

Submitter : Miss. Kousha Zarnegar
Organization : West Covina PET Medical Center, LLC
Category : Physician

Date: 07/22/2005

Issue Areas/Comments

GENERAL

GENERAL

My comments are regarding the procedures currently billed using CPT codes 78491 and 78492. These myocardial PET procedures may be performed with or without gating similar to myocardial SPECT procedure billed using CPT codes 78464 and 78465. For SPECT studies, there are additional codes of 78478 and 78480 available to assure proper reimbursement for gated studies versus non-gated studies. However, for myocardial PET perfusion studies, there are no additional codes to assure proper payments for gated studies. The providers receive the same fees regardless of performing gated studies versus non gated studies. The rates for 2006 should be adjusted to address this issue.

Submitter : Ms. Sheila Goethel
Organization : Rural Wisconsin Health Cooperative
Category : Hospital

Date: 07/22/2005

Issue Areas/Comments

GENERAL

GENERAL

Drug Administration - I understand that the AMA may have new drug administration codes for 2006 and CMS will provide necessary crosswalks to those new codes; however, I do have a couple of comments to ensure uniformity and clarity of drug administrations. First, in Addendum B, there is a code G0258 which indicates IV infusion during OBS stay. This was in the 2005 Final Rule Addendum B and had a SI of B - however, this proposed rule indicates the SI is/will be X with a payment of \$37.72. Providers will assuredly need instructions whether this code is to "replace" the G0345 or G0347 (hydration/diagnostic IV) when performed on OBS patient - and if it is, I question the need for separate code rationale, for you indicate that the OCE will incorporate claims intelligence to determine observation payment status for those 3 payable categories.

Second - hospitals yet need clarification on the issue of the IV started by EMS crew and continued in the hospital. It would be appreciated to have all these questionable issues clarified in one document regarding the new drug administration codes.

I have two other concerns/comments - however they both address findings in the document itself. First, on page 240 of the word document regarding immunizations/vaccines, there is a typo. Codes 96471 and 94672 were provided, when I do believe they should have been 90471 and 90472. The other comment deals with G code additions in Addendum B - those being G9021-G9032. I'm assuming that these deal with the exemption of packaging antiemetic drugs; however, Providers will need clarification on reporting of these codes as well.

Thank you very much for your attention to these comments and the availability to provide electronic comments to the 2006 Proposed OPPS rule.

Submitter : Ms. Suzanne Cabriales
Organization : East Valley Hematology and Oncology
Category : Nurse

Date: 07/28/2005

Issue Areas/Comments

GENERAL

GENERAL

I just read through the brief describing how seniors receiving chemo will now obtain their medications. This is unbelievable. Seniors will have to see the doctor, take a prescription "somewhere" for chemo that will somehow be less expensive, take the drug back to the hospital 2 days later for treatment then follow up with their doctor for control of side effects. This simply is not cost effective. It will destroy continuity of care. Seniors will get lost in the system and will have diminished quality of life. I don't see physicians/nurses in the private arena getting rich. My physicians work 14 hour days, on call at night, making house calls and keeping people with dreaded illnesses alive. These extra layers of bureaucracy will profoundly impact the safe delivery of chemotherapy to our patients. This is difficult even in a closed environment such as a physician's office. In our office, the orders go directly from the physician into the patient file and then to the nurse. Any questions are directly addressed to the physician and answered immediately. Under the CAP program, orders will go to a vendor who will have to interpret, call back and delay treatment for the patient. This is plain stupid. No one will save money. Medicare will waste money with this plan. Patients will suffer and because of the loss of continuity, some will die much sooner than necessary. SHAME. Just imagine yourself or one of your parents seeing the MD one day, coming back in two days for treatment, coming back a third day for symptom management, on and on and on. SHAME AGAIN.

Submitter : Mr. William Richardson
Organization : Mr. William Richardson
Category : Individual

Date: 07/30/2005

Issue Areas/Comments

GENERAL

GENERAL

It is my understanding that medicare payments are to be reduced for 2006 according to the proposed bill. The Cryocare procedure should be less expensive overall for Medicare than the other methods. Why would it be wise to reduce the Medicare payments to Surgeons for Cryocare, making it less financially attractive for them to perform that procedure? I would think that Medicare payments should encourage the surgeons to perform the procedures that are most effective and less expensive overall for Medicare. Please vote against CMS-1501-P. Thank you, WMR

Submitter : Dr. Mark McClellan, M.D., Ph.
Organization : Centers for Medicare and Medicare Services
Category : Health Plan or Association

Date: 08/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,

The purpose of this letter is to let you know of my interest in prostate cryosurgery procedures. I recently had cryosurgery for prostate cancer. Two years ago I had radiation treatment for my problem and it did not work. My only other option would have been a radical prostatectomy. This would have been a more invasive surgery with hospital stay and a lengthy recovery. Also, the expense would have been much more. I am referring to the July Federal Register on Outpatient payment rates for prostate cryosurgery. The new proposed rates will not cover the hospital costs. If the inadequate payment rate for 2006 is adopted, fewer hospitals will offer it. I can speak from experience that cryosurgery is minimally invasive, so, recovery time is quicker and there is no hospital stay.

Sincerely,

Richard Holshey
730 Green Valley Ln.
Melbourne, FL 32940

Submitter : Mrs. REBECCA KIDDER
Organization : MARIETTA MEMORIAL HOSPITAL
Category : Nurse

Date: 08/03/2005

Issue Areas/Comments

GENERAL

GENERAL

Commenting on the proposed drug administration rules. We believe it would be quite burdensome for a hospital to track the difference between an IV infusion for "hydration" vs. "therapeutic". Hydration is a therapeutic infusion and to make this distinction seems to be redundant and does not represent any difference in APC payment. In addition, the initial hour of infusion followed by 8 subsequent hours followed by additional sequential hours seems very confusing and again would be burdensome for hospitals to track and bill properly. It would seem more appropriate to define a therapeutic infusion utilizing flow rates or other criteria such as represented in intensity of service criteria (ie. Interqual). The same would be true of initial and subsequent intravenous push medications. Would an initial for each type of substance/drug be billed (multiple initials?) followed by sequential substances/drugs? The definition of sequential would need to be understood and then each drug would need tracked to determine initial doses and subsequent doses. This would require a huge effort by hospital personnel to differentiate these drugs and the sequence of doses. As these all group to the same APC and do not represent differences in reimbursement levels it seems to be an unfair burden to place on hospitals in order to receive reimbursement we are entitled to while avoiding unintentional billing errors that feed into the payment error prevention programs. Preparation, administration, and monitoring of infuseable or injectable drugs is the same for the first dose as it is for the last, and in most instances does not differ between drug types. It is appropriate to differentiate between non-chemo and chemo administrations. Chemo injections or infusions are distinctly different in the risk, means of administration, prep time, and monitoring time. However, it would again be burdensome to differentiate between hormonal and non-hormonal antineoplastics as well as initial and sequential infusions. The instructions for drug administration have been quite confusing to date and already represent complex billing processes in order to capture charges. Changing from Q codes to CPT was beneficial once the processes were altered. To change again to G codes seems to be an un-necessary move that would only increase the burden on hospitals.

Submitter : Dr. Mingxiong Huang
Organization : Univ of California San Deigo/San Diego VA Hospital
Category : Other Health Care Professional

Date: 08/03/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-7-Attach-1.DOC



UCSD Medical Center
HILLCREST

August 3, 2005

Shirl Ackerman-Ross, DFO, CMS, DOC
Attention: CMS-1501-P
Mail Stop C4-05-17
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Ref: CMS MEG Reimbursement

Dear Ms. Ackerman-Ross:

I am very surprised to know from the government website for MEDICARE, indicating that the new APC values for all 3 MEG codes will be changed to \$620 from about \$5200 previously for an epilepsy MEG scan. As an MEG scientist for more than ten years, I strongly encourage CMS to re-evaluate this decision.

When making the decision about the CMS MEG reimbursement, the following crucial factors should be considered: 1) The cost of MEG system (MEG sensor unit plus the magnetic shielded room) is in the order \$2M ~ \$3M, and siting cost can easily be \$0.5M ~\$1M; 2) The cost for operating an MEG system includes the service contract costs of \$60,000 ~ \$120,000/year plus the liquid helium cost of ~\$40,000/year; 3) The MEG scanning time for each epilepsy case is about 4 hours (in two sessions), much longer than the scanning times for other imaging methods such as MRI; 4) The cost of manpower -- In general, it takes a PhD level MEG scientist about 20 hours to identify and localize spikes in one patient. Considering all these costs, it is clear that the previous rate at about \$5200/scan is more reasonable than the new rate at \$620/scan.

As a large number of publications have demonstrated that MEG's high temporal resolution and high spatial resolution and localization accuracy is unique for non-invasively localizing epileptic foci, **the new APC codes at approximately \$ 620 per scan may drive many MEG clinical programs out of business and lead to a major lost to our epileptic patients.**

I sincerely hope that CMS can re-evaluate new MEG Reimbursement rate. If you have any questions about this letter, please feel free to contact me. Thank you very much for your time and consideration.

Sincerely,

Mingxiong Huang, Ph.D.
Associate Adjunct Professor, Associate Director of MEG
Department of Radiology Service, University of California San Diego/
VA San Diego Healthcare System
3350 La Jolla Village Drive
San Diego, CA 92161
Tel: 858-552-8585 ext 2947
Fax: 858-552-7404 or 858-642-3836
Email: mxhuang@ucsd.edu

Submitter :

Date: 08/04/2005

Organization : Banner Health

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-8-Attach-1.DOC



Banner Health

1441 North 12th Street, Phoenix, AZ 85006
602-495-4000
BannerHealth.com

Centers for Medicare & Medicaid Services
Dept of Health and Human Services
Attn. CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

RE: "DRUG ADMINISTRATION"

To Whom It May Concern:

This letter is in regards to the 2006 OPSS proposed drug administration changes noted in the Federal Register/Volume 70, No. 141 dated 7/25/05. The required method of reporting these services for outpatient hospitals changed from reporting Q codes in 2004 to CPT codes in January, 2005. The concern with the 2006 OPSS lies in the method for reporting these services is proposed to change again in January, 2006. I understand from reading the proposed changes that the existing CPT codes for reporting IV and chemo administration will be deleted and new CPT codes will be issued that correspond with the HCPCS G codes physician offices are using to report these services in 2005. It can be cumbersome and difficult for hospital providers to identify, get clear direction on the application of CPT reporting changes (for example, it took several months to get clarification to round up the number of units for the additional hours for the IV and chemo infusion > 30 minutes in 2005) and implement the required hospital changes associated with CMS changes that are so substantial. Since the loss of the three month grace period for implementing the annual CPT code changes and the timing of the OPSS final rule it can be difficult for providers to be ready by the first of the year.

Within the Banner Health system of hospitals, CPT codes for IV hydration and chemo administration are hard-coded in the Charge Description Master (CDM) which in all probability is typical of hospitals around the country that provide outpatient IV and chemo administration services. While the proposed changes may offer CMS more "clinical" information such as the "reason" for the IV infusion; hydration vs. therapeutic/diagnostic reasons, it potentially may add confusion, frustration and an additional administrative burden for clinical staff who are focusing on caring for many patients who now must decide among many new charge codes which are the most appropriate to bill.

Regarding reimbursement, these proposed changes will not change the mapping of these APC groups as noted in the 2006 OPSS proposal. Hospitals will be burdened with "breaking out" the reporting of these services without any change to the APC mapping in 2006. The APC groupings will still be collapsed by the OCE into per visit APC payments as they are in 2005.

