

Submitter : Dr. Benjamin Russell
Organization : Portland Surgical Associates
Category : Device Industry

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

I am commenting on the proposed rule change CMS-1501-P Medicare Program; Changes to the Hospital Outpatient Payment System and Calendar year 2006 Payment rates. The change would potentially seriously effect chronic wound care in the United States. Since most of the chronic wound care effects the elderly, they would end up bearing the burden of the cost. Although Apligraf and Dermagraft are more expensive up front, savings in long term wound therapy would more than make up the difference. In the case of Apligraf and Dermagraft, the proposed ruling is reimbursement at 30% below the selling price of the product. I am asking you to correct this error and in the proposed ruling. Thank you for your consideration.

Submitter : Dr. Christopher Rogers
Organization : Portland Surgical Associates
Category : Device Industry

Date: 09/09/2005

Issue Areas/Comments

GENERAL

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I am commenting on the proposed rule change CMS-1501-P Medicare Program; Changes to the Hospital Outpatient Payment System and Calendar year 2006 Payment rates. In the case of Apligraf and Dermagraft, the proposed ruling is reimbursement at 30% below the selling price of the product. I am asking you to correct this error in the proposed ruling. Since most of the chronic wound care involves the elderly, they would end up bearing the burden of the cost. Although Apligraf and Dermagraft are more expensive up front, the savings in long term wound treatment would more than make up the difference. Thank you for your consideration.

Submitter : Dr. Robert Neilson
Organization : Portland Surgical Associates
Category : Device Industry

Date: 09/09/2005

Issue Areas/Comments

GENERAL

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I am commenting on the proposed rule change CMS-1501-P Medicare Program; Changes to the Hospital Outpatient Payment System and Calendar year 2006 Payment rates. The change would seriously effect chronic wound care in the United States. Since most of the chronic wound care effects the elderly, they would end up bearing the burden of the cost. Although Apligraf and Dermagraft are more expensive up front, savings in long term wound therapy would more than make up the difference. In the case of Apligraf and Dermagraft, the proposed ruling is reimbursement at 30% below the selling price of the product. I am asking you to correct this error in the proposed ruling. Thank you for your consideration.

Submitter : Ms. Shirley Lappi, RN NP
Organization : St. Joseph Hospital Wound Center
Category : Nurse Practitioner

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

We are users of APLIGRAF (C 1305) and need to continue using this advanced wound care therapy to maintain good patient care standards.
We are aware of a reduced 2006 reimbursement schedule.
Please correct this error and provide adequate reimbursement so we can offer the patients the best in Medical Care.

Submitter : Miss. Karen DeMelo
Organization : Kingston Hospital Wound Center
Category : Health Care Professional or Association

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Mr Herb Kuhn,

It has come to my attention there has been a technical error for the reimbursement rate of both apligraf and dermsgraft. This error will retriect the access to both diabetic and venous stasis ulcer patients who can benefit from these products. Please make this a priority to correct the 2006 reimbursement rate.

Thanks,
Karen DeMelo

Submitter :

Date: 09/09/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

It has come to my attention that there has been an error in the 2006 reimbursement rates for Apligraf and Dermagraft. This error could limit the scope of care for my patients. Please correct this error so that my patients can continue to receive the best care possible.

Submitter :

Date: 09/09/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

It has come to my attention that the 2006 reimbursement rates for Apligraf and Dermagraft have been lowered due to an error. Please correct this problem so that my patients can continue to receive the best care possible.

Submitter : Mrs. Kathy Smith
Organization : Kingston Hospital Wound Center
Category : Nurse Practitioner

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

MR. Herb Kuhn,
it has come to my attention that there has been a technical error for reimbursement rate for both appligraf and dermagraft. This error will restrict the access to both diabetic and venous stasis ulcer patients, who can benefit from these products. Please make this a priority to correct the reimbursement rate of 2006.
Kathy Smith RN, WCC

Submitter :

Date: 09/09/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

It has come to my attention that the 2006 reimbursement rates for Apligraf and Dermagraft have been lowered to due an error. Please correct this problem so that my patients can continue to receive the best care available.

Submitter : Dr. Robert Warriner
Organization : Praxis Clinical Services
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

I am the chief medical officer of a wound care service provider company representing 60 hospital based physician driven wound care centers across the United States. 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 (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. Patient access to these important products is jeopardized by the payment rates in the proposed rule. 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. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving 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. 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 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 in stead of payment at ASP plus eight percent. 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. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and 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. 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%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Mr. Don Davezac
Organization : Progressive Health Center, Inc. (#194653)
Category : Health Care Provider/Association

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-283-Attach-1.DOC

1 September 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comment to CMS-1501-P Changes to Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates - Proposed Rule

Our agency, **Progressive Health Center, Inc. (Provider No. 194653)** is a freestanding community mental health center in Zachary, Louisiana. We serve approximately 22,000 patients on an annual basis. We employ approximately 80 employees and contract workers in our community. We provide intensive psychiatric programs that are much needed by the patients that attend our program.

Our Partial Hospitalization patients are primarily chronically mentally ill adults from lower socio-economic populations who need intensive follow-up after inpatient treatment to manage their psychiatric symptoms to prevent re-hospitalization. The largest percentage of these patients are from within 100 miles of Zachary, Louisiana. Those patients receiving outpatient treatment come from a broad midsection of the community including all age groups and socio-economic means.

We are requesting the proposed 15% cut for our program be stopped. The current payment rate is not sufficient to cover the costs needed for our intensive programs. Our costs are higher than hospitals who can share and spread their costs to other departments. Our patient acuity level is also more intense than the hospital patients receiving one or two therapy sessions.

This service is especially needed for our rural communities who are not serviced by hospital programs. Additionally our state does not offer this program as a Medicaid service.

Please consider not cutting the Partial Hospitalization Program cost so drastically when most outpatient costs are receiving a 3.5% increase in payment rates.

Sincerely,

Don Davezac
COO

Submitter : Michele Billotte
Organization : DuBois Regional Medical Center
Category : Hospital

Date: 09/09/2005

Issue Areas/Comments

GENERAL

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In reviewing the OPPS Proposed rule dated July 25, 2005, we made an observation regarding CPT codes 11620 and 11621. In the addendum B CPT 11620 is under APC 0020 for a payment rate of \$410.22, and CPT 11621 is under APC 0019 for a payment rate of \$239.55. We believe that one or both of these codes is assigned an incorrect APC because 11621 is the more invasive procedure of the two, but assigned a lower reimbursement. Thank you for your consideration of this comment.

Submitter : Dr. christopher locke
Organization : Boston Medical Center
Category : Physician

Date: 09/09/2005

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 access of these therapies to my Diabetic patients that not only need them but can benefit from them. With out these products, I am concerned about a greater rate of infection and amputation among my Diabetic patients with wounds. Please make it a priority to correct this error.

Submitter : Dr. Gary Gibbons
Organization : Boston Medical Center
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

It has come to my attention that the proposed rule CMS -1501-P Medicare changes to the hospital outpatient perspective payment system for the year 2006 would seriously undermine wound care in the US. The proposed rate changes would restrict access to therapies like Apligraf and Dermagraft that patients with Venous insufficiency and Diabetes not only need, but can greatly benefit from. Apligraf is the only FDA approved therapy for Venous leg ulcers and Dermagraft and Apligraf are 2 of only 3 FDA approved products for Diabetic foot ulcers now available. The proposed reimbursement rates would jeopardize access to the patients who need them most. I am asking CMS to please correct this error. It has been my clinical experience that these products close more of our tougher wounds faster, lowering both infection rates but potential amputations as well. Please make sure that both Dermagraft and Apligraf are reimbursed at their correct rates of ASP+ 8%.

