

CMS-1501-P-121

Submitter : Dr. Dorothy Kurtz
Organization : Seacoast Foot & Ankle Specialists
Category : Physician

Date: 09/01/2005

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, relating to the payment rates for the wound healing products Apligraf (C1305) and Dermagraft (C9201).

These products have been paid in the outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these drugs is jeopardized by the payment rates in the proposed rule. Many of these patients would have to undergo limb amputations without the benefits of these unique human tissue substitutes for the treatment of chronic ulcers.

In the proposed rule both Apligraf and Dermagraft would be incorrectly paid. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule.

Thank you for your attention to this issue.

Sincerely,

Dorothy Kurtz, DPM

Submitter : Dr. michael umanoff
Organization : n. martini pain management center
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Rechargeable implanted spinal cord stimulators, although they cost more than RF systems or implanted nonrechargeable generators, will significantly reduce the cost of SCS over time by reducing the number of battery replacements that a patient will be faced with. In addition patient compliance with this system is far superior than with the RF systems.

Submitter : Dr. Robert Kuvent
Organization : Advanced Foot Care
Category : Device Industry

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

This proposed rule contains errors which would seriously undermine wound care. Apligraf is a bioengineered tissue therapy for diabetic foot ulcers. It is advanced treatment that speeds up healing rates dramatically. Apligraf and Dermagraft are currently reimbursed at hospital prospective payment system as a covered drug. This will jeopardize patient access and would have a negative impact on quality of care. I request CMS to correct this error in the proposed ruling and ensure that these products are reimbursed as a specific covered drug at ASP +8%

Sincerely,
Robert Kuvent, DPM, FACFAS

CMS-1501-P-124

Submitter : Dr. Dirk Parvus
Organization : Sebastian River wound center
Category : Device Industry

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P "Medicare Program; Changes to the hospital Outpatient Prospective Paymeny System and Calender year 2006 payment rates" contains erros 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, as ASP + 8%.

Submitter : Ms. ronna newell
Organization : Wheeling Hospital Wound care center
Category : Nurse

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

it has come to our attention that there has been a technical error regarding the proposed 2006 reimbursement rates for both Apligraf and Dermagraft. This error will restrict access to our Diabetic and venous compromised patients who not only need the product but can also benefit from these treatment options. Please make it a priority to get this technical error address and allow for the patients to have access to these products in 2006.

Submitter : Mrs. Sharon Mick Manager
Organization : Sebastian River wound center
Category : Device Industry

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advance bioengineered tissue based therapy indicated for treatemnt 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 severly affected patients. it is the only tissue based therpy approved for treatment of venous leg ulcers.

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%

Submitter : Mrs. Janet Stonebraker
Organization : Wound Care Center
Category : Nurse

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

It has come to our attention that there has been a technical error regarding the proposed reimbursement rates for Apligraf and Dermagraft. This error will restrict access to our Diabetic and Venous compromised patients. They not only need this product, but can benefit from these treatment options. Please get this technical error addressed and allow for the patients to have access to these products in 2006.

Submitter : Dr. Timothy Swartz
Organization : Keystone Podiatric Medical Associates
Category : Device Industry

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

apligrft is an important element of advanced wound care, shown to speed up healing rates and reduce amputation in affected patients...it is the only tissue based therapy approved for treatment of venous leg ulcers...the proposed reduction in payment for apligrft below ASP will jeopardize access to this essential therapy for medicare beneficiaries. Apligrft has significantly lowered costs for treatment of chronic wounds and has been shown to reduce infection rate, accelerating healing, and reducing pain.

Submitter : Mrs. Karen Obermiller
Organization : First Coast Diabetic Foot and Wound Management Cen
Category : Nurse

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule is intended to provide reimbursement of ASP+8% for covered products, in 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 very negative impact on quality of care.

Submitter : Dr. Hadi Shalhoub
Organization : Sebastian River Medical Center
Category : Device Industry

Date: 09/01/2005

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, as ASP +8%

CMS-1501-P-131

Submitter : Dr. Jeffrey Wilps
Organization : Organogenesis
Category : Health Care Professional or Association

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Kuhn

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

Weirton Medical Wound Treatment Center is 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 paymmy rates for the woun-healing products Apligraf(C1305) and Dermagraft (C9201).

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.

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 = six percent methodology under J7340 (Metabolic active Dermal?Epidermal Tissue) and J7342 (Metabolically active Dermal tissue) respectively

Thank you for your attention tho this issue and we lod forward to working with you to correct the issue in the final rule.

Sincerely,

Jeffrey Wilps Medical Director Wound Treatment Center

Submitter : Mr. Fred Kagarise
Organization : MidMichigan Health
Category : Hospital

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment for comments

CMS-1501-P-132-Attach-1.DOC

MidMichigan Health

August 31, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services

RE: Medicare Program; Proposed Changes to the
Hospital Outpatient Prospective Payment System
and Calendar Year 2006 Payment Rates
CMS-1501-P

I am submitting these comments for consideration in the finalization of Policy on behalf of MidMichigan Health ("MH"). MidMichigan Health provides a cross section of medical services to Medicare Beneficiaries from mainly Midland, Gratiot, Clare, Isabella, and Gladwin Counties, including Hospital Outpatient care.

Multiple Diagnostic Imaging Procedures

On the face of it, this proposal would seem reasonable, except for the fact that it is based on a flawed starting point. The current process over-values the cost of these types of procedures and then you propose to remove the over-stated cost. The only proper basis to make this proposal would be to first fix the costing methodology to properly allocate the cost between single occurrence procedures and combined procedures and then the lower payment would fall in line.

The foundation of the rate calculation is the Cost-to-Charge Ratio ("CCR") from Cost Reports. This cost average compares actually incurred costs spread over all services based on the charge of that service. The rules also require that all services of the same kind be charged at the same amount, regardless if some of the procedures take less time or more time than other same kind procedures.

It is likely that the vast majority of hospitals, if not all, do not maintain a charge differentiation for these imaging procedures between those separately occurring and those done in combination with other procedures.