If the existing CPT codes that describe drug administration services are deleted in 2006, I'd like to see CMS develop HCPCS codes that more closely match the existing CPT code descriptions for hospitals to use for reporting these services.

Sincerely,

Pam Sticklen B.S., R.N., CPC-H
CDM Analyst, Banner Health

Submitter : Mr. Chris Sauder
Organization : Adventist Health
Category : Hospital

Date: 08/04/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1501-P-9-Attach-1.DOC

August 4, 2005

Comment Reference: Rural Hospital Adjustment

Comment: Please provide clarification on whether the proposed rural hospital adjustment of 6.6 percent would apply to a rural (geographic location) Sole-Community Hospital (SCH) that has been reclassified to an urban area for purposes of its hospital wage index (IPPS).

Chris Sauder, MBA, CPA, CFE
Analyst II, Budget & Reimbursement
Adventist Health - Roseville, CA
Phone: (916) 774-3376
Fax: (916) 774-7382

AUG - 4 2005

July 30, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: APC 674 Cryosurgery of the Prostate

Dear Dr. McClellan:

I am writing in regards to the upcoming changes to Medicare's schedule of payments for Hospital Outpatient procedures which include cryosurgery for prostate cancer. I am a survivor of prostate cancer, blessed by the advances in cryosurgery techniques.

My wife and I were very proactive in seeking the appropriate treatment for my situation. My diagnosis came while we were between insurance plans so it was considered pre-existing and, of course, that meant we would be paying the entire medical bill. We reasoned that since cryosurgery was being used for salvage (where other treatments had failed and cancer returned), and since it was the least invasive form of surgical treatment allowing a much shorter recovery time, and the overall cost of the procedure was quite a bit less than other forms of treatment, it made good sense to choose cryosurgery. I refer to it as 'my treatment of choice.'

I need to add that I was a young 59, not yet a Medicare recipient, when diagnosed and was very physically active. I've often noted that I didn't have time for such a condition. It was a good thing to have cryosurgery available because it allowed me to return to a normal lifestyle much quicker than many men I've heard from.

And I speak with a good number of men facing their own choices for prostate cancer. I am a part of a peer support system which offers encouragement to those men seeking information and direction.

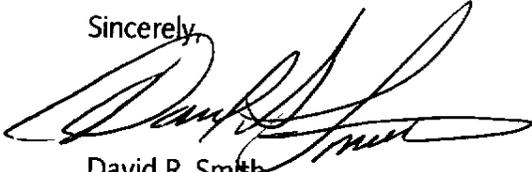
While my own experience included an overnight stay, the surgical process can be effectively performed in an outpatient setting. It's generally less costly and, as such, the reasoning behind Medicare's intended plans to reduce or eliminate paying for cryosurgeries performed in outpatient facilities is baffling to me.

I would encourage Medicare to revisit this issue and restructure their payments to reflect a facility's actual cost, whether a hospital outpatient center or a stand-alone outpatient facility. The procedure, itself, would provide a cost savings to Medicare if more men and doctors elected cryosurgery over the more complex, expensive, and sometimes troublesome treatments.

The direction Medicare appears to be taking will, no doubt, reduce the number of cryosurgeries performed. That serves the best interests of no one. It will only cause a reduction in the availability to the many men who would greatly benefit from such a successful procedure.

More hospitals need to make this life-saving treatment a part of their ongoing procedures. More doctors need to be trained as certified cryosurgeons. More men need to be informed as to this excellent option so they can make informed choices for treatment. And I firmly believe Medicare needs to play a viable and supportive role in expanding the use of cryosurgery rather than taking action which will only stifle it and, perhaps, damage its acceptance within the medical community.

Sincerely,

A handwritten signature in black ink, appearing to read "David R. Smith", written in a cursive style.

David R. Smith
CEO & Managing Partner
Financial Education Services, LLC
P.O. Box 3777
Turlock, CA 95381-3777

Cc. James I. Hart, CMS
Mary Syiek, Endocare, Inc.

//
AUG - 4 2005

August 1, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am writing this letter as a Medicare recipient and a prostate cancer survivor due to Cryotherapy and my interest in seeing others are afforded the same life saving and nerve-sparing procedure.

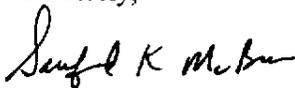
My ordeal began in September 2003 with a PSA level of 4.6 and a biopsy in December of that same year. Mistakenly I thought I was out of the woods when no cancer was detected. However in October, 2004 my PSA level was at 6.9 and another biopsy was ordered. This time 3 of the 12 samples taken showed cancer cells. I was devastated, unless one has heard a diagnosis of cancer there are no words to express the fear and dread it conveys. I was certain if I lived, my life would be forever altered and I would no longer be able to contain my bladder or have sexual relations.

God led me to a skilled urologist, Dr. Steven Hulecki, who performed Cryotherapy on January 28, 2005. Today my PSA level is 2.8 and I am able to enjoy all aspects of a normal, healthy life. I know had I not had this procedure things would be very different for me.

A notice in the July Federal Register mentioned that the proposed Medicare hospital outpatient payment rates for prostate Cryotherapy in 2006 would not cover the hospital costs. This is distressing to me as I think fewer patients will have access to this procedure if Medicare lowers the rate it pays hospitals. The hospitals will no longer offer this option due to the inadequate payment rate Medicare is proposing. Therefore the benefits of Cryotherapy, which is a minimally invasive procedure and produces fewer side effects, would be lost. Ultimately Medicare would pay out more for subsequent health care, which are caused by the other prostate cancer removal options.

In closing, I urge Medicare to adjust the proposed payment rate for APC 674 upward—to reflect the actual costs incurred by the hospital in performing this procedure. In my opinion the benefits to Cryotherapy are numerous. They include a quicker recovery time, less chances of bladder control problems and a possible return of sexual functions, while still curing the prostate cancer.

Sincerely,



Sanford K. McBee

Cc: James L. Hart, CMS
Mary Syiek, Endocare

Submitter : vaughan parker
Organization : vaughan parker
Category : Individual

Date: 08/06/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing about hospital reimbursements for Cryosurgery.

I had this procedure done on my prostate in June, 2005. I considered it to clearly be the best alternative to treat my aggressive prostate cancer.

I understand, per the July Federal Register, that proposed payment rates to hospitals for this procedure are being drastically reduced.

This is a great procedure. Payments to hospitals should be sufficient to cover their costs. I urge you to raise the payment rate for APC 674.

Submitter : Mr. George Miranda
Organization : DeKalb Medical Center, Decatur, GA
Category : Other Health Care Professional

Date: 08/07/2005

Issue Areas/Comments

GENERAL

GENERAL

DRUG ADMINISTRATION

In general, I do not support changing the drug administration CPT codes to the proposed G codes because (1) we just changed from HCPCS codes to CPT codes LAST year, creating a huge administrative burden for all hospitals. Now you're doing it to us again!
(2) Most of the codes seem to be designed to differentiate between types of drugs administered, or whether they were administered first or later. Since you pay only a set amount, what benefit is there for us to differentiate the number of infusions, for instance, that we administer? As for the type of drug administered, the charge for the drug under Rev Code 636 will tell you which drugs were administered, without having to resort to creating new G codes. Finally,
(3) the general intent is to move from HCPCS level 2 codes to CPT codes when they are available. In fact, you're moving away from CPT codes now. I understand that the current CPT codes don't give you the level of specificity you're looking for, but you can, again, get that same information from the other charges on the claim without creating more administrative burden for our clinic staff.
The more complicated you make billing and coding every year, the more expensive you make it for us to provide services, and the less time the nurse can spend at the patient's bedside.

I will make specific comments on proposed codes under separate cover.

Submitter : Mr. George Miranda
Organization : DeKalb Medical Center, Decatur, GA
Category : Other Health Care Professional

Date: 08/07/2005

Issue Areas/Comments

GENERAL

GENERAL

RE: Drug Administration

1. 90780/G0345/G0347: You do not need to create separate G codes to differentiate between hydration fluids and therapeutic/diagnostic agents. The pharmacy charges on the claim will give you this same information.
2. G0349, G0350: Instead of creating G codes for additional infusions and concurrent infusions, just allow us to charge additional units for 90780. You don't pay for more than one unit, anyway. And the drug charges will tell you how many additional drugs are being given. Additionally, why do you need to know if an infusion is concurrent or sequential?
3. 90784/G0353, G0354: I'm very happy that you are going to pay for each IV push; however, I don't think you need two G codes. Just let us charge additional units for 90784. The drug charges on the claim will let you know how many different drugs we administered.
4. 96400/G0355, G0356: Again, if you want to differentiate between hormonal antineoplastic and non-hormonal chemo SQ/IM injections, just look at the pharmacy charges. Don't create more G codes.
5. 96408/G0357, G0358: Well, I'm quite happy that you are finally paying us for each chemo IV push, as you've already done with the physicians' offices; however, you can do this by allowing multiple units of 96408, rather than creating additional G codes. And to differentiate the different drugs, you can look at pharmacy charges for that DOS.
6. G0362- since you consider chemo a per visit charge, and the status indicator is 'N' for this service, what benefit is there to differentiating additional chemo infusions on the same visit? Are you planning on paying per procedure instead of per visit? If so, don't you want to create a code for sequential drug, additional hours beyond the first hour? If you want to differentiate the number of chemo infusions administered in a visit, just allow us to charge additional units of 96410, and instruct the OCE to pay for only one unit. The Rev Code 636 charges will tell you which chemo drugs we administered.
7. G0363 - thank you for creating a port flushing code. In the past you have asked us to wrap that into an E&M code, but the cost associated with caring for a port are greater than reimbursement for a low level E&M. I assume that you will collect data on this code for two years and initiate payment in 2008 if the data warrant payment (in other words, this is the only G code I support).

Submitter : Mr. Jared Perkins

Organization : Mr. Jared Perkins

Category : Individual

Date: 08/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

It has come to my attention that the proposed hospital outpatient payment rates by Medicare for prostate cryosurgery procedures in 2006 are going to be lowered and will not even cover the current cost of treatment.

I have a vested interest in the procedure as I underwent cryosurgery after my radiation treatment failed and my cancer was coming back at an accelerated rate. The cryosurgery has been a positive blessing as my cancer is apparently gone and I still have cryo available if it does come back.

I urge you to support an upward adjustment in the proposed payment rate for APC674. Hopefully more hospitals will offer this service which for me has been a life saver.

Thank you
Jared Perkins

Submitter : Mr. Geoff MacKay

Organization : Organogenesis, Inc.

Date: 08/12/2005

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-16-Attach-1.DOC

Organogenesis Inc.

LIVING TECHNOLOGY

150 Dan Road, Canton, Massachusetts 02021

August 12, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006 Payment Rates --
Drugs, Biologicals, and Radiopharmaceuticals Non Pass-throughs

Dear Administrator McClellan:

Organogenesis, Inc. is writing to comment on an error in the proposed rule, CMS-1501-P, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rate for our product Apligraf®. Organogenesis is a biotechnology company based in Canton, Massachusetts and we manufacture and market Apligraf® (C1305), a unique human skin substitute for diabetics and the elderly who suffer from chronic ulcers. As set out below, Apligraf® has been paid in the hospital outpatient prospective payment system as a specified covered outpatient drug and should be paid in 2006 similar to other such drugs. We are notifying the agency as soon as possible due to the significant decrease in reimbursement for Apligraf® as a result of the error in Addendum A of the proposed rule and the negative impact on beneficiary access to wound care treatment. We respectfully request that CMS reimburse hospitals for Apligraf® as a specified covered outpatient drug in the final rule based on the average sales price (ASP) data that has been reported to CMS on a quarterly basis under Apligraf®'s NDC number (NDC #09978-0001-99).

