

Sincerely,
Shanna Forman

CMS-1392-P-572 **Medicare**

Submitter : Mr. George Goff **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

I have Spasmodic Dystonia and receive botulinum toxin injestions to relieve symptoms. I request that the current payment formula be maintained for 2008. Thank you.

CMS-1392-P-573 **Medicare**

Submitter : Mrs. Rita Novak **09/10/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P,OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with spasmodic torticollis a movement disorder resulting from sustained involuntary muscle spasms, I have serious concerns about CMS's proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective. I have had this condition for 30 years, and if you know anything about the condition, you would not try and change anything, especially when it would make it

harder for me to cope every day. It is bad enough to have to live with this dystonia, so please do not make it any harder to handle. I am not talking for myself only, but also for my family (my caretakers). Please leave things the way they are.

Thank you for allowing me to provide these comments.

Sincerely,

Rita J. Novak

CMS-1392-P-574 **Medicare**

Submitter : Dr. Robert Jason **09/10/2007**

Organization : ExAblate of Metro New York Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-574-Attach-1.DOC

#574

Robert A. Jason, M.D. FACOG
1999 Marcus Ave. Suite 108 • Lake Success, NY 11042
Off. (516) 466-4020•Fax (516) 773-6617

September 13, 2007

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

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

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

Dear Deputy Kuhn:

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

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

I welcome CMS' proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

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

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

I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

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

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Robert A. Jason, MD FACOG
Medical Director
ExAblate of Metro New York/Long Island
Tel. 516 466 4020
Fax. 516 773 6617
Toll Free: 1-877 EXABLATE
email: drjason@lvri-ny.com
website: www.exablateofmetronewyork.com

CMS-1392-P-575 **Medicare**

Submitter : T. Jordan **09/10/2007**

Organization : T. Jordan
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Sir, Madam, AS A REGISTERED VOTER, I would like to remind you that this legislation,referencing-Docket:Cms-1392-P,will add financial stress to a population already dealing with physical,emotional and even some instances mental hardships.I would urge very,very deep consideration to not changing benefits to the outpatient payment system proposed in DOCKET:CMS-1392-P.---THANK YOU-Jordan

CMS-1392-P-576 **Medicare**

Submitter : Mr. Paul Pitts **09/10/2007**

Organization : Bio-Tissue, Inc.
Health Care Industry

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Status Indicators

Status Indicators

See Attachment

CMS-1392-P-576-Attach-1.PDF

CMS-1392-P-576-Attach-1.PDF

#576

BIO

September 10, 2007

BY ELECTRONIC FILING AND OVERNIGHT MAIL

Hon. Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4–26–05,
7500 Security Boulevard
Baltimore, MD 21244–1850

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

Dear Ms. Norwalk:

Bio-Tissue, Inc. ("Bio-Tissue") is pleased to submit the following comments to the above referenced proposed rule (the "Proposed Rule") appearing in the Federal Register at 72 Fed. Reg. 42628 (August 2, 2007).

Bio-Tissue is a bio-tech company specializing in the procurement and processing of high quality amnion-based tissue and cell products that provide healing and regeneration of ocular surface tissue including the cornea and the conjunctiva. Bio-Tissue's current products, AMNIOGRAFT® and PROKERA™, use cryopreserved human amniotic membrane tissue to treat ocular surface disease and damage, such as corneal defects/ulcers, tumors/scars, viral infections, leaking glaucoma blebs, chemical burns, high-risk corneal transplants, conjunctivochalasis, and many other conditions. Our comments to the Proposed Rule are limited to the payment status indicator assigned to amniotic membrane tissue.

Addendum B of the Proposed Rule will assign an "N" status indicator to V2790, the HCPCS Level II code assigned to human amniotic membrane tissue. Accordingly, payment of V2790 is bundled with its related procedure, CPT 65780, amniotic membrane transplant. For reasons discussed below, the bundling of V2790 results in a payment rate for CPT 65780 that does not cover the cost of the tissue supplied in the procedure. In order to continue to make this innovative tissue and treatment available, the payment rate must accurately reflect the cost of obtaining, processing and distributing the tissue, as well as performing the procedure.

