ADVANCED BIOHEALING

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September 14, 2007

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Kerry Weems
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

ATTN: CMS-1392-P

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

Via: Federal Express Tracking number 7987 6278 0848 and Carol.Bazell@cms.hhs.gov

Dear Acting Administrator Weems:

Thank you for the opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008.

Advanced BioHealing, Inc. manufactures Dermagraft®, human fibroblast derived dermal substitute. Dermagraft is indicated for the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure.

We are concerned that patient access to advanced wound healing products like Dermagraft will be significantly compromised by the CY 2008 Proposed Rule's changes to the Skin Repair Procedures ambulatory payment classifications (APCs). Proposing to reduce the CY 2008 payment amounts for the application of Dermagraft by *more than 50 percent* from CY 2007 will not cover a hospital's overhead to provide advanced technologies and ongoing care needs for these diabetic patients. In the absence of this treatment option, many of these Medicare beneficiaries are at greater risk of foot amputations.

In the CY 2008 proposed rule, CMS proposes replacing the four existing skin repair APCs for procedures involved with the grafting application of various skin substitute products, including Dermagraft, with the following five new APCs to improve resource and clinical homogeneity: APC 0133 Level I Skin Repair with a CY 2008 proposed payment of $ 84.97; APC 0134 Level II Skin Repair with a CY 2008 proposed payment of $ 134.48; APC 0135 Level III Skin Repair with a CY 2008 proposed payment of $ 298.19; APC 0136 Level IV Skin Repair with a CY 2008 proposed

payment of $ 983.41; and APC 0137 Level V Skin Repair with a CY 2008 proposed payment of $ 1,333.34.

DERMAGRAFT

Dermagraft is a resource intensive metabolically active skin repair product. The Food and Drug Administration (FDA) requires a 24-step thawing and handling process to ensure metabolic activity. Dermagraft is also the only existing skin substitute product that requires continuous storage in a -70 Celsius freezer until usage, which requires a uniquely designed freezer and specific handling requirements.

The proposed CY 2008 rule assigns CPT code 15365 (*Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children)* for the application of Dermagraft to APC 134 (Level II Skin Repair) with a payment rate of $134.48. As compared to previous CMS payments for Dermagraft this represents a more than fifty percent reduction in payment from Dermagraft's CY 2007 payment of $ 323.28 (APC 25, Level II Skin Repair).

However, when resource intensive metabolically active skin repair products are compared to other proposed payment for non-metabolically active skin repair products, which do not have these handling and storage requirements, the less resource intensive products are assigned to a higher level APC 135 (Level III Skin Repair) with a payment of $298.19.

Exhibit A: 2008 (P) Skin Repair APC Assignment by CPT Code

	APC 24, Level I Skin Repair $92.32	APC 25, Level II Skin Repair $323.28	APC 134 Level II Skin Repair $ 134.48
	APC 24, Level I Skin Repair $92.32	APC 25, Level II Skin Repair $323.28	APC 134 Level II Skin Repair $ 134.48
	APC 25, Level II Skin Repair $315.71	APC 25, Level II Skin Repair $323.28	APC 135 Level III Skin Repair $ 298.19
	Coding effective 2007	APC 25, Level II Skin Repair $323.28	APC 135 Level III Skin Repair $ 298.19

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The following information provides documentation that CPT code *15365* for the application of Dermagraft is more appropriately placed in APC 0135, Level III Skin Repair to best support its metabolically active status, as well as FDA and JCAHO tracking, storing, and handling requirements and associated wound preparation and debridement services considered standard medical practice for treatment with a skin substitute.

- **Assignment of Dermagraft CPT code 15365 to APC 0134 Level II Skin Repair does not account for the clinical resources and costs based on the necessary resources and time involved to store and provide Dermagraft**. Dermagraft must be stored at negative 70 Celsius to maintain metabolic activity and also has an FDA-required 24-step handling and thawing process. Hospital protocols must also meet JCAHO standards for human tissue, specifically related to product traceability, adverse event reporting, and control of disease transmission. This includes, FDA-required storage, handling and thawing processes, wound assessment and wound preparation materials.

- **Dermagraft was removed from the market by the previous manufacturer Smith & Nephew in October 2005. Because Dermagraft was unavailable, the reimbursement level proposed is artificially low because the CY 2006 claims and cost report data for Dermagraft can not accurately reflect costs associated with this procedure (CPT 15365).** For example, we understand that only 469 claims were reported for CPT 15365 in CY 2006. Additionally, claims data from the last full year that Dermagraft was available for sale (CY 2005) reflects median costs for the previous skin substitute application codes CPT 15342/15343 as $ 183.57 and $ 104.73, respectively. The previous full year of data (CY 2004) also supports a higher costs associated with CPT 15342/15343, with median costs reported as $188.39 and $133.34, respectively.

- **Wound preparation and debridement services are not included in the costs.** While wound preparation procedures represented by CPT 15002-15004 are not restricted in the 2007 CPT coding book when used with CPT 15365, the majority of Medicare contractors severely restrict this procedure and its payment for <u>all</u> skin substitutes. Significant wound preparation is required for Dermagraft to achieve meticulous homeostasis and ensure Dermagraft optimally adheres to the wound site. Many patients also present with multiple wounds, which then increases the time for assessment and debridement. Therefore, the time and resources associated with providing Dermagraft treatment to patients also requires the facility to include the resources and costs associated with CPT 15002-15004 wound preparation procedures.

- **2006 CPT coding changes for CPT 15365 has caused confusion.** The American Medical Association (AMA) updated codes for all skin substitute products in January 2006; however, this coding change caused a great deal of confusion within the provider community. The AMA subsequently published a CPT Assistant in October of 2006 to clarify

these coding changes and how they apply to each skin substitute product (see attached). We believe this situation also contributed to the low number of appropriately tracked and submitted claims.

- **2006 CPT 15365 coding change does not support a typical diabetic foot ulcer sizing as compared to the CPT coding of similar products.** Because Dermagraft was no longer available on the market, the American Medical Association (AMA) 2006 CPT coding changes for CPT 15365 does not reflect the size of a typical diabetic foot ulcer. Instead, the updated CPT 15365 reflects a burn vignette patient, which is more typically treated for 100 sq. cm. wound size (see attached burn vignette). However, comparable products used for the treatment of the same indication of a diabetic foot ulcer reflect a 25 sq. cm. sizing. This coding change leads to an inequity in billing and payment between similar skin substitute products for the treatment of the same size ulcer because comparable products coding include the initial 25 sq cm (CPT 15340) and subsequent 25 sq cm (CPT 15341) compared to coding and billing of one APC up to 100 sq cm for CPT 15365. Advanced BioHealing is in the process of requesting additional clarification around an appropriate vignette associated with CPT 15365 and the descriptor sizing of 100 sq cm.

Explanation of Procedure

Because the typical wound patient does not present with a clean, easy-to-manage diabetic foot ulcer, Dermagraft is more appropriately assigned to APC 0135 (Level III Skin Repair). For example, the debridement required to prepare a wound for Dermagraft® is more thorough and time consuming than one the physician would ordinarily do, because meticulous hemostatis must be achieved in order for Dermagraft to adhere optimally to the wound bed.

The clinical resource associated with Dermagraft also includes staff time to observe the 24-step thawing process to ensure the product's metabolic activity at application. Treatment also includes approximately 20 minutes to assess the patient's wound, including a more thorough and time consuming debridement to achieve meticulous hemostatis and ensure Dermagraft optimally adheres to the wound site. Many patients also present with multiple wounds, which then increases the time for assessment and debridement.

Another 10- 20 minutes of professional time is required to ensure the product's metabolic activity at application, as well as the expertise to cut and apply Dermagraft, apply the appropriate wound dressing, and provide patient instructions. Overall, to ensure metabolic activity rates, physicians must handle Dermagraft carefully to minimize damage to the product prior to application. As a result, the range of time to provide each application (dependent upon the number of wounds, wound condition, etc.) is an average of 25 minutes/procedure.

The majority of Medicare contractors' local coverage decisions (LCD) also recognize the necessity of wound care expertise to treat with Dermagraft and include extensive medical documentation requirements to ensure that providers follow wound preparation, the 24-step thawing and handling Processes, and provide extensive patient counseling and medical treatment management for diabetes to ensure Dermagraft is used appropriately.

Placing Dermagraft in APC 0135 Level III skin substitute will ensure that Dermagraft is not penalized by another manufacturer's removal from the market during a time of change in the skin substitute coding and payment mechanisms and is treated equitably compared to other skin substitutes.

Therefore, based on the information detailed above, we respectfully request that CMS place Dermagraft's application CPT code 15365 into APC 0135 (Level III Skin Repair) to best reflect the resource cost and process of applying Dermagraft as evidenced by previous years data and to ensure that patients continue to have access to this limb-saving treatment.

Thank you again for the opportunity to comment on the proposed hospital outpatient rule for CY 2008. Please do not hesitate to contact me if I can provide additional information at 813.741.3234.

Sincerely,

Therésa K. Dixon

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Enclosures: Dermagraft® Labeling and Directions for Use
2006 CPT Assistant: Skin Substitutes
CPT Changes 2006: An Insiders View, p. 56-57
Smith & Nephew October, 15, 2007 Press Release
Advanced BioHealing February 15, 2006 Press Release

cc: Carol Bazell via email submission to carol.bazell@cms.hhs.gov

AMA
AMERICAN
MEDICAL
ASSOCIATION

cpt® Assistant

Your Practical Guide to Current Coding

October 2006 / Volume 16, Issu

At Issue This Month

Skin Replacement Surger titutes

Due to major advances in skin replacement su ti i ity and morbidity, particularly with respect to b ies, has been a significant increase in the use of skin substitutes. Skin utes hav found to i wound healing, control pain, rapidly close n wound, i e fu metic appearance, and in the cases of seriou injuries, in val.

Comprehensive changes (ie, additions, deletions, vi od nied by new and revised introductory language, paren ot s g)

and cross-references) have been made to the Integumentary, Repair (Closure) subsection of Surgery to accommodate the reporting of skin grafts, skin replacements, skin substitutes, and local burn wound care. The Free Skin Grafts subheading under the Repair (Closure) heading was deleted and replaced with a new subheading titled Skin Replacement Surgery and Skin Substitutes. A major impetus driving these changes is the physician work involved in providing these services, which include harvesting the graft, caring for the donor site; the application of the skin replacement or substitute by location and incremental units; and the application ("surgical fixation") of the skin substitute or graft.

The rationale for changes to the Integumentary System CPT codes include:

- The development of novel materials used to treat skin wounds
- The differences among grafts and materials:
  - Temporary vs permanent
  - Skin components (see skin grafts, autografts below)
  - Natural vs manufactured
- Standardization of definitions with the American Society for Testing and Materials (ASTM) for skin replacements and skin substitutes

Temporary skin substitutes are used to decrease pain, augment healing, and close the clean wound until skin is available for grafting. Permanent skin substitutes are used to add or replace remaining skin components and provide a higher quality of skin than a thin skin graft.

Key Definitions

Skin grafts differ by their origin and, for autografts, by their anatomic source. Skin grafts, by origin, are:

- **Autograft:** Tissue transplanted from one part of the body to another in the same patient
- **Allograft (homograft):** Tissue transplanted from one individual to another of the same species
- **Xenograft (heterograft):** Tissue transplanted from one species to an unlike species (eg, non-human, baboon to human)

There are four types of autografts defined by anatomic source:

- **Epidermal:** Grafts composed of the epidermis, the outermost layer of the two layers that makes up the skin, the epidermis, and dermis
- **Dermal:** Grafts composed of the dermis, the second layer of skin immediately below the epidermis
- **Split-thickness skin grafts:** Grafts composed of the full layer of epidermis and part of the dermis
- **Full-thickness skin grafts:** Grafts composed of the full layer of both the epidermis and dermis

Other key definitions:

- **Skin replacement:** A tissue or graft that permanently replaces lost skin with healthy skin
- **Skin substitute:** A biomaterial, engineered tissue or combination of materials and cells or tissues that can be substituted for skin autograft or allograft in a clinical procedure
- **Temporary wound closure:** Not the final resurfacing material but provides closure of the wound surface until the skin surface can be permanently replaced

There exists a distinction between debridement and excision. *Debridement* is the removal of loose, devitalized, necrotic and/or contaminated tissue, foreign bodies, and other debris on the wound, using mechanical or sharp techniques. *Excision* is the surgical procedure through the deep dermis or subcutaneous tissues to prepare a wound for immediate or later grafting.

A key change to the Integumentary System CPT codes include the deletion of CPT codes *15342, Application of bilaminate skin substitute/neodermis; 25 sq cm*, and *15343, Application of bilaminate skin substitute/neodermis; each additional 25 sq cm (List separately in addition to code for primary procedure).* These codes have been replaced with codes 15170-15176, 15340-15341, and 15360-15366.

Additionally, 15350 and 15351 have been deleted and replaced with 15300-15321.