MedPAC's assertion that the APC Rates are based on singularly performed tests is wrong. Under the rules, hospitals charge the same for a single, full time consuming, procedure as for the same procedure done in conjunction with another procedure, ostensibly on a less costly basis. The CCR assigns the same cost to both procedures, even though we know the cost wasn't the same. This is your basis for the proposed rate

adjustment, these procedures get full payment when they cost less to provide. That means those procedures that are done in conjunction with other procedures are assigned costs that are not related to that procedure by taking cost from the other procedures. So, all the other procedures have to be under valued because part of the cost incurred in doing the other procedures are assigned to these procedures done in conjunction with another procedure. The singularly performed test gets under-valued to make up for the over-value assigned to combined procedures.

To make your proposal accurate, you must first assign the proper cost to these combined procedures by not assigning to them the same cost as a single procedure. You must remember the foundation of all the values assigned to any procedure is the "average" cost of all services compared to the charge. You destroy the "average" by trying to single out an instance where paying at the "average" is not logical, resulting in an over-payment. That means somewhere else there must be an illogical under-payment as well, because it all has to average out.

All you have to do is look at the DRG payment method to see this in action. There are instances where a DRG payment will exceed the charge for the care, but a full DRG payment is made. Why? Because the DRG payment is an average of all the instances of care for that particular type of service. So, in some individual cases the payment exceeds the cost of care and in others the payment is less. In the end it is supposed to average out.

This proposal's foundation is the assignment of cost not related to these combinely preformed procedures by under-stating the cost through the use of the CCR to the other procedures, and then, taking that cost away and thus leaving the cost shortage assigned to the remaining other procedures.

Let's turn the focus around to the cost incurred by hospitals. If there are efficiencies in doing multiple procedures in one sitting as opposed to being done in individual sittings as you propose, then hospitals' imaging department costs reflect that efficiency. That means the hospital is staffed and incurs other costs based on a level of efficiency from doing multiple procedures at some level. So again that brings us to the problem that it is the cost that is not assigned to the procedures correctly. The efficiency generated is spread across all procedures because of the use of imaging department's CCR average. That efficiency is not assigned to only those procedures in which the efficiency is generated. The proper way to account for this is to adjust the CCR down to allocate a lower amount of cost when multiple procedures are done together and assigning a higher CCR to the remaining procedures. But, the current costing method used to set PPS Rates does not do this as it assigns the average cost instead.

If your analysis is correct about the 50% factor for secondary procedures, then in the costing process only half of the CCR should be used to assign cost to secondary

procedures and the other half of the cost should be allocated across all the other primary procedures to recognize the under valuation of using the straight CCR.

If you go ahead with the proposal without correcting the costing method, what are the results? What happens is the imaging services are under valued and the current payments will be shifted to other APC services. In the total scheme of things, as long as a hospital has a wide array of outpatient services, then total payments would supposedly balance out. But, for hospitals that provide significantly more imaging services than other services, they cannot make up for the under valuing of the imaging APC Rates.

What should be done is to establish codes to differentiate between when services are preformed singularly and when they are done in combination, as you do with lab test panels. Once you have this data in the paid claims data that is used to set APC Rates, then you would be able to properly cost the services, resulting in the proper weighting of imaging services. With these new codes, hospitals would adjust charging practices to differentiate the charge of a single procedure verses one done in combination with other procedures. You admit you don't have the paid claims data to accurately assign cost to multiple procedures verses single ones. Get good data before making such a drastic re-valuation of imaging service payments.

Summary

If the APC payment method is going to be changed to discount the payment on secondary imaging procedures as is done with surgeries, the proper cost weight of the imaging services must be done first to reflect the reality that the CCR over costs these combinely performed procedures and thus under costs the remaining ones. If the costing is not adjusted, this would under value imaging services as compared to the other APCs and shift payments out of imaging services. This payment shift will hurt hospitals that disproportionately provide imaging services or lack sufficient other APC services to recover the shifted payments. CMS should wait to get good paid claims data before making this drastic arbitrary payment shift.

Submitted on behalf of MidMichigan Health,

Fred Kagarise

Fred Kagarise
Manager of Corporate Reimbursement
4005 Orchard Drive
Midland, MI 48670
989-839-3336

Submitter : Mrs. Susan DeZutel
Organization : Columbia-St. Marys Hospital
Category : Nurse

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf/Dermagraft is not being reimbursed correctly/adequately for 2006. This would negatively impact patient outcomes and care that they receive. Please correct this. Thank you.

Submitter : Dr. Edward Bienowicz
Organization : Southside Hospital
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. James Knight
Organization : Forest Park Wound Care Center
Category : Physician

Date: 09/01/2005

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 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. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. The new reimbursement rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality 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%.

Submitter : Dr. Mark Finkelstein

Date: 09/01/2005

Organization : Southside Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Peter Mancuso
Organization : Southside Hospital
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Bruce Zappia
Organization : Southside Hospital
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Michael Sacca
Organization : Southside Hospital
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Vito Rizzo
Organization : Southside Hospital
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Lou Riina
Organization : Southside Hospital
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Alexander Melman
Organization : Island Surgical & Vascular
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Terry Palatt
Organization : Island Surgical & Vascular
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Bradley Cohen
Organization : Island Surgical & Vascular
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Jason Schneider

Date: 09/01/2005

Organization : Island Surgical & Vascular

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter :

Date: 09/01/2005

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

data

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

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

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

Submitter : Dr. Scott Wodicka
Organization : Island Surgical & Vascular
Category : Physician

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Manal Hegazy

Date: 09/01/2005

Organization : Island Surgical & Vascular

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Ms. debra kimmons`
Organization : Mainland Medical Center
Category : Nurse

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

It greatly concerns me as the director of a comprehensive wound care center that the reimbursement for Apligraf is being cut. We are able to keep our patients out of the hospital by offering this procedure as an outpatient. With the reduction in reimbursement we will be forced to admit these patients for split thickness skin grafts and these patients may end up with other complications. We all know our patients do much better when we can keep this as outpatients. We have treated several patients using apligraf with wonderful results.

Submitter : Mrs. Rosanne Morin
Organization : Mainland Medical
Category : Nurse

Date: 09/01/2005

Issue Areas/Comments

GENERAL

GENERAL

We were notified today that the reimbursement for Apligraf will be decreased next year. As a nurse in an outpatient wound center this is very concerning. Apligraf as part of a comprehensive treatment plan in an outpatient setting has been very successful in healing many of our out patients with diabetic foot wounds as well as wounds from venous insufficiency. If we are unable to obtain this product for use in our outpatient department this could prolong the patients treatment and or require hospitalization and surgery for split thickness skin grafts.