Submitter : Dr. Hau Pham
Organization : Boston Medical Center
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

My colleagues have informed me that there has been an error with the calculations for 2006 reimbursement rates for both Dermagraft and Apligraf. This error would restrict access to these therapies for my diabetic population that not only need them, but could greatly benefit from them. Please consider revising the reimbursement rate for both these products in 2006.

Submitter : Ms. Sarah Kowalski
Organization : Orange Regional Medical Center Wound Care Center
Category : Health Care Professional or Association

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

To Mr. Kuhn, it has come to my attention that there has been a technical error for reimbursement for both Apligraf and Dermagraft. This error will restrict the access to both diabetic and venous stasis patients, who could greatly benefit from these products. Please make this a priority to correct this.

Submitter : Mrs. Pamela Violetto
Organization : Orange Regional Medical Center Wound Care Center
Category : Health Care Professional or Association
Issue Areas/Comments

Date: 09/09/2005

GENERAL

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To Mr. Kuhn, it has come to my attention that there has been a technical error for reimbursement for both Apligraf and Dermagraft. This error will restrict the access to both diabetic and venous stasis patients, who could greatly benefit from these products. Please make this a priority to correct this.

Submitter : Mrs. Suzanne Tofallas
Organization : Orange Regional Medical Center Wound Care Center
Category : Health Care Professional or Association

Date: 09/09/2005

Issue Areas/Comments

GENERAL

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To Mr. Kuhn, it has come to my attention that there has been a technical error for reimbursement for both Apligraf and Dermagraft. This error will restrict the access to both diabetic and venous stasis patients, who could greatly benefit from these products. Please make this a priority to correct this.

Submitter : Dr. Helen Gelly
 Organization : Hyperbaric Physicians of Georgia
 Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

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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 (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. Patient access to these important products is jeopardized by the payment rates in the proposed rule. 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. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving 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. 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 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 in stead of payment at ASP plus eight percent. 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. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and 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. 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%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Dr. Marianne Taryla
Organization : Hyperbaric Physicians of Georgia
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

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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 (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. Patient access to these important products is jeopardized by the payment rates in the proposed rule. 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. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving 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. 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 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 in stead of payment at ASP plus eight percent. 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. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and 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. 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%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Dr. Daniel Beless
 Organization : Hyperbaric Physicians of Georgia
 Category : Physician
 Issue Areas/Comments

Date: 09/09/2005

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Submitter : Dr. Julie Anderson
Organization : Hyperbaric Physicians of Georgia
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

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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 (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. Patient access to these important products is jeopardized by the payment rates in the proposed rule. 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. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving 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. 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 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 in stead of payment at ASP plus eight percent. 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. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and 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. 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%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Dr. Belinda Marcus
 Organization : Hyperbaric Physicians of Georgia
 Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

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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 (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. Patient access to these important products is jeopardized by the payment rates in the proposed rule. 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. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving 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. 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 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 in stead of payment at ASP plus eight percent. 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. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and 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. 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%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Dr. Jann Blanton
Organization : Hyperbaric Physicians of Georgia
Category : Physician

Date: 09/09/2005

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 (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. Patient access to these important products is jeopardized by the payment rates in the proposed rule. 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. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving 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. 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 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 in stead of payment at ASP plus eight percent. 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. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and 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. 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%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Mr. Mark Smith
Organization : Nebraska Heart Hospital
Category : Hospital

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

As a major cardiovascular health care provider in our area, we implant medical devices and perform other procedures on a number of Medicare beneficiaries in the outpatient setting. We are writing to express our 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 the cost to many hospitals for the ICD device, leaving hospitals with a loss for the device acquisition cost and no payment for their procedural costs. These losses make it very difficult for hospitals 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. We 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,

Mark Smith
Chief Financial Officer
Nebraska Heart Hospital

Submitter : Dr. Jeffrey Thurlow
Organization : Seacoast Surgery, LLC
Category : Device Industry

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

I endorse the petition to CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug. Thank you for your consideration

Submitter : Mrs. Barbara Lacourciere

Date: 09/09/2005

Organization : Sun Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Lowering the reimbursement for Apligraf from \$1130 to \$746 will impact the ability of patients to receive this product which has been shown to effectively close wounds and reduce healing time.

Submitter : Ms. Joanne Gilbert
Organization : Catskill Regional medical Center
Category : Health Care Professional or Association

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr.Kuhn,

It has come to my attention there was a technical error with the reimbursement for both Apligraf and Dermagraft. This error would restrict the access for diabetic and venous stasis ulcer pts who could benefit from the products. Please make this a priority to adjust the 2006 reimbursement rates.

Sincerely, Joanne Gilbert RN WOCN

Submitter : Ms. MARIA cannonier
Organization : Catskill Remgional Medical Center
Category : Health Care Professional or Association
Issue Areas/Comments

Date: 09/09/2005

GENERAL

GENERAL

It has come to my attention their was a technical error with the reimbursement for both apligraf and dermagraft. This error would restrict the access for diabetic and venous stasis ulcer pts who could cbenefit from the products. Please make this a priority to adjust the 2006 reimbursement rates.
Sincerely, Maria Cannonier LPN

Submitter : Dr. Albert Kocurek
Organization : Mainland Medical Center
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

I believe that Apligraf is one of the greatest improvements that has come along in wound care in recent years. It needs to be covered and reimbursed so that patient's will have access to it. The cost is only a fraction of other alternatives such as hospitalization and skin grafting.

Submitter : Ms. Beth skulky
Organization : Catskill Regional medical Center
Category : Health Care Professional or Association

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

It has come to my attention there was a technical error with the reimbursement for both Apligraf and Dermagraft. This error would restrict the access for diabetic and venous stasis ulcer patients who could benefit from the products. Please make this a priority to adjust the 2006 reimbursement rates.
Sincerely, Beth Sculky

Submitter : Dr. Shishir Shah
Organization : Boswell Wound Center
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

I understand the reimbursement for bilaminate skin substitutes will be reduced significantly for 2006. This will directly impact the 9 clinics my group practices in and will force us not to use the product. This will cause a significant loss to patient healing time and an increase in amputation rates. Please reconsider this. Your decision has a national impact,

Sincerely
Shishir Shah DO

Submitter : Dr. Marc Katz
Organization : Memorial Hospital Wound Care
Category : Physician

Date: 09/09/2005

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 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

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%.

Submitter : Mr. John Gaspelin
Organization : Orlando Regional Healthcare
Category : Hospital

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-306-Attach-1.DOC

Centers for Medicare Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore MD 21244-8018

Multiple Diagnostic Imaging Procedures:

Your proposal to reduce payment for multiple diagnostic procedures in the same treatment session is unfair to hospitals. Hospitals do have some cost savings for multiple procedures, but that is spread over all procedures when APC rates are set. Cost information from cost reports, or cc ratio's from them is used to determine the cost to be paid for a given procedure. This cost is lower due to the efficiencies that the hospital has had, given the multiple procedures, therefore single procedure tests are getting a lower reimbursed cost due to these efficiencies. This is then made up to the hospital by paying a full procedure on all diagnostic procedures. So it may be true that multiple procedures are slightly over reimbursed, but then it is also true that single procedures are under reimbursed. By reducing the payment on multiple procedures CMS is under reimbursing hospitals on their entire diagnostic procedure book of business. This will cause hospitals financial hardship and should not be implemented.