Choosing the Appropriate Code

The first step to choosing an appropriate skin replacement code is to identify the size and location of the defect (recipient area) and the type of graft or skin substitute. Simple debridement of granulation tissue or recent avulsion is included in the graft or skin substitute codes. However, when a primary procedure such as orbitectomy, radical mastectomy, or deep tumor removal requires skin graft for definitive closure, see the appropriate anatomical subsection for the primary procedure and this section for skin graft or skin substitute.

It should be noted that the codes provided in Table 1 are not intended to report simple graft application alone or application stabilized with dressings (eg, by simple gauze wrap) without surgical fixation of the skin substitute or graft. However, the skin substitute or graft is anchored using the surgeon's choice of fixation. While routine dressing supplies are not reported separately, the supply of the skin substitute or graft is reported separately when services are performed in the office setting.

Surgical Preparation

Codes 15000 and 15001 describe burn and wound preparation by excision of tissue or incisional or excisional release of scar contracture resulting in an open wound requiring a skin

Table 1
Codes for Skin Replacement Surgery

Code Range	*Type of Graft*	*Definition and Product Examples*
15150-15157	Tissue cultured epidermal autograft	Cultured autologous skin with only an epidermal layer (eg, CEA, Epicel®, EpiDex®)
15170-15176	Acellular dermal replacement	A tissue-derived or manufactured device that provides immediate, temporary wound closure and that incorporates into the wound and promotes the generation of a neodermis that can support epidermal tissue (eg, Integra®)
15300-15321	Allograft skin	Cadaveric human skin allograft (eg, homograft—from skin banks)
15330-15336	Acellular dermal allograft	Decellularized allogeneic dermis may require immediate concurrent coverage with autologous tissue (eg, Alloderm®, Graft Jacket®)
15340-15341	Tissue cultured allogeneic skin substitute	Cultured allogeneic skin with both a dermal and epidermal layer (eg, Apligraf®, Orcel™)
15360-15366	Tissue cultured allogeneic dermal substitute	Cultured allogeneic neonatal dermal fibroblasts (eg, Transcyte®, Dermagraft®)
15400-15421	Xenogeneic dermis	Nonhuman dermis for temporary wound closure (eg, EZ Derm™, Mediskin®)
15430-15431	Acellular xenogeneic implant	Decellularized nonhuman connective tissue (eg, Oasis®, Surgisis®, PriMatrix®)

This table represents only examples. Codes are based on the anatomic source and type of graft, not on the brand name of the material.

graft. These codes are used for initial wound recipient site preparation.

15000 Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture; first 100 sq cm or one percent of body area of infants and children

Description of Procedure (15000)

After the induction of anesthesia, the subcutaneous tissue beneath the full-thickness burn is infiltrated with crystalloid solution containing epinephrine in order to minimize blood loss. The eschar is excised down to viable subcutaneous tissue. Hemostasis is obtained with electrocautery, epinephrine-soaked laparotomy pads, and/or a topical hemostatic agent. A total of 100 sq cm is excised in preparation for immediate or staged skin grafting and/or application of a skin substitute or replacement.

Grafts: Autograft/Tissue-Cultured Autograft Codes 15040-15157

This section is used to report autografts and tissue-cultured autografts. Codes 15050 and 15100-15136 are used to report autografts other than those that are tissue-cultured. Codes 15040 and 15150-15157 are used to report tissue-cultured autografts.

An autograft is harvested from a donor site and applied to the recipient site. A tissue-cultured autograft is one that has been first cultured in the laboratory from skin cells harvested from the patient and then, once grown into sheets of graft material, are shipped in sterile containers by the laboratory to arrive in the operating room where they are applied to the recipient site(s). These codes are reported in incremental units and are generally performed as part of a staged procedure.

Code 15040 is used to report harvest of skin cells for tissue-cultured autograft.

15040 Harvest of skin for tissue cultured skin autograft, 100 sq cm or less

Description of Procedure (15040)

After the induction of anesthesia, the subcutaneous tissue beneath the donor site is infiltrated with crystalloid solution containing epinephrine in order to minimize blood loss and facilitate donor skin harvesting. A split-thickness skin graft 0.010 to 0.015 inches in depth is harvested using a dermatome. A total of 100 sq cm is recovered. Hemostasis is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. A dressing is applied to the donor site and covered with dry gauze.

CPT code *15110, Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children,* is used to report "ultrathin" epidermal autografts.

Description of Procedure (15110)

After the induction of anesthesia, the subcutaneous tissue beneath the donor site is infiltrated with crystalloid solution containing epinephrine in order to minimize blood loss and facilitate donor skin harvesting. An epidermal skin graft 0.004 to 0.006 inches in depth is harvested using a dermatome. The dermatome is adjusted as necessary during donor skin harvesting to ensure that almost no dermal tissue is harvested. A total of 100 sq cm is recovered and meshed for expansion prior to placement on the excised wound. Hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The epidermal skin graft is applied to the trunk and secured to the excised wound with interrupted sutures, surgical staples, and/or fibrin sealant. A dressing is applied to the graft site and secured to prevent mechanical shear. A dressing is applied to the donor site and covered with dry gauze.

The following dermal autograft codes are illustrated by the following examples:

15130 Dermal autograft, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children

+15131 each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Description of Procedure (15130)

After the induction of anesthesia, the subcutaneous tissue beneath the donor site is infiltrated with crystalloid solution containing epinephrine in order to minimize blood loss and facilitate donor skin harvesting. A split-thickness skin graft 0.010 to 0.015 inches in depth is raised but not removed from the underlying dermal bed using a dermatome. The dermatome is adjusted to facilitate removal of the graft from the device. A second pass of the dermatome is made over the freshly created donor site at a depth of 0.010 inches for the recovery of the dermal graft. A total of 100 sq cm of dermal autograft tissue is recovered. Hemostasis of the donor site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The split-thickness skin graft that was originally raised is applied to the donor site and secured with interrupted sutures, surgical staples, and/or fibrin sealant. The dermal graft is secured to the surgically prepared wound in the popliteal fossa. Dressings are applied to both the grafted donor site and the surgically prepared wound in the popliteal fossa and both are secured to prevent mechanical shear.

Description of Procedure (15131)

After the induction of anesthesia, the subcutaneous tissue beneath the donor site is infiltrated with crystalloid solution containing epinephrine in order to minimize blood loss and facilitate donor skin harvesting. A split-thickness skin graft 0.010 to 0.015 inches in depth is raised but not removed from the underlying dermal bed using a dermatome. The dermatome is adjusted to facilitate removal of the graft from the device. A second pass of the dermatome is made over the freshly created donor site at a depth of 0.010 inches for the recovery of the dermal graft. Two hundred square centimeters of dermal autograft tissue is recovered. Hemostasis of the donor site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The split-thickness skin graft that was originally raised is applied to the donor site and secured with interrupted sutures, surgical staples, and/or fibrin sealant. The dermal graft is secured to the surgically prepared wound in the popliteal fossa. The first 100 sq cm is separately reported. Dressings are applied to both the grafted donor site and the surgically prepared wound in the popliteal fossa and both are secured to prevent mechanical shear.

Codes 15150 and 15155 have been added to describe tissue-cultured epidermal autograft for the first 25 sq cm or less. Add-on codes 15151, 15152, 15156, and 15157 have been established to report each additional 1 sq cm to 75 sq cm, and each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof. Instructional parenthetical notes following 15151 and 15156 have been added to preclude the reporting of 15151 and 15156 more than once per session.

15150 Tissue cultured epidermal autograft, trunk, arms, legs; first 25 sq cm or less

+15151 additional 1 sq cm to 75 sq cm (List separately in addition to code for primary procedure)

(Do not report 15151 more than once per session)
(Use 15151 in conjunction with 15150)

Description of Procedure (15150)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The tissue-cultured epidermal autografts are removed from the transport medium and a total of 25 sq cm is applied to the trunk and secured to the excised wound with interrupted sutures, surgical staples, and/or fibrin sealant. A dressing is applied to the graft site and secured to prevent mechanical shear.

Description of Procedure (15151)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The tissue-cultured epidermal autografts are removed from the transport medium. Additional grafts measuring 100 sq cm (the first 25 sq cm will be coded separately) are applied to the trunk and secured to the excised wound with interrupted sutures, surgical staples, and/or fibrin sealant. A dressing is applied to the graft site and secured to prevent mechanical shear.

Acellular Dermal Replacement Codes 15170-15176

Codes 15170 and 15175 have been added to describe acellular dermal replacement for the first 100 sq cm or less, or 1% of body area of infants and children. Add-on codes 15171 and 15176 have been established to report each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof.

15170 Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children

+15171 each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
(Use 15171 in conjunction with 15170)

Description of Procedure (15170)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The acellular dermal replacement is removed from the rinsing solution and a total of 100 sq cm is applied to the trunk and secured to the excised wound with interrupted sutures or surgical staples. A net dressing is applied and expanded over the graft site and secured with staples to prevent mechanical shear. The wound is covered with gauze dressings and secured with a bulky dressing to further prevent mechanical shear.

Description of Procedure (15171)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. The acellular dermal replacement is removed from the rinsing solution. Two hundred square centimeters (the first 100 sq cm will be coded separately) is applied to the trunk and secured to the excised wound with interrupted sutures or surgical staples. A net dressing is applied and expanded over the graft site and secured with staples to prevent mechanical shear. The wound is covered with gauze dressings and secured with a bulky dressing to further prevent mechanical shear.

Allograft/Tissue-Cultured Allogeneic Skin Substitute Codes 15300-15366

This section is used to report the application of a non-autologous human skin graft (ie, homograft) from a donor to a part of the recipient's body to resurface an area damaged by burns, traumatic injury, soft tissue infection, and/or tissue necrosis or surgery.

Specific guidelines apply to codes 15330-15336 for application of acellular dermal allograft. Acellular dermal allograft is a product that may require immediate, concurrent coverage with autologous tissue such as split-thickness autograft or a tissue flap. Report the appropriate acel-

lular dermal autograft code and the appropriate code for application of the autologous tissue graft from the 15100-15261 code set.

Following the new subheading titled Allograft/ Tissue Cultured and the accompanying introductory language, codes 15300 and 15320 have been added to describe allograft skin for temporary wound closure for the first 100 sq cm or less, or 1% of body area of infants and children. Add-on codes 15301 and 15321 have been established to report each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof.

15300	Allograft skin for temporary wound closure, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children
+15301	each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

(Use 15301 in conjunction with 15300)

Description of Procedure (15300)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. Human allograft skin is obtained from the skin bank. A total of 100 sq cm is applied to the leg and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Description of Procedure (15301)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. Human allograft skin is obtained from the skin bank. An additional 400 sq cm is applied to the legs and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Codes 15330 and 15335 have been added to describe acellular dermal allograft for the first 100 sq cm or less, or 1% of body area of infants and children. Add-on codes 15331 and 15336 have been established to report each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof.

15330	Acellular dermal allograft, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children
+15331	each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

(Use 15331 in conjunction with 15330)

Description of Procedure (15330)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. Acellular dermal allograft is removed from the transport package. A total of 100 sq cm is applied to the trunk and secured to the wound with absorbable sutures. The dermal graft is covered with a local skin flap (separately coded). The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Description of Procedure (15331)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or a topical hemostatic agent. Acellular

dermal allograft is removed from the transport package. Two hundred square centimeters (the first 100 sq cm is coded separately) is applied to the trunk and secured to the wound with absorbable sutures. The dermal graft is covered with a local skin flap (separately coded). The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

15335	Acellular dermal allograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children
15336	each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure) (Use 15336 in conjunction with 15335)

Description of Procedure (15335)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or topical thrombin. Acellular dermal allograft is removed from the transport package. A total of 100 sq cm is applied to the hand and fingers and secured to the wound with absorbable sutures. The dermal graft is covered with a local skin flap (separately coded). The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Description of Procedure (15336)

After the induction of anesthesia, hemostasis of the graft site is obtained with epinephrine-soaked laparotomy pads and/or topical thrombin. Acellular dermal allograft is removed from the transport package. Two hundred square centimeters (the first 100 sq cm is coded separately) is applied to the hand and fingers and secured to the wound with absorbable sutures. The dermal graft is overgrafted with a split-thickness skin graft that is also secured with interrupted sutures or surgical staples (separately coded). The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Code 15340 has been added to describe tissue-cultured allogeneic skin substitute for the first 25 sq cm or less. Add-on code 15341 has been established to report each additional 25 sq cm. As the site preparation for these procedures is typically minimal, an exclusionary parenthetical note has been added to preclude reporting 15340 and 15341 with the site preparation code 15000 and the debridement codes 11040-11042.

15340	Tissue cultured allogeneic skin substitute; first 25 sq cm or less
+15341	each additional 25 sq cm (Use 15341 in conjunction with 15340)

Description of Procedure (15340)

The wound is debrided and, after adequate hemostasis has been achieved and administration of anesthesia has occurred, graft materials were obtained. The wound was measured. Approximately 25 sq cm of tissue-cultured allogeneic skin substitute was fenestrated, grafted to the excised surface, and secured with interrupted sutures.

Description of Procedure (15341)

The wound is debrided and, after adequate hemostasis has been achieved and administration of anesthesia has occurred, graft materials were obtained. The wound was measured. Approximately 50 sq cm of tissue-cultured allogeneic skin substitute was fenestrated, grafted to the excised surface, and secured with interrupted sutures.