Apligraf® Is A Unique, Medically-Necessary And Cost-Saving Treatment

Apligraf® is a unique, bioengineered, cell-based living human skin substitute for the treatment of chronic, hard-to-heal venous leg ulcers and diabetic foot ulcers. Like human skin, it is made from living cells and it is composed of two layers, a dermis and

an epidermis comprised of healthy, functioning, responsive cells that stimulate the wound to heal. Apligraf® is the only active wound-healing product approved by the U.S. Food and Drug Administration (FDA) to treat both venous leg ulcers and diabetic ulcers. The incidence of chronic wounds in the United States is approximately 5 to 7 million per year, and the annual costs for management of these wounds is greater than \$20 billion. No other active wound-healing product is indicated for treatment of venous leg ulcers. Before the development of Apligraf®, physicians had few options for treating hard-to-heal venous leg ulcers, which comprise approximately one-third of all treated venous ulcers. Apligraf® has preserved and improved the quality of life of tens of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of them would have had to undergo limb amputations without the benefit of Apligraf®. Apligraf® and similar advanced bioactive products have been specified by leading clinicians in published algorithms as the standard of care for wounds that have not responded to conventional therapy. Apligraf® is a proven cost-effective therapy for chronic foot ulcers, providing savings in wound care costs of \$7,500 for these patients.

Apligraf® is a Specified Covered Outpatient Drug

The Medicare history of Apligraf® demonstrates that Apligraf® has been recognized and paid as a biologic and under MMA recognized as a specified covered outpatient. The following background may help clarify for the agency the classification of Apligraf® in the hospital outpatient setting.

- **In 2001 and 2002:** Apligraf® was paid in the hospital outpatient setting as a biological under the pass through list. In February, 2001 CMS (then HCFA) issued a Program Memorandum (Transmittal B-01-07) that states "*Apligraf® has met the statutory requirement as a biologic.*" (See attachment 2).
- **In 2003:** Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 Apligraf® has been paid in the hospital outpatient setting as a sole source biological at 88% of AWP in 2004 and 83% of AWP in 2005 under the specified covered outpatient drug provision.
- **As recent as 2005 in the GOA:** As a specified covered outpatient drug Apligraf® was included in the General Accountability Office (GAO) survey of acquisition costs for hospital outpatient drugs. The GAO Report dated June 30, 2005 (GAO-05-581R) on specified covered outpatient drugs states "[GAO] obtained from our survey data the average and median purchase prices for each of the 53 SCOD drug categories." Apligraf® is listed under number 38 in Table 1 of the report detailing the acquisition costs for specified covered outpatient drugs. (See attachment 1.)

Apligraf®'s History of HCPCS C1305 and J7340

On February 7, 2001, the Program Memorandum (Transmittal B-01-07) that CMS (then HCFA) issued also provided two HCPCS codes for Apligraf®: C1305 for hospital outpatient and Q0185 for the physician office. (See attachment 2).

The transmittal states:

For these services, physicians should not bill Apligraf® using HCPCS code C1305 since this code has been approved solely for use under the hospital outpatient prospective payment system.

Effective July 1, 2002, in Transmittal B-02-015, CMS assigned J7340 to Apligraf® for billing in the physician setting and eliminated the use of the temporary Q0185. The new J code was provided the descriptor of "Metabolic active Dermal/Epidermal tissue". (See attachment 3). Consequently, since July 1, 2002 Apligraf® has been billed under J7340 in physician's office.

It has been CMS policy that the C1305 code is for sole use in the hospital outpatient setting. In Chapter 17 of the Medicare Claims Processing Manual covering payment for drugs and biologics CMS provided the following guidance for pass-through drugs:

Only HCPCS code C1305 is reportable under the hospital OPSS. HCPCS J7340 should NOT be reported for Apligraf under the hospital OPSS.

(See attachment 4.)

Apligraf®'s Payment Rate is Incorrectly Listed in Addendum A

In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services (CMS) proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent.

We understand based on communication with the agency that CMS paid Apligraf® based on mean costs derived from historical hospital claims data because there had been no ASP payment rate specific to HCPCS C1305. We believe the confusion in the proposed rule is because the ASP rate for Apligraf is reported by CMS under HCPCS J7340.

The Honorable Mark McClellan
August 12, 2005
Page 4

Based on the April 1, 2005 ASP rate for Apligraf, payment at ASP plus 8% would be \$1,203.69. However, Apligraf is listed in addendum A of the proposed rule at \$766.84 which is clearly in error. (See attachment 5.)

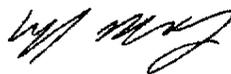
It is important to note that the CMS reporting requirements for ASP submissions are by NDC not HCPCS code. Organogenesis has reported ASP data for Apligraf since the inception of the ASP system and regularly submits ASP quarterly updates to CMS under the NDC # 09978-0001-99. In the July 2005 quarterly update, CMS published an ASP rate for Apligraf of \$1,182.72 (\$26.88 sqcm). The ASP data submitted by Organogenesis includes all sales irrespective of the site of care for the respective quarter. **Therefore, Apligraf's ASP is comprised of sales billed by providers under C1305 in the hospital OPPS and under J7340 in the physician setting.**

Conclusion

The proposed payment rate is incorrect and will significantly underpay hospitals for Apligraf. We have already been contacted by a number of leading wound care providers in the country regarding their concern that the proposed payment rate will have a significant negative impact on beneficiary access to standard of care wound treatment. Thus, we believe it is very important that in the final hospital outpatient rule it is clarified that hospitals will be reimbursed for the acquisition of Apligraf at ASP plus six percent and an additional two percent for pharmacy overhead cost similar to other specified covered outpatient drugs. In this regard, we would like to meet with agency staff during the comment period. You may contact me directly at 1 (781) 401-1040.

Thank you for your attention to this issue

Sincerely,



Geoff MacKay
President & CEO

Submitter : Mr. Dennis Perez

Date: 08/13/2005

Organization : Mr. Dennis Perez

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

August 13, 2005

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore MD 21244-8018

RE: CMS-1501-P: Medicare Program; changes to the hospital outpatient prospective payment system and calendar year 2006 payment rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am writing this letter to let you (Medicare) know that I am a pretty-recent cryosurgery patient, and I am concerned that the downward payment rate for this surgery will hurt other cancer sufferers because it will mean that some may not be able to afford this surgery option. I want continued access to this type of surgery for myself as well as others. It is my understanding that if further cancer develops, the procedure can be done again, unlike other types of prostate surgery.

I am responding to a notice in the July Federal Register that contained the proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006. I believe that the new proposed payment rate will not cover what the hospital's costs are. Cryosurgery for prostate cancer is new in Washington State, and I want to make sure that others have the option of this surgery. If Medicare payment rates are reduced, I feel sure that fewer hospitals will offer this option.

I chose cryosurgery for my prostate cancer after talking with a fellow from my wife's place of employment. He had had the surgery about a year before, and had excellent results. I also attended a Man-to-Man meeting of people who are prostate cancer survivors, and all those there who had cryosurgery had fewer side effects and had the same prognosis as those who had chosen other prostate surgery. I know from personal experience that the procedure was less invasive than if I had chosen an alternative, and I was back to my volunteer work in just a few days, compared to six weeks or more of required inactivity that others spoke about.

I urge Medicare to adjust the proposed payment rate for APC 674 upward to reflect the hospital's actual cost to perform this procedure. Medicare recipients deserve the same treatment as people who have private insurance.

Thank you for reading this letter.

Sincerely,

Dennis M. Perez
1715 Oxbow St. NE
Olympia, Washington 98516-3841

Submitter : Dr. Sanford Fitzig
Organization : Wichita Clinic
Category : Physician

Date: 08/17/2005

Issue Areas/Comments

GENERAL

GENERAL

Attached is a letter to Dr. McClellan

CMS-1501-P-18-Attach-1.DOC

CMS-1501-P-18-Attach-2.RTF

Wichita Clinic
3311 E. Murdock
Wichita, KS 67208
August 16, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for SPC 674 Cryosurgery of The Prostate

Dear Dr. McClellan:

I am an urologist in South Central Kansas and have been performing Cryosurgery of the Prostate for Prostate Carcinoma for almost 2 years. The proposed changes in payment schedule are very alarming. Many of my patients come from quite a distance and ability to perform this procedure in one sitting without having to come back and forth daily, as is the case with radiotherapy, has been very helpful in this population of men. Radiation therapy services are limited in our geographic region requiring long drives to obtain this service. With the proposed reduction in payments, hospitals will not be able to offer cryosurgery services to this group of men.

My patients have definitely benefited from the availability of the cryosurgery. There is minimal morbidity and well tolerated in the Medicare age population. The results of this treatment are equal to radiation therapy and particularly helpful when surgery, radical prostatectomy, is not indicated either by age or other co-morbidities.

This treatment has been helpful in those patients who have failed radiation therapy, reserving hormone therapy for cases where local recurrence has not occurred. Unfortunately, there is no therapy that is 100% effective for prostate cancer, but this is ideal for local radiation failures. It should also be available for those patients, who have had primary cryosurgery, who have a local recurrence.

Currently, it costs each hospital over \$9,000 to provide this service. The proposed payment for 2006 is only \$5,659. If this payment schedule is implemented, local hospitals, which act as tertiary referral centers for Kansas, will not be able to offer this service, adversely affecting my patients.

Thank you for your consideration.

Respectfully yours,

Sanford Fitzig, M.D., FACS
Urologist

Submitter : Ms. Bob Schaefer
Organization : Trover Foundation
Category : Laboratory Industry

Date: 08/17/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed APC reimbursement rates for blood products are woefully inadequate. For example P9016 Red Blood Cells Leukoreduced cost us \$239.42 when purchased from the ARC but proposed reimbursement is only \$162.42. All of the proposed rates would have us being reimbursed for less than the blood products cost us to purchase. We simply cannot afford to transfuse products at a loss. We are a small community hospital trying our best to take care of our patients

Submitter : Dr. Thomas Yearwood

Date: 08/18/2005

Organization : Comprehensive Pain and Rehabilitation

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

IV.D.2.c Criteria for Establishing New Pass-Through Device Categories - Existing Device Category Criteria

I would like to state my OPINION that the existing device category for implantable neurostimulator generators does not appropriately describe rechargeable IPG technology. The existing category descriptor is overly broad, and it was never intended to describe rechargeable IPG technology that did not exist at the time the original category was created.

Furthermore, I would like to SUPPORT CMS's finding in the recently released final rule on the Hospital Inpatient Prospective Payment System for fiscal year 2006 that RECHARGEABLE NEUROSTIMULATORS are significantly different than predecessor devices and represent a substantial clinical improvement for a large portion of patients who receive implantable neurostimulators.

Submitter : Dr.
Organization : Dr.
Category : Physician

Date: 08/19/2005

Issue Areas/Comments

GENERAL

GENERAL

Date: August 16, 2005
To: Centers for Medicare and Medicaid Services
From: Alexander Volfson, M.D.
Re: TEACHING ANESTHESIOLOGISTS RULE

I am writing to urge a change in payment policy for teaching anesthesiologists. The current Medicare teaching anesthesiologist payment rule is unwise, unfair and unsustainable. Quality medical care, patient safety, and an increasingly elderly Medicare population, demand that the United States have a stable and growing pool of physicians trained in anesthesiology.