CMS-1501-P-151

Submitter : Dr. Patricia Walters
Organization : Tarzana Wound Care Center
Category : Physician

Date: 09/01/2005

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

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 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%.
Regards,

Patricia Lec Walters DPM

Submitter : Ms. Jugna Shah
Organization : Nimit Consulting Inc.
Category : Private Industry

Date: 09/02/2005

Issue Areas/Comments

GENERAL

GENERAL

Drug Administration

The AMA released an early version of the 2006 CPT drug administration codes for public review in response to the OPSS Proposed Rule. I am concerned about the language in the drug administration section of CPT 2006 related to the use of only one 'initial' service code being reported for a patient visit/encounter. These codes/descriptions were created in response to physician pressure in late 2004 which led to the development and use of G-codes for the physician setting in 2005. While the use of only one 'initial' service code may work in the physician setting, it will not work in the hospital setting. The concept of reporting only one 'initial' service code works in the physician setting because physicians are paid for almost every single drug administration code they report. Moreover, this concept is easy to operationalize in the physician setting since patients are typically treated in one location and not across multiple departments. In the hospital setting, payment is not expected to be made for each new 2006 CPT code especially the 'additional hours codes' as listed in the OPSS proposed rule; nor are patients always treated in a single location/department. The drug administration table released in the Federal Register shows the hydration, initial hour code mapped to APC 120, but the hydration, additional hours codes is not assigned to an APC since it has an 'N' status indicator. If hospitals are only allowed to report one 'initial' service code, then they will never receive separate payment for a hydration service or a therapeutic/diagnostic infusion when provided during the same visit as chemotherapy. I do not believe CMS intends for this to happen since it currently pays separately for these services in addition to the chemotherapy. The operational burden related to these codes stems from the fact that hospitals are fundamentally different from physician's offices in that a patient can start receiving services in one department and then move to another where additional services are provided. For example, a patient receives hydration in the emergency department and is then admitted to observation where he/she receives several injections. Given the 2006 CPT code descriptions, the hydration would be reported as the 'initial' service and the injections would need to be reported using the 'subsequent' injection codes. This scenario raises an operational issue related to each department knowing whether a service was already provided by another department in order to charge/code correctly. CMS simply cannot assume that the charging staff in the observation unit in the example above will know to charge for a 'subsequent' injection given that hydration was already provided in the ER. If anything, they will want to charge the 'initial' injection code since it was the first injection they provided. Finally, CMS should understand that drug administration services are typically Charge Description Master driven, but if hospitals are forced to implement the 2006 CPT codes as written it is very likely that coding staff will have code for these services rather than allowing departments to 'charge' for them. This will be problematic for many hospitals given the current shortage of coders and existing workload. Therefore, I request CMS to release guidance instructing hospitals to 'ignore' the word 'initial' in each drug administration code. There is precedent for CMS to do in cases where the codes or definitions are not applicable to hospitals. Accepting this recommendation will not only facilitate appropriate payment for multiple services when provided, but it will also remove the operational burden of staff in different departments having to know whether to charge an 'initial code?', 'additional hours code?' or a 'subsequent code'. Thank you for listening and if you have questions please feel free to contact me at jugna@nimit.com.

Jugna Shah, MPH
President, Nimit Consulting Inc.
www.nimit.com

Submitter : Dr. Michael Kesler
Organization : Interfaith Meidcal Center
Category : Physician

Date: 09/02/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express my strong feeling against Proposal # 1501-P. This proposal would be a gross mistake on CMS' part. This in no way is going to save money. Also, this will severely limit patient access to Apligraf & Dermagraft, which in my experience has healed many ulcers thus sparing these patients costly hospitalizations, amputations, prosthesis and need for prolonged rehabilitation. The bottom line is Apligraf & Dermagraft used on an outpatient saves money & helps patients. Please reverse this proposal.

Submitter : Dr. Donovan Gowdie
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

Issue Areas/Comments

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Submitter : Dr. John Hawkins
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

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Submitter : Dr. Valentine Ayanru
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

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Submitter : Dr. Kelvin Barry
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

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Submitter : Dr. O. Joseph Falcone
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

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Submitter : Dr. Simon Raskin
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

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Submitter : Dr. Frederick Matthews
Organization : Intrafaith Medical Center
Category : Physician

Date: 09/02/2005

Issue Areas/Comments

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Submitter : Dr. Terence Saadvandi
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

Issue Areas/Comments

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Submitter : Dr. James De Meo
Organization : Interfaith Medical Center
Category : Physician

Date: 09/02/2005

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GENERAL

I am writing to express my strong feeling against Proposal # 1501-P. This proposal would be a gross mistake on CMS' part. This in no way is going to save money. Also, this will severely limit patient access to Apligraf & Dermagraft, which in my experience has healed many ulcers thus sparing these patients costly hospitalizations, amputations, prosthesis and need for prolonged rehabilitation. The bottom line is Apligraf & Dermagraft used on an outpatient saves money & helps patients. Please reverse this proposal.

Submitter : Mrs. Dorothy Wong
Organization : Methodist Hospital of S.Ca.
Category : Hospital

Date: 09/02/2005

Issue Areas/Comments

GENERAL

GENERAL

Reimbursement of intravenous gamma globulin (IVIG) following the ASP plus 8% as proposed for 2006 would not be enough to cover our cost of buying the IVIG. As it is, we are receiving calls from patients telling us they have not been able to receive their IVIG infusion as the infusion center or hospital that they have been receiving the infusions have closed down or terminated their service. The reimbursement for IVIG should be at least \$80/gm.

Submitter : Dr. Stanley Cowen

Date: 09/02/2005

Organization : Sherman Oaks Hospital Center for Wound Care

Category : Physician

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

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%.

Regards,

Stanley Cowen MD FACS
Medical Director
General Surgery

Submitter : Jewel Um

Date: 09/02/2005

Organization : Sherman Oaks Hospital Center for Wound Care

Category : Nurse

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

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Regards,

Jewel Um RN MSN
Clinical Coordinator

Submitter : Dr. Gary Boghossian
Organization : Sherman Oaks Hospital Center for Wound Care
Category : Physician

Date: 09/02/2005

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

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Regards,

Gerard Boghossian DPM

Submitter : Pippa Jensen

Date: 09/02/2005

Organization : Sherman Oaks Hospital Center for Wound Care

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

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Regards,

Pippa Jensen RN BSN PHN

Submitter : Lisa Alban

Date: 09/02/2005

Organization : Sherman Oaks Hospital Center for Wound Care

Category : Nurse

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

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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%.