Codes 15360 and 15365 have been added to describe tissue-cultured allogeneic dermal substitute for the first 100 sq cm or less, or

1% of body area of infants and children. Add-on codes 15361 and 15366 have been established to report each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof.

15360 Tissue cultured allogeneic dermal substitute, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children

+15361 each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

(Use 15361 in conjunction with 15360)

Description of Procedure (15360)

Hemostasis of the debrided or excised graft site is obtained. The tissue-cultured allogeneic dermal substitute is removed from the transport container and a total of 100 sq cm is applied to the trunk and secured to the excised wound with interrupted sutures, surgical staples, or sterile adhesive strips. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Description of Procedure (15361)

Hemostasis of the debrided or excised graft site is obtained. The tissue-cultured allogeneic dermal substitute is removed from the transport container. Two hundred square centimeters (the first 100 sq cm is coded separately) is applied to the trunk and secured to the excised wound with interrupted sutures, surgical staples, or sterile adhesive strips. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Xenograft

This section reports the application of a non-human skin graft or biologic wound dressing (eg, porcine tissue or pigskin) to a part of the recipient's body following debridement of the burn wound or area of traumatic injury, soft tissue infection and/or tissue necrosis, or surgery.

Following the new subheading titled Xenograft and the accompanying introductory language, 15400 has been revised to include "(dermal)" and "or one percent of body area of infants and children." Additionally, add-on code 15401 has been revised to include "or each additional one percent of body area of infants and children or part thereof."

15400 Xenograft, skin (dermal), for temporary wound closure; trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children

+15401 each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

(Use 15401 in conjunction with 15400)

Description of Procedure (15400)

Hemostasis of the debrided or excised graft site is obtained. Xenograft skin (dermal) is obtained from the tissue bank. A total of 100 sq cm is applied to the left shoulder and arm and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Description of Procedure (15401)

Hemostasis of the debrided or excised graft site is obtained. Xenograft skin (dermal) is obtained from the skin bank and thawed.

Two hundred sq cm (the first 100 sq cm is coded separately) is applied to the left shoulder and arm and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

15420 Xenograft skin (dermal), for temporary wound closure, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or one percent of body area of infants and children

+15421 each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

(Use 15421 in conjunction with 15420)

Description of Procedure (15420)

Hemostasis of the debrided or excised graft site is obtained. Xenograft skin (dermal) is obtained from the tissue bank. A total of 100 sq cm is applied to the face and neck and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Description of Procedure (15421)

Hemostasis of the debrided or excised graft site is obtained. Xenograft skin (dermal) is obtained from the tissue bank. Two hundred square centimeters (the first 100 sq cm is coded separately) is applied to the hand and fingers and secured to the excised wound with interrupted sutures or surgical staples. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

15430 Acellular xenograft implant; first 100 sq cm or less, or one percent of body area of infants and children

15431 each additional 100 sq cm, or each additional one percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

(Use 15431 in conjunction with 15430)

Description of Procedure (15430)

The wound is debrided and after adequate hemostasis has been achieved in the excised surface, the acellular xenograft implant was obtained. The wound was measured and the acellular xenograft implant was cut to shape, grafted to the excised surface, and secured.

In summary, the foregoing changes reflect the ongoing advances in medicine which allow surgical application of skin graft(s) and skin substitutes for the treatment of burns and other cutaneous wounds. The primary stimulus for advances in skin substitutes is to improve the quality of the closed burn wound, control the pain, and avoid poor skin quality. These CPT coding changes reflect these medical advances and will be updated as further innovative materials and techniques become available. ■

Coding Communication: Eyelid Repair: Brow Ptosis, Blepharoptosis, Lid Retraction, Ectropion, Entropion

The series of CPT codes used to report repair of various eyebrow and eyelid defects is 67900-67924. Two codes within that series—67901 and 67902—were revised for 2006 to more usefully distinguish different methods of repair of blepharoptosis by frontalis suspension. The descriptors now distinguish the methods based on whether the surgeon harvests autologous fascia for use as a suspension material vs use of an alternative suspension material (eg, fascia obtained from a tissue bank). In the first method (67901), the physician harvests the fascia with a fascial stripper from the same patient (autologous) who will be receiving this autologous fascia to repair an eyelid defect (eg, brow ptosis, blepharoptosis). In the second method (67902), graft material is obtained from a supplier.

The revised codes are as follows:

67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	frontalis muscle technique with autologous fascial sling (includes obtaining fascia)

Clinical Example: 67901

A 57-year-old female presents with complete upper eyelid ptosis due to damage to the ipsilateral oculomotor nerve and absent levator function. A repair of blepharoptosis is required.

Description of Procedure

The correct surgical site is confirmed. A marking pen is used to delineate the planned six incisions in the eyelid and above the brow. Antibiotic ointment and a protective device (eg, protective shell) are placed on the cornea. Lidocaine with epinephrine is infiltrated for hemostasis and for anesthesia. Five minutes are allowed to pass.

A traction suture is placed through the upper eyelid margin and clamped inferiorly under tension. The eyelid incisions are made just above the lash line through skin and orbicularis oculi muscle. The suprabrow incisions are made to the level of periosteum. A superiorly-directed pocket is created at each suprabrow incision.

A fascia needle is used to thread the banked fascia between the incisions in the eyelids and brow forming two rectangles with two pieces of fascia. The eyelid incisions are closed with absorbable 7-0 suture. The upper eyelid traction suture is removed. The corneal protective device is removed. Tension on the four fascia ends that finally exit the suprabrow incision is adjusted until optimal eyelid height and contour are obtained. Square knots are tied in the fascia, secured with suture, and buried deep in the suprabrow wounds.

The suprabrow incisions are closed in layers with 7-0 absorbable sutures. The eyelid incisions may be closed according to the surgeon's preference. Antibiotic ointment is placed on the wounds and in the conjunctival cul-de-sac. A traction suture is placed in the lower lid margin and taped to the brow with adhesive strips.

The patient is seen in the postoperative area after the operative note is dictated. Postoperative instructions are given and arrangements for next day follow-up are confirmed.

Clinical Example: 67902

An 8-year-old child with a 3-mm left upper lid ptosis with poor levator function experiences visual obstruction due to the drooping

of the lid. The surgical plan is to perform a frontalis suspension of the left upper lid using autologous fascia lata.

Description of Procedure

The correct surgical site and the site for harvesting the fascia autograft are confirmed. The thigh is positioned. An incision is made in the thigh approximately 2.5 inches above the knee joint. The incision is carried through skin and subcutaneous tissue until the fascia lata is identified. Three cuts in the fascia are made to create a U shape. The fascia is separated from the underlying muscle. A ligature is placed on the free end of fascia. The free end of fascia is threaded into the fascia stripper. The stripper is directed superiorly beneath the skin for about 20 cm in a line from the head of the fibula to the iliac crest. The fascia is cut superiorly by activating the cutting mechanism of the stripper. The fascia and stripper are removed. The skin wound is closed in layers and the thigh is dressed with a pressure dressing.

The fascia is cleaned of subcutaneous tissue and fat and trimmed to produce two strips of appropriate length. A marking pen is used to delineate the planned six incisions in the eyelid and above the brow. Antibiotic ointment and a protective device (eg, protective shell) are placed on the cornea. Lidocaine with epinephrine is infiltrated for hemostasis. Five minutes are allowed to pass. A traction suture is placed through the upper eyelid margin and clamped inferiorly. The three eyelid incisions are made just above the lash line through skin and orbicularis oculi muscle. The three suprabrow incisions are made to the level of periosteum. A superiorly-directed pocket is created above each suprabrow incision.

A fascia needle is used to thread the two pieces of fascia between the incisions in the eyelids and brow forming two rectangles. The eyelid incisions are closed with absorbable 7-0 sutures. The upper eyelid traction suture is removed. The protective device is removed. Tension on the four fascial ends that exit two of the suprabrow incisions is adjusted until optimal eyelid height and contour are obtained. Square knots are tied in the fascia, secured with a suture, and buried deep in the suprabrow wounds.

The suprabrow incisions are closed in layers with 7-0 absorbable sutures. Antibiotic ointment is placed on wounds and in the conjunctival cul-de-sac. A traction suture is placed in the lower lid margin and taped to the brow with adhesive strips.

The patient is seen in the postoperative area after the operative note is dictated. The family is counseled and postoperative instructions are given and arrangements for next day follow-up are confirmed. ■

Coding Tip

Codes 67901 and 67902 describe unilateral procedures. If these procedures (ie, 67901 and 67902) are performed bilaterally at the same operative session, append modifier 50, *Bilateral Procedure.*

Coding Communication: Vertebral Body Embolization or Injection

What Is Percutaneous Vertebroplasty?

Percutaneous vertebroplasty describes a procedure in which a sterile biomaterial such as methyl methacrylate is injected from one side or both sides into the damaged vertebral body to act as a bone cement to reinforce the fractured or collapsed vertebra.

What Conditions Are Treated With Percutaneous Vertebroplasty?

Percutaneous vertebroplasty is indicated primarily for relief of pain related to vertebral compression fractures secondary to osteoporosis. However, other conditions, such as aneurysmal bone cysts, hemangioma, giant cell tumor, or metastatic malignancy, may also result in vertebral compression fractures. It is important to note that these conditions are merely provided as examples. They do not reflect a comprehensive listing of acceptable conditions for which percutaneous vertebroplasty may be indicated.

How Is a Vertebral Compression Fracture Diagnosed?

Findings on plain radiographs, computed tomography (CT), and magnetic resonance imaging (demonstration of edema) within a fractured vertebral body may correlate with the level of tenderness upon palpation of the spinous process. A bone scan may show activity in the fracture and confirm either a recent fracture or multiple fractures over an extended period of time.

What Material Is Used in Percutaneous Vertebroplasty?

Various polymethymethacrylate cements are commonly used; however, a cement indicated for craniofacial defect repair mixed with commercially available barium sulfate may be utilized.

How Long Will the Bone Cement Last in the Spine?

Polymethylmethacrylate has been used for more than 40 years as an orthopedic cement. The strength of the bone cement and durability would be expected to outlast the native bone in elderly, osteoporotic patients.

How Is a Percutaneous Vertebroplasty Coded?

The percutaneous vertebroplasty code set—22520-22522—is intended to report a unilateral or bilateral injection and is delineated based upon spinal level, ie, thoracic and lumbar.

22520	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; thoracic
22521	lumbar
+22522	each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

What Is Percutaneous Vertebral Augmentation?

Percutaneous vertebral augmentation (kyphoplasty) is a new minimally invasive surgical technique for treating fractures of the spine that occur due to osteoporosis, usually in postmenopausal women. Generally, osteoporotic fractures of the spine result in a collapsing of the front portion of the vertebrae causing them to compact into a wedge shape, thus causing pain, a loss of height, and a hunched-over appearance (called "dowager's hump" or "widow's hump").

What Conditions Are Treated With the Percutaneous Vertebral Augmentation Procedure?

The percutaneous vertebral augmentation procedure is most commonly used to treat osteoporotic compression fractures.

How Is the Percutaneous Vertebral Augmentation Procedure Coded?

With the advent of new mechanical devices (miniature expandable jacks, curved tamps,

expandable balloon tamps, or otherwise) recently developed to provide physicians with new tools and options to treat vertebral body compression fractures, three new codes were added in 2006 to describe vertebral fracture augmentation and injection of polymethylmethacrylate (bone cement) under imaging guidance.

22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic
22524	lumbar
+22525	each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

It should be noted that cavity creation using a mechanical device at a single thoracic and lumbar vertebral body are included in codes 22523 and 22524. As indicated in the code descriptors, fracture reduction and bone biopsy are incidental to the procedure and not reported separately. An exclusionary parenthetical note was added following code 22525 to preclude the use of the deep bone biopsy code 20225 with the percutaneous vertebral augmentation codes 22523-22525.

Add-on code 22525 was established to describe each additional thoracic or lumbar vertebral body on which percutaneous vertebral augmentation is performed. A parenthetical note was added to delineate the reporting of code 22525 in conjunction with 22523 and 22524, as appropriate.

The procedures described by codes 22523-22525 are performed under either local or general anesthesia and involve percutaneous access into the vertebral body by introduction of a working cannula. This is followed by the insertion of a mechanical device (eg, expandable jack, curved tamp, expandable balloon) containing radiopaque dye to create a cavity or void, reduce the endplate fractures (ie, restore the height, elevate the collapsed endplates), and restore overall spinal alignment from within the vertebral body. The final step involves the vertebral body augmentation and internal stabilization by introducing or filling the resultant cavity with bone graft, enhanced bone graft slurries, allograft bone, polymethylmethacrylate, or bone graft substitute at the physician's discretion.

How Is the Radiological Supervision and Interpretation Portion Reported?

The radiological supervision and interpretation portions of the percutaneous vertebroplasty and percutaneous vertebral augmentation procedures are reported separately based upon the type of guidance used, ie, fluoroscopic guidance (76012) or CT guidance (76013) with the following codes:

76012	Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity creation, per vertebral body; under fluoroscopic guidance
76013	under CT guidance

It should be noted that codes 76012 and 76013 will be deleted for *CPT 2007* and codes 72291 and 72292 should be used to report fluoroscopic or CT guidance.