Anesthesiology teaching programs are suffering severe economic losses that cannot be absorbed elsewhere. Academic research in anesthesiology is increasingly difficult to sustain, as department budgets are broken by this arbitrary Medicare payment reduction. The current Medicare payment policy is unfair.

The CMS anesthesiology teaching rule must be changed to allow academic departments to cover their costs. It is not fair, and it is not reasonable. Please recognize the unique delivery of anesthesiology care and pay Medicare teaching anesthesiologists on par with their surgical colleagues.

Sincerely,

Alexander Volfson, M.D.
Resident in Anesthesiology
Weill Cornell Medical College
New York Presbyterian Hospital

Submitter : Dr. Thomas Fassuliotis
Organization : Gainesville Urology PC
Category : Physician

Date: 08/19/2005

Issue Areas/Comments

GENERAL

GENERAL

August 19, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P. O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

An interesting concept has arisen as you well know in reference to cryosurgery and its definitive cure for prostate cancer. I am responding to a notice in the July Federal Register that contained the proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006.

Dr. McClellan, cryosurgery of the prostate has been more refined and has changed the whole aspect of prostate cancer surgery in that this provides men and especially older men a definitive cure with minimal morbidity and hopefully with no mortality.

I am a practicing urologist and have done many cryosurgical procedures in the hospital setting. I can only imagine what my practice would be like if cryotherapy was not a modality. In the past we have done multiple radical procedures which is open surgery and this works out very well and is definitive for those men who are younger, i.e., 40s to 60s. For those in the 70s, cryosurgery is a viable option. This service has been offered to our patients for over three years now and our results are very good. Radiation of the prostate incurs a great deal of morbidity and side effects and cryotherapy has minimized these potential problems.

It should be noted that the proposed payment rate for APC 674: Prostate Cryoblation is too low.

In reference to cryotherapy, it is a primary treatment for prostate cancer and also it may be a treatment for those men who have failed radiation therapy. Because of the limited options beforehand, cryotherapy now provides an extra glimmer of hope for these men who have failed radiation and who cannot undergo salvage radical prostatectomy and the multiple complications that could follow.

An instance comes to my mind of a gentleman who had radiation therapy and has had multiple comorbid factors, i.e., coronary artery disease and peripheral vascular disease. A PSA increased and his prostate was found to have residual prostate cancer and cryotherapy was done and now his prostate specific antigen levels (PSA) are negligible and the prostate is nonexistent on rectal examination.

It should be noted that with an advent of more technology that patient access to these technological advances are afforded. It would be a shame that we could not afford the adequate amount of reimbursement to supply patients a modern technology that could minimize their stay in the hospital and any further comorbid factors. Those who suffer are the patients. Adequate reimbursement will be necessary to allow hospitals to continue and also especially ambulatory surgical centers.

Your consideration in this matter is most appreciated and please consider the reimbursement cost of the outpatient as equitable to the reimbursement established to reflect the hospitals cost of performing the procedure.

Submitter : Mr. Tom Bombardier

Date: 08/22/2005

Organization : Mr. Tom Bombardier

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I heard that Medicare's reimbursement rates to hospitals for outpatient cryosurgery are about to drop. Does this mean that fewer patients will have access to it? I sincerely hope not. I was diagnosed with prostate cancer around last December. After a lot of research, I opted to have cryosurgery and it was successfully done in February of 2005. My ph went from 7.5 to .47. I hope and pray that my cancer is gone.

I was very pleased with cryosurgery and thankful that my insurance was able to cover most of the expense. This is a less cvasive type of surgery and one that I consider to be a must for many people. Please make it possible for more people to have it in the future.

If you have any questions for me or if there is anything else I need to do to have this continue to be a procedure that cancer patients can have, please call or write me.

Sincerely,

Tom Bombardier
802 East Kansas
Smith Center, Ks 66967
785-282-6501

Submitter : Dr. Costa Papastephanou
Organization : Ortec International, Inc.
Category : Device Industry

Date: 08/22/2005

Issue Areas/Comments

GENERAL

GENERAL

Ortec International is a development stage biotechnology company located in New York. An investment of over \$150 million has been made to make our product ORCEL a reality. ORCEL is a skin substitute composed of dermal and epidermal cells coated on a layer of collagen sponge. This product was designed for the treatment of hard to heal wounds such as venous leg ulcers and diabetic foot ulcers.

I would like to request your assistance in resolving an issue of critical importance to Ortec. In the Hospital Outpatient Prospective Payment System Proposed Rule, CMS has set the current APC reimbursement rate for ORCEL (APC 9200) at \$159.59 per unit. This represents an 86% reduction from the CY 2005 rate of \$991.85. Furthermore, the manufacturing cost for ORCEL has increased rather than decreased due to the cryo-preservation process.

We believe this inaccurate rate results from an error in the rate setting process. In the Proposed Rule, CMS identified its rate setting methodology for CY 2006 as resulting from data obtained from three sources: 1) the GAO hospital outpatient drug acquisition cost survey; 2) average sales price (ASP) data from the fourth quarter of 2004; and, 3) the mean and median costs derived from the CY 2004 hospital claims data.

Although ORCEL has been available in limited quantities as part of approved clinical trials; Ortec ceased marketing ORCEL commercially in 2002 to develop a longer shelf life product and focus on clinical trials for the use of ORCEL in venous leg ulcers. Therefore, data should not have appeared in any of the three databases. If cost data did appear, it would have been a result of erroneous billing on the part of hospitals or other providers.

We would like to meet with the appropriate individuals in your office to clear any misunderstanding and would be very grateful if your office could call us to arrange a meeting and help us reach an equitable reimbursement rate for our product. I can be reached at 646.522.1927 or by Email at costa.papastephanou@ortecinternational.com.

Submitter : Mr. Manuel H. Rodriguez
Organization : Prostate Cancer Patient
Category : Individual

Date: 08/22/2005

Issue Areas/Comments

GENERAL

GENERAL

August 22, 2005

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P

RE: CMS-1501-P: Medicare Program Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am writing this correspondence to you due to my concern regarding the possibilities that Medicare is currently considering reducing reimbursement rates or even eliminating coverage for Cryosurgery, which was disclosed to me from a notice in the July Federal Register back in September of 2004. I was diagnosed with prostate cancer which was a disheartening and traumatic revelation to me. Immediately I conducted intensive research in order to determine my treatment options. There I became aware of Cryosurgery, which I chose due to the fact that the procedure would be less detrimental to me, both physically and mentally in comparison with radical prostate removal or radioactive treatments, along with the fact that the recovery time would be much less.

After almost a year after I received Prostate Cryosurgery my PSA levels have been reduced dramatically and my cancer is in remission.

I strongly urge you to adjust the proposed payment rate upward for APC674, for in the longrun, I believe it would be more cost effective to the insurance carriers and provide another alternative to prostate cancer patients.

Sincerely,

Manuel H. Rodriguez

Submitter : Mr. Stephen Glatt
Organization : Via Christi Regional Medical Center
Category : Pharmacist

Date: 08/23/2005

Issue Areas/Comments

GENERAL

GENERAL

Drug handling codes, as proposed, as an additional line item would be impractic. This would force the organization to manually bill for the medication and the fee. This would have a net effect of increasing our cost for the service and decreasing accuracy of billing. I believe a better solution is to have two different codes for the medication, one with a handling fee and one without. We could then choose the code that corresponds with how we dispense the medication.

Submitter : tim washowich

Date: 08/24/2005

Organization : tim washowich

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

GPCIs

I am very concerned with the inequities of Medicare reimbursement rate for Santa Cruz County physicians out in california. The county is classified as a rural based on a 1960's decision. This situation clearly is not the case, as Santa Cruz County is now one of the most expensive counties in the country to live. We face a strong possibility of adequate health care availability as young doctors are not able to move into the county due to the high cost of living, with relative lower reimbursement rates compared to surrounding less expensive counties. I URGE the county be reclassified immediately, or an increase in reimbursement rates be made ASAP. This has been ignored for way too long. Making reimbursement rates based on a 40 year old decision is appalling to say the least. Please help the county be able to recruit and retain the young physicians needed to take care of the over 32,000 eligible citizens there.

Submitter :

Date: 08/25/2005

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am a patient who suffers from cardiovascular disease and am grateful that my current physician has purchased a device (BioZ) to help manage my disease. It has been brought to my attention that Medicare is proposing to reduce the amount paid to physicians for this service, Thoracic Electrical Bioimpedance as well as many of services. My physician is questioning whether he can continue to perform this service if the payment changes. I strongly encourage you to reconsider this reduction. I can attest to how valuable this test is.

Submitter : Thomas Fredrick
Organization : Thomas Fredrick
Category : Health Care Professional or Association

Date: 08/27/2005

Issue Areas/Comments

GENERAL

GENERAL

As a recipient of Prostate Cryosurgery I am requesting you not change Medicare reimbursement for outpatient surgery. This type surgery has spared me a great amount of pain and certainly reduced the cost of treatment compared to other type surgeries. Your consideration of my comments will be appreciated.

T. W. Fredrick

Submitter : Ms. Rosale Bolton
Organization : Our Lady of Fatima Hospital
Category : Hospital

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

1. Apligraf & Dermagraf is currently reimbursed in the hospital prospective payment system as a specified covered drug
2. Although the proposed rule is intended to provide reimbursement of ASP+ 8% for covered products, in the case of Apligraf and Dermagraf, the reimbursement rate proposed to be 30% below the selling price of the product
Apligraf-2005 out patient rate is \$1,130.88; 2006 proposed out patient rate is \$766.84
3. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraf are reimbursed as a specified covered drug, at ASP = 8%

Submitter : Dr. Alan ` Disimone
Organization : Our Lady of Fatima Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

1. Apligraf & dermagraf is currently reimbursed in the hospital propective payment system as a specified vovered drug (2) Although the proposed rule is intended to provide reimbursement of ASP +8% for covered products, in the case of Apligraf & Dermagraf, the reimbursement rate proposed to be 30% below the selling prive of the product. Apligraf- 2005 out patient rate is \$1,130.88; 2006 proposed out patient rate is \$766.84. Dermagraf- 2005 out patient rate is \$529.54; 2006 proposed out patient rate is \$368.32. (3) We petition CMS to correct the error in the propsed ruling and ensure that Apligraf and dermagraf are reimbursed as a specified cover drug, at ASP + 8%

Submitter : Dr. Salvatore Azzoli
Organization : Our lady of Fatima Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

1. APLIGRAF & DERMAGRAF IS CURRENTLY REIMBURSED IN THE HOSPITAL PROPECTIVE PAYMENT SYSTEM AS A SPECIFIED COVERED DRUG. (2) ALTHOUGH THE PROPOSED RULE IS INTENDED TO PROVIDE REIMBURSEMENT OF ASP + 8% FOR COVERED PRODUCTS, IN THE CASE OF APLIGRAF & DERMAGRAF, THE REIMBURSEMENT RATE PROPOSED TO BE 30% BELOW THE SELLING PRICE OF THE PRODUCT. APLIGRAF -2005 OUT PATIENT RATE IS \$1,130.88; 2006 PROPOSED OUT PATIENT RATE IS \$766.84. DERMAGRAF - 2005 OUT PATIENT RATE IS \$529.54; 2006 PROPOSED OUT PATIENT RATE IS \$368.32.(3) WE PETITION CMS TO CORRECT THE ERROR IN THE PROPOSED RULING, AND ENSURE THAT APLIGRAF & DERMAGRAF ARE REIMBURSED AS A SPECIFIED COVER DRUG,AT ASP + 8%