Regards,

Lisa Alban RN

Submitter : Betty Werner

Date: 09/02/2005

Organization : Sherman Oaks Hospital Center for Wound Care

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

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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%.

Regards,

Betty Werner
Director Wound Care
Sherman Oaks Hospital Center for Wound Care

Submitter : Judy Lupercio
Organization : Sherman Oaks Hospital Center for Wound Care
Category : Hospital

Date: 09/02/2005

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

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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%.

Regards,

Judy Lupercio
Office Coordinator

Submitter : Ms. Mary Harless, RHIT, CCS-P
Organization : Olathe Medical Center, Inc.
Category : Hospital

Date: 09/02/2005

Issue Areas/Comments

GENERAL

GENERAL

Observation Services;

I applaud the proposed changes to the policy for separate payments for observation services, and I know that at our facility this will result in a much less manual and cumbersome coding process. However, I question the creation of two new G-codes to report whether the patient was directly admitted or admitted through the Emergency Department or other hospital clinic. I don't understand why new codes should be created when systems will be editing for qualifying conditions electronically, and the edits could be developed for currently valid CPT codes, i.e. 99218 - 99220. Please clarify the decision to develop new G-codes for the purpose of reporting separately payable observation services.

Thank you for your attention to this matter.

Submitter : Ms. Bonnie Munroe
Organization : Methodist Healthcare
Category : Health Care Professional or Association

Date: 09/02/2005

Issue Areas/Comments

GENERAL

GENERAL

Combine Cobalt 60 based stereotactic radiosurgery treatment planning (G0242) with treatment delivery (G0243) to create a single code that is all inclusive and assign this new combination code to a higher paying New Tehnology APC.

Submitter : Dr. Richard Steinmetz
Organization : Dr. Richard Steinmetz
Category : Physician

Date: 09/03/2005

Issue Areas/Comments

GENERAL

GENERAL

Re: proposed change in reimbursement for calendar year 2006 for Apligraf(C 1305) and Dermograft(C 9201).

As a podiatric physician treating many patients with diabetes and vascular disease, lower extremity ulceration is a very common complication. When these patients fail to heal with traditional wound care within 2-4 weeks, it usually indicates a protracted costly healing process. This requires multiple debridements, office visits, visiting nurse care that can go on for weeks and months. For these complicated wound patients; I have found the use of Apligraf to dramatically shorten healing time and therefore the overall expense to the health-care system.

These products are effective, and are the only living skin substitutes in their class. Hospitals should be reimbursed at the appropriate rate using the ASP plus 8% method. Failure to do so may prevent many patients from the benefits of these products, leading to less effective treatment, more hospitalizations, surgical procedures ,amputations and their associated costs.

Submitter : Raymond Smith
Organization : Raymond Smith
Category : Individual

Date: 09/05/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-174-Attach-1.RTF

161 Marine Parade.
Santa Cruz, CA 95062-3830
Phone 831-471-0471; Fax 831-471-0471
E-mail: r-smith@uchicago.edu

September 7, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8017

Attention CMS-1502-P

To Whom it May Concern:

Re: GPCI

My wife and I are Medicare beneficiaries who receive care through excellent physicians of the Santa Cruz Medical Clinic. I understand that this proposed rule will remove my county from The Rest of California physician payment locality designation.

I understand further that the physicians in my community will now receive payments from Medicare on a par with those in other counties in the San Francisco Bay Area.

I wholeheartedly support the proposed changes and greatly appreciate your attention to this very important issue.

Yours sincerely,

Raymond T. Smith
Flora A. Smith

Submitter : joyce meisel
Organization : Catholic Medical Center
Category : Nurse

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

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.

Apligraf 2005 out patient reate \$1130.88; 2006 proposed outpatient reate is \$766.84
Dermagr5aft 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. Rebecca Burfeind
Organization : Anesthesia Associates of Kansas City
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing to address CMS-1501-P, particularly in reference to rechargeable neurostimulators such as the Medtronic Restore spinal cord stimulator generator and leads. I believe that the Restore system should be eligible for a pass-through payment in an outpatient setting.

The rechargeable system has several advantages over the older non-rechargeable systems. The rechargeable system permits a reduction in surgeries related to neurostimulator replacement caused by battery depletion. Also, patient who require high amplitudes to achieve the maximum benefit from their stimulators will not have to limit the use of their stimulators as they had with the older systems due to battery conservation.

Allowing a pass through payment on the rechargeable neurostimulator will thus lead to higher patient satisfaction and decreased overall cost due to fewer generator replacements.

Please favorably consider Medtronics application for a pass-through payment in an out-patient setting.

Sincerely,

Rebecca Burfeind,MD

Submitter : DEBRA WURTZ
Organization : DEBRA WURTZ
Category : Physical Therapist

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

PLEASE CORRECT THE ERROR ON C1305 FOR THE YEAR 2006. THESE ITEMS (APLIGRAF AND DERMAGRAFT)_HAVE BECOME VERY USEFUL ITEMS IN OUR FACILITY WITH WOUND CARE. OUR PATIENTS WITH DIABETES AND LONG NON HEALING WOUNDS HAVE GREATLY BENEFITTED FROM THESE PRODUCTS. WE HOPE THAT THIS ERROR WILL BE CORRECTED SO THAT WE CAN CONTINUE TO USE THIS PRODUCT.

Submitter : Dr. Powen Hsu
Organization : Catholic Medical Center
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

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 proposed to be 30% below the selling price of the product. Apligraf-2005 outpatient rate \$1,130.88 proposed outpatient rate for 2006 is \$766.84. Dermagraft- 2005 out patient rate \$529.54; 2006 proposed outpatient rate \$366.32.

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 : Mr. Craig Thomas
Organization : St. Mary's Medical Center
Category : Hospital

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Please change the recognized error in the 2006 payment to product code C1305. The product has assisted the organization in cost effectively treating and healing both diabetic wounds and venous stasis ulcerations.

In order to utilize the products it is believed necessary changes in the 2006 payment system must be made.