72291	Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity creation, per vertebral body; under fluoroscopic guidance
72292	under CT guidance

Clinical Example (22523)

A 75-year-old woman presents with severe, persistent back pain and progressive spinal deformity, secondary to osteoporotic vertebral collapse. Radiographic imaging, including magnetic resonance imaging, confirms the recent compression fracture at T10. A bone biopsy is performed as well as a per-

continued on back page

Coding Consultation: Questions and Answers

Coding Clarification: Pathology and Laboratory—Chemistry

The following is provided in response to a previously published article titled *Changes to Pathology and Laboratory-Part I* from the February 2006 *CPT Assistant* (page 7) and *CPT Changes 2006: An Insider's View* (page 188). The following excerpt is followed by a question and answer that clarifies the previously published discussion of code *83037, Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use.*

CPT code *83036, Hemoglobin; glycosylated (A1C)*, was revised to replace the word "glycated" with "glycosylated (A1C)" to better reflect current nomenclature. CPT code *83037, Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use*, was established for reporting a glycosylated hemoglobin (A1C) test that is obtained in the patient's home with a Food and Drug Administration (FDA) cleared device. This testing platform may be used in a clinical setting to provide rapid turnaround Hg A1C levels as a means to enable physicians and other health care providers to manage glycemic control in people with diabetes while the patient is being seen in the clinic. A1C testing is widely accepted as medically necessary for the assessment of glycemic control, an essential aspect of diabetes management. In extensive clinical trials, A1C has been demonstrated to be a significant correlate for evaluating the efficacy of interventions, especially intensive therapies, in reducing microvascular and macrovascular complications. Several professional and governmental organizations have acknowledged the important relationship between A1C and diabetes complications by supporting a common set of A1C testing recommendations, treatment goals, and performance measures. Furthermore, several cost analyses have concluded that glycemic control, as measured by A1C, has economic as well as therapeutic benefits.

Question: Is CPT code 83037 intended to report A1C test results obtained in the patient's home?

AMA Comment: CPT code 83037 is not intended to report a glycosylated hemoglobin (A1C) test that is obtained in the patient's home by the patient or family. Rather, code 83037 is intended to report rapid result testing for Hg A1C levels to assist the physician in management of glycemic control in the patient with diabetes while the physician is present with the patient. Code 83037 is reported for testing and interpretation of results during a patient encounter using a device cleared by the FDA or home use.

Evaluation and Management

Question: If a preventive medicine service (99381-99397) and an office or other outpatient service (99201-99215) are each provided during the same patient encounter to a new patient, is it appropriate to report each evaluation and management (E/M) service as a new patient visit? Or is it appropriate to report the preventive medicine service as a new patient and the acute visit (ie, office or other outpatient service, 99201-99215) as an established patient?

AMA Comment: It is important to first take careful note of the New and Established Patient instructions provided in the E/M services guidelines of *CPT 2006* (page 1). Specifically, the guidelines state:

Solely for the purposes of distinguishing between new and established patients, professional services are those face-to-face services rendered by a physician and reported by a specific CPT code(s). A new patient is one who has not received any professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the past three years.

An established patient is one who has received professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the past three years.

Therefore, if a preventive medicine service and an office or other outpatient service are each provided during the same patient encounter, then it is appropriate to report both E/M services as new patient codes (ie, 99381-99387 and 99201-99205, as appropriate), provided the patient meets the requirements of a new patient based upon the previously noted guidelines.

If, however, the acute visit (ie, office or other outpatient service, 99201-99215) is performed on a date subsequent to the new patient preventive medicine service and within 3 years, then it would be appropriate to report the established office or other outpatient visit code (ie, 99211-99215, as appropriate). ■

Cooding Communication, contined from page 14

cutaneous vertebral augmentation with fracture reduction using a mechanical device to create a cavity.

Description of Procedure (22523)

A small skin incision is made at the appropriate position based on fluoroscopic visualization of the pertinent anatomy. Using anteroposterior and lateral plane fluoroscopy (separately reported), the follow-ing are placed sequentially: a needle, guidewire, 4.2-mm cannula (working channel), and drill. This is in contradistinction to just using a small bone biopsy needle to inject bone cement into a vertebral body. These are followed by a mechanical cavity creation device that is placed via either a transpedicular or extrapedicular approach into the compressed vertebral body. The entire process is repeated on the contralateral side; hence, this is a bilateral procedure. The mechanical cavity creation and fracture reduction device is deployed gradually to create a cavity. The device is removed, leaving behind the formed cavity. Bone cement is mixed and allowed to set for 18 to 25 minutes to achieve a consistency appropriate for injection. The cavities are filled with a mixture of bone substitute and bone cement. Final intraoperative imaging is obtained to confirm alignment and fill. The working cannulae are removed and the incisions are closed with a single stitch. Sterile dressings are applied.

Summary

The two surgical procedures of percutaneous vertebroplasty and percutaneous vertebral augmentation are intended to provide stability to the spine after a fracture. This code set represents the latest medical advances in this area and provides the mechanism to report appropriately these minimally invasive yet effective surgical techniques. ■

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CPT Assistant is designed to provide accurate, up-to-date coding information. We continue to make every reasonable effort to ensure the accuracy of the material presented. However, this newsletter does not replace the CPT codebook; it serves only as a guide.

decision is made to debride the wound and proceed with application of a tissue-cultured allogeneic skin substitute,

Description of Procedure (15341)
The wound is debrided and, after adequate hemostasis has been achieved and administration of anesthesia has occurred, graft materials were obtained. The wound was measured. Approximately 50 sq cm of tissue-cultured allogeneic skin substitute was fenestrated, grafted to the excised surface, and secured with interrupted sutures.

Clinical Example (15360)
A 15-year-old child sustained 20% total body surface area second-degree burns. The wounds are superficial and of intermediate depth. In an effort to promote healing without the use of topical antibiotic dressings, the patient is taken to the operating room for debridement of the burn wounds and simultaneous application of a tissue-cultured allogeneic dermal substitute.

Description of Procedure (15360)
Hemostasis of the debrided or excised graft site is obtained. The tissue-cultured allogeneic dermal substitute is removed from the transport container and a total of 100 sq cm is applied to the trunk and secured to the excised wound with interrupted sutures, surgical staples, or sterile adhesive strips. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Clinical Example (15361)
A 15-year-old child sustained 20% total body surface area second-degree burns. The wounds are superficial and of intermediate depth. In an effort to promote healing without the use of topical antibiotic dressings, the patient is taken to the operating room for debridement of the burn wounds and simultaneous application of a tissue-cultured allogeneic dermal substitute.

Description of Procedure (15361)
Hemostasis of the debrided or excised graft site is obtained. The tissue-cultured allogeneic dermal substitute is removed from the transport container. Two hundred square centimeters (the first 100 sq cm is coded separately) is applied to the trunk and secured to the excised wound with interrupted sutures, surgical staples, or sterile adhesive strips. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Clinical Example (15365)
A 15-year-old child sustained 20% total body surface area second-degree burns. The wounds are superficial and of intermediate depth. In an effort to promote healing without the use of topical antibiotic dressings, the patient is taken to the operating room for debridement of the burn wounds and simultaneous application of a tissue-cultured allogeneic dermal substitute.

Description of Procedure (15365)
Hemostasis of the debrided or excised graft site is obtained. The tissue-cultured allogeneic dermal substitute is removed from the transport container and a total of 100 sq cm is applied to the hands and fingers and secured to the excised wound with interrupted sutures, surgical staples, or sterile adhesive strips. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Clinical Example (15366)
A 15-year-old child sustained 20% total body surface area second-degree burns. The wounds are superficial and of intermediate depth. In an effort to promote healing without the use of topical antibiotic dressings, the patient is taken to the operating room for debridement of the burn wounds and simultaneous application of a tissue-cultured allogeneic dermal substitute.

Description of Procedure (15366)
Hemostasis of the debrided or excised graft site is obtained. The tissue-cultured allogeneic dermal substitute is removed from the transport container. Two hundred square centimeters (the first 100 sq cm is coded separately) is applied to the hands and fingers and secured to the excised wound with interrupted sutures, surgical staples, or sterile adhesive strips. The wound is covered with gauze dressings and secured with a bulky dressing to prevent mechanical shear.

Clinical Example (15400)
A 22-year-old mechanic suffered burns of the left neck, shoulder, and arm from a radiator scald injury. The burns involved 10% body surface and were deep partial thickness. During the first operative session, the patient underwent surgical preparation of the burn on the left shoulder and arm by excision down to viable dermis. After adequate hemostasis had been achieved in the excised surface, the xenograft was grafted to the excised surface and secured with 60 interrupted sutures. The graft was dressed with a low adherent dressing and reinforced with absorbent dressing and secured with net dressing.

Description of Procedure (15400)
After adquate hemostasis had been achieved in the excised surface, xenograft dressings were obtained from the skin bank and thawed. Approximately 500 sq cm of xenograft was grafted to the excised surface and secured with 60 interrupted sutures.

Clinical Example (15401)
A 22-year-old mechanic suffered burns of the left shoulder, arm, and forearm from a radiator scald injury. The burns involved 10% body surface. These burns were deep partial thickness. During the first operative session, the patient underwent surgical preparation of the burn on the left shoulder, arm, and forearm by excision down to viable dermis (reported separately). After adequate hemostasis had been achieved in the excised surface, xenograft skin was grafted to the excised surface and secured with interrupted sutures and surgical staples. The graft was dressed

smith&nephew

26 October, 2005 | Corporate

Positive Outlook After Slower Quarter

Smith & Nephew plc (LSE: SN, NYSE: SNN), the global medical technology business, announced today its results for the third quarter ended 1 October 2005.

View Smith & Nephew Q3 Results Including Accounts and Notes
[PDF 126 KB]

Visit Our Q3 Day Centre

Q3 Highlights

- Group revenue up 10%[1] to £341m
- Orthopaedics revenue up 15%*, US up 16%[1]
- Endoscopy revenue up 8%[1]
- Wound Management revenue up 3%[1]
- Trading profit up 11%, margin achieved of 19%
- EPSA up 10%[2] to 5.41p
- BSN Medical realisation underway
- Decision to exit DERMAGRAFT*
- Dollar reporting in 2006

Commenting on the third quarter and the outlook for the year, Sir Christopher O'Donnell, Chief Executive of Smith & Nephew, said:

"Although our growth in revenue and profits slowed slightly in the third quarter, Orthopaedics continued to grow at a market leading rate. We are confirming our guidance of EPSA growth for the year of 12% - 13% as our businesses continue to introduce outstanding new products and to invest in their sales channels.

We have decided to exit DERMAGRAFT* and related products and are announcing this to affected employees today, and have therefore brought the timing of this announcement forward. The decision to exit DERMAGRAFT*, along with that to realise our investment in BSN Medical, will improve the growth profile of the Group. Additionally we are looking to align our reporting currency with the main trading currency of our business and accordingly are moving to US dollar reporting in 2006."

A presentation and conference call for analysts to discuss the company's third quarter results will be held at 12.00 noon BST / 7.00am EST tomorrow, Thursday 27 October. The conference call will be broadcast live on the web and will be available on demand shortly following the close of the meeting at http://www.smith-nephew.com/Q305. If interested parties are unable to connect to the web, a listen-only service is available by calling 020 7365 1834 in the UK or 718 354 1158 in the US. Analysts should contact Julie Allen on +44 (0) 20 7960 2254 or by email at julie.allen@smith-nephew.com for conference call details.

[1] Unless otherwise specified as 'reported', all revenue increases throughout this

document are underlying increases after adjusting for the effects of currency translation, the acquisition of MMT in Q1 last year and the effect of one less sales day in the first half of the year. See note 3.

[2] EPSA is stated before restructuring and rationalisation costs, taxation thereon and amortisation of acquisition intangibles. See note 2.

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Introduction

As announced in our trading update on 13 September, trading conditions this quarter have been tighter. Orthopaedics achieved 15% sales growth in the quarter, ahead of the market in all areas except knees in the US, despite tighter market conditions and the impact of Hurricane Katrina. Endoscopy has continued its momentum and generated 8% sales growth in the quarter, driven by shoulder and knee repair revenues. Advanced Wound Management revenues grew 3% as it continued to experience distributor de-stocking in the US. Encouragingly we have seen no change in the overall pricing trends of our products and the fundamental drivers of our markets remain strong.

During the quarter we announced our intention to divest BSN Medical, our joint venture with Beiersdorf AG. This is progressing well, with strong interest expressed by a large number of potential buyers, and we anticipate completing the sale in the early part of 2006.

We are also announcing today that we have received a "non-approvable" letter from the FDA in relation to the marketing of DERMAGRAFT* in the US for the treatment of venous leg ulcers, as a result of which we have taken the decision to exit from DERMAGRAFT* and related products. This is expected to benefit trading profits in 2006 by approximately £7m.

Third Quarter Results

Underlying revenue growth in the quarter was 10% relative to the third quarter last year. Translational currency added 1% to revenue growth, resulting in reported third quarter revenue increasing by 11% to £341m.