We urge CMS to change the status indicator of V2790 in order to permit separate payment of amniotic membrane tissue. Alternatively, we ask that CMS create a separate APC for amniotic membrane transplantation that accurately reflects the cost of amniotic membrane tissue.

Preserved Human Amniotic Membrane Tissue

Amniotic membrane is the innermost lining of the placenta. The tissue is carefully processed and preserved using a specialized cryopreservation method. Since 2001, amniotic membrane has been recognized by the FDA for use in ocular surface wound repair and wound healing. The clinical efficacy of amniotic membrane transplantation for ocular surface reconstruction is well established in peer-reviewed scientific journals.

After transplantation on the ocular surface, cryopreserved amniotic membrane provides physical protection while simultaneously delivering therapeutic biologic actions that aid in ocular surface wound repair and wound healing. An ocular surface protected by amniotic membrane that has been properly processed and preserved is receiving FDA confirmed biologic actions which reduce inflammation, minimize scarring, facilitate epithelial wound healing, and aid in the migration of limbal stem cells.

Amniotic membrane provides a treatment option otherwise unavailable to ophthalmologist. It serves as a viable tissue replacement for the conjunctival for surgeries, like glaucoma surgery, in which the patient's conjunctiva is too brittle to properly close after surgery and there is no available tissue for an autograft.

Amniotic membrane, when properly processed and preserved, also acts as a therapeutic graft to help the eye's natural healing take place. The tissue's biologic actions are especially useful in indications like non-healing corneal defects in which amniotic membrane can be used to aid in corneal healing before the defect progresses and the patient needs a corneal transplant. Similarly, patients that have had corneal transplants and run the risk of rejecting the transplant can be treated with amniotic membrane to help save the transplanted cornea. Use of the tissue to avoid a corneal transplant or avoid a rejection of corneal transplant offer a significant treatment option to patients and dramatically decreases costs associated with additional corneal transplants.

Current Coding and Status Indicator

As recently as 2004 CMS added CPT 65780 to the list of procedures covered in an outpatient hospital setting. In a final rule issued November 24, 2006, CMS published its calendar year ("CY") 2007 payment rates for the hospital outpatient prospective payment system ("OPPS"). The final rule set the OPPS payment rate for CPT 65780 at $2,352.42 and bundled V2790 with CPT 65780. This represents the total Medicare payment for the transplantation procedure and the amniotic membrane tissue. In the Proposed Rule CMS again proposes to bundle V2790 with CPT 65780 by assigning an "N" status indicator to V2790. The Proposed Rule sets the CY 2008 OPPS payment rate for CPT 65780 at $2,438.93.

In order to determine the payment rate for CPT 65780, CMS assigned CPT 65780 to APC 244 "Corneal Transplant". The following seven CPT codes are grouped with APC 244:

HCPCS / CPT	Payment Rate	Single Frequency	Total Frequency	"True" Median Cost
65710 Corneal transplant	$2,438.93	608	933	$2,539.20
65730 Corneal transplant	$2,438.93	2033	3534	$2,433.19
65750 Corneal transplant	$2,438.93	170	429	$2,318.28

The leader in ocular surface tissue therapies.

7000 SW 97th Avenue, Suite 211, Miami, FL 33173 • V: 305-412-4430 • F: 305-412-4429 • E: info@biotissue.com

65755 Corneal transplant	$2,438.93	1799	2848	$2,420.71
65780 Ocular surface reconstruction; amniotic membrane transplantation	$2,438.93	220	651	$2,125.02
65781 Ocular surface reconstruction; limbal stem cell allograft	$2,438.93	8	26	$1,899.50
65782 Ocular surface reconstruction; limbal conjunctival autograft	$2,438.93	12	30	$1,849.45

As the chart above indicates the same payment rate applies to each CPT code in APC 244. All procedures in APC 244 involve the tissue on the front of the eye and require a source tissue to complete the procedure. However, ***the source tissue is not bundled into the payment rate for every CPT code in APC 244, only amniotic membrane tissue.***

CPT codes 65710, 65730, 65750 and 65755 can bill for corneal tissue with a claim for HCPCS Code V2785 which has a special designation for separate payment in the OPPS environment. CPT 65781 can either bill for the corneal tissue using HCPCS Supply Code V2785 or bill a separate procedure for harvesting the tissue (CPT 68371 – Harvesting conjunctival allograft, living donor). CPT 65782 does not require a separate payment for tissue because the transplanted tissue is an autograft which would be taken from the same and there is no added cost of a tissue supplied by a third party.