Sincerely,

John Gaspelin
Orlando Regional Healthcare

Submitter : Miss. shawn christenson

Date: 09/09/2005

Organization : banner good samaritan

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

In my professional opinion, lowering the coverage on Apligraf would minimize the ability for my patients to receive this treatment. This would lengthen healing times, in turn increasing your cost.

Submitter : Mrs. Debra Umlauf
Organization : Elmbrook Memorial Hospital
Category : Other Technician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

FILE CODE CMS-1501-P: As a taxpayer I can understand the need to cut costs. However, as a manager of a nuclear medicine department, it is increasingly difficult to manage to my budgets when Medicare payments for expensive exams are being reimbursed at a lower cost than the cost to do the exam. It is unfair that we are being reimbursed at a lower payment rate than clinics. Clinics are not forced to treat non-payers, indigent, etc. Hospitals are. If we are expected to treat everyone, we should be reimbursed appropriately. Please raise the reimbursement rates for PET and PET/CT imaging. It is a necessary modality for those who are stricken with cancer, alzheimers and other very serious ailments. Thank you for your attention to this matter.

Submitter : Dr. Marc Gottlieb
Organization : Good Samaritan Medical Center, Phoenix, AZ
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Apligraf (Organogenesis) is one of the few products that has a stimulatory effect on wound healing. Used PROPERLY, it has been crucial in the effective management of properly selected chronic and pathological ulcers. It has become a keystone tool that allows the resolution (healed) of certain ulcers that failed to heal by any other means. By getting refractory wounds healed, it's proper use results in a net savings in care and costs for properly selected individual patients and ulcers.

Apligraf is used largely in wound clinics, usually hospital sponsored. If reimbursement to hospitals is reduced, then the use of this effective product will become red ink for the hospitals and clinics, or it will result in denials of service, or else in costs to the patient that they often cannot afford. Denials of service are already a defacto reality for patients on certain insurance plans, making Apligraf "untouchable" for many patients who would benefit from it. Because of the central role that CMS plays in setting reimbursement standards, any reduction in Apligraf reimbursement will impact not only Medicare patients, but, as the dominoes fall, potentially many other patients who would otherwise benefit and be healed by this very important product.

As a physician who has dedicated his career to managing problem wounds, loss of this product would be a sad setback. A reduction in reimbursement would have the effect of removing the product from the accessible market. Please reconsider any actions that would limit availability of this product.

Submitter : Dr. Alan Hartstein
Organization : St Mary's Wound Center
Category : Device Industry

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

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%.

CMS-1501-P-311

Submitter : Dr. Thomas Rosen
Organization : St Mary's Wound Center
Category : Device Industry

Date: 09/09/2005

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.

Submitter : Mrs. Melissa Hull
Organization : Harris Methodist-Fort Worth Hospital
Category : Pharmacist

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Please consider standardizing medication descriptions in Addendum B so the drug names appear first (and can be sorted alphabetically), rather than using 'INJECTION' as the first word. Currently the descriptions vary in format. I have modified them on the attached spreadsheet to match my suggested format. * Also I have noted in BLUE on the spreadsheet some doses that need clarification or that seem illogical. Obsolete forms or drugs are shaded in tan, unless you are aware of formulations I did not find in FirstDataBank (FDB). My price column may not be 100% correct, but I researched brands myself from FDB. If we could see Addendum B in this format, it would help both pharmacists and coding personnel.

*Per the statement issued by CMS, electronic comments were supposed to allow attachment of Excel documents (though Microsoft Word was preferred). Excel is not an option under 'file type.'

Please advise how or to whom I may send the file. _____

Melissa Hull, R.Ph. (Manager, Pharmacy; Harris Methodist-Fort Worth Hospital); melissahull@texashealth.org

Submitter : Dr. Henry Stark
Organization : St Mary's Wound Center
Category : Device Industry

Date: 09/09/2005

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

Submitter : Mrs. Susan Becker
Organization : Chilton memorial hospital
Category : Nurse
Issue Areas/Comments

Date: 09/09/2005

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 Prospective Payment System and Calander Year 2006 Payment Program Rates' relating to the payment rates for the wound healing products Apligraf (c1305) and Dermagraft(c9201).I am petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASPand 8%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule

Submitter : Dr. aymen eraiba
Organization : chilton memorial hospital
Category : Physician

Date: 09/09/2005

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 relating to the payment rates for the wound healing products Apligraf(C1305) and Dermagraft (C9201).I am 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 plus 8. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Dr. Patrick Turski
Organization : American Society of Neuroradiology
Category : Health Care Professional or Association
Issue Areas/Comments

Date: 09/09/2005

GENERAL

GENERAL

See Attachment

CMS-1501-P-316-Attach-1.DOC



ASNR

AMERICAN SOCIETY OF NEURORADIOLOGY

2210 Midwest Road
Suite 207
Oak Brook
Illinois
60523-8205

Ph 630.574.0220
Fax 630.574.0661
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Meetings:
meetings@asnr.org

Membership:
membership@asnr.org

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05,
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Proposed Reimbursement Changes in the Hospital Outpatient Prospective Payment System for Magnetoencephalography (MEG)

Dear Mr. McClellan,

The American Society of Neuroradiology (ASNR) represents over three thousand physicians specializing in the diagnosis and treatment of neurological diseases. The specialty is internationally recognized as a leader in the anatomic and functional imaging of the brain, using a variety of technologies including magnetoencephalography (MEG). The ASNR supports the August 18, 2005 CMS decision to defer adjustments in the level of reimbursement for MEG until accurate billing data is available. Furthermore, the society strongly supports maintaining the current level of reimbursement. These values realistically address the expenses associated with MEG examinations and should be sustained.

Access to care: The ASNR is concerned that reductions in reimbursement for clinical MEG would compromise the financial viability of existing facilities and would severely curtail the development of new MEG programs. MEG is an essential component of the pre-surgical evaluation of patients with intractable epilepsy and has a proven value in mapping the cerebral cortex prior to resection of tumors and vascular lesions such as arteriovenous malformations. A payment reduction of this magnitude would have detrimental effect on patient's access to this technology, which reduces the morbidity associated with epilepsy surgery and tumor resection. Although the number of claims filed with Medicare over the last few years has been low, Medicare is still regarded by other payer groups as the reimbursement standard; therefore a much larger patient population would be affected by the negative consequences of payment reductions for MEG.

Accuracy of data: CMS's APC advisory panel clearly recognized the limitations of current data regarding MEG charges and utilization. We enthusiastically support the recommendation for additional data gathering prior to any decision regarding reimbursement. Several MEG programs have already started the process of identifying appropriate billing information for future reviews.

We are especially concerned about the proposed \$674 reimbursement for CPT 95965 (Epilepsy/Spontaneous Recording and Analysis), which was previously \$5,250. The MEG

instrument plus its mandatory magnetically-shielded room costs about \$2.5 million dollars, which is significantly more than many MRI scanners. Additional operational costs such as initial siting costs (\$300,000+); liquid helium costs (\$30,000/year), and maintenance contract for the instrument (\$120,000/year) are fixed costs. MEG patient throughput is much less than other modalities because much more detailed information must be obtained by MEG. It requires about 20 hours of data analysis by the MEG scientist to fully identify and localize the sources of epileptic spikes within a patient's brain (CPT 95965); as well as about an hour to analyze and pictorially summarize the data from MEG pre-surgical mapping of such brain functions as vision, hearing, motion of hand or foot, language, etc. (CPTs 95966, 95967). In comparison, processing the images of clinical MRIs is automated and virtually instantaneous, and clinically reading these images is relatively fast.