Trading profit in the quarter was £65½m, a trading margin of 19%. Tax thereon amounted to £19½m, an effective tax rate of 30%, and the share of after tax results of the BSN joint venture was £5m; resulting in attributable profit before restructuring and rationalisation costs, taxation thereon and amortisation of

acquisition intangibles of £51m. Attributable profit after restructuring and rationalisation costs and related tax relief, and the amortisation of acquisition intangibles was £35m.

Earnings per share, before restructuring and rationalisation costs, taxation thereon and amortisation of acquisition intangibles ("EPSA"), was 5.41p (27.05p per American Depositary Share, "ADS"), a 10% increase on the third quarter last year. A reconciliation of EPSA to reported earnings per share is given in note 2 to the accounts.

Restructuring and rationalisation costs in the quarter comprise £8½m for the rationalisation of manufacturing facilities at Endoscopy announced with the results for the second quarter, and £15½m of asset impairment following the decision to exit from DERMAGRAFT* and related products.

Orthopaedics

Orthopaedics revenues grew by 15% relative to the third quarter last year to £168m. Revenue growth in the US was 16% and outside the US 13%.

In the US our knee products experienced competition ahead of the launch of two new OXINIUM* products; a revision knee (LEGION*) in the fourth quarter and an anatomic knee (JOURNEY*) in 2006. Knee revenues grew 13%, 10% in the US and 18% outside the US.

Hip revenues grew by 10% both in and outside the US, ahead of the market, with the BHR* product continuing to provide momentum to revenues outside the US. The FDA Advisory Panel review during the quarter of our BHR* product recommended conditional approval to the FDA for use in the US.

Trauma revenue growth was 15%. Within the US, trauma revenues increased by 19%, ahead of the market, and continued to benefit from the establishment of a dedicated sales force and the launch of the PERI-LOC* locking compression plate system earlier this year. Outside the US, trauma growth improved to 10%.

Clinical Therapy revenues, comprising the EXOGEN* ultrasound bone healing and SUPARTZ* joint fluid therapy products, continued to benefit from previous sales force investment and grew 35% compared with the same quarter last year.

Endoscopy

Endoscopy revenue growth was 8% to £79m; with US growth of 5% and growth outside the US of 12%.

Knee and shoulder repair revenues continued strongly with growth of 23%, benefiting from new product introductions. Blade revenues grew 6% and visualisation and digital operating room revenues grew 2%, as did radio frequency, including spine.

Our patent dispute with ArthroCare was settled during the quarter enabling us to market again a full range of arthroscopic radiofrequency products. These, together with our new camera, pump and hip arthroscopy products, provide added momentum for growth next year.

In order to improve our competitive position and lower the overall costs of production we announced with our second quarter results the closure of one of Endoscopy's US manufacturing facilities. A rationalisation charge of £8½m has been

taken in this quarter and the project is progressing on schedule.

Advanced Wound Management

Advanced Wound Management revenues grew 3%, compared to the third quarter last year, to £94m. Our leading products ALLEVYN* and ACTICOAT* revenues grew by 12% and 25% respectively in the quarter. Revenues in the US declined by 6%, reflecting lower intermediate products sales and a continued contraction of distributors' inventories. Clearer supply chain visibility leads us to believe that this inventory contraction is nearing completion but not sufficiently to completely reverse the decline in the fourth quarter. Encouragingly end user traced sales improved to 8% in the quarter. Outside the US revenue growth was 6% reflecting healthcare spending pressures holding back market growth in parts of Europe.

We recently received a 'non-approvable' letter from the FDA relating to our Pre Marketing Approval supplement for the use of DERMAGRAFT* for venous leg ulcers which would require further clinical work for re-submission. This work would delay approval for 18-24 months, with a consequent delay in achieving economic viability. On a global basis the lack of clear regulatory frameworks for tissue engineered products has resulted in delays that have become commercially unacceptable. After careful consideration we have now decided to exit the manufacture and sale of DERMAGRAFT* and related products. We have therefore taken a £15½m asset impairment charge this quarter and will take a £25m charge in the fourth quarter to cover the cash cost of exit; both charges to be taken as restructuring costs. Revenues and trading profit of Advanced Wound Management will be largely unaffected in 2005. In 2006 we expect revenues will be adversely affected by around £14m, whereas we expect trading profits will benefit by approximately £7m from cost elimination.

Year to Date Results

Underlying revenue growth for the year to date was 11%. Reported revenue growth was 12%, after adjusting for the benefit of the acquisition of MMT in the first quarter last year offset by one less sales day in the first half of the year, and the benefit of 1% positive translational currency in the year to date.

Trading profit for the year to date was £201m, with margins 0.7% ahead of a year ago at 19.7% and interest income and finance costs net to £3m positive. Taxation thereon amounted to £60½m and the share of the after tax results of the BSN joint venture was £12½m, resulting in attributable profit before restructuring and rationalisation costs, taxation thereon and amortisation of acquisition intangibles of £156m. Attributable profit after restructuring and rationalisation costs, and related tax relief thereon, and the amortisation of acquisition intangibles was £137m.

EPSA was 16.63p (83.15p per ADS) for the year to date, an increase of 14% compared to the same period last year. Reported earnings per share, including discontinued operations, was 14.56p (72.80p per ADS). A reconciliation of reported earnings per share to EPSA is provided in note 2 to the accounts.

Restructuring and rationalisation costs comprise £8½m for the rationalisation of manufacturing facilities at Endoscopy and £15½m of asset impairment following the decision to exit from DERMAGRAFT* and related products.

Operating cash flow, defined as cash generated from operations less capital expenditure, was £74m. This is a trading profit to cash conversion ratio of 47%, before rationalisation and integration expenditure of £2m and £19m of funding of settlement payments to patients in respect of macrotextured revisions which are

not being reimbursed by insurers, and compares with 47% a year ago.

Had our results been reported in US dollars translated at average rates of exchange, reported revenues and adjusted earnings per ADS would have been as follows:

	Third Quarter		Year to Date	
Reported revenues	$612m	+10%	$1882m	+13%
Adjusted earnings per ADS	$0.48	+9%	$1.53	+15%

Dollar reporting

The international spread of the Group's businesses, with approximately 50% of revenues, trading profits and operating assets in US dollars, substantially exposes the Group to currency movements relative to its sterling capital base. We have decided therefore to redenominate the functional currency of the parent company into US dollars and produce group accounts in US dollars from the beginning of 2006.

Appendix C contains a restatement of this year's and last year's quarterly results as if they had been consolidated in US dollars at the average exchange rates then prevailing. An extraordinary general meeting will be convened in December to redenominate the share capital of the parent company into US dollars. Future dividends will be declared in US dollars, but paid to UK residents in sterling. The Group's shares will continue to be listed on the London Stock Exchange, priced in sterling, and on the NYSE, priced in dollars.

Outlook

For the full year we expect Orthopaedics to achieve revenue growth of around 17%, driven by sales force investment and our new product pipeline. We expect Endoscopy to achieve full year revenue growth of around 8% as new products continue to drive revenues. We expect revenue growth of around 5% for Advanced Wound Management as some of the adverse factors that have affected revenues in the US abate. Translational currency should add 1½% to revenue and we expect a trading margin of 20½% for the full year. As previously indicated EPSA growth for the year before restructuring and rationalisation costs is expected to be in the range of 12% - 13%.

The fundamentals for each of our businesses remain strong and we anticipate continuing growth in the orthopaedic market, particularly in the US. We view 2006 positively with continued strong revenue growth in Orthopaedics and improved revenue growth in Endoscopy. In Advanced Wound Management the exit from DERMAGRAFT* will reduce the revenue growth rate, but will contribute to an expected Group margin enhancement of around 1½% for 2006. Underlying EPSA growth for 2006 is expected to be around mid-teens, before any dilution arising from the realisation of our investment in BSN Medical and the change to dollar reporting.

About us

Smith & Nephew is a global medical technology business, specialising in Orthopaedics, Endoscopy and Advanced Wound Management products. Smith & Nephew is a global leader in arthroscopy and advanced wound management and is one of the fastest growing global orthopaedics companies.

Smith & Nephew is dedicated to helping improve people's lives. The company prides itself on the strength of its relationships with its surgeons and professional healthcare customers, with whom its name is synonymous with high standards of performance, innovation and trust. The company has over 8,500 employees and operates in 33 countries around the world generating annual sales of £1.25 billion.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the US Private Securities Litigation Reform Act of 1995. In particular, statements regarding expected revenue growth and operating margins discussed under "Outlook" are forward-looking statements as are discussions of our product pipeline. These statements, as well as the phrases "aim", "plan", "intend", "anticipate", "well-placed", "believe", "estimate", "expect", "target", "consider" and similar expressions, are generally intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors (including, but not limited to, the outcome of litigation, claims and regulatory approvals) that could cause the actual results, performance or achievements of Smith & Nephew, or industry results, to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Please refer to the documents that Smith & Nephew has filed with the U.S. Securities and Exchange Commission under the U.S. Securities Exchange Act of 1934, as amended, including Smith & Nephew's most recent annual report on Form 20F, for a discussion of certain of these factors.

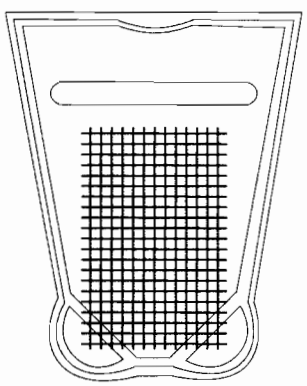
All forward-looking statements in this press release are based on information available to Smith & Nephew as of the date hereof. All written or oral forward-looking statements attributable to Smith & Nephew or any person acting on behalf of Smith & Nephew are expressly qualified in their entirety by the foregoing. Smith & Nephew does not undertake any obligation to update or revise any forward-looking statement contained herein to reflect any change in Smith & Nephew's expectation with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Directions for Use

ADVANCED BIOHEALING

Dermagraft®

Human Fibroblast-Derived
Dermal Substitute



Caution: *Federal (U.S.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).*

1. Device Description

Dermagraft® is a cryopreserved human fibroblast-derived dermal substitute; it is composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold.

Dermagraft is manufactured from human fibroblast cells derived from newborn foreskin tissue. During the manufacturing process, the human fibroblasts are seeded onto a bioabsorbable polyglactin mesh scaffold. The fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors and cytokines, to create a three-dimensional human dermal substitute containing metabolically active, living cells. Dermagraft does not contain macrophages, lymphocytes, blood vessels, or hair follicles.

The human fibroblast cells are from a qualified cell bank, which has been extensively tested for animal viruses, retroviruses, cell morphology, karyology, isoenzymes, and tumorigenicity. Reagents used in the manufacture of Dermagraft are tested and found free from viruses, retroviruses, endotoxins, and mycoplasma before use. Dermagraft is manufactured with sterile components under aseptic conditions within the final package.

Prior to release for use, each lot of Dermagraft must pass USP Sterility (14-day), endotoxin, and mycoplasma tests. In addition, each lot meets release specifications for collagen content, DNA, and cell viability. Maternal blood sera were tested for evidence of infection with human immunodeficiency virus type 1 (HIV-1), human immunodeficiency virus type 2 (HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, human T-lymphotropic virus type 1 (HTLV-1), and found negative

for the purposes of donor selection. During subsequent screening of the fibroblast cell strain at various stages in the manufacturing process, testing for these same viruses, as well as Epstein-Barr virus (EBV) and human T-lymphotropic virus type 2 (HTLV-2), is carried out and found to be negative.

Dermagraft® is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single-use application.

2. Intended Use/Indications

Dermagraft is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. Dermagraft should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot.

3. Contraindications

Dermagraft® is contraindicated for use in ulcers that have signs of clinical infection or in ulcers with sinus tracts.

Dermagraft is contraindicated in patients with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution.

4. Warnings

None

5. Precautions

Caution: Do not use any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with Dermagraft as such preparations may cause reduced viability of Dermagraft.

Caution: To ensure the delivery of metabolically active, living cells to the patient's wound, do not hold Dermagraft at room temperature for more than 30 minutes. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation for Use instructions.

Caution: The persistence of Dermagraft in the wound and the safety of this device in diabetic foot ulcer patients beyond six months has not been evaluated. Testing has not revealed a tumorigenic potential for cells contained in the device. However, the long-term response to these cells is unknown.

Caution: Do not use the product if there is evidence of container damage or if the date and time stamped on the shipping box has expired.

Caution: Do not reuse, refreeze, or sterilize the product or its container.

Caution: Always thaw and rinse product according to the Preparation for Use instructions to ensure the delivery of metabolically active, living cells to the patient's wound.

Caution: Dermagraft® is packaged with a saline-based cryoprotectant that contains 10% DMSO (Dimethylsulfoxide) and bovine serum. Skin and eye contact with this packaging solution should be avoided.

Caution: Do not use Dermagraft after the expiration date indicated on the labeled unit carton.

Caution: The product must remain frozen at -75°C ± 10°C continuously until ready for use.

Caution: Dermagraft has not been studied in patients receiving greater than 8 device applications.