Submitter : Dr. Joseph Newman
Organization : St. John's Wound Center
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

I work in a wound center and use Apligraf only on recalcitrant venous leg ulcers. This product works wonders in these patients and with the proposed price structure I'm certain that many people will go unhealed. The overall cost of these type of patients will increase well above the cost of the product. When these patients are not healed we have to see them once or twice a week to control their drainage and tend to their wounds. These multiple repeat visits will far exceed any reduction in the cost of the product.

We will not be able to help these patients if we cannot afford to purchase the product. Currently we break even on using this product. If the proposed fee schedule is implemented we will have to stop using the product and will never be able to heal these difficult patients.

Please contact me if any further information would be useful.

Submitter : Dr. Michael Gilligan
Organization : Orange Park Medical Wound Center
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501 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. 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. 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 plus 8%.

Submitter : Mrs. nancy bennett
Organization : Orange Park Medical Center
Category : Nurse

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the United States.

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

Submitter : Mr. DARYL MAY
Organization : NEWMAN REGIONAL HOSPITAL
Category : Nurse

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

PLEASE CORRECT THE RECOGNIZED MISTAKE IN REIMBURSEMENT FOR C-1305 FOR 2006. WE HAVE USED APLIGRAF FOR SEVERAL MONTHS NOW AND HAVE BEEN VERY PLEASED WITH THE RESULTS. WE WOULD LIKE TO CONTINUE USING APLIGRAF IN THE FUTURE. THANKS YOU FOR YOUR TIME.

Submitter : Dr. patrick dwyer
Organization : Associates in Podiatry
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

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 proposed to be 30% below the selling price of the product.

Apligraf - 2005 out patient rate \$1,130.88. 2006 proposed outpatient rate is \$766.84. Dermagraft - 2005 out patient rate is \$529.54; 2006 proposed outpatient rate is \$366.32. 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. Michael Tran
Organization : Manhattan Foot Specialists, PA
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Please correct the recognized error for C1305 for 2006.

The apligraf application has helped my patients with diabetic and venous ulceration significantly.

Submitter : Dr. Raef Fahmy
Organization : Associates in Podiatry
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

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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 proposed reimbursement rate is to be 30% below the selling price of the products.

Apligraf - 2005 outpatient rate \$1,130.88; 2006 - proposed outpatient rate is \$766.84. Dermagraft - 2005 outpatient rate is \$529.54; 2006 proposed outpatient rate is \$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 : Ms. Peggie Delparte BSN,RN,WOCN
Organization : Mercy Hospital
Category : Device Industry

Date: 09/06/2005

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.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% Sincerely Peggie Delparte BSN,RN,WOCN

Submitter : Ms. Laura Landon
Organization : Alegent Health Wound Care Clinic
Category : Health Care Professional or Association

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Please correct the recognized error for c1305 for 2006. This product has enabled us to treat chronic wounds in the wound care clinic for venous stasis and diabetic ulcers that we've had problems with before. Sincerely,

Laura Landon RN
Alegent Health Wound Care Clinic
Omaha, Nebraska 68124

Submitter : Ms. Katherine Hill BSN, RN, CWOCN

Date: 09/06/2005

Organization : Mercy Hospital

Category : Device Industry

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. Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug. 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%. Sincerely, Katherine Hill BSN, RN, CWOCN

Submitter : Dr. Jonathan Deitch

Date: 09/06/2005

Organization : SUNY Downstate

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Gary Gewirtzman
Organization : SUNY Downstate
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Mrs. Deirdre McGagh
Organization : SUNY Downstate
Category : Physician Assistant

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Ms. Beth Brueggemann
Organization : Jefferson Memorial Hospital
Category : Nurse Practitioner

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P contains errors which would seriously undermine wound care in the US. 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. 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 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. Gwen McDomy
Organization : Jefferson Memorial Hospital
Category : Nurse

Date: 09/06/2005

Issue Areas/Comments

GENERAL

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Proposed rule CMS-15-1-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. 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%.

Submitter : Dr. Barry Wisler
Organization : St Francis Medical Center
Category : Physician

Date: 09/06/2005

Issue Areas/Comments

GENERAL

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The proposed rule CMS-1501-P "Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Rates" contains errors which would seriously undermine wound care in the US. 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 products. Apligraf--2005 outpatient rate \$1130.88; 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, at ASP+8%.

Submitter : Ms. Elizabeth Kappler
Organization : St Francis Medical Center
Category : Nurse

Date: 09/06/2005

Issue Areas/Comments

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The proposed rule CMS-1501-P "Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Rates" contains errors which would seriously undermine wound care in the US. 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 products. Apligraf--2005 outpatient rate \$1130.88; 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, at ASP+8%.

Submitter : Mr. Agapito Tablate
Organization : Southwest Medical Center
Category : Other Health Care Professional

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

September 6, 2005

Dear Sir:

Reduction in the payment of Leukoreduced RBCs and Plateletpheresis, leukoreduced, irradiated will greatly affect the financial viability of our Hospital blood bank. We are serving considerable number of outpatients and with the purchased price of blood components still the same, the loss will be substantial. I am requesting for your reconsideration.

Respectfully,

Mr. Agapito Tablate MT(AMT),BB(ASCP)
Blood Bank Supervisor

Submitter : Miss. Amy Gendron
Organization : Trinity Health
Category : Other Health Care Professional

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

E/M Services. I have attached documents which may assist the Panel in establishing E/M service levels for the Emergency department. I have attached two types of models, one based on a point system and an intervention based model. They both avoid using interventions which are separately reimbursable and omit services performed by physicians. Please consider these tools to aide in the development of standard E/M guidelines for facilities.

Thank You,
Amy Gendron
Organizational Integrity Specialist
Trinity Health
34605 W. 12 Mile Rd
Farmington Hills, MI 48331