Moreover, each scanning session in the MEG requires about one hour for each modality of pre-surgical functional data acquisition (CPT 95966 and 95967); and about four hours of data acquisition for epilepsy interictal spike generation, measurement, and monitoring.

Summary comment: There is great value to performing MEG studies, which justifies the current level of reimbursement. MEG is the only non-invasive technique which can so accurately localize interictal spikes in epilepsy; and which directly images the active brain cells responsible for vital human functions such as hearing, vision, hand motion, etc. This information is extremely valuable to the neurosurgeon; who seeks to remove a brain tumor, vascular malformation, or abnormal brain tissue responsible for seizures; because it allows him/her to avoid devastating outcomes that would result from resection of the adjacent functional brain tissue. The current charges for these three MEG CPT codes are appropriate when compared to the actual costs of performing the studies.

Sincerely,

Patrick A. Turski, MD
Chair, ASNR Clinical Practice Committee

A handwritten signature in black ink, appearing to read "P. Turski, MD". The signature is written in a cursive style with a large, looping initial "P".

Submitter : Dr. Gerald Yospur
Organization : Banner Baywood Hospital
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

As a plastic surgeon I believe that lowering reimbursement for apligraf would be detrimental to wound care. It is unlikely that if hospitals take a loss in purchasing apligraf it shall not be long before they decide not to order it at all.

Submitter : Ms. Paula drever
Organization : Plastic Surgery
Category : Nurse

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

I have seen the results of apligraf first hand. Many patients NEED this product. Please don't lower reimbursement I'm sure we will see it used less.

Submitter : Dr. Robert Pugach
Organization : Pacific Coast Urology Medical Center
Category : Physician

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Re: APC 0674: Cryosurgery of the prostate. As a community urologist practicing in communities with large numbers of seniors, I am extremely concerned about the effect of the proposed outpatient reimbursement for this procedure. Cryoablation of the prostate is as effective or more effective than radical surgery for prostate cancer and causes far fewer complications than either surgery or the various forms of radiation therapy. There is virtually no incidence of urinary incontinence, which is a significant complication of other therapies for prostate cancer, thus making cryoablation an ideal treatment for the senior population, many of whom already have other bladder control problems. Avoiding incontinence is a significant cost saving for the Medicare program when looking at the long term results of prostate cancer care. By setting outpatient reimbursement at a low level, the result will be that many hospitals will no longer offer the procedure, thus limiting patient access to an effective treatment with the least number of serious side effects. I urge you to raise reimbursement levels to the point where I and other treating community physicians can continue to offer cryoablation to the senior population.

Submitter : Dr. Jason Harrill

Date: 09/09/2005

Organization : Banner Mesa Wound Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a podiatrist that works in a wound center I beleive that lowering the reimbursement for Apligraf would be detrimental to wound care. If the hospital takes a loss in the reimbursement we will be told to stop using this product.

Submitter : Mrs. Deb Quarry
Organization : Sun Health Hospital
Category : Nurse
Issue Areas/Comments

Date: 09/09/2005

GENERAL

GENERAL

The apligraf is a good product we use in our outpatient wound clinic. If reimbursement is decreased we may not be able to use this in our arsenal to treat wounds. The apligraf has closed hard to heal wounds decreasing cost to Medicare and other insurances by reducing nursing care, Home Health visits which can cost over \$100 a visit , dressing, MD visits and prevent infections as well as improving the quality of life of a patient. I hope this product will be available for our patients as they truly benefit from it. If reimbursement is dropped patients will lose in the quality of their health care.

Submitter : Ms. sue garber
Organization : sun health wound management center
Category : Nurse Practitioner

Date: 09/09/2005

Issue Areas/Comments

GENERAL

GENERAL

Re: Apligraph bioengineered dressing reimbursement

We currently use these products with great success in healing wounds, reducing potential amputations, reducing healing times and returning clients to productive lifestyles. Reduction of the reimbursement would place the financial burden on these clients, limiting use and prolonging healing time and health care costs. Please reconsider the reimbursement for this product. Thank you. Sue Garber, FNP

Submitter : DARLA PERRY
Organization : PERRY & COMPANY CPA'S APC
Category : Other
Issue Areas/Comments

Date: 09/10/2005

GENERAL

GENERAL

CMS 1501-P PARTIAL HOSPITALIZATION PROGRAM

CMS-1501-P-324-Attach-1.DOC



514 W. NAPOLEON ST. SULPHUR, LA 70663

(337)528-4000 (Telephone)

(337)528-4010 (FAX)

Date: August 31, 2005

FILE CODE: CMS-1501-P PARTIAL HOSPITALIZATION

Re: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates – Proposed Rule

I serve as an outside Certified Public Accountant to over 25 freestanding Community Mental Health Centers based in Louisiana, Mississippi and Texas.

The proposed rule referenced above effectively decreases the net daily partial hospitalization reimbursement rate for freestanding providers to approximately \$169. per day. What this means is that many Medicare Beneficiaries will no longer have access to the mental health care they need and should have under 1833(t)2, because freestanding CMHC's (especially rural providers) will be forced to close with that reimbursement rate. The APC rate for PHP code 033 is not sufficient to keep these agencies open.

None of the providers that I represent received outlier payments for 2004 therefore receiving only the daily APC payment. That payment is not representative of the partial program costs. The OPSS final rule (FR Vol. 65, No. 68, April 7, 2000) requires representation of the median cost of providing partial hospitalization services. CMS noted in the final rule that they would accumulate appropriate data and determine if refinements to the per diem methodology was warranted. The current proposed rule acknowledges that appropriate cost data from CMHC's has not been utilized due to aberrant data. The proposed cut of approximately 15% is not reflective of the cost pattern for the freestanding CMHC partial programs that I represent. The inflation rate alone for the medical industry is approximately 3.5%.

For 2006 the national APC proposed rate for PHP code 033 is \$241.57. (inclusive of copay of \$48.31). For many providers due to wage index and copay, the actual daily remittance rate is approximately \$169. For 2006 the APC payment rate will drop by approximately \$41. or 15%. This is an effective \$169. average daily payment rate for Louisiana providers due to wage index and coinsurance. This is not sufficient to run a program as intense as a partial program. This program generally includes 4 to 5 group/individual psychotherapy sessions per day. Based upon CMS Outpatient PPS Psychiatric data, the mean costs for this service would be \$329.24 to \$404.35 (CMS cost analysis attached).

Re: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

The APC panel sets the payment rates for the outpatient services including APC code 033. The Federal Register issued on February 28, 2003 (Vol. 68, No. 40) pages 9671-9672 specifically states, "Qualified nominees will meet those requirements necessary to be a Panel member. Panel members must be representatives of Medicare providers (including Community Mental Health Centers) subject to the OPPTS, with technical and/or clinical expertise in any of the following areas:.." CMHC representation has not been provided on the APC panel even though qualified nominees have been submitted in the past.

Medicare regulations state that partial hospitalization may be provided *in lieu* of inpatient hospitalization, so the acuity level of the patients and the amount of therapy provided is similar. With similar requirements and such a dramatic reimbursement difference, it is clear why many partial hospitalization programs in the country have closed.

Medicare Beneficiaries will have very little access to appropriate services for their illness that will render the same successful outcomes. The State Offices of Mental Health is not able to absorb these patients, and hospital beds are already few and far between and more expensive to operate. The state of Louisiana does not provide a partial day reimbursement program for Medicaid patients; therefore there are more Louisiana providers(CMHC's) relying on Medicare to be able to provide this needed benefit. Of the Louisiana providers I surveyed over 147,000 patient days were delivered during 2004.