Caution: Dermagraft has not been studied in patients with wounds that extend into the tendon, muscle, joint capsule, or bone. Dermagraft has not been studied in children under the age of 18 years, in pregnant women, in patients with ulcers over a Charcot deformity of the mid-foot, or in patients receiving corticosteroids or immunosuppressive or cytotoxic agents.

6. Adverse Events

A total of 695 patients were evaluated in four clinical trials, 389 treated with Dermagraft, and 306 treated with Control. Adverse events that were reported in the pivotal 314-patient clinical trial at a frequency of greater than 1% for patients treated with Dermagraft are presented in Table 1. Adverse Event data are also presented combined, from three previous studies.

Table 1 - Adverse Events Reported in Greater than 1% of Patients Treated with Dermagraft®

Infection (study wound)[1]	17 (10.4)	27 (17.9)	63 (27.9)	43 (27.7)
Infection (non-study wound)	17 (10.4)	14 (9.3)	33 (14.6)	22 (14.2)
Accidental injury[2]	17 (10.4)	18 (11.9)	17 (7.5)	11 (7.1)
Skin dysfunction/Blister	16 (9.8)	20 (13.2)	38 (16.8)	31 (20.0)
Flu syndrome	15 (9.2)	9 (6.0)	7 (3.1)	8 (5.2)
Osteomyelitis (study wound)	14 (8.6)	13 (8.6)	17 (7.5)	8 (5.2)
Surgeries involving study ulcer[3]	13 (8.0)	21 (13.9)	35 (15.5)	13 (8.4)
Wound enlargement/Skin ulcer (non-study wound)	12 (7.4)	17 (11.3)	30 (13.3)	16 (10.3)
Cellulitis (study wound)	12 (7.4)	14 (9.3)	25 (11.1)	10 (6.5)
Cellulitis (non-study wound)	10 (6.1)	7 (4.6)	15 (6.6)	13 (8.4)
Peripheral edema/ Localized swelling	9 (5.5)	7 (4.6)	20 (8.8)	6 (3.9)
Pharyngitis/URI	7 (4.3)	5 (3.3)	13 (5.8)	11 (7.1)
Pain	6 (3.7)	5 (3.3)	24 (10.6)	12 (7.7)
Lab test abnormal – chemistry[4]	6 (3.7)	5 (3.3)	37 (16.4)	31 (20.0)
Skin disorder[5]	5 (3.1)	4 (2.6)	0 (0.0)	0 (0.0)
Osteomyelitis (non-study wound)	5 (3.1)	2 (1.3)	10 (4.4)	6 (3.9)
Wound enlargement/ Skin ulcer (study wound)	4 (2.5)	8 (5.3)	12 (5.3)	15 (19.7)
Urinary tract infection	4 (2.5)	1 (0.7)	7 (3.1)	6 (3.9)
Diarrhea	4 (2.5)	5 (3.3)	4 (1.8)	3 (1.9)
Rash	3 (1.8)	2 (1.3)	4 (1.8)	4 (2.6)
Myocardial infarct	3 (1.8)	0 (0.0)	0 (0.0)	4 (2.6)
Fever	3 (1.8)	0 (0.0)	8 (3.5)	3 (1.9)
Allergic reaction	3 (1.8)	1 (0.7)	1 (0.4)	1 (0.6)
Rhinitis	2 (1.2)	1 (0.7)	2 (0.9)	2 (1.3)
Nail disorder	2 (1.2)	3 (2.0)	1 (0.4)	3 (1.9)
Myalgia	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Joint disorder	2 (1.2)	1 (0.7)	1 (0.4)	0 (0.0)
Headache	2 (1.2)	1 (0.7)	3 (1.3)	3 (1.9)
Gastrointestinal disorder	2 (1.2)	3 (2.0)	0 (0.0)	1 (0.6)

Table 1 (cont.) - Adverse Events Reported in Greater than 1% of Patients Treated with Dermagraft®

Chest pain	2 (1.2)	1 (0.7)	4 (1.8)	5 (3.2)
Anemia	2 (1.2)	0 (0.0)	4 (1.8)	0 (0.0)
Bronchitis	1 (0.6)	1 (0.7)	7 (3.1)	1 (0.6)
Eccymosis	1 (0.6)	0 (0.0)	5 (2.2)	0 (0.0)
Sinusitis	1 (0.6)	0 (0.0)	4 (1.8)	3 (1.9)
Neuropathy	1 (0.6)	0 (0.0)	4 (1.8)	0 (0.0)
Nausea	1 (0.6)	2 (1.3)	4 (1.8)	1 (0.6)
Dyspnea	1 (0.6)	1 (0.7)	4 (1.8)	0 (0.0)
Vomiting	1 (0.6)	1 (0.7)	3 (1.3)	2 (1.3)
Sepsis/Septicemia	1 (0.6)	1 (0.7)	3 (1.3)	0 (0.0)
Gastroenteritis	1 (0.6)	0 (0.0)	3 (1.3)	1 (0.6)
Chills	1 (0.6)	0 (0.0)	3 (1.3)	3 (1.9)
Cataract	1 (0.6)	0 (0.0)	3 (1.3)	1 (0.6)
Angina pectoris	1 (0.6)	0 (0.0)	3 (1.3)	3 (1.9)
Wound drainage	0 (0.0)	0 (0.0)	11 (4.9)	5 (3.2)
Cerebrovascular accident	0 (0.0)	0 (0.0)	7 (3.1)	1 (0.6)
Congestive heart failure	0 (0.0)	3 (2.0)	6 (2.7)	1 (0.6)
Cough increased	0 (0.0)	2 (1.3)	5 (2.2)	2 (1.3)
Back pain	0 (0.0)	1 (0.7)	5 (2.2)	4 (2.6)
Peripheral vascular disorder	0 (0.0)	0 (0.0)	4 (1.8)	0 (0.0)
Retinal disorder/Retinopathy	0 (0.0)	0 (0.0)	3 (1.3)	1 (0.6)
Neoplasm[5]	0 (0.0)	0 (0.0)	3 (1.3)	1 (0.6)
Lab test abnormal – urinalysis	0 (0.0)	0 (0.0)	3 (1.3)	2 (1.3)
Cyst	0 (0.0)	0 (0.0)	3 (1.3)	1 (0.6)
Asthenia	0 (0.0)	0 (0.0)	3 (1.3)	0 (0.0)

1 Infections include all local wound infections, regardless of etiology (e.g., bacterial, fungal), not including osteomyelitis and cellulitis.

2 Examples of verbatim codes included in this category are: laceration, foreign body in eye, head injury, dislocation of hip, coccyx fracture post fall, skin tear, and burn right index finger.

3 Surgical procedures to the study ulcer are defined as any procedure (i.e., surgical debridement more extensive than required by protocol, incision and drainage, revision, excision, or amputation) that occurred during the course of the study.

4 Pilot study codes to "Lab Tests Abnormal" and does not distinguish between Chemistry, Hematology, and Urinalysis.

5 None of the events reported under "Skin disorder" involved the study ulcer. Under "Neoplasm", none of the events reported involved the study leg for the Dermagraft-treated patients.

7. Clinical Study

The pivotal study was a multi-center, controlled randomized clinical trial in which 314 patients were treated with either Dermagraft® plus conventional therapy or conventional therapy alone (sharp debridement, saline-moistened gauze, and pressure-reducing footwear). Patients were eligible to be screened if they had a plantar diabetic foot ulcer on the heel or forefoot (including toes) that was ≥ 1cm^2 and ≤ 20cm^2. At the screening visit, the patients began treatment with sharp debridement and saline-moistened gauze. If the study ulcer had not decreased in size by more than 50% during the next 2 weeks and the patient met all other inclusion and exclusion criteria, the patient was randomized into the study. Key study exclusion criteria included the following: a) the Ankle-Arm Index on the study foot was <0.7; b) the study ulcer was over a Charcot deformity of the mid-foot; c) the study ulcer had sinus tracts or tunnels that could not be completely debrided; d) the study ulcer had increased or decreased in size by >50% during the two week screening period; e) the patient had a serum albumin <2.0g/dl; f) the patient was receiving corticosteroids or immunosuppressive or cytotoxic agents; and g) the study ulcer showed clinical signs of infection.

Except for the application of Dermagraft, treatment of study ulcers was identical for patients in both the Dermagraft and Control groups. Patients in the Dermagraft group received up to 8 applications of Dermagraft over the course of the 12-week study. All patients received pressure-reducing footwear and were encouraged to stay off their study foot as much as possible. Total off-weighting (e.g., use of crutches and wheelchairs) was not required by the study protocol.

Patients were followed weekly until their study wounds were confirmed healed or they completed the week 12 study visit. At the weekly study visits, ulcer tracings were obtained for computer planimetry and photographs of the wounds were taken as a pictorial record of the study ulcer.

The primary endpoint for the pivotal study was complete wound closure by week 12. Wound closure was defined as full epithelialization without drainage. Furthermore, a determination of wound closure was only made if the wound remained closed at a second, confirmatory visit occurring within 4 weeks of the first assessment of closure. If the wound was not healed at the confirmatory visit, the wound was not deemed closed.

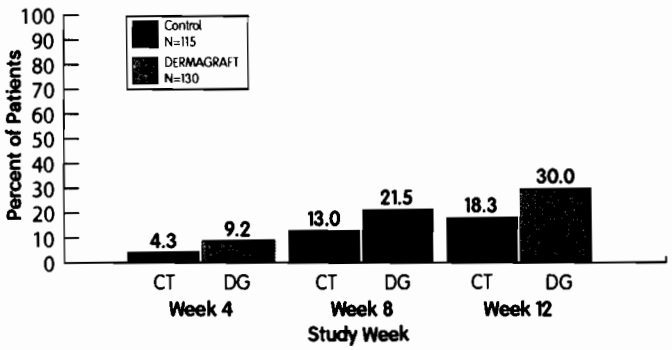
A planned interim analysis was performed during the study that showed a relationship between ulcer duration at the time of screening and incidence of ulcer healing with Dermagraft®. Consequently, a modified (after the interim analysis) statistical plan specified that (1) the effectiveness analyses would be based only on the patients with ulcers greater than 6 weeks duration at the time of the screening visit and (2) the primary endpoint would be analyzed using Bayesian statistical methods. Bayesian methods provide for information obtained during the initial part of a trial to be utilized prospectively in the latter part of the trial to enable overall estimation of measures of effectiveness. The effectiveness data are therefore based on the 245 patients with ulcers of greater than 6 weeks duration. The safety analyses were performed on all 314 patients who were randomized into the study.

The Bayesian analysis concluded that the probability that Dermagraft plus conventional therapy increased the chance of achieving wound closure in patients with ulcers greater than 6 weeks duration over and above that of conventional therapy alone was 98.4%. Furthermore, there is a 95%

probability that the chance of achieving closure in patients with ulcers greater than 6 weeks duration ranges from 22% to 38% in the Dermagraft® group and 12% to 26% in the Control group.

Figure 1 – presents the proportion of patients who achieved complete wound closure during the course of the study.

Figure 1 - Complete Wound Closure
Ulcers >6 Weeks Duration
N=245



Patients reported being ambulatory an average of 8 hours per day.

Patient characteristics, demographics, and healing results by patient category are provided in Table 2.

Table 2 - Summary of Complete Wound Closure Results by Patient Category for Patients with Wounds of Greater than 6 Weeks Duration[1]

Age (years)[3]				
≤55	17/65	(26.2)	14/63	(22.2)
>55	22/65	(33.8)	7/52	(13.5)
Albumin (g/dL)[3]				
≤4.0	24/70	(34.3)	12/67	(17.9)
>4.0	14/59	(23.7)	9/48	(18.8)
Alcohol Use				
Yes	6/37	(16.2)	5/28	(17.9)
No	33/93	(35.5)	16/87	(18.4)
Ankle-Arm Index[3]				
≤1.1	20/70	(28.6)	12/54	(22.2)
>1.1	18/58	(31.0)	9/60	(15.0)
Body Mass Index (kg/m²)[3]				
≤31.1	21/68	(30.9)	14/55	(25.4)
>31.1	18/62	(29.0)	7/60	(11.7)
Diabetes Type				
Type I	8/32	(25.0)	5/27	(18.5)
Type II	31/98	(31.6)	16/88	(18.2)
Gender				
Male	22/90	(24.4)	15/91	(16.5)
Female	17/40	(42.5)	6/24	(25.0)
Hemoglobin A1c (%)[3]				
≤8.5	19/65	(29.2)	13/58	(22.4)
>8.5	20/64	(31.2)	8/56	(14.3)
Mean Hours Non-Weight Bearing[3]				
≤15.7	15/54	(27.8)	13/58	(22.4)
>15.7	21/65	(32.3)	7/47	(14.9)
Number of Ulcers on Study Foot				
1	37/126	(29.4)	20/108	(18.5)
>1	2/4	(50.0)	1/7	(14.3)
Race				
Caucasian	27/90	(30.0)	16/87	(18.4)
Non-Caucasian	12/40	(30.0)	5/28	(17.9)
Smoker				
Yes	8/27	(29.6)	4/17	(23.5)
No	31/103	(30.1)	17/98	(17.3)
Ulcer Area (cm²)[3]				
≤1.5	24/60	(40.0)	15/63	(23.8)
>1.5	15/70	(21.4)	6/52	(11.5)
Ulcer Location				
Forefoot or Toe	33/112	(29.5)	20/102	(19.6)
Heel	6/18	(33.3)	1/13	(7.7)

1 Data observed at Screening except for Ulcer Area (obtained at the day 0 randomization visit) and Mean Hours Non-Weight Bearing (compiled from patient diary information received from Study Weeks 1 through Termination; patients were included if they turned in at least one diary from any post randomization visit).