Submitter : Dr. ERNEST ZUENA
Organization : OUR LADY OF FATIMA HOSPITAL
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

1. APLIGRAF & DERMAGRAF IS CURRENTLY REIMBURSED IN THE HOSPITAL PROPECTIVE PAYMENT SYSTEM AS A SPECIFIED COVERED DRUG. (2) ALTHOUGH THE PROPOSED RULE IS INTENDED TO PROVIDE REIMBURSEMENT OF ASP+8% FOR COVERED PRODUCTS, IN THE CASE OF APLIGRAF AND DERMAGRAF, THE REIMBURSEMENT RATE PROPOSED TO BE 30% BELOW THE SELLING PRICE OF THE PRODUCT.. APLIGRAF - 2005 OUT PATIENT RATE IS # 1,1,30.88; PROPOSED 2006 PROPOSED OUT PATIENT RATE IS \$766.84. DERMAGRAF - 2005 OUT PATIENT RATE IS \$529.54; 2006 PROPOSED OUT PATIENT RATE IS \$366.32. (3) WE PETITION CMS TO CORRECT THE ERROR IN THE PROPOSED RULING, AND ENSURE THAT APLIGRAF & DERMAGRAF ARE REIMBURSED AS A SPECIFIED COVERED DRUG, AT ASP +8%

Submitter : Dr. BRIAN PONTERELLI
Organization : OUR LADY OF FATIMA HOSPITAL
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

1. APLIGRAF & DERMAGRAF IS CURRENTLY REIMBURSED IN THE HOSPITAL PROPECTIVE PAYMENT SYSTEM AS A SPECIFIED COVERED DRUG. (2) ALTHOUGH THE PROPOSED RULE IS INTENDED TO PROVIDE REIMBURSEMENT OF ASP +8% FOR COVERED PRODUCTS, IN THE CASE OF APLIGRAF & DERMAGRAF, THE REIMBURSEMENT RATE PROPOSED TO BE 30% BELOW THE SELLING PRICE OF THE PRODUCT.. APLIGRAF- 2005 OUT PATIENT RATE IS \$1,130.88. PROPOSED 2006 OUT PATIENT RATE IS \$766.84. DERMAGRAF-2005 OUT PATIENT RATE IS \$766.84. 2006 PROPOSED RATE IS \$366.32. (3) WE PETITION CMS TO CORRECT THE ERROR IN THE PROPOSED RULING, AND ENSURE THAT APLIGRAF & DERMAGRAF ARE REIMBURSED AS A SPECIFIED COVERED DRUG, AT ASP +8

CMS-1501-P-35

Submitter : Dr. Walter Keller
Organization : Organogenesis
Category : Device Industry

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

ATTN: File code CMS-1501-P

Dr. Keller is submitting this public comment about the error in the proposed rule, CMS-1501-P, it relates to payment rates for the wound healing products Apligraf (C1305) and Dermagraft (C92010)

These Products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs, I respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule.

Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic leg ulcers.

The proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay Specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposed to pay a pharmacy overhead charge of an additional two percent. This results in the ASP plus eight percent total payment

In the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data instead of payment at ASP plus eight percent.

There may have been some confusion in the proposed rule because the products are reimbursed in the physician's office under codes with different descriptors. Apligraf and Dermagraft have been paid based on the ASP plus six percent methodology under J7340 and J7342 respectively

Thank you for your attention to this issue and I look forward to working with you to correct the issue in the final rule.

Sincerely

Walter F. Keller D.O.

Submitter : Mrs. Mary Stevens
Organization : Smyth County Community Hospital
Category : Hospital

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

Ladies and Gentlemen::

This letter is in regard to the proposed rules for Outpatient Perspective Payment System 2006, specifically the proposal to reduce payment on multiple imaging procedures that fall within contiguous body areas. The proposed rule represents the potential to reduce by 50% payment for over 100 radiology codes when performed on the same day.

We oppose this rule for the hospital based outpatient setting. The demand for services and equipment vary significantly between an independently operated imaging clinic and a Hospital based outpatient service. In many cases, hospital operated imaging uses the same equipment that serves the outpatient population to serve the ED and inpatient population and services must be available 24/7.

We find the comparison of the use of million dollar diagnostic imaging equipment to a surgical procedure to be an inequitable comparison. Preparation time has little to do with the cost of these procedures. It is the initial cost and continuous maintenance cost of the equipment that is pertinent.

Any reduction for contiguous imaging will create hardship for hospital based services; a 50% reduction for contiguous imaging would create unreasonable hardship.

Please consider the effect passage of this proposal will have on the ability of many hospitals to maintain services.

Mary Jayne Stevens RTR, CNMT, CRA, BSHCA
Director Radiology & Outcomes Management

Submitter : Dr. Alberto Estrada
Organization : Warren Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%. The current proposed reimbursement rate for 2006 which is 30% below the selling price of the product could jeopardize patient access to Apligraf and Dermagraft and have a negative impact on quality of care.

Submitter : Mr. Richard Berthelot
Organization : Organogenesis
Category : Device Industry

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

Reimbursement at the proposed rates of \$766.84 for Apligraf and \$368.32 for Dermagraft would greatly reduce the access of Medicare beneficiaries to these products and would increase the rate of amputations from diabetic foot ulcers in the medicare patient population. Increased amputations leads to higher costs due to rehabilitation costs and in some cases institutionalization of the patient who was previously ambulatory. The mortality rate for post amputation diabetic patients according to the American Diabetes Association approaches 60% within 5 years of the first amputation.
Please correct the error in the proposed ruling and insure that Apligraf and Dermagraft are reimburses as a covered drug at ASP+8%.

Submitter : Ms. judith shea
Organization : milton hospital
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

it has come to my understanding that there has been a technical error regarding the 2006 reimbursement rate for both apligraf and dermagraft. This error will restrict access to the product for patients who need and benefit from it. Please make this a priority to correct for 2006.

Submitter : Mrs. Denise Creavin
Organization : Milton HOSPITAL
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

IT HAD COME TO MY ATTENTION THAT THERE HAS BEEN A TECHNICAL ERROR REGARDING THE 2006 REIMBERSEMENT RATE FOR BOTH APPLIGRAPH & DERMAGRAFT. THIS WILL LIMIT ACCESS TO THE PATIENTS WHO NEED IT & CAN BENEFIT BY IT. PLEASE MAKE THIS A PRIORITY TO CORRECT IT FOR 2006.

Submitter : Mrs. MARYANNE DONAHUE
Organization : MILTON HOSPITAL
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

IT HAS COME TO MY ATTENTION THAT THERE HAS BEEN A TECHNICAL ERROR REGARDING THE 2006 REIMBURSEMENT RATE FOR BOTH APLIGRAF AND DERMAGRAFT. THIS ERROR WILL LIMIT ACCEES TO THE PRODUCT FOR BOTH PATIENTS WHO NEED IT AND CAN BENEFIT FROM IT. PLEASE MAKE THIS A PRIORITY TO CORRECT FOR 2006 AND ALLOW THE PATIENTS WHO CAN BENEFIT TO HAVE ACCESS TO IT.

Submitter : Dr. GREGORY KECHIJIAN
Organization : MILTON HOSPITAL
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

IT HAS COME TO MY ATTENTION THAT THERE HAS BEEN A TECHNICAL ERROR REGARDING THE 2006 REIMBURSEMENT RATE FOR BOTH APLIGRAF AND DERMAGRAFT. THIS ERROR WILL RESULT IN LIMITED ACCESS TO THE PRODUCT FOR BOTH MY DIABETIC AND VENOUS COMPROMISED PATIENTS, WHO CAN BOTH BENEFIT FROM ITS ABILITY TO HEAL THEIR WOUNDS. PLEASE MAKE THIS A PRIORITY AS WE HAVE MANY CURRENT PATIENTS WHO WILL BENEFIT.
SINCERELY

Submitter : Dr. Andrew Smith
Organization : Warren Hospital Wound Care Center
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I would like to draw your attention to the proposed reimbursements for 2006 regarding engineered skin substitutes, ie apligraf and dermagraft. The proposed reimbursement is below the cost of the product and if implemented will effectively prevent us from using these products on our Medicare patients. As the Medical Director of the Wound Healing Center at Warren Hospital in Phillipsburg, NJ I can assure you this would be a significant hardship for our patients to bear.

Submitter : Dr. Robert Abrahamsen
Organization : St Mary's Regional Medical Center
Category : Device Industry

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing you about the proposed rule change CMS-1501-P "Medicare Program; Changes to the hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates". The change proposed would seriously affect and undermine wound care in the USA. Apligraf is an advanced bioengineered tissue based therapy indicated for the treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP-8%.

Thank you for your consideration, and for your support to use these products to care for our patient population and save more limbs.

Robert Abrahamsen, MD FACEP

Submitter : Dr. Wayne Caputo
Organization : Clara Maass Medical Center
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P "Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates: contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. Although the proposed rule is intended to provide reimbursement of ASPplus 8%for the covered products ,in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Apligraf - 2005 outpatient rate \$1,130.88: 2006 proposed outpatient rate \$766.84. Dermagraft -2005 outpatient rate \$529.54: 2006 proposed outpatient rate \$368.32. Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, as ASP plus 8%

Submitter : Dr. Brian McCann
Organization : St Mary's Regional Medical Center
Category : Device Industry

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing you about the proposed rule change CMS-1501-P "Medicare Program; Changes to the hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates". The change proposed would seriously affect and undermine wound care in the USA. Apligraf is an advanced bioengineered tissue based therapy indicated for the treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP-8%. Thank you for your consideration, and for your support to use these products to care for our patient population and save more limbs. Brian McCann, MD FACEP

Submitter : Dr. michael hutzel
Organization : nassau orthopedic surgeons
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

It has come to my attention that proposed rule cms-1501p contains errors which will be detrimental to our patient's wound care. apligraf and dermagraft are currently reimbursed as a covered drug. however, your proposed rate will be at 30% below the cost of the drug making it impossible to use. i am requesting that cms correct the error and return to the original ammount of asp + 8% as the reimbursment.

Submitter : Dr. NISSAGE CADET
Organization : MILTON HOSPITAL
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

IT HAS COME TO MY ATTENTION THAT THERE HAS BEEN A TECHNICAL ERROR POTENTIALLY DECREASING THE 2006 REIMBURSEMENT RATE FOR BOTH APLIGRAF AND DERMAGRAFT. THIS WILL LIMIT ACCESS TO BOTH THESE TREATMENT OPTIONS FOR MY DIABETIC PATIENTS AND VENOUS COMPROMISED PATIENTS WHO NEED AND CAN BENEFIT FROM THESE TREATMENT OPTIONS. PLEASE MAKE IT A PRIORITY TO CORRECT THE REIMBURSEMENT FOR THESE PRODUCTS IN 2006

Submitter : Dr. Frederick Lorenzo
Organization : Pinnacle Health Wound Care Center
Category : Device Industry

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I am bringing your attention to and error in the proposed rule, CMS-1501-P, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rates for the wound-healing products Apligraf (c1305) & Dermagraft (C9201). The category for these products needs to be corrected. The reimbursement at the proposed rate would jeopardize patient access to Apligraf & Dermagraft and that would have a very negative impact on the quality of care my patients receive.