CMHC'S are requesting that a fair rate be paid for an intensive day of outpatient PHP services. A payment decrease of 15% for APC Code 033 is definitely too drastic for the intense services delivered based upon CMS cost analysis data of the components involved. In recognition by CMS that medical costs have increased an average of 3.5%, I am requesting that the current payment rate for partial hospitalization programs not be cut. In light of the recent tragedy in our state caused by Hurricane Katrina, the services for these patients will be extremely important. We are asking to leave the 2005 rate in place for 2006 to avoid interruption of services for these patients.

I appreciate your consideration of my comments.

Darla B. Perry, CPA

ATTACHMENT: CMS MEDIAN COST DATA PER hcpcs_medians-1501p.xls CMS1501-P

BREAKDOWN OF CMS PUBLISHED COSTS FOR OUTPATIENT PSYCHIATRIC SERVICES

The following information is from the CMS 1501-P calculated median costs for services.

This information is based on CMS gathered data for the HCPCS codes, provided within an outpatient hospital setting. Please take into account that the cost for providing these outpatient services is generally less than that in a partial hospital program, due to the additional components which are expected to be included within a day of partial hospitalization, as well as the additional acuity of the patients being treated.

CMS has clearly defined what must be included in a day of partial hospitalization. The Local Medical Review Policy calls for a minimum of 4 hours per day, five days per week. The minimum which will pass through the OCE is 3 separate therapies per day, a minimum of four out of every seven days. It has clearly been defined and expected that providers will exceed this minimum level.

The average provider of Partial Hospital Services within Louisiana provides 4 therapies per day, five days per week. CMS has also specified that each therapy must be a minimum of 45 minutes. The following is a chart which provides data on the costs of the HCPCS codes which are included within APC 33.

CPT	Description	True Median Cost
90853	Group Therapy	82.31
90847	Family Psychotherapy w/patient present	140.10
90818	Individual Psychotherapy in a Partial Hospital Setting 45-50 minutes	99.63

Based on the figures above, an average day of services median cost for 4 group sessions would be \$329.24 For a day with mixed sessions it would be \$404.35 median cost (2 group sessions, one individual session, one family therapy session) How can a rate of \$241.57 be appropriate for APC 033?

Under the proposed rule Louisiana providers will be receiving \$169.00 per day (due to wage index and copay). Clearly this rate is inadequate. We are only requesting that providers be paid a rate which at a minimum covers the cost of providing services.

Please consider the above information for inclusion in comment to the proposed rule 1501-P.

Submitter : Dr. Thomas Kraven
Organization : Presbyterian Hospitals of Plano and Greenville
Category : Device Industry

Date: 09/10/2005

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1510-P has errors which will seriously undermine my ability, and the other providers in the Wound Care Centers of The Presbyterian Hospital of Plano and Greenville in Texas, to deliver appropriate wound care to our patients. I understand that the proposed facility reimbursement for Apligraf and Dermagraft is 30% less than the selling price instead of the usual ASP plus 8%. This means that our patients covered by CMS would not have these products available to them, and these are vital products for the treatment of venous stasis and diabetic foot ulcers, which are very prevalent in these patients. Please consider correcting this error.

Submitter : Dr. Michael Springer
Organization : Dr. Michael Springer
Category : Physician

Date: 09/10/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposal to cut reimbursement rates to hospitals for ICD implants is ill conceived. Due to the vagueries of CMS reimbursement formulas, some hospitals (eg urban university hospitals) receive higher rates than other (eg suburban unaffiliated) hospitals. Rather than cut the DRG why not reapportion these payments and cut across the board by a lower amount. This might still allow hospitals to provide ICD implants without losing money. Sudden cardiac death is the number 1 cause of death in the US and is exceeded only by all cancer deaths combined. When compared to costs of other therapies like dialysis, bypass surgery and coronary stents, ICD's are very cost effective at saving lives. We only recently stopped being harrassed by our hospital about putting in ICD's. I don't want to have to fight the hospital again. If CMS decides to ration ICD therapy I think it should require truly public debate before that happens.

Submitter : Dr. Robert Felden
Organization : Aultman Center for Pain Management
Category : Physician

Date: 09/11/2005

Issue Areas/Comments

GENERAL

GENERAL

CMS-1501-P

Aultman Center for Pain Management
2302 Fulton Drive, N.W.
Canton, Ohio 44709
330.454.7237
330.580.9142 (fax)

Rechargeable neurostimulators are a SIGNIFICANT improvement in the current technology. It provides more options for those patients that require this type of therapy. It will reduce the number of subsequent procedures i.e. battery changes, OR visits, and possibility for infection with subsequent procedures. It enables the patient to use higher stimulation currents for longer periods of time than previously available. Since the system is fully implanted and does not require an external battery source, as with RF units, so the patient is given further freedom.

Since this type of device is indeed novel, it should qualify for the pass-through device category with respect to hospital reimbursement. The procedure can safely be done on an outpatient basis, also reducing overall costs even further.

Thank you for your consideration.

Sincerely,

Robert M. Felden, D.O., F.A.O.C.A

Submitter : Mrs. Kim Moore
Organization : St. John Health
Category : Hospital

Date: 09/11/2005

Issue Areas/Comments

GENERAL

GENERAL

Comments ? CMS-1501-P

Section VIII ? Proposed Coding and Payment For Drug Administration

For 2006, CMS has proposed the use of new CPT codes for the reporting of Drug Administration services. The proposal provided a crosswalk table to convert existing codes to the new proposed codes, which will expand the number of CPTs available. Having experienced educating nurses at 7 hospitals on the process of coding (charging) for the correct drug administration method is challenging, particularly for Intravenous Infusion and Chemo Therapy. From a clinical aspect the process of code selection by the nursing staff in a hospital setting will be less than optimal. The more minor variations between CPT codes (hydration versus therapeutic, concurrent versus sequential) will cause confusion and the data submitted will be less accurate. In an office setting which is very controlled and limited personnel are coding the patient's account the codes are sensible. In a hospital setting when services may be provide in several different settings on the same day coding appropriately will be difficult, as these services are normally coded through the Charge Master and not Health Information Systems.

If the new codes are adopted clear definition of the terms must be established immediately. When Intravenous (IV) Infusion CPT codes were implemented by CMS it took several years to obtain clear definitions and guidance from our FIs and there is still some ambiguity. Clear and simple definitions of what constitutes hydration versus diagnostic/therapeutic, concurrent versus sequential. Is there a time limit on the initial codes, meaning the therapy needs to last at least 15 minutes to be considered an initial hour, as was just clarified by CMS in the last few months. If two IV Infusion lines are running on a patient, one for therapeutic and the other for hydration may the facility code for the initial on one and concurrent on the other? How do the IV Infusion codes work with the Chemo Therapy codes? Currently, when medically necessary CPT codes are billed and paid for both IV Infusion and Chemo IV. Under the new codes would facilities be limited to using the IV Infusion ? Concurrent code which will decrease our payment since this service has a status indicator of ?N?.

Please consider the additional work placed on clinical resources in those areas where nursing shortages already exist.

Thank you for your review and consideration of this comment.

Submitter : Dr. Samuel Zimmern

Date: 09/11/2005

Organization : Sanger Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am a cardiologist who practices clinical electrophysiology in Charlotte, NC. I am writing to ask that payment not be reduced for insertion of implantable cardiovertors/defibrillators in outpatients.