2 Note: For individual categories the N will vary based on available patient information.

3 Cut-off values for each category are based on the overall median value.

The healing results presented in Table 2 are presented for general information purposes only. Outcome data based on an analysis of one demographic parameter in isolation may not be predictive of wound closure, as multiple factors influence ulcer healing.

Table 3 - Summary of Complete Wound Closure Results by Ulcer Duration

<6 weeks[1]	13/33 (39.0)	15/36 (42.0)
6-26 weeks	19/68 (27.9)	11/55 (20.0)
>26 weeks	20/62 (32.3)	10/60 (16.7)

[1]These 69 patients with ulcers less than 6 weeks duration were not included in the primary effectiveness analysis.

Recurrence

In the previous multi-center controlled trial 139 patients were treated with Dermagraft and 142 patients were treated with control. All patients were followed to week 32. Ulcer recurrence (defined as ulcers that healed by week 12 and reopened on or before week 32) was 26% (11/42) for patients in the Dermagraft group and 22% (9/41) for patients in the Control group. Among this group of patients that experienced recurrence, the median time from healing to recurrence was 10 weeks for the Dermagraft group, and 7 weeks for the Control group. These results are reflective of the entire study population, regardless of ulcer duration, and include patients who received Dermagraft that did not meet the final metabolic release criterion.

After this study was completed, the metabolic release criterion for Dermagraft and the intended patient population were modified. Therefore, a retrospective analysis was also performed on a subset of patients with ulcer duration of greater than 6 weeks who received

Dermagraft® that met the final metabolic release criterion versus Control patients with ulcer duration of greater than 6 weeks. Ulcer recurrence was 18.8% (3/16) for patients in the Dermagraft group and 20.7% (6/29) for patients in the Control group.

Immunology and Persistence Studies

The potential for Dermagraft to elicit an immune response was evaluated by examining the baseline and terminal sera of patients enrolled in a clinical trial for Dermagraft using Western Blot technique. A comparison of pre- and post-immune sera did not indicate an immunologic response to Dermagraft in patients treated with up to 8 pieces of Dermagraft. In investigating the persistence of the product in the wound bed, testing using Y-chromosome (male donor) marker SRY, amplified by a nested PCR technique revealed the presence of cells from Dermagraft in biopsies of treated venous ulcers up to 6 months after treatment from a single piece of Dermagraft. Six of 10 patients evaluated at 2 months demonstrated DNA from cells from Dermagraft. Three of 10 patients evaluated at 6 months demonstrated DNA from cells from Dermagraft. In addition, biopsies of these wounds were evaluated for histologic evidence of an immunologic response to the product. This assessment found no histologic changes suggestive of an immune response to Dermagraft.

8. Patient Counseling Information

After implantation of Dermagraft®, patients should be instructed not to disturb the ulcer site for approximately 72 hours (three days). After this time period, the patient, or caregiver, should perform the first dressing change. The frequency of additional dressing changes should be determined by the treating physician. Patients should be given detailed instructions on proper wound care so they can manage dressing changes between visits. Compliance with off weight-bearing instructions should be emphasized.

Patients should be advised that they are expected to return for follow-up treatments on a routine basis, until the ulcer heals or until they are discharged from treatment. Patients should be instructed to contact their physician, if at any time they experience pain or discomfort at the ulcer site or if they notice redness, swelling, or discharge around/from the ulcer.

9. How Supplied

Dermagraft is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single-use application. The clear bag is enclosed in a foil pouch and labeled unit carton.

Caution: Dermagraft is limited to single-use application. Do not reuse, refreeze, or sterilize the product or its container.

Dermagraft is manufactured using sterile components and is grown under aseptic conditions. Prior to release for use, each lot of Dermagraft must pass USP Sterility (14-day), endotoxin, and mycoplasma tests. In addition, each lot meets release specifications for collagen content, DNA, and cell viability.

Dermagraft® is packaged with a saline-based cryoprotectant. This solution is supplemented with 10% DMSO (Dimethylsulfoxide) and bovine serum to facilitate long-term frozen storage of the product. Refer to the step-wise thawing and rinsing procedures to ensure delivery of a metabolically active product to the wound bed.

10. Storage

Dermagraft must be stored continuously at -75°C ± 10°C.

11. Shelf Life

The unit carton containing Dermagraft is marked with the expiration date of the product. Do not use the product after this date.

12. Peel-Off Label

Two peel-off labels are provided on the box containing Dermagraft. One of the peel-off labels should be removed and placed on the patient's chart. This label bears a unique lot number and expiration date that facilitates the collection of product monitoring information.

13. Directions for Use

In clinical studies evaluating Dermagraft for the treatment of ulcers in diabetic patients, Dermagraft was applied weekly for up to a total of 8 applications over a 12-week period.

Application Notes

- Diabetic foot ulcers must receive adequate sharp debridement, removing any necrotic or hyperkeratinized tissue, leaving a wound bed that meets the clinical criteria for skin grafting prior to application of Dermagraft® (i.e., clean, granulating wound bed).
- If extensive bleeding is observed after sharp debridement, the bleeding must be controlled before applying Dermagraft; no topical agents may be used to stop the bleeding.

Materials Required for Preparation and Application of Dermagraft®

- Water bath/thawing tub (containing 37°C water) with lid
- Thermometer
- Sterilized scissors
- Surgical gloves
- Clock or timer
- Sterile normal saline (0.9% sodium chloride) at room temperature
- Permanent ink marker
- Sterilized blunt-end forceps
- Rinsing stand for Dermagraft
- Dressing supplies

Preparation for Use

Caution: Do not use Dermagraft after the expiration date indicated on the labeled unit carton.

Caution: Follow all instructions to ensure delivery of metabolically active, living cells to the patient's wound.

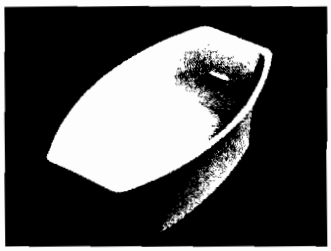
Caution: Do not use the product if there is evidence of container damage or if the time on the shipping box has expired.

Caution: Product must remain frozen at -75°C ± 10°C until ready to thaw. Do not reuse, refreeze, or sterilize this product or its container.

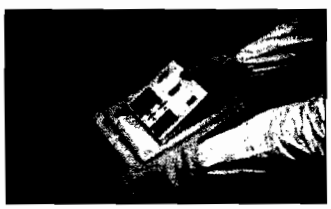
Note: *The transfer of Dermagraft from freezer or original shipping container into the 34°C to 37°C water bath must take no longer than 60 seconds to ensure delivery of living cells to the patient's wound.*

Note: *Do not thaw more than one (1) piece of Dermagraft in the same water bath at the same time.*

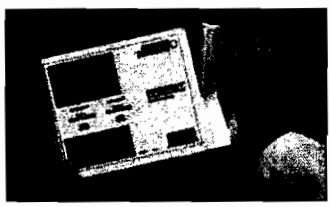
1. For each bag containing Dermagraft®, prepare a 2-liter water bath or thawing tub containing 2 liters of water at 34°C to 37°C. Water temperature must not exceed 37°C.



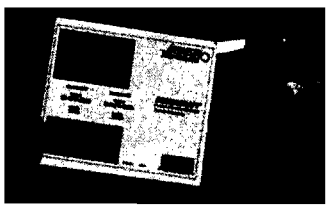
2. Remove the box containing Dermagraft from either the freezer or the shipping box per the Storage and Transfer Instructions found in the shipping box. Close the freezer door or the shipping box, and then immediately begin the thawing process, as detailed below.



3. Tear the cardboard box open along perforation.



4. Remove the foil pouch from the box.



5. Tear open the foil pouch with your hands at the tear notch.

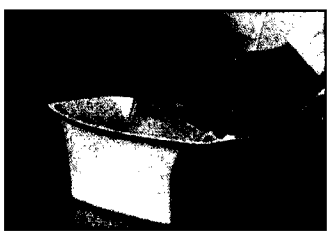
Note: *Do not cut foil pouch with scissors.*

6. Remove the clear bag containing Dermagraft®. Do not open the clear bag.

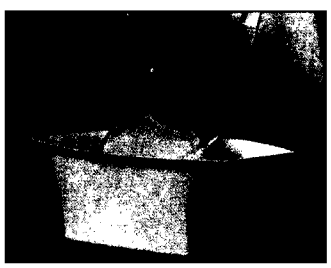
Note: *During the thawing and rinsing steps, touch the outer margins of the bag only and avoid touching the areas of the bag that come in contact with Dermagraft.*

7. Within 60 seconds of removal from the freezer or original shipping container, completely submerge the clear bag in the 34°C to 37°C water. Place the thawing tub lid on the tub during the thawing process to keep the Dermagraft® submerged. Water temperature does not need to be monitored from this point. Allow approximately two (2) minutes for thawing. The process is complete when there are no visible ice crystals within the clear bag.

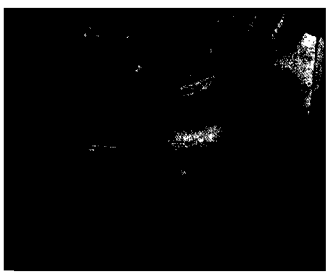
Note: *Do not thaw longer than three (3) minutes to ensure delivery of living cells to the patient's wound.*



8. Promptly remove the thawing tub lid and remove the clear bag from the water.

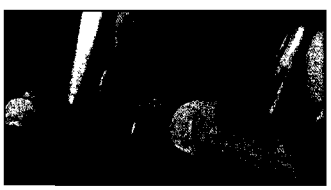


9. Handling by the clear bag's outer margins, place the bag into the rinsing stand without touching the areas of the bag that come in contact with Dermagraft®.



Note: *A thin layer of cells in addition to the Dermagraft may be present inside the clear bag. This is a normal result of the manufacturing process.*

10. Secure the clear bag inside the rinsing stand by using the locking clip at the bottom of the stand. Leave the bag in this locked position throughout the rinsing procedure. Immediately begin the rinsing process (Steps 11-15).

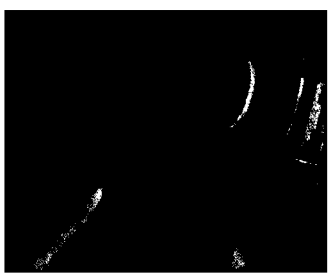


Note: *Steps 11-15 should be carried out promptly and without interruption to ensure delivery of living cells to the patient's wound.*

Caution: Dermagraft® is packaged with a saline-based cryoprotectant that contains 10% DMSO (Dimethylsulfoxide) and bovine serum. Skin and eye contact with this packaging solution should be avoided.

11. Put on surgical gloves and cut the clear bag open above the cut line with sterilized scissors.

12. Gently squeeze the solid plastic bar to open the clear bag. Pour the liquid out. Fill the bag up to the plastic bar with room temperature sterile normal saline. Wait for five (5) seconds and then pour out the saline.



13. Refill the clear bag to the bar a second time with room temperature sterile normal saline. Wait for five (5) seconds and then pour out the saline.

14. Refill the clear bag to the bar again with room temperature sterile normal saline. Wait for five (5) seconds and then pour out the saline. The product has now been rinsed three (3) times.

15. Fill the clear bag a fourth time with sterile normal saline and hold. If you are immediately ready to implant the product, hold the product in the saline for a minimum of five (5) seconds and then proceed to Step 16. If the patient is not ready or you need to transport the product to the patient, then cap the rinsing stand. Dermagraft may be held in saline up to 30 minutes.

Note: *Do not hold Dermagraft® at room temperature for more than 30 minutes to ensure delivery of living cells to the patient's wound. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation for Use instructions.*

Note: *Dispose of all liquid, rinsing solutions, and unused pieces of Dermagraft in accordance with institution or government environmental regulations.*

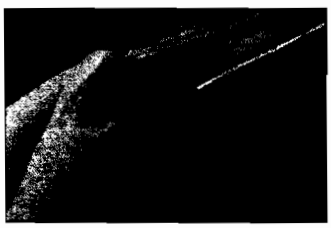
Application

Caution: Do not use any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with Dermagraft® as such preparations may cause reduced viability of Dermagraft.

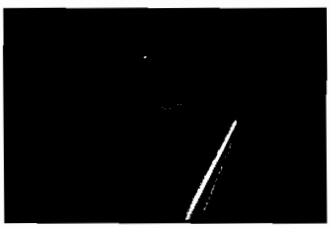
16. When ready for application, completely drain the clear bag of liquid. Then release the locking clip and remove the bag from the rinsing stand.