Submitter : Dr. peter salzer

Date: 08/29/2005

Organization : lihbo

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

Submitter : Dr. John Hoina

Date: 08/29/2005

Organization : Long Island Wound care and Hyperbaric Medical Asso

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

to whom it may concern. i believe there is an error in your proposed changes to the outpatient hospital prospective payment in relation to Apligraf and Dermagraft which will affect our ability to use these valuable products. these products help speed healing of wounds and help prevent amputations. these items are currently covered by your payment system. However, the proposed change will result in these products being reimbursed at 30% below their cost. Most hospitals will no longer be able to provide them. this of course will jepordize their availability to our patients. Please correct this error and return to the original proposal of asp + 8%. thank you.

Submitter : Miss. Denise Trivett
Organization : Clara Maass Wound Center
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

This public comment is being submitted to bring to your attention to an error in the proposed rule, CMS-1501-P, "Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201). These products have been paid in the hospital and outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule. Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. These products have preserved and improved the quality of life of thousands diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have to undergo limb amputations without the benefits of Apligraf and Dermagraft. Although the proposed rule is intended to provide reimbursement of ASP plus 8% for the covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Apligraf - 2005 outpatient rate \$1130.88: 2006 proposed outpatient rate \$766.84, Dermagraft- 2005 outpatient rate \$529.54: 2006 proposed outpatient rate \$268.32. Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact of quality of care.

Submitter : Mrs. Janice Reilly

Date: 08/29/2005

Organization : NYHBO

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Please correct the error in the proposed ruling and ensure that Apligraf & Dermagraqft are reimbursed as a specified covered drug at ASP = 8%.

Submitter : Dr. Eric Slone
Organization : New Island Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf and Dermagraft are currently reimbursed in the HPPS as a specified covered drug. Although the proposed rule is intended to provide reimbursement of ASP +8% for covered products, in this case Apligraf & Dermagraft, the reimbursement rate is proposed to be 30% BELOW the selling price of the product. Reimbursement at this rate would jeopardize patient access to Apligraf and dermagraft. Please correct this error.

Submitter : Mrs. Suzanne Lee-Allen

Date: 08/29/2005

Organization : New Island Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I am petitioning to correct the error in the proposed ruling and ensure that APligraf & Dermagraft are reimbursed as a specified covered drug, at ASP+8%. APligraf is the only tissue based therapy approved for treatment of venous leg ulcers.

Submitter : Miss. Patricia Monterosa
Organization : Wound Center at Clara Maass
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

To the Medicare Program, I'm writing to you on behalf of a Wound Center in N.J. This comment comes after reviewing proposed changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. As you know, in the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent. In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005. However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid. Instead of payment as ASP plus eight percent, both products experienced a significant decrease in payment: Apligraf-2005 outpatient rate \$1130.88; proposed outpatient rate \$766.84. Dermagraft- 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32 There may have been some confusion in the proposed rule because the products are reimbursed in the physician's office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP = six percent methodology under J7340 and J7342 respectively.

It is respectfully requested to correct the Apligraf and Dermagraft payments in the final rule. Thank you

Submitter : Dr. Chanchal Saha
Organization : New Island Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I petition you to correct the reimbursement rate for Apligraf & dermagraft for 2006. It should be as a specified covered drug at ASP+8%

Submitter : Miss. Julie Balaco
Organization : Clara Maass Wound Center
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advance bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers. Proposed rule CMS-1501-P "Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement is proposed to be 30% below the selling price of the product. Apligraf-2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 Dermagraft - 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : Dr. David Kaufman
Organization : New Island Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I am petitioning to have a correction made in the proposed ruling and ensure that Apligraf & Dermagraft are reimbursed as a specified covered drug at ASP +8%

Submitter : Dr. David Lotfi
Organization : New Island Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

Submitter : Dr. Terrance McElgun
Organization : New York Hyperbarics
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

Submitter : Dr. Walter Ramsey

Date: 08/29/2005

Organization : New Island Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

Submitter : Dr. Frank Ross
Organization : New Island Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

please correct the error in the proposed ruling and ensure that Apligraf & Dermagraft are reimbursed as a specific covered drug, at ASP + 8%

Submitter : Miss. Elizabeth Pichler
Organization : Wound Center at Clara Maass
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. Although the proposed rule is intended to provide reimbursement rate is proposed to be 30% below the selling price of the product. Apligraf -2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 Dermagraft - 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32. Reimbursement at this rate would jeopardize Diabetic and Venous Stasis Ulcer patients access to Apligraf and Dermagraft. This would have a very negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%

Submitter : Dr. Joseph Lobiondo
Organization : Clara Maass
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

This public comment is to bring to your attention an error in the proposed rule, CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201). Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. These products have preserved and improved the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft. Proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Apligraf-2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84, Dermagraft- 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32. Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, as ASP+8%.

Submitter : Dr. Edward Ferdinando
Organization : Staten Island University Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I have been informed of the pending changes to hospital outpatient payment system for adv. bioengineered tissues. After review of these proposed outpatient rates for both Apligraf and Dermagraft it is blatantly obvious that this would have a serious negative effect on the future of wound management in our community. Both of the products have proven extremely valuable in diabetic wound care and limb salvage. The proposed rates would eliminate the use of these products in the outpatient setting. Therefore, I am requesting that these rates that have been proposed for 2006 be reconsidered and revised in order that we continue to use both of these items in the office and hospital settings.

Submitter : Dr. Merabi Zonenashvili
Organization : Staten Island University Hospital
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I would like to petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specific covered drug, at ASP+ 8%. They are currently proposed to be 30% below the selling price of the product for 2006. This rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on the quality of care, and would seriously undermine wound care in the United States. Please correct this error in the proposed 2006 reimbursement rates.

Submitter : Ms. Cindy Taylor
Organization : Wound, Ostomy & Continence Nursing Society
Category : Nurse

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

Patient access to Apligraf (c1305) is critical for the healing chronic wounds. Apligraf is the only product that is FDA approved for Venous Leg Ulcers and only one of three products that is FDA approved for Diabetic Foot ulcers. Of those three, Apligraf has the best healing outcomes. Apligraf is cost effective and demonstrates the highest efficacy in wound healing. By decreasing the reimbursement rate, as proposed, many patients will not receive the benefits of Apligraf and will be faced with amputations.

Thank you,

Cindy Taylor RN, MSN, WOCN

Submitter : Dr. Maurice Nicholson
Organization : Gamma Knife Center of the Pacific
Category : Other Health Care Provider

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing to let you know we adamantly support CMS's proposal to place cobalt-60 stereotactic radiosurgery in a New Technology APC that appropriately covers all the costs associated with this procedure. Currently the reimbursement is deficient.

Thank you for your consideration of the matter.

Maurice W. Nicholson M.D,
Gamma Knife Center of the Pacific

Submitter : Dr. VAL ATANASSOV
Organization : BGPMA
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

IT HAS COME TO MY ATTENTION THAT THERE HAS BEEN A TECHNICAL ERROR THAT HAS EFFECTED THE 2006 REIMBURSEMENT RATE FOR DERMAGRAFT AND APLIGRAF. THIS WILL LIMIT ACCESS TO MY DIABETIC AND VENOUS COMPROMISED PATIENTS WHO CAN BENEFIT FROM THESE THERAPIES. PLEASE MAKE IT A PRIORITY TO CORRECT THE REIMBURSEMENT SCHEDULE FOR 2006.

Submitter : Dr. STEPHEN PIDGEON
Organization : BGPMA
Category : Physician

Date: 08/29/2005

Issue Areas/Comments

GENERAL

GENERAL

IT HAS COME TO MY ATTENTION THAT THERE HAS BEEN A TECHNICAL ERROR REGARDING THE 2006 REIMBURSEMENT SCHEDULE FOR BOTH APLIGRAF AND DERMAGRAFT. THIS WILL RESTRICT ACCESS TO MY DIABETIC PATIENTS THAT NEED AND COULD BENEFIT FROM THESE THERAPIES. PLEASE MAKE THE NECESSARY CORRECTIONS TO THE 2006 FEE SCHEDULE FOR THESE NEEDED PRODUCTS.

Submitter : Mr. Geoff MacKay
Organization : Organogenesis
Category : Device Industry

Date: 08/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. previously filed under incorrect item

CMS-1501-P-72-Attach-1.DOC

CMS-1501-P-72-Attach-2.DOC

Organogenesis Inc.

LIVING TECHNOLOGY

150 Dan Road, Canton,
Massachusetts 02021

August 12, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006 Payment Rates --
Drugs, Biologicals, and Radiopharmaceuticals Non Pass-throughs

Dear Administrator McClellan:

Organogenesis, Inc. is writing to comment on an error in the proposed rule, CMS-1501-P, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rate for our product Apligraf®. Organogenesis is a biotechnology company based in Canton, Massachusetts and we manufacture and market Apligraf (C1305), a unique human skin substitute for diabetics and the elderly who suffer from chronic ulcers. As set out below, Apligraf has been paid in the hospital outpatient prospective payment system as a specified covered outpatient drug and should be paid in 2006 similar to other such drugs. We are notifying the agency as soon as possible due to the significant decrease in reimbursement for Apligraf as a result of the error in Addendum A of the proposed rule and the negative impact on beneficiary access to wound care treatment. We respectfully request that CMS reimburse hospitals for Apligraf as a specified covered outpatient drug in the final rule based on the average sales price (ASP) data that has been reported to CMS on a quarterly basis under Apligraf's NDC number (NDC #09978-0001-99).

Apligraf® Is A Unique, Medically-Necessary And Cost-Saving Treatment

Apligraf is a unique, bioengineered, cell-based living human skin substitute for the treatment of chronic, hard-to-heal venous leg ulcers and diabetic foot ulcers. Like human skin, it is made from living cells and it is composed of two layers, a dermis and an epidermis comprised of healthy, functioning, responsive cells that stimulate the wound to heal. Apligraf® is the only active wound-healing product approved by the

U.S. Food and Drug Administration (FDA) to treat both venous leg ulcers and diabetic ulcers. The incidence of chronic wounds in the United States is approximately 5 to 7 million per year, and the annual costs for management of these wounds is greater than \$20 billion. No other active wound-healing product is indicated for treatment of venous leg ulcers. Before the development of Apligraf, physicians had few options for treating hard-to-heal venous leg ulcers, which comprise approximately one-third of all treated venous ulcers. Apligraf has preserved and improved the quality of life of tens of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of them would have had to undergo limb amputations without the benefit of Apligraf. Apligraf and similar advanced bioactive products have been specified by leading clinicians in published algorithms as the standard of care for wounds that have not responded to conventional therapy. Apligraf is a proven cost-effective therapy for chronic foot ulcers, providing savings in wound care costs of \$7,500 for these patients.

Apligraf is a Specified Covered Outpatient Drug

The Medicare history of Apligraf demonstrates that Apligraf has been recognized and paid as a biologic and under MMA recognized as a specified covered outpatient. The following background may help clarify for the agency the classification of Apligraf in the hospital outpatient setting.

- **In 2001 and 2002:** Apligraf was paid in the hospital outpatient setting as a biological under the pass through list. In February, 2001 CMS (then HCFA) issued a Program Memorandum (Transmittal B-01-07) that states "*Apligraf has met the statutory requirement as a biologic.*" (See attachment 1).
- **In 2003:** Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 Apligraf has been paid in the hospital outpatient setting as a sole source biological at 88% of AWP in 2004 and 83% of AWP in 2005 under the specified covered outpatient drug provision.
- **As recent as 2005 in the GAO:** As a specified covered outpatient drug Apligraf was included in the General Accountability Office (GAO) survey of acquisition costs for hospital outpatient drugs. The GAO Report dated June 30, 2005 (GAO-05-581R) on specified covered outpatient drugs states "[GAO] obtained from our survey data the average and median purchase prices for each of the 53 SCOD drug categories." Apligraf is listed under number 38 in Table 1 of the report detailing the acquisition costs for specified covered outpatient drugs. (See attachment 2.)