CMS-1501-P-198-Attach-1.DOC

CMS-1501-P-198-Attach-2.DOC

Level I	Level II	Level III	Level IV	Level V	Critical Care
RN Triage & initial assessment (1 set vitals)	Wound recheck, suture removal	Ace wrap, collar, sling, immobilizer (off the shelf) application	O2 administration NRB - Mask	Hyper/Hypothermia treatment	Crash Cart Ventilator Cardio version/Defibrillation CPR/BLS/ACLS
PO (SAD) Medication	Nursing assessment with repeat (2-3 vitals)	Nasal Cannula O2	Acute Psychiatric Care	O2 via Bipap/established tracheostomy/intubation	
TB test assess	Orthostatic vital signs	Fetal heart monitor	Comatose patient care	Sex Crime evidence kit collection	
Topical medication	IV start (1 line)	Repeat vitals (4≤8)	Isolation	Decontamination with HAZMAT	
Adhesive strip application	PO hydration	Request medical records	BP/Cardiac monitoring	ICU/CCU admission	
Patient left without being seen wait time < 2 hours.	Topical medications	Access/Check Ports	Vitals > 8 Neuro checks >4	Helicopter transport in or out	
	Epistaxis control (non-packing)	Access/Check ostomy	Complex restraint		
	Wound cleansing without irrigation/procedure	Difficult/repeat IV insert (restart/retry line or additional IV)	Insert NG tube Gastric suction		
	Small dressing application (4X4)	Simple restraint	Control (manual) hemorrhage		
	Eye/Ear irrigation	Wound irrigation	Decontamination without hazmat		
	Ring Cutter	Dressing – large or multiple sites (<3) Stage 3 wounds (no			

Level I	Level II	Level III	Level IV	Level V	Critical Care
	<p>Specimen Collection (wound, urine, stool, RSV, eye, throat, vomitus heme-occult studies)</p> <p>Hot/cold pack application</p>	<p>procedure)</p> <p>Urinary cath</p> <p>Enema or suppository administration</p> <p>Induce vomiting</p> <p>Eye exam (any method)</p> <p>Fecal disimpaction</p> <p>Mast trouser application or removal</p> <p>Crutch training</p> <p>Observe exam – Visual only (opposite sex, child)</p> <p>Quadra/hemi/paraplegic care</p> <p>Consults – Social work, police, CPS, poison control, gift of life, ME, SANE, OSHA,</p>	<p>RN accompanies to diagnostic test</p> <p>Dressing – Complex multiple sites (>4) stage 4 or greater (no procedure)</p> <p>Assist Exam – hands on (opposite sex, child, difficult patient)</p> <p>DOA with/without Coroner contact</p> <p>Transfer to another acute care facility</p> <p>Admit to psych/OR/telemetry monitoring</p>		

Level I	Level II	Level III	Level IV	Level V	Critical Care
		Interpreter needed General medical admission/observation Outpatient Surgical preparation Ambulance transportation in or out Discharge to nursing home			

Pick highest level of acuity based upon interventions documented in the patient medical record.

**Emergency Non-Physician
Evaluation and Management
Criteria Worksheet**

July 1, 2002

ASSESS/MONITOR	Units	Pts.	EXAMS/TESTS/TREATMENTS	Units	Pts.
BP/Cardiac Monitor	10		ABG each stick	5	
Continuous Fetal Monitor	20		Bladder Residual Study	15	
Fetal Heart Tones	5		Bleeding Control	20	
Neuro Checks	5		Charcoal Ad/Induce Vomiting	20	
Nursing Assessment Complex	25		Decontamination without hazard material	50	
Nursing Assessment Triage	5		Decontamination with hazard material	100	
Nursing Assessment Initial	20		Diagnostic Accompanied	20	
Nursing Assessment Repeat	10		Doppler	10	
Pulse O ₂ /CO ₂	10		Enema (per episode)	20	
Recheck / Suture Removal/Staple Removal	5		Eye Exam w/o procedure	10	
Repeat Vital Signs	5		Eye-Ear Irrigation	20	
Request Medical Records	5		Fecal Dis-impaction w/o Anesthesia	30	
Urinary Output Measurement	5		Glucose Scan (unless part of a lab draw)	10	
TOTAL			Hemocult/Gastrocult/Multistix	10	
			Mast Trousers Removal	10	
			Mast Trousers Application	20	
			Med Tox./Chain of Custody	20	
			O ₂ Administration	5	
			Order EKG	5	
			Order Lab	5	
			Order Radiology	5	
			Order Respiratory	5	
			Orthostatic Vital Signs	10	
			Ring cutter	10	
			RT Peak Flow	5	
			RT Respiratory Tx by RN	10	
			RT Vent/CPAP Mask	25	
			Silt Lamp Eye Exam w/o procedure	10	
			Specimen Collect (Urine, Sputum, RSV, Blood, Stool)		
			Wound, Throat Culture, Pap Smear, Phlebotomy)	10	

PATIENT ID: _____

RN SIGNATURE: _____

DATE: _____

LEVEL

Level 0	
Level I	0-30 or 0-35
Level II	31-50 or 36-55
Level III	51-85 or 56-90
Level IV	86-125 or 91-125
Level V	>125

Critical Care 30-74 mins*

Animal Bites, Child Abuse (3200 form)	10	Suction/Irrigation	20
Care after death	10	Urethral Cath (mini)	10
Combative, Confused, Incontinent,		Visual Acuity	10
Psych, Comatose Patient	15	TOTAL	
Consults, Auths, Empl. Contr., S.W., AMA		OB/GYN	
Appointments, Notify, Authorize, EMS	10	Pelvic by Speculum, Bi-manual/Digital	5
radio		Pelvic Exam Complex	30
Emotional Needs	20	TOTAL	
Isolation	10	ADMIT/DISCH/TRANS	
Non-English Speaking: Use of Interpreter	10	Admit ICU/CCU/Psych	30
Notification of: Social Svcs, Police, Poison		Admit OR (includes consents)	30
Control,		Admit Regular Room/Observation	15
Gift of Life, Medical Examiner, SANE	10	Admit Telemetry/Peds	20
Picture taking	10	Trans/w Nurse to Another Fac	40
Restraint Complex	30	Transfer to Another Facility	30
Restraint Simple	20	Transfer to Skilled Nursing Facility	15
		Transport in by ambulance	10
Sex Crime Reporting, Consents (98 only)	30	TOTAL	
OR/Outpatient (Emergency Procedures)		Crutch Training	10
Adhesive Strips w/o procedure	5	Discharge Instructions Extensive	20
Ace Wrap/Collar/Sling/Immobilizer w/o	10	TOTAL	
procedure		Discharge Instructions	
Dressing--Large to Complex w/o procedure	20		10
Dressing--Small to Moderate w/o procedure	10		20
Wound Cleansing, no sutures w/o	5		10
procedure			
TOTAL			

Procedures - See separate list

Submitter : Mr. James Porter
Organization : Riverview Hospital
Category : Health Care Professional or Association

Date: 09/06/2005

Issue Areas/Comments

GENERAL

GENERAL

As a major health care provider in our area, we implant medical devices and perform other procedures on a number of Medicare beneficiaries in the outpatient setting. I am writing to express my concerns about the proposed Outpatient Payment rule for calendar Year 2006.