Under OPPS, there are two HCPCS codes that are used to report services related to corneal tissue and amniotic membrane transplants:

Code Description	Status Indicator	Payment
V2785 corneal tissue, processing	"F"	Corneal tissue acquisition; paid at reasonable cost
V2790 amniotic membrane for surgical reconstruction	"N"	Items and Services Packaged into the APC rates; no separate payment

As required by status indicator "F", hospitals are paid separately (in addition to the APC rate) for costs associated with corneal tissue. Conversely, hospitals are not separately reimbursed for costs associated with processing amniotic membrane tissue for transplants.

We believe that because amniotic membrane transplant procedures are relatively new and because the costs for amniotic membrane tissue can vary widely (just as the costs vary widely for corneal tissue), that CMS may not have considered the inconsistency of assigning an "N" status indicator to HCPCS code V2790 when the bundled procedure is included in an APC where the vast majority of procedures are unbundled from their associated tissue. The cost of amniotic membrane tissue will never be accurately reflected in the APC payment rate because of the relatively low frequency of amniotic membrane transplant when compared to corneal transplant and the wide variance in cost of the tissue. The variance in cost is due to the necessity of offering different sized tissue to accommodate various treatments and patient requirements. Larger grafts result in fewer tissues from each placenta and, therefore, increase the cost of procuring the tissue.

The leader in ocular surface tissue therapies.

7000 SW 97th Avenue, Suite 211, Miami, FL 33173 • V: 305-412-4430 • F: 305-412-4429 • E: info@biotissue.com

Maintaining the current "N" status indicator creates an improper financial incentive for hospitals to promote treatment using one type of "tissue" over another based on financial considerations rather than clinical indicators and efficacy. Hospitals and ambulatory surgery centers (ASCs) are invoiced and must pay for the costs associated with retrieving, processing and storing amniotic membrane tissue just as they pay for the costs associated with processing corneal tissue.

Bio-Tissue estimates that the processing fees (costs) associated with amniotic membrane tissue can range from approximately $600 to over a $1,000, depending on the size of the graft. These costs reflect the fact that processing amniotic membrane tissue for use on the ocular surface is a multi-step process that takes place over several months. Cryopreservation of human amniotic membrane tissue requires the following FDA reviewed processing steps:

1. Procurement of the tissue after scheduled cesarean section birth;
2. Serologically test the mother at the time of birth for transferable diseases;
3. Storage of the placenta in a -80° freezer until donor testing is complete and tissue is released for processing;
4. Aseptically dissect the amniotic membrane from the placenta;
5. Place tissue on carrier paper;
6. Manually cut the tissue on the carrier paper into sizes appropriate for use on ocular surfaces;
7. Package pre-cut tissue in validated storage medium and seal pouch;
8. Sterilize the outside of the validated inner pouch and place in the validated outer peel pouch;
9. Test cultures are taken from randomly selected pieces from each placenta processed to insure there was no contamination in processing and packaging;
10. Store tissue in -80° freezer until it is released for distribution; and
11. Ship tissue on dry ice via overnight carrier in validated shipping container to insure tissue integrity.

These steps add significant processing costs that are not reflected in the payment rate for the procedure. As noted in the first table above, the median cost of amniotic membrane transplantation is approximately the same as corneal transplant. Both procedures require similar preparation of the ocular surface, similar instruments and approximately the same amount of time in the procedure room and for patient recovery. Despite these similarities, corneal tissue is paid separately from a corneal transplant procedure while the payment rate remains the same as amniotic membrane transplantation.