These procedures sometimes go quickly but at other times the procedures can be long and difficult. Examples of difficult cases include patients with previously implanted pacemakers. Patients in whom the usual ICD lead and device configuration do not allow defibrillation at acceptable shock strengths also take extra time because other leads, such as subcutaneous coils, must be placed.

Reimbursement should remain at a level high enough to allow our hospitals to afford to continue to offer ICD insertions.

Sam Zimmern, MD

Submitter : Mr. Edward Hanchett
Organization : Glens Falls Hospital
Category : Health Care Professional or Association

Date: 09/12/2005

Issue Areas/Comments

GENERAL

GENERAL

Comments regarding proposed change 'Multiple Diagnostic Imaging Procedures'

The results of this proposed change would be disastrous to the revenue stream of hospitals performing outpatient procedures. Imaging procedures are a significant source of revenue to hospitals especially in the CT and MRI modalities. Although CMS's rationale for this change sounds reasonable, CMS does not project the financial and long-term damage to hospitals. CMS must study the impact of such changes as part of the complete picture and take into account the fallout before making this decision.

As we all know, most hospitals across the country struggle financially to survive while providing healthcare services to our communities. A significant change like this one challenges hospital to make tough decisions about programs and where to cut costs. Do we continue to offer a beneficial healthcare service to people in our region when we know it loses money? The answer will become commonly no as financially supporting services like imaging are whittled away at by such proposed changes as this one. The long-term picture is that healthcare will become even more expensive to provide as preventative programs and the likes will be dropped.

Revenue streams like imaging also support other major initiatives to improve healthcare services through acquisition of technology and infrastructure. It is well documented that healthcare is significantly behind other industries when it comes to information technology. Implementing IT is expensive, but worth the cost to improve our systems and reduce medical errors another well documented problem of healthcare services. Hospitals will likely delay the purchase of electronic medical records and clinical systems that for example would affect an area like medication errors.

The proposed change is a classic 'shifting the burden' scenario. It will save our government money in one area, but result in higher cost and consequences in the long run.

It would not be fair to simply argue against this change without offering an alternative look at reducing imaging costs. If CMS really wanted to help reduce some of the unnecessary expenses associated with imaging, start with physician owned imaging services. Stark laws have not significantly affected this practice of self-referral. What difference does it make if the imaging service is owned by a group practice versus investment in an imaging center? This loop hole continues to allow physicians to own imaging services. You now have cardiologists operating CT scanners, oncologists have PET/CT scanners, and orthopedics with MRI units in their offices. The physicians are still self-referring and there is considerable incentive to order too many test when they know this is a revenue stream.

I hope my comments will be given consideration since the consequences of this change are significant. Thank you for your time.

Sincerely,
Edward L. Hanchett
Administrative Director, Medical Imaging
Glens Falls Hospital

Submitter : Mrs. Beth Werner
Organization : Vermilion Behavioral Health Center
Category : Social Worker

Date: 09/12/2005

Issue Areas/Comments

GENERAL

GENERAL

September 12, 2005

Re: Comment to CMS-1501-P - Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

To Whom It May Concern:

Thank you for the opportunity to comment on the above proposed rule.

As the program director of a partial hospitalization program at a rural CMHC, I am writing to oppose the proposed 15% cut to the per diem payment for CMHCs. If this proposal is implemented, many Medicare beneficiaries will no longer be able to access the mental health care that they require; instead numerous CMHCs will be forced to close due to the paltry reimbursement rate.

As you know, partial hospitalization programs are designed to keep mental health consumers out of inpatient psychiatric hospitals. Group educational and psychotherapy sessions are provided by professionals daily in the hopes of preventing decompensation of the mental health consumer. The amount of therapy provided is similar to, if not more than, what is provided in an inpatient psychiatric setting. At this point, inpatient programs seem to have adequate funding; so the question that begs to be asked is, why not partial hospitalization programs as well?

I am requesting that a fair rate be paid for partial hospitalization services, particularly at CMHCs. If not, the long-term consequences, not only for mental health consumers, but for the general public as well, could be devastating. I appreciate your consideration of my comments.

Beth Werner, GSW

Submitter : Mrs. Cheryl Bridgewater
Organization : Wound Healing Center at Harlingen Medical Center
Category : Nurse
Issue Areas/Comments

Date: 09/12/2005

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 (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. Patient access to these important products is jeopardized by the payment rates in the proposed rule. 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. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving 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. 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 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 in stead of payment at ASP plus eight percent. 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. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate \$1,130.88; 2006 proposed outpatient rate \$766.84 and 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. 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%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Mrs. Kristy Martin
Organization : Woodland Heights Wound Care
Category : Nurse

Date: 09/12/2005

Issue Areas/Comments

GENERAL

GENERAL

We have had great success with Apligraf, it would be a shame if the reimbursement of this product will affect our ability to use this product. Hopefully CMS will do the right thing for our patients.
Kristy Martin RN

Submitter : Dr. Rick Martin
Organization : Woodland Heights Wound Care Center
Category : Physician

Date: 09/12/2005

Issue Areas/Comments

GENERAL

GENERAL

I have used Apligraf in my clinic with great results. It would be a shame if the reimbursement of this product affects our ability to use this product for our patient.
Please CMS do the right thing for our patient.
Thanks,

Dr. Rick Martin

Submitter : Mrs. Ann Perry
Organization : Fremont Rideout Health Group
Category : Hospital

Date: 09/12/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express my concerns with the proposed rule, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule", published in the Federal Register on July 25, 2005.

In the proposed rule, the payment rates for procedures involving ICDs were significantly decreased. As a health care provider of these services to Medicare beneficiaries, these payment reductions are a serious concern. Changes should be made to the 2006 proposed payment rates for ICDs that are more closely aligned with the real cost of providing these services. The 2006 proposes a 14.1% payment decrease relative to 2005 payments for ICD APCs 0107 and 0108 resulting in an unsustainable financial burden for our institution. The resulting APC rates are lower than our institution's cost for the device itself, leaving us with an out-of-pocket loss for device acquisition and no payment for the procedure. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting.

To fix this problem, we request that CMS base the 2006 payment rates for ICD implant procedures on 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, while not entirely adequate, would be more in line with our facility's actual cost of performing these services.

In the proposed rule, CMS requested comments on the February 2005 APC Advisory Panel recommendation to increase the number of single procedure claims available for rate setting for APCs 0107 and 0108. Although the scenarios displayed in the proposed rule increase the number of single procedure claims, single procedure claims have shown no ability to provide appropriate payment in the last five years and we are not able to support this proposal.

For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resynchronization devices (CPT 33225) from APC 1525 to APC 0418. Although the payment rate for the implant would increase, the move to the new APC actually equates to a lower rate of reimbursement than in 2005 due to the change in the status indicator. In the proposed rule 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 a status indicator "T" does not make sense in an APC where the device cost is 90% of the procedure. There is not a 50% reduction in acquisition cost when implanting it at the same time as the device resulting in an out-of-pocket loss to the hospital. To address this problem, we request that CMS retain the "S" status indicator for the left sided lead APC.

Thank you for the opportunity to comment.

Sincerely,

Ann Perry, RDCS
Fremont Rideout Health Group
425 Fourth Street, Suite 200
Marysville, CA 95901

Submitter : Jackie Barnard
Organization : Abraxis Oncology
Category : Drug Industry

Date: 09/12/2005

Issue Areas/Comments

GENERAL

GENERAL

CMS-1501-P _ Section E: New Procedure Codes.