In the proposed rule, CMS recommends a decrease of 14.1% from last year's rate for ICD devices. Payment decreases of 14% from one year to the next are problematic on their face and can not be justified, particularly when the 2005 rates show a 2.3% reduction from the year before. No aspect of health care has dropped that much in two years. The resulting APC rates are actually lower than our institution's cost for the ICD device, leaving us with a loss for the device acquisition cost and no payment for our procedural costs. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting.

To rectify this issue, our facility requests that CMS calculate the 2006 payment rates for ICD implant procedures using the 2005 payment rates plus the 3.2% hospital update. I understand that the August 2005 APC Advisory Panel has made the same recommendation to CMS. The resulting payment rates would be more in line with our facility's costs of performing these services.

CMS also requested comments on the February 2005 APC Advisory Panel recommendations related to increasing the single procedure bills available for rate setting to improve the accuracy of median costs for APCs 0107 (ICD generator replacement) and 0108 (full system implant). Although the scenarios displayed in the proposed rule may increase the number of single procedure claims used for rate setting, single procedure claims have not resulted in adequate payment. We are therefore unable to support the proposal.

For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resynchronization pacing and defibrillation systems (CPT 33225) from APC 1525 to APC 0418, resulting in a change in the status indicator. The status indicator would change from a status "S" meaning that it was always paid at 100% of the APC payment rate, to a status "T" which means that it is subject to a 50% reduction in multiple procedure scenarios.

The assignment of status indicator "T" does not adequately compensate hospitals for additional procedural time and resources associated with this service. The implant procedure for the cardiac resynchronization pacing and defibrillator systems parallel that of a conventional dual chamber pacemaker or ICD with the exception of the implantation of a left ventricular lead and is not duplicative. The cost of the lead itself is not reduced by 50% when implanted along with other procedures. Please do not change the status indicator for this procedure.

Thank you for this opportunity to provide comments.

Sincerely,

James Porter, FHFMA, CPA
VP Finance / CFO
Riverview Hospital
395 Westfield Road
Noblesville, Indiana 46060

Submitter : Mrs. De Anna Bell

Date: 09/06/2005

Organization : First Coast Diabetic Foot & Wound Management Ctr.

Category : Nurse Practitioner

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 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, which has been shown to increase healing rates and reduce amputations in severely affected patients. Currently, 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, 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, which would have a negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and to ensure that both Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Please feel free to contact me with any further questions or concerns.

Thank you for your time,

De Anna M. Bell, MSN, ARNP, BC, DAPWCA

Submitter : Dr. Desmond Bell, Jr.

Date: 09/06/2005

Organization : First Coast Diabetic Foot & Wound Management Ctr.

Category : Physician

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 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, which has been shown to increase healing rates and reduce amputations in severely affected patients. Currently, 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, 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, which would have a negative impact on quality of care. We petition CMS to correct the error in the proposed ruling and to ensure that both Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Thank you for your time,

Desmond P. Bell, Jr., DPM, CWS, FCCWS, FAPWCA

Submitter : Dr. William Lagaly
Organization : Arkansas Hyperbaric Associates
Category : Physician

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

In review of the proposed reimbursement for Apligraf and Dermagraft, I believe an error has been made in determining the appropriate payment for these biological dressings. I am concerned because if this is not corrected, many of my patients will be unable to obtain these products, and this will lead to more amputations ultimately. The cost of amputations fiscally and emotionally has been shown to be far worse than the cost of these products. Please review this and adjust the reimbursement of these products so that we do not lose these extremely valuable tools for treating our patients.

Thank you,
William J. Lagaly, D.O.

Submitter : Ms. Celeste McDonald

Date: 09/07/2005

Organization : The Center for Wound Care and Hyperbarics

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I strongly feel that reimbursement rates should remain at present levels to allow patient access and use of this valuable product in our wound center. We have had great success with our healing rates when we use this product.

Submitter : Miss. Colleen Miller

Date: 09/07/2005

Organization : Carroll Hospital Center Wound care center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I strongly feel that the current reimbursement rates should remain in place --so the patients will receive full benefits and the facilities will be able to provide these supplies to their pts and get reimbursed

Submitter : Ms. Kara Couch

Date: 09/07/2005

Organization : Georgetown University Wound Healing Center

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

We utilize a great deal of Apligraf in our clinics and our operative procedures. We feel that it should continue to be reimbursed at current levels to ensure maximum patient access. It has been shown to dramatically improve healing rates in extremely recalcitrant ulcers.

Submitter : Dr. Christopher Attinger
Organization : Georgetown University Hospital Wound Healing Cente
Category : Physician

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

We feel that Apligraf should continued to be reimbursed at the current rate. It has been proven to dramatically improve healing times and to decrease hospital length of stays.

Submitter : Ms. Kerry Moose
Organization : Georgetown University Hospital Wound Healing Cente
Category : Nurse Practitioner

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

We feel that Apligraf should continued to be reimbursed at the current rate. It has been proven to dramatically improve healing times and to decrease hospital length of stays.

Submitter : Ms. Margaret Kugler
Organization : Georgetown University Hospital Wound Healing Cente
Category : Nurse Practitioner

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

We feel that Apligraf should continued to be reimbursed at the current rate. It has been proven to dramatically improve healing times and to decrease hospital length of stays. It also is very effective on colonized wounds.

Submitter : Ms. Katherine Hubley

Date: 09/07/2005

Organization : Georgetown University Hospital Wound Healing Center

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

We feel that Apligraf should continued to be reimbursed at the current rate. It has been proven to dramatically improve healing times and to decrease hospital length of stays.

Submitter : Mr. Gary Heard
Organization : BayState Medical Center
Category : Hospital

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf and Deragraft 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 proposed to be 30% below the selling price of the product.

Apligraf- 2005 outpatient rate \$1,130.88; 2006 - proposed outpatient rate is \$766.84. Dermagraft- 2005 outpatient rate \$529.54; 2006- proposed outpatient rate is \$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 : Ms. Heather Lee

Date: 09/07/2005

Organization : Georgetown University Hospital Wound Healing Center

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

We feel that Apligraf should continued to be reimbursed at the current rate. It has been proven to dramatically improve healing times and to decrease hospital length of stays.