Apligraf's History of HCPCS C1305 and J7340

On February 7, 2001, the Program Memorandum (Transmittal B-01-07) that CMS (then HCFA) issued also provided two HCPCS codes for Apligraf: C1305 for hospital outpatient and Q0185 for the physician office. (See attachment 1).

The transmittal states:

For these services, physicians should not bill Apligraf using HCPCS code C1305 since this code has been approved solely for use under the hospital outpatient prospective payment system.

Effective July 1, 2002, in Transmittal B-02-015, CMS assigned J7340 to Apligraf for billing in the physician setting and eliminated the use of the temporary Q0185. The new J code was provided the descriptor of "Metabolic active Dermal/Epidermal tissue". (See attachment 3). Consequently, since July 1, 2002 Apligraf® has been billed under J7340 in physician's office.

It has been CMS policy that the C1305 code is for sole use in the hospital outpatient setting. In Chapter 17 of the Medicare Claims Processing Manual covering payment for drugs and biologics CMS provided the following guidance for pass-through drugs:

Only HCPCS code C1305 is reportable under the hospital OPPS. HCPCS J7340 should NOT be reported for Apligraf under the hospital OPPS.

(See attachment 4.)

Apligraf's Payment Rate is Incorrectly Listed in Addendum A

In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services (CMS) proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent.

We understand based on communication with the agency that CMS paid Apligraf based on mean costs derived from historical hospital claims data because there had been no ASP payment rate specific to HCPCS C1305. We believe the confusion in the proposed rule is because the ASP rate for Apligraf is reported by CMS under HCPCS J7340.

Based on the April 1, 2005 ASP rate for Apligraf, payment at ASP plus 8% would be \$1,203.69. However, Apligraf is listed in addendum A of the proposed rule at \$766.84 which is clearly in error. (See attachment 5.)

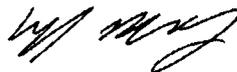
It is important to note that the CMS reporting requirements for ASP submissions are by NDC not HCPCS code. Organogenesis has reported ASP data for Apligraf since the inception of the ASP system and regularly submits ASP quarterly updates to CMS under the NDC # 09978-0001-99. In the July 2005 quarterly update, CMS published an ASP rate for Apligraf of \$1,182.72 (\$26.88 sqcm). The ASP data submitted by Organogenesis includes all sales irrespective of the site of care for the respective quarter. Attached is the most recent ASP filing submitted by Organogenesis for Apligraf (See Attachment 6). **Therefore, Apligraf's ASP is comprised of sales billed by providers under C1305 in the hospital OPPS and under J7340 in the physician setting.**

Conclusion

The proposed payment rate is incorrect and will significantly underpay hospitals for Apligraf. We have already been contacted by a number of leading wound care providers in the country regarding their concern that the proposed payment rate will have a significant negative impact on beneficiary access to standard of care wound treatment. Thus, we believe it is very important that in the final hospital outpatient rule it is clarified that hospitals will be reimbursed for the acquisition of Apligraf at ASP plus six percent and an additional two percent for pharmacy overhead cost similar to other specified covered outpatient drugs. In this regard, we would like to meet with agency staff during the comment period. You may contact me directly at 1 (781) 401-1040.

Thank you for your attention to this issue

Sincerely,



Geoff MacKay
President & CEO

Submitter : Dr. David Richmand
Organization : Muhlenberg Wound Care Center
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

RE: Proposed rule CMS-1501-P I am aware of the proposed changes in the reimbursement for bioengineered tissues. The proper use of bioengineered tissues in wound and burn management has become essential to cost effective treatment, particularly elderly and debilitated patients. The fee structure should encourage use of these materials. I feel that any reduction in reimbursement is short-sighted. Bioengineered tissues markedly reduce the time for wound healing and have reduced total costs to payers.

Submitter : Dr. Peter Mlynarczyk
Organization : Trinitas Hospital
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs,

With respect to CMS 1501-B I am appalled at the reduction of the bioengineered tissues ie: Apligraf and Dermagraft. This is the same scenario that occurred several years ago when your department previously made these decisions. This caused the prolongation of healing in multiple patients, in several indications. Thus increasing the cost to the government program. With the decreasing physician fees and increasing malpractice, the advances in medical technology cannot be offered to patients at a loss. There has to be some balance in the system. I encourage you to readjust this error and ensure that the institutions are reimbursed at the ASP+6%.

Submitter : Dr. Jerald Carmel
Organization : Mt. Sinai Medical Center wound center
Category : Device Industry

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advance bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. it is the only tissue based therapy approved for treatment of venous leg ulcers

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

Submitter : Ms. Elizabeth Redmond
Organization : Mt Sinai Medical center wound care center
Category : Device Industry

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advanced bioengineered tissue therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers.

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

Submitter : Mrs. Pearl Shapiro
Organization : Mt Sinai Medical Center Wound Center
Category : Device Industry

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advanced bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers.

Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug.

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

Submitter : Sonya Steiner
Organization : HealthEast Vascular Center
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Please rectify the reimbursement issues with Apligraf/Dermagraft for 2006 to reflect current reimbursement. An increase in costs for these products will limit patient access to these treatments.

Submitter : Dr. Brian Miller
Organization : HealthEast Vascular Center
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Please rectify the reimbursement issues with Apligraf/Dermagraft for 2006 to reflect current reimbursement. An increase in costs for these products will limit patient access to these treatments. I have found these products to be of great benefit to our patients with chronic wounds.

Submitter : Dr. Charles Kurtzer
Organization : the FOOT group
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed CMS-1501-P contains errors in calculations which seriously undermine wound care in the US.

As you know Apligraf is an advanced bioengineered tissue base therapy with studied clinical outcomes indicated for the treatment of venous leg ulcers and diabetic foot ulcers.

Currently, Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug.

Although the proposed rule is intended to provide reimbursement of ASP + 8%, the erroneously calculated new reimbursement price would be 30% below AWP.

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft which would negatively impact availability and resulting in a negative impact on the quality of care.

Therefore, I petition the CMS to correct the error in the proposed ruling and ensure the Apligraf and Dermagraft are reimbursed as a specified covered drug at ASP +8%.

Thank you,

Charles M. Kurtzer, DPM, FACFAS

CMS-1501-P-81

Submitter : Dr. mark Decotiis
Organization : Bayshore
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Regarding proposed rule CMS-1501-P Medicare Program: changes to the Hospital Outpatient Perspective Payment system for 2006. It contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified drug. The reimbursement rate is proposed to be 30% below the selling price of the products. This will jeopardize patient access to Apligraf and Dermagraft and will have a negative effect on pt care. Please reevaluate and correct this error.

Submitter : Dr. Irwin Schultz
Organization : Forest Park Wound Care Center
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P "Medi8care Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States.

Apligraf is an advance bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers.

Although the proposed rule is intended to provide reimbursement of ASP + 8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : Ms. Christine Heady
Organization : Forest Park Wound Care
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States. Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP + 8%.

Submitter : Ms. Ann Oldani
Organization : Forest Park Wound Care
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. Reimbursement at the proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : Dr. Jaime Carbonell
Organization : Jackson South wound center
Category : Device Industry

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of patient care.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

CMS-1501-P-86

Submitter : Dr. Tim Oldani
Organization : Forest Park Wound Care
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Apligraf is an advanced bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of Venous Leg Ulcers. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specific covered drug, at ASP+8%

Submitter : Mrs. Donna Silva
Organization : Jackson South Wound Care Center
Category : Device Industry

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advance bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. it is the only tissue based therapy approved for treatment of venous leg ulcers.

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

CMS-1501-P-88

Submitter : Ms. Audrey Moyer
Organization : Forest Park Wound Care
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%.

CMS-1501-P-89

Submitter : Ms. Karen Presley
Organization : Forest Park Wound Care Center
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in teh case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : Dr. Jeffrey Boberg
Organization : Forest Park Wound Care
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as as specified covered drug. Although the proposed rule is to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. This rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as as specified covered drug, at ASP+8%.

CMS-1501-P-91

Submitter : Dr. Nick Martin
Organization : Forest Park Wound Care Center
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Reimbursement at the proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

CMS-1501-P-92

Submitter : Ms. Kathleen Furdek
Organization : Forest Park Wound Care Center
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. This rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%.

Submitter : Ms. Helen Wilson
Organization : Forest Park Hospital
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Reimbursement at the proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%.

Submitter : Ms. Christina Schlaikjer
Organization : Forest Park Hospital
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as as specified covered drug. Reimbursement at the proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP + 8%.

CMS-1501-P-95

Submitter : Ms. Veronica Moloney

Date: 08/30/2005

Organization : Forest Park Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as aspecified covered drug. Reimbursement at the proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%.

CMS-1501-P-96

Submitter : Ms. Theza Fitzpatrick
Organization : Forest Park Hospital
Category : Nurse

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Reimbursement at the proposed rate would jeopardize patient access to Apligraf and Dermagraft, and this would have a negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as as specified cover drug, at ASP +8%.

Submitter : Dr. Julian Mosley
Organization : Forest Park Hospital
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Apligraf is an advanced bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers. Reimbursement would jeopardize access to Apligraf and Dermagraft and that would have a very negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%.

CMS-1501-P-98

Submitter : Dr. Herbert Shapiro
Organization : Forest Park Hospital
Category : Physician

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS- 1501-P contains errors which would seriously undermine wound care in the United States. Proposed reimbursement rates for CMS 1501-P would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP + 8%.

Submitter :

Date: 08/30/2005

Organization :

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-99-Attach-1.DOC

August 30, 2005

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Washington DC 20201

ATTENTION: FILE CODE CMS-1501-P

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates-Drugs, Biologicals and Radiopharmaceuticals Non Pass-throughs

Dear Mr. Kuhn:

It has come to our attention that proposed rule CMS-1501-P as described above contains errors which would seriously impact and undermine wound care in our clinic and the United States. These errors relate to the payment rates for the wound healing products Apligraf and Dermagraft.

To date these products have been paid in the *hospital outpatient* prospective payment system as specified covered outpatient drugs. We think they should continue to be paid in this manner in 2006. Patient access to these products will be seriously jeopardized by the payment rates in the proposed rule.

Apligraf and Dermagraft are important elements of advanced wound care and have been shown to speed rates of healing and have preserved and improved the quality of life for many people. Many people would likely have required limb amputations without the benefit of these products.

It is our understanding that in the proposed rule, both Dermagraft and Apligraf would be incorrectly paid based on rates from claims data instead of the current method of payment based on average sales price plus 8%. With the proposed method of payment, both products will experience a significant decrease in reimbursement. The proposed reimbursement is actually 30% below the selling price of the products. This may make it impossible for us to offer these very effective therapies to our patients and will have a very negative impact on the quality of care.

This letter is actually to petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug at average sale price plus 8%.

Thank you for your attention to this matter.