On June 17, 2005 CMS released its 3rd Quarter update to the Hospital Outpatient Prospective Payment System. Abraxane for injectable suspension (paclitaxel protein-bound particles for injectable suspension) was granted pass-through status effective July 1, 2005. The C-code assigned to Abraxane in the 2nd Quarter, C9127 per 1 mg, was listed as applicable in the hospital outpatient setting for third quarter.

Per the HOPPS PR for CY 2006 Abraxane is listed with a status indicator K (Non-Pass-Through Drugs, Biologics) rather than G (Pass-Through Drugs and Biologics). Abraxis Oncology is commenting to ensure that Abraxane is listed with status indicator K indicating pass-through status in the HOPPS PR for CY 2006.

Jackie Barnard
National Reimbursement Manager
jackiebarnard@appdrugs.com

CMS-1501-P-336-Attach-1.PDF

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 585

Department of Health &
Human Services

Center for Medicare and
&
Medicaid Services

Date: June 17, 2005

Change Request 3915

SUBJECT: July 2005 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to the OPPS, to be implemented in the July 2005 update. This notification further describes changes to payment policy and billing procedures under the OPPS.

NEW/REVISED MATERIAL :

EFFECTIVE DATE : July 01, 2005

IMPLEMENTATION DATE : July 05, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED – *Only One Per Row.*

R/N/D	Chapter / Section / SubSection / Title
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N/A	
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III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Recurring Update Notification

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 585	Date: June 17, 2005	Change Request 3915
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SUBJECT: July 2005 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to the OPPTS, to be implemented in the July 2005 update. This notification further describes changes to payment policy and billing procedures under the OPPTS. The July 2005 OPPTS OCE and OPPTS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this notification. Unless otherwise noted, all changes addressed in this notification are effective for services furnished on or after July 1, 2005. July 2005 revisions to the OPPTS OCE data files, instructions, and specifications are provided in Change Request 3871, 'July 2005 Outpatient Prospective Payment System Code Editor (OPPTS OCE) Specifications Version 6.2.'

B. Policy:

1. Smoking and Tobacco-Use Cessation Counseling Services

Effective March 22, 2005, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is adequate to conclude that smoking and tobacco use cessation counseling is reasonable and necessary for a patient with a disease or an adverse health effect that has been found by the U.S. Surgeon General to be linked to tobacco use, or who is taking a therapeutic agent whose metabolism or dosing is affected by tobacco use as based on FDA-approved information. These individuals will be covered under Medicare Part B when certain conditions of coverage are met, subject to certain frequency and other limitations. Conditions of Medicare Part A and Medicare Part B coverage for smoking and tobacco-use cessation counseling services are located in the Medicare National Coverage Determinations Manual, Publication 100-3, Section 210.4.

Effective for services furnished on or after March 22, 2005, hospitals should report the following HCPCS codes when billing for smoking and tobacco-use cessation counseling service:

HCPCS	SI	Descriptor	APC
G0375	S	Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes Short Descriptor: Smoke/Tobacco counseling 3-10	1501
G0376	S	Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes Short Descriptor: Smoke/Tobacco counseling greater than 10	1501

NOTE: The above G codes will NOT be active in contractors' systems until July 5, 2005. Refer to CR 3834, Business Requirements 3834.15 through 3834.18, for detailed business requirements related to reporting smoking and tobacco use cessation counseling furnished by hospitals and paid under the OPSS. This coverage decision, as described in the Medicare National Coverage Determinations Manual (Publication 100-3, section 210.4), does not modify existing coverage for minimal cessation counseling (defined as 3 minutes or less in duration) which is already considered to be covered as part of each Evaluation and Management (E/M) visit and is not separately billable.

2. Drugs and Biologicals

a. Drugs with Payments Based on Average Sales Price (ASP) Effective July 1, 2005

The table below lists the drugs and biologicals whose payments under the OPSS will be established in accordance with the ASP methodology that is used to calculate payment for drugs and biologicals in the physician office setting. In the 2005 OPSS final rule (69 FR 65777), it was stated that payments for drugs and biologicals based on ASP will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary, we will incorporate changes to the payment rates in an appropriate quarterly release of the OPSS PRICER and we will not be publishing the updated payment rates in the program instructions implementing the associated quarterly update of the OPSS. However, the updated payment rates can be found in the July update of OPSS Addendum A and Addendum B on the CMS web site.

Single-indication orphan drugs payable under OPSS are also listed below. The methodology used to establish payment rates for these drugs is discussed in the 2005 OPSS final rule (69 FR 65807).

HCPCS	APC	Long Description
C9123	9123	Human fibroblast derived temporary skin substitute, per 247 square centimeters
C9127	9127	Injection, paclitaxel protein-bound particles, per 1 mg
C9128	9128	Injection, pegaptamib sodium, per 0.3 mg
C9129	9129	Injection, Clofarabine, per 1 mg
C9203	9203	Injection, Perflexane lipid microspheres, per single use vial
C9205	9205	Injection, Oxaliplatin, per 5 mg
C9206	9206	Collagen-glycosaminoglycan bilayer matrix, per cm ²
C9211	9211	Injection, Alefacept, for intravenous use per 7.5 mg
C9212	9212	Injection, Alefacept, for intramuscular use per 7.5 mg
C9218	9218	Injection, azacitidine, 1 mg

C9220	9220	Sodium hyaluronate per 30 mg dose, for intra-articular injection
C9221	9221	Acellular dermal tissue matrix, per 16cm ²
C9222	9222	Decellularized soft tissue scaffold, per 1 cc
J0128	9216	Abarelix for injectable suspension, per 10 mg
J0135	1083	Injection, adalimumab, 20 mg
J0180	9208	Injection, IV, Agalsidase beta, per 1 mg
J0205	900	Injection, Alglucerase, per 10 units
J0256	901	Alpha 1 proteinase inhibitor-human, 10 mg
J0595	703	Injection, Butorphanol tartrate 1 mg
J0878	9124	Injection, daptomycin per 1 mg
J1457	1085	Injection, gallium nitrate, 1 mg
J1785	916	Injection imiglucerase, per unit
J1931	9209	Injection, laronidase, 0.1 mg
J2185	729	Injection, meropenem, 100 mg
J2280	1046	Injection, moxifloxacin 100 mg
J2355	7011	Oprelvekin injection, 5 mg
J2357	9300	Injection, omalizumab, per 5 mg
J2469	9210	Injection, palonosetron HCl, 25 mcg
J2783	738	Injection, rasburicase, 0.5 mg
J2794	9125	Injection, risperidone, long acting, 0.5 mg
J3240	9108	Injection Thyrotropin Alpha , 0.9 mg, provided in 1.1 mg vial
J3411	1049	Injection, Thiamine HCL 100 mg
J3415	1050	Injection, Pyridoxine HCL 100 mg
J3465	1052	Injection, voriconazole, 10 mg
J3486	9204	Injection, Ziprasidone mesylate, per 10 mg
J7308	7308	Aminolevulinic acid HCL for topical administration, 20%, single unit dosage form (354mg)
J7513	1612	Daclizumab, parenteral, 25 mg
J7518	9219	Mycophenolic acid, oral, per 180 mg
J7674	867	Methacholine chloride administered as inhalation solution through a nebulizer, per 1mg
J8501	868	Aprepitant, oral, 5 mg
J9010	9110	Alemtuzumab, 10 mg
J9015	807	Aldesleukin, per single use vial
J9017	9012	Arsenic trioxide, 1 mg
J9035	9214	Injection, Bevacizumab, per 10 mg
J9041	9207	Injection, Bortezomib, 0.1 mg
J9055	9215	Injection, Cetuximab, per 10 mg
J9160	1084	Denileukin diftitox, 300 mcg
J9216	838	Interferon gamma 1-b, 3 million units