Failure of Hospitals to Report Claims

Despite instruction that hospitals should report claims for bundled tissue, hospitals do not consistently report use of amniotic membrane tissue when used in a transplant procedure. CPT 65780 is the code associated with "ocular surface reconstruction; amniotic membrane transplantation." By definition amniotic membrane tissue is used in the procedure. Yet, claims data consistently shows that V2790 is dramatically under reported. The following claims are reported in the OPPS claims file:

OPPS Claim File	**Claims for CPT 65780**	**Claims for V2790**

7000 SW 97th Avenue, Suite 211, Miami, FL 33173 • V: 305-412-4430 • F: 305-412-4429 • E: info@biotissue.com

2004	437	50
2005	605	50
2006 (includes only claims filed by December 31, 2006)	646	91

Under reporting of the use of amniotic membrane tissue further aggravates the payment disparity by invalidating the methodology used to determine the tissue's median cost, as well as the overall payment rate for APC 244. The cost of procuring, processing, storing, and distributing amniotic membrane tissue is not reflected in the payment rate for CPT 65780.

We have reviewed claims data provided to us by The Moran Company for both CPT 65780 and V2790 during 2005 and 2006. The claims data reveals that in the vast majority of cases hospitals that purchased amniotic membrane tissue from Bio-Tissue did not submitted a claim for V2790 although they filed multiple claims for ocular surface reconstruction using amniotic membrane tissue. We have both the invoices and proof of payment for the tissue despite the fact that the hospital has not submitted a claim for the tissue to the Medicare program. In 2006 claims filed for human amniotic membrane tissue provided in the hospital outpatient setting equaled just over 14% of the claims filed for amniotic membrane transplant during the same time and in the same clinical location.

We believe that hospitals often fail to file a claim for V2790 because they are aware that the tissue is not separately payable. In some cases, we believe that coding personnel in the hospital consider it too much extra work to retrieve the invoice for the tissue from the accounts payable department in order to submit the claim. Whatever the cause, it is clear from the claims data that the cost of V2790 is not accurately attributed to the bundled payment rate for CPT 65780 under APC 244.

In order to correct payment of V2790 and continue to make amniotic tissue available to patients, we urge CMS to change the status indicator of V2790 in order to permit separate payment of amniotic membrane tissue. Alternatively, we ask that CMS create a separate APC for amniotic membrane transplantation that accurately reflects the cost of amniotic membrane tissue.

We sincerely appreciate the opportunity to submit these comments and recommendations. We are available and would be pleased to discuss these issues further with CMS.

Sincerely,

Amy Tseng

Amy Tseng, MBA
President

cc: Dana Burley, CMS
Pam West, CMS
Cherie McNett, Director of Health Policy, American Academy of Ophthalmology
Gail Daubert, Esq.
Paul Pitts, Esq.

The leader in ocular surface tissue therapies.

7000 SW 97th Avenue, Suite 211, Miami, FL 33173 • V: 305-412-4430 • F: 305-412-4429 • E: info@biotissue.com

CMS-1392-P-577 **Medicare**

Submitter : Antoinette Nelson **09/10/2007**

Organization : none
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
Thank you for allowing me to provide these comments.

Sincerely,
Antoinette Nelson

CMS-1392-P-578 **Medicare**

Submitter : Antoinette Nelson **09/10/2007**

Organization : none
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.
Sincerely,
Antoinette Nelson

CMS-1392-P-579 **Medicare**

Submitter : Dubose Clara **09/10/2007**

Organization : Methodist Hospital
Health Care Professional or Association

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

Hi, my name is Clara Dubose. I am a Cardiac Sonographer at Methodist DeBakey Heart Center. I would like to say that in my experience as an echo tech, I know that contrast agents are in many cases necessary because they help to enhance the studies. We do not use contrast agents on every single patient, but we reserve this tool for cases where the pictures are suboptimal so the physicians can accurately assess the cardiac function of the patients. In cases when patients are in a critical situation and with suboptimal images, if we do not have this tool available, the studies most probably are going to be inconclusive and the physicians would need to request more tests that could not only be invasive but also a lot much more costly in addition to a longer permanence of the patients in the hospital, which will increase a lot the bill to Medicare.
For all the above reasons, I think it is in the best interest of Medicare to provide separate reimbursement for echo contrasts.