Submitter : Ms. Rebecca Bruneau

Date: 09/07/2005

Organization : Georgetown University Hospital Wound Healing Cente

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

We feel that Apligraf should continued to be reimbursed at the current rate. It has been proven to dramatically improve healing times and to decrease hospital length of stays.

Submitter : Dr. Steven Silver
Organization : Baystate Medical Center
Category : Hospital

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

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 proposed to be 30% below the selling price of the products.

Apligraf- 2005 outpatient rate \$1,130.88: 2006 - proposed outpatient rate is \$766.84. Dermagraft- 2005 outpatient rate is \$529.54: 2006- proposed outpatient rate is \$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. John Steinberg
Organization : Georgetown University Hospital Wound Healing Cente
Category : Physician

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

We feel that Apligraf should continued to be reimbursed at the current rate. It has been proven to dramatically improve healing times and to decrease hospital length of stays. Changing of the reimbursement may decrease the feasibility of use for this product which has helped to prevent amputations in our practice.

Submitter : Mrs. Maryann Sharpe-Cassese
Organization : Vassar Brothers Medical Center
Category : Hospital

Date: 09/07/2005

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 restrict the access to both our diabetic and venous compromised patients who can benefit from these treatments. Please make it a priority to correct the reimbursement for 2006 for these products.

Submitter : Ms. Sherry Ferro
Organization : Baystate Medical Center
Category : Hospital

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

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 proposed to be 30% below the selling price of the product.

Apligraf-2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate is \$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%.

CMS-1501-P-217

Submitter : Mr. joseph kurtz
Organization : newark beth israel medical center
Category : Nurse

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

In reference to cms-1501-p, it has come to my attention that there has been a mistake in the proposed reimbursements in 2006 for both apligraf and dermagraft. reimbursement at the current proposed rates would seriously undermine wound care in the united states. We petition that this be reevaluated and corrected.

Submitter : Dr. David Webster
Organization : Baptist Wound Care
Category : Physician

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

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

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

Submitter : Dr. Jason Manuel
Organization : Baptist Wound Care
Category : Physician

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

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

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

Submitter : Dr. Mark Matey
Organization : Baptist Wound Care
Category : Physician

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

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

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

Submitter : Dr. Joseph Sindone
Organization : Dr. Joseph L. Sindone DPM, P.A.
Category : Device Industry

Date: 09/07/2005

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 tissued 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.

Submitter : Kate Madden-Harper
Organization : St. Elizabeth Medical Center
Category : Ambulatory Surgical Center

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf and Dermagraft are advanced bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot wounds. They are important elements in advanced wound care, shown to speed healing rates and reduce amputations.

CMS-1501-P-223

Submitter : Dr. Joseph Addiego
Organization : Access Wound Care & Podiatry
Category : Physician

Date: 09/07/2005

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

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%.

Joseph A. Addiego DPM

Submitter : Dr. Jittima Jirasetpatana
Organization : Access Wound Care & Podiatry
Category : Physician

Date: 09/07/2005

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

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%.

Jittima Jirasetpatana DPM

Submitter : Ms. Jane Charnetski
Organization : St. Vincent Hospital
Category : Nurse Practitioner

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Kuhn,

I'm submitting this public comment to bring to your attention an error in this proposed rule as it relates to the payment rates for two wound-healing products. Apligraf (C1305) and Dermagraft (C9201) have been paid in the hospital outpatient PPS as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. I respectfully request that the payment rates for these products 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 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.

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 a sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product.

However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data instead of payment as ASP plus eight percent. Accordingly, both products experienced a significant decrease in payment:
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 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 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively.

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

Sincerely,
Jane Charnetski APNP-BC, CWOCN
Nurse Practitioner and Program Manager
Center for Wound Care and Hyperbaric Medicine
St. Vincent Hospital
Green Bay, Wisconsin

Submitter : Ms. Patricia Gill
Organization : Banner Good Samaritan Medical Center
Category : Other Practitioner

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

I am against the proposal to lower the payment for Apligraf. This would be extremely detrimental to our practice at the Wound Clinic as the payment does not now cover our costs.

Submitter : Ms. AnnZ. Moore
Organization : Palomar Pomerado Center for WoundCare and Hyperbar
Category : Hospital

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

I am the System Director for Wound Care and Hyperbaric Medicine. We have a multidisciplinary staff (7 physicians) who provide outpatient case managed wound care to a census of 145 patients. We see over 500 visits a month and have a healing rate of over 85%. Average heal time is less than 12 weeks of treatment. We achieve these great outcomes #1 by having a great medical staff, clinical nursing staff and support staff, #2 by following a clinical path for wound healing, #3 by using advanced wound care treatments to speed healing. Namely Apligraf and Dermagraft.

We have had great results from these bioactive products.

As the Director of the clinic I am not only concerned about clinical outcomes I am also concerned about cost and reimbursement.

I must ensure we are using the right product for the right reason coupled with cost effectiveness, which includes appropriate reimbursement.

Reduction in reimbursement would impact the ability of the clinic to provide these products for those patients who have hard to heal wounds. The reimbursement would not offset the cost thereby reducing the likelihood of product use in the clinic.

These high dollar bioactive products are not used on your every day wound care patients. These products are utilized on those truly hard to heal long standing Diabetics or venous ulcer patients who need assistance to heal.

These are the folks you want to heal to reduce the cost of long standing wound treatment and life style compromise.

The above comments are just a few reasons to reconsider increasing the reimbursement for Dermagraft and Apligraf.

Thank you for your kind attention to these comments.

Ann Z. Moore
Systems Director
Diabetes Program
Center for Wound Care and Hyperbaric Medicine

Submitter : Dr. Antonius Su
Organization : Chandler Wound Care Center
Category : Physician

Date: 09/07/2005

Issue Areas/Comments

GENERAL

GENERAL

By lowering the rate of Apligraf it would directly effect the rate we would heal our patients. With the lowering of the reimbursement It would limit the amount of patients that could recieve this and hence increase the healing time to heal them. This would increase the over all amount that is spent. Thank you

Submitter : Dr. David Laurino
Organization : Chandler Wound Center
Category : Physician

Date: 09/08/2005

Issue Areas/Comments

GENERAL

GENERAL

The Apligraf is a major asset to our wound center. By lowering the reimbursement of this product it would limit the amount of patients that would receive this product and hence increase the length the wound stayed open as well as increase the cost to everybody. Thank You