J9300	9004	Gemtuzumab ozogamicin, 5 mg
J9305	9213	Injection, Pemetrexed, per 10 mg
Q2019	1615	Injection, Basiliximab, 20 mg
Q4075	1062	Injection, Acyclovir, 5 mg
Q4076	1070	Injection, Dopamine HCL, 40 mg
Q4077	1082	Injection, Treprostinil, 1 mg
Q4079	9126	Injection, Natalizumab, per 1 mg

b. Updated Payment Rates for Certain Drugs, Biologicals and Services Effective April 1, 2005 through June 30, 2005

The payment rate for the drug listed below was incorrect in the April 2005 OPSS PRICER. The corrected payment rate will be installed in the July 2005 OPSS PRICER, effective for services furnished on April 1, 2005 through implementation of the July 2005 update. By September 15, 2005, Fiscal Intermediaries shall mass adjust all claims with dates of service on or after April 1, 2005 through implementation of the July 2005 update, that were processed to payment between April 1, 2005 and July 5, 2005 (implementation of the July 1, 2005 OPSS OCE update), containing J0135, correcting the payment rate to \$294.63.

HCPCS	APC	Long Description	Corrected Payment Rate
J0135	1083	Injection, Adalimumab, 20 mg	\$294.63

c. Newly-Approved Drugs and Biologicals Eligible for Pass-Through Status

The following drugs and biologicals have been designated as eligible for pass-through status under the OPSS effective July 1, 2005. Payment rates for these items can be found in the July update of OPSS Addendum A and Addendum B on the CMS web site.

HCPCS	APC	SI	Long Description
C9127	9127	G	Injection, Paclitaxel Protein Bound Particles, per 1 mg
C9128	9128	G	Injection, Pegaptamib Sodium, per 0.3 mg
C9129	9129	G	Injection, Clofarabine, per 1 mg
J8501*	0868	G	Aprepitant, oral, 5 mg

*J8501 was approved for pass-through status effective April 6, 2005.

3. Medical Nutrition Therapy Services

If a medical nutrition therapy service is provided in the hospital outpatient department, hospitals should **not** bill the Fiscal Intermediary (FI) using the UB-92 for an evaluation and management code. Hospitals should be reporting CPT codes 97802, 97803, and 97804 for medical nutrition therapy services to carriers using the CMS-1500.

4. Reprocessing of OPSS Claims Containing Certain Surgical Procedures

The CMS discovered an error in the 2005 OPSS PRICER that miscalculates the outlier payment amount. The CMS has corrected the problem in the July 2005 version of the OPSS PRICER software. By September 15, 2005, FIs shall mass adjust claims that meet all of the following criteria using the July 2005 OPSS PRICER:

- 1) Claims processed using the January or April 2005 OPSS PRICER that were processed to payment prior to installation of the July 2005 OPSS PRICER; and
- 2) Claims with one or more surgical procedure lines (lines with a status indicator of "T" (any HCPCS) or "S" with HCPCS codes greater than 09999 and less than 70000) that contain no surgical procedure lines with charges less than \$1.01; and
- 3) Claims with dates of service January 1, 2003 or greater.

Note: The MSP mass adjustment instructions included in JSM-05356, issued on May 20, 2005, also apply to these reprocessed claims.

5. No-Cost Device Coding

Effective for services furnished on or after April 1, 2005, all hospitals paid under the OPSS must report a code for a device when reporting the code for inserting the device. (See Transmittal 403, CR 3606, issued December 17, 2004.) If an OPSS hospital fails to report a device code, edits installed in the outpatient code editor (OCE) for services furnished on or after April 1, 2005 will not allow the claim to be processed to payment. For example, if a hospital doesn't report the code for a pacemaker with the CPT code for the procedure performed to insert the pacemaker, OCE edits will cause the claim to be returned to the provider.

However, there are occasions when a hospital may furnish a device for surgical insertion for which it incurs no cost. These cases include, but are not limited to, devices replaced under warranty, due to recall, or due to defect in a previous device; devices provided in a clinical trial; or devices provided as a sample. The hospital charge for a device furnished to the hospital at no cost should equal \$0.00. Some hospitals paid under the hospital outpatient prospective payment system (OPSS) might ordinarily report neither a code nor a charge for a device for which it incurred no cost, which would result in the claim failing the device edits installed in the OCE. Other hospitals have billing systems which require that a charge be reported for separately payable codes in order for the claim to be submitted for payment, even items for which the hospital incurs no cost.

Hospitals paid under the OPSS have asked that CMS clarify how devices furnished to beneficiaries for which the hospital incurs no cost should be reported. Therefore, take immediate action to broadcast and disseminate the following instructions to hospitals for services furnished on or after April 1, 2005:

- Hospitals paid under the OPSS that surgically implant a device furnished at no cost to the hospital shall report the appropriate HCPCS code for the device on type of bill 13x.
- Hospitals paid under the OPSS that surgically implant a device furnished at no cost to the hospital shall report a charge of zero for the device, or, if the hospital's billing system requires

that a charge be entered, the hospital shall submit a token charge (e.g. \$1.00) on the line with the device code.

We recognize that showing a charge for a device that has been furnished without cost is not optimal, but showing a token charge in this circumstance will allow claims for reasonable and necessary services that might otherwise be denied due to OCE edits to be paid, and will ensure that beneficiaries receive the care they need.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)							
		F I	RHHI	C a r r i e r	D M E R C	Shared System Maintainers			Other
						F I S S	M C S	V M S	C W F
3915.1	The FISS maintainer shall install the July 2005 OPPS PRICER.					X			
3915.2	By September 15, 2005, Fiscal Intermediaries shall mass adjust claims that meet all of the following criteria, through the July 2005 OPPS PRICER: 1) Claims processed using the January or April 2005 OPPS PRICER that were processed to payment prior to installation of the July 2005 OPPS PRICER; <u>and</u> 2) Claims with one or more surgical procedure lines (lines with a status indicator of "T" (any HCPCS) or "S" with HCPCS codes greater than 09999 and less than 70000) that contain no surgical procedure lines with charges less than \$1.01; <u>and</u> 3) Claims with dates of service January 1, 2003 or greater.	X	X						
3915.3	By September 15, 2005, Fiscal Intermediaries shall mass adjust all claims with dates of service on or after April 1, 2005 through implementation of the July 2005 update, that were processed to payment between April 1, 2005 and July 5,	X	X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)							
		F I	RHHI	C a r r i e r	D M E R C	Shared System Maintainers			Other
F I S S	M C S					V M S	C W F		
	2005 (implementation of the July 1, 2005 OPSS OCE update), containing J0135, correcting the payment rate to \$294.63.								
3915.4	The SSM shall provide FI's with the SuperOp event for creation of the mass adjustments listed in this CR.					X			

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)							
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers			Other
F I S S	M C S					V M S	C W F		
3915.1	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X						

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: July 1, 2005 Implementation Date: July 5, 2005 Pre-Implementation Contact(s): Melissa Dehn melissa.dehn@cms.hhs.gov ; Marina Kushnirova marina.kushnirova@cms.hhs.gov Post-Implementation Contact(s): Appropriate Regional Office	No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.
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***Unless otherwise specified, the effective date is the date of service.**

Submitter : Dr. Michelle Jupin, DPM

Date: 09/12/2005

Organization : Michigan Foot & Ankle

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am a user of APLIGRAF to heal chronic wounds. The reimbursement problem for 2006 will negatively effect patient care & healing.

Please review and change the mistake.