Pam Hyatt, RN
Nurse Manager
St. Vincent Wound Care Center

CMS-1501-P-100

Submitter : Dr. James Donahue

Date: 08/30/2005

Organization : Costal Health Care

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

I am submitting my comments about the proposed rule change CMS-150-P "Medicare Program; Changes to the hospital Outpatient Prospective Payment System an Calendar year 2006 Payment Rates". The Changes would seriously affect and undermine wound care in the USA. Apligraf and Dermagraft are advanced bioengineered tissue based therapy for the treatment of venous leg ulcers and diabetic foot ulcers. Apligraf and Dermagraft have been shown to heal ulcers and reduce amputatiopn rates in these patients. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. The proposed rule is intended to provide reimbursement of ASP+8% for covered products however the proposed rate is 30% below the selling price of the product. Reinbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and would have a negative impact on Wound care. The proposed rule would incorrectly pay on rates based on derived claim data in stead of payment at ASS+8%. Apligraf-2005 outpatient rate \$1'130.88; 2006 proposed outpatient rate \$766.84 Dermagraft- 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32. There may have been some confusion in the proposed rule because the products are reimbursed in the physicians office under codes with different discriptors. Thank you for your attention to this issue and I look forward to working with you to correct the issue in the final rule
Sincerely James B. Donahue D.O. CMD

CMS-1501-P-101

Submitter : Mrs. Linda Donahue RN
Organization : Costal Health Care
Category : Device Industry

Date: 08/30/2005

Issue Areas/Comments

GENERAL

GENERAL

I am submitting this public comment to bring to your attention an error in the proposed rule CMS-1501-P " Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rates for the wound-healing products Apligraf (C1350) and Dermagraft (C9201) These products have been paid in the hospital outpatient prospective payment system as Specific covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Apligraf and Dermagraft are living human tissue substitutes for the treatment of Venous leg ulcers and Diabetic foot ulcers. As you are aware in the proposed Hospital Outpatient Rule for 2006 the Centers for Medicare and Medicaid Services prpposed to pay specified covered drugs at ASP+6% for the acquisition cost of the drug and allows the Pharmacy overhead charge of an additional 2% which results in a total payment for specified covered outpatient drugs of ASP+8% . However in the proposed rule both Apligraf and Dermagraf would be incorrectly paid based on rates derived from claims data instead of payment at ASP+8% .

Thankyou for your attention to this issue and the correction of this in the final Rule
Sincerely Linda Donahue RN

Submitter : Dr. Jerome Casey

Date: 08/31/2005

Organization : Wayne Memorial Hospital Wound CareCenter

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing podiatrist and a staff wound care specialist of the Wayne Memorial Hospital Wound Center in Honesdale, Pa. Also, I am a member of the American Professional Wound Care Association. It has been brought to my attention that an extremely valuable treatment option for my wound care patients is in jeopardy. It appears that there is an error in the proposed rule, CMS-1501-P, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" as it relates to reimbursement for Apligraf and Dermagraft. The plan to reduce payment to below actual selling price would virtually eliminate patient access to these products. I urge the CMS to correct this obvious error to ensure there continued access so that current wound care protocols and advancements will continue. I, also, ask this on behalf of my wound care patients!

Submitter : Dr. Jmaes De Meo
Organization : Dr. Jmaes De Meo
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule to CMS-1501-P deeply concerns me as a practicing surgeon. Apligraf is an advanced bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important tool in advanced wound care both in and out of the hospital setting. It has the ability to speed up healing rates and reduce amputations in severely affected patients. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in this case Apligraf & Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product, thus making it cost prohibitive. Reimbursement at this rate will jeopardize patient access to Apligraf & Dermagraft and that would have a very costly negative impact on the quality of care. As a practicing surgeon I can attest to the cost savings these products have when used on an outpatient basis. Not every patient with a non healing ulcer needs to go to the operating, on the other hand every patient with a non healing ulcer needs a bioengineered tissue based product. The proposed rule CMS-1501-P contains errors which seriously undermine wound care as well as increase costs in an ever escalating fiscal healthcare environment. I petition CMS to correct this error in the proposed ruling and ensure that Apligraf & Dermagraft are reimbursed as a specified covered drug at ASP+8%. Thank you.

CMS-1501-P-104

Submitter : Dr. Andrew Candelore
Organization : A J Candelore DO
Category : Device Industry

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P"Medicare Program: Changes to HospitalOutpatient Prospective Payment System and Calender Year 2006Rates ".I petition CMS to correct the error in the ptoposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug,ASP+8%. Andrew cANDELORE do

Submitter : Dr. David Eisenbud
Organization : Millburn Surgical Associates
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

My medical practice focuses on wound management. I believe the bioengineered skins such as Apligraf and Dermagraft are very valuable approaches to accelerate wound healing in venous and diabetic wounds. The new reimbursement proposed for these products is not sufficient to cover the costs of production, distribution and quality assurance and the net result of such reimbursement will be that the product will not be available for me to use on patients: either the companies will not realize sufficient profit to continue production, or hospitals will be asked to pay full price and take a loss. As I understand this is the result of a mistake in the calculations, not a deliberate policy decision, I hope that correcting this problem will not be a "politically charged" situation.

Submitter : Dr. RAMANATH IYER
Organization : SOUTHERN MAINE MEDICAL CENTER
Category : Device Industry

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

PROPOSED RULE CMS-1501 p "medicare program; Changes to the hospital outpatient prospective payment system and calendar year 2006 payment rates" contains errors which would seriously undermine wound care in the United States.

Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Sincerely,

Ramanath Iyer, M.D.

Submitter : Ms. Sandra Candelore
Organization : Andrew J Candelore DO
Category : Nurse

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

We recently obtained and placed a Apligraf on an elderly patient who has not shown any hope of healing a diabetic leg ulcer. I have also seen this grafting help others to avoid extended expensive nursing care and eventual amputation for diabetic ulcers that refuse to heal. We would like to continue to give such treatments to others if needed, but if you reduce your reimbursement by almost half most if not all of our patients will be unable to afford to have this valuable procedure done. This is a valuable treatment for a nearly incurable problem. Please correct the technical error in the 2006 Hospital Outpatient Department Proposed Rule CMS-1501-P and ensure Apligraf and Dermagraft are reimbursed as a specific covered drug.

Submitter : Ms. Timber Keys
Organization : Wound Care Center-Arkansas Heart
Category : Device Industry

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States. Apligraf and Dermagraft greatly improve the quality of life for individuals affected by chronic non-healing ulcers, saving amputations for many.

Submitter : Dr. James Balshi
Organization : St. Luke's Hospital & Health Network
Category : Device Industry

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed reduction in payment for Apligraf below ASP will jeopardize access to this essential therapy for Medicare beneficiaries. Apligraf has dramatically lowered costs for treatment of Chronic wounds by accelerating healing and reducing pain.

Submitter : Dr. Michael Perouansky
Organization : University of Wisconsin
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-110-Attach-1.DOC

8-28-05

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P/TEACHING ANESTHESIOLOGISTS
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare and Medicaid Services (CMS) to change the Medicare anesthesiology teaching payment policy. I am an Associate Professor of Anesthesiology who has worked in academics both in the USA and abroad. I have seen first hand how academic anesthesiologists are being discriminated against with a policy that singles out anesthesiology with reduced payment. At the University of Wisconsin Hospital, we have over 30 faculty anesthesiologists and over 36 anesthesiology residents. Every time I work with two residents, I am penalized by Medicare's policy. Our reimbursement rate has threatened our department's survival and only by receiving temporary "hand-outs" from our hospital and physician group are we able to maintain quality faculty.

Medicare's policy has had a serious adverse impact on the ability of programs to retain skilled faculty and to train the new anesthesiologists necessary to help alleviate the widely-acknowledged shortage of anesthesia providers -- a shortage that will be exacerbated in coming years by the aging of the baby boom generation and their need for surgical services.

Under current Medicare regulations for other specialties, teaching surgeons and internists are permitted to work with residents on overlapping cases and receive full payment so long as the teacher is present for critical or key portions of the procedure. Teaching surgeons may bill Medicare for full reimbursement for each of the two procedures in which he or she is involved. An internist may supervise residents in four overlapping office visits and collect 100% of the fee when certain requirements are met.

Teaching anesthesiologists are also permitted to work with residents on overlapping cases so long as they are present for critical or key portions of the procedure. However, unlike teaching surgeons and internists, since 1995 the teaching anesthesiologists who work with residents on overlapping cases face a discriminatory payment penalty for each case. The Medicare payment for each case is reduced 50%. This penalty is not fair, and it is not reasonable. The Medicare anesthesia conversion factor is less than 40% of prevailing commercial rates. Reducing that by 50% for teaching anesthesiologists results in a revenue

grossly inadequate to sustain the service, teaching and research missions of academic anesthesia training programs.

Correcting this inequity will go a long way toward assuring the application of Medicare's teaching payment rules consistently across medical specialties and toward assuring that anesthesiology teaching is reimbursed on par with other teaching physicians.

Please end the anesthesiology teaching payment penalty.

Regards,

Michael Perouansky, MD

5832 Woods Edge road

Madison, WI 53711

Submitter : Leigh Kauwell
Organization : Carle Wound Healing Center
Category : Nurse

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Please do not change the coverage for Apligrat Dermagraft. These products increase our healing rates significantly.

Submitter : Dr. Charles LaRosa
Organization : Southside Hospital
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Please correct the error in the proposed ruling and ensure that Apligraf & Dermagraft are reimbursed as a specified covered drup at ASP+8%

Submitter : Dr. Kyle Wahlstrom
Organization : HealthEast Vascular Center
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Please rectify the reimbursement issues with Apligraf/Dermagraft for 2006 to reflect current reimbursement. An increase in costs for these products will limit patient access to these treatments.

Submitter : Ms. Christine Fanelli
Organization : Southside Hospital
Category : Nurse

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Please correct the error in the proposed ruling and ensure that Apligraf & Dermagraft are reimbursed as a specific covered drug at asp + 8%

Submitter : Dr. Wayne Winston
Organization : Southside Hospital
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Please correct the error in the proposed ruling and ensure that Apligraf & Dermagraft are reimbursed as a specific covered drug at asp + 8%

Submitter : jamie henry
Organization : healtheast vascular center
Category : Nurse

Date: 08/31/2005

Issue Areas/Comments

GENERAL

GENERAL

Please rectify the reimbursement issues with Apligraf/Dermagraft for 2006 to reflect current reimbursement. An increase in costs for these products will limit patient access to these treatments.

Submitter : Dr. Penny Phillips-Deines
Organization : RGV Footcare
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

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Apligraf and Dermagraft have improved our patient healing rate significantly. Decreasing the reimbursement of these products will negatively impact our patient's treatment and healing potential. To ensure that the best treatments are available to our patients and to aid in the healing of their diabetic foot ulcerations, this error must be corrected.

Submitter : Mr. Stephen Jones
Organization : Mr. Stephen Jones
Category : Other Health Care Professional

Date: 08/31/2005

Issue Areas/Comments

GENERAL

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My father has suffered from Diabetic Foot Ulcers. I have been made aware that there is a chance the product Apligraf (C1305) might not be reimbursed in 2006 in an amount that will make it feasible for them to offer this advanced treatment in 2006. Please correct this error to ensure the continued use of this product for those that suffer from this condition.

Submitter : Dr. Gabriel Halperin
Organization : Gabriel Halperin DPM
Category : Physician

Date: 08/31/2005

Issue Areas/Comments

GENERAL

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Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates? contains errors which would seriously undermine wound care in the United States

Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84

Dermagraft -- 2005 outpatient rate \$529.54; 2006 proposed outpatient rate \$368.32

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Thank you

Gabriel J. Halperin, DPM, FACFS

Submitter : Mrs. Hillary McClure
Organization : Mrs. Hillary McClure
Category : Individual

Date: 08/31/2005

Issue Areas/Comments

GENERAL

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The 2006 Proposed reimbursement for Apligraf and Dermagraft would significantly impact patient care. These products are the only ones available indicated to heal diabetic and venous stasis ulcers faster. Please correct this error.