17. Holding the clear bag by the outer margins, use a permanent marker to trace the edge of the wound onto the bag either directly or from a separate tracing of the ulcer.

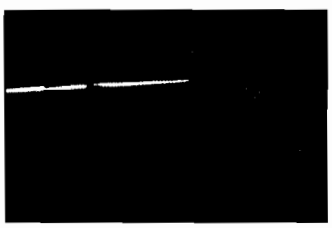
18. Using sterilized scissors, cut the Dermagraft® from the edge of the clear bag along the traced lines making allowance for the wound depth, and creating a handling tab to facilitate the implantation of Dermagraft.



19. Carefully peel the plastic from both sides of the Dermagraft using sterilized forceps.



20. Implant the Dermagraft into the debrided ulcer, covering the surface of the wound to just below the epithelial layer. With sterilized scissors, trim the excess handling tab.



21. Cover the wound with a non-adherent dressing. Fill, but do not pack, the wound with a dressing that provides a moist wound environment.

22. Between routine applications of Dermagraft®, it is important to maintain a moist wound environment.

23. After the initial application of Dermagraft, subsequent sharp debridement of the wound should continue as necessary. Subsequent wound preparation should minimize disruption or removal of previously implanted Dermagraft.

Note: *If a dressing change is needed prior to 72 hours, the non-adherent dressing layer should be left in place.*

24. Following each application of Dermagraft, the first wound dressing change should take place in approximately 72 hours.

Dermagraft® Human Fibroblast-Derived Dermal Substitute Essential Prescribing Information

Numbers in parentheses ( ) refer to sections in the main part of the product labeling.

Device Description

Dermagraft is a cryopreserved human fibroblast-derived dermal substitute. (1)

Intended Use / Indications

Dermagraft is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. Dermagraft should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. (2)

Contraindications

- Dermagraft is contraindicated for use in ulcers that have signs of clinical infection or in ulcers with sinus tracts.
- Dermagraft is contraindicated in patients with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution. (3)

Warnings

None (4)

Precautions

Caution: The product must remain frozen at -75°C ± 10°C continuously until ready for use.

Caution: Do not use any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with Dermagraft® as such preparations may cause reduced viability of Dermagraft.

Caution: Do not reuse, refreeze, or sterilize the product or its container.

Caution: Do not use the product if there is evidence of container damage or if the date and time stamped on the shipping box has expired.

Caution: Dermagraft is packaged with a saline-based cryoprotectant that contains 10% DMSO (Dimethylsulfoxide) and bovine serum. Skin and eye contact with this packaging solution should be avoided.

Caution: Dermagraft has not been studied in patients receiving greater than 8 device applications.

Caution: Dermagraft has not been studied in patients with wounds that extend into the tendon, muscle, joint capsule, or bone. Dermagraft has not been studied in children under the age of 18 years, in pregnant women, in patients with ulcers over a Charcot deformity of the mid-foot, or in patients receiving corticosteroids or immunosuppressive or cytotoxic agents.

Caution: To ensure the delivery of metabolically active, living cells to the patient's wound, do not hold Dermagraft at room temperature for more than 30 minutes. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation for Use instructions.

Caution: The persistence of Dermagraft® in the wound and the safety of this device in diabetic foot ulcer patients beyond six months has not been evaluated. Testing has not revealed a tumorigenic potential for cells contained in the device. However, the long-term response to these cells is unknown.

Caution: Always thaw and rinse product according to the Preparation for Use instructions to ensure the delivery of metabolically active, living cells to the patient's wound.

Caution: Do not use Dermagraft after the expiration date indicated on the labeled unit carton. (5)

Adverse Events

In clinical studies conducted to date, the overall incidence of reported adverse events was approximately the same for patients who received Dermagraft compared to those who received the Control treatment. (6)

Maintaining Device Effectiveness

Dermagraft must be stored continuously at -75°C ± 10°C. Dermagraft must be thawed and rinsed according to the Preparation for Use instructions. After the initial application of Dermagraft, subsequent sharp debridement of the ulcer should continue as necessary. Additional wound preparation should minimize disruption or removal of previously implanted Dermagraft. (13)

Patient Counseling Information

After implantation of Dermagraft, patients should be instructed not to disturb the ulcer site for approximately 72 hours (three days). After this time period, the patient, or caregiver, should perform the first dressing change. The frequency of additional dressing changes should be determined by the treating physician. Patients should be

given detailed instructions on proper wound care so they can manage dressing changes between visits. Compliance with off weight-bearing instructions should be emphasized. Patients should be advised that they are expected to return for follow-up treatments on a routine basis, until the ulcer heals or until they are discharged from treatment. Patients should be instructed to contact their physician, if at any time they experience pain or discomfort at the ulcer site or if they notice redness, swelling, or discharge around/from the ulcer. (8)

How Supplied

Dermagraft® is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single-use application. The clear bag is enclosed in a foil pouch and labeled unit carton.

Caution: Dermagraft is limited to single-use application. Do not reuse, refreeze, or sterilize the product or its container.

Dermagraft is manufactured using sterile components and is grown under aseptic conditions. Prior to release for use, each lot of Dermagraft must pass USP Sterility (14-day), endotoxin, and mycoplasma tests. In addition, each lot meets release specifications for collagen content, DNA, and cell viability.

Dermagraft is packaged with a saline-based cryoprotectant. This solution is supplemented with 10% DMSO (Dimethylsulfoxide) and bovine serum to facilitate long-term frozen storage of the product. Refer to the step-wise thawing and rinsing procedures to ensure delivery of a metabolically active product to the wound bed. (9)

Customer Assistance:
For product orders, technical support, product questions, reimbursement information, or to report any adverse reactions or complications, please call the following number which is operative 24 hours a day:

Advanced BioHealing Customer Service
(877) Dermagraft or (877) 337-6247

Caution: *Federal (U.S.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).*

Advanced BioHealing, Inc.
10933 North Torrey Pines Road
Suite 200
La Jolla, CA 92037-1005

US PAT Nos.
4,963,489; 5,266,480; 5,443,950

DG-1001 11092/003

Press Releases

Advanced BioHealing Launches Dermagraft®

- Commercial Operations in Place; Sales Commence -

La Jolla, CA, February 15, 2007 – Advanced BioHealing, Inc. (ABH) announced today that selling and shipping the bioengineered tissue product Dermagraft®. Dermagraft is approved Food and Drug Administration (FDA) as a treatment for full-thickness diabetic foot ulcers.

"Since acquiring Dermagraft in June of 2006, we have diligently worked on building the mani commercial infrastructure necessary for success in the marketplace, meeting our stated goa Dermagraft during the first quarter of 2007," said Kevin Rakin, Chief Executive Officer of Adv BioHealing. "Over the next two years we will be focused on re-establishing Dermagraft as a advanced wound care treatment. By accomplishing this goal, we will drive the commercial su company while simultaneously supporting development of our next-generation bioengineere

ABH has established commercial operations which include sales, marketing, health econom service, product reimbursement and technical support professionals. The company has strat initial representatives in markets that generated significant revenues in the past. In addition, professionals will be focusing on opportunities in other geographic regions, in particular large centers. ABH will continue to add representatives throughout 2007 commensurate with proje growth.

In addition to commercial operations, ABH also has a state-of-the art manufacturing facility s professionals already familiar with the production and quality control elements of Dermagraft passed numerous inspections, including a critical State of California licensing process. Since previously available in the U.S. market, the product already has appropriate purchase and a to ensure physicians are reimbursed for utilizing the product.

"This launch is a significant milestone and points to the strength and commitment of the ABH and team," said Stephen Bloch, MD, Venture Partner with Canaan Partners and Chairman o of Directors. "In addition to the launch of Dermagraft, ABH has made significant progress in l pipeline of complementary wound healing products, evidenced by the recent initiation of a pi evaluating the safety of Celaderm™ in treating venous leg ulcers."

Dermagraft is a cryopreserved human fibroblast-derived dermal substitute. It is supplied froz containing one piece of approximately 2 x 3 inches for a single-use application. The product marketing in the U.S. and in a number of other countries.

About Advanced BioHealing, Inc.
Advanced BioHealing is an industry leader in the science of regenerative medicine. The Con on the commercialization of cell-based and tissue-engineered products including two that ha for marketing: Dermagraft, for diabetic foot ulcers and TransCyte, to treat full and partial thic company's development pipeline includes a next-generation bioengineered tissue product w trials. ABH is a privately held company with research & development offices in New York, N manufacturing operations in La Jolla, CA.

For more information about ABH visit http://www.advancedbiohealing.com/
For more information about Dermagraft visit http://www.dermagraft.com/

[redacted]

DERMAGRAFT®

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

1. DEVICE DESCRIPTION

DERMAGRAFT® is a cryopreserved human fibroblast-derived dermal substitute; it is composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold. DERMAGRAFT is manufactured from human fibroblast cells derived from newborn foreskin tissue. During the manufacturing process, the human fibroblasts are seeded onto a bioabsorbable polyglactin mesh scaffold. The fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors and cytokines, to create a three-dimensional human dermal substitute containing metabolically active, living cells. DERMAGRAFT does not contain macrophages, lymphocytes, blood vessels, or hair follicles.

The human fibroblast cells are from a qualified cell bank, which has been extensively tested for animal viruses, retroviruses, cell morphology, karyology, isoenzymes, and tumorigenicity. Reagents used in the manufacture of DERMAGRAFT are tested and found free from viruses, retroviruses, endotoxins, and mycoplasma before use. DERMAGRAFT is manufactured with sterile components under aseptic conditions within the final package. Prior to release for use, each lot of DERMAGRAFT must pass USP Sterility (14-day), endotoxin, and mycoplasma tests. In addition, each lot meets release specifications for collagen content, DNA, and cell viability. Maternal blood sera are tested for evidence of infection with human immunodeficiency virus type 1 (HIV-1), human immunodeficiency virus type 2 (HIV-2), hepatitis B virus, (HBV), hepatitis C virus (HCV), syphilis, human T-lymphotropic virus type 1 (HTLV-1), and found negative for the purposes of donor selection. During subsequent screening of the fibroblast cell strain at various stages in the manufacturing process, testing for these same viruses, as well as Epstein-Barr virus (EBV) and human T-lymphotropic virus type 2 (HTLV-2), is carried out and found to be negative.

DERMAGRAFT is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single-use application.

2. INTENDED USE / INDICATIONS

DERMAGRAFT is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. DERMAGRAFT should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot.

3. CONTRAINDICATIONS

- DERMAGRAFT is contraindicated for use in ulcers that have signs of clinical infection or in ulcers with sinus tracts.
- DERMAGRAFT is contraindicated in patients with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution.

4. WARNINGS

None.

5. PRECAUTIONS

Caution: Do not use any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with DERMAGRAFT as such preparations may cause reduced viability of DERMAGRAFT.

Caution: Do not reuse, refreeze, or sterilize the product or its container.

Caution: Do not use the product if there is evidence of container damage or if the date and time stamped on the shipping box has expired.

Caution: Do not use DERMAGRAFT after the expiration date.

Caution: The product must remain frozen at -75°C±10°C continuously until ready for use.

Caution: DERMAGRAFT is packaged with a saline-based cryoprotectant that contains 10% DMSO (Dimethylsulfoxide) and bovine serum. Skin and eye contact with this packaging solution should be avoided.

Caution: Always thaw and rinse product according to the Preparation For Use instructions to ensure the delivery of metabolically active, living cells to the patient's wound.

Caution: To ensure the delivery of metabolically active, living cells to the patient's wound do not hold DERMAGRAFT at room temperature for more than 30 minutes. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation for Use instructions.

Caution: The persistence of DERMAGRAFT in the wound and the safety of this device in diabetic foot ulcer patients beyond six months has not been evaluated. Testing has not revealed a tumorigenic potential for cells contained in the device. However, the long-term response to these cells is unknown.

Caution: DERMAGRAFT has not been studied in patients receiving greater than 8 device applications.

Caution: DERMAGRAFT has not been studied in patients with wounds that extend into the tendon, muscle, joint capsule, or bone. DERMAGRAFT has not been studied in children under the age of 18 years, in pregnant women, in patients with ulcers over a Charcot deformity of the mid-foot, or in patients receiving corticosteroids or immunosuppressive or cytotoxic agents.

6. ADVERSE EVENTS

A total of 695 patients were evaluated in four clinical trials, 389 treated with DERMAGRAFT, and 306 treated with Control. Adverse events that were reported in the pivotal 314-patient clinical trial at a frequency of greater than 1% for patients treated with DERMAGRAFT are presented in Table 1. Adverse Event data are also presented combined, from three previous studies.

Table 1
Adverse Events Reported in Greater than 1% of Patients Treated with DERMAGRAFT

Event	Pivotal Study		Previous Studies	
	DERMAGRAFT N = 163 n (%)	Control N = 151 n (%)	DERMAGRAFT N = 226 n (%)	Control N = 155 n (%)
Infection (study wound)[1]	17 (10.4)	27 (17.9)	63 (27.9)	43 (27.7)
Infection (non-study wound)	17 (10.4)	14 (9.3)	33 (14.6)	22 (14.2)
Accidental injury[2]	17 (10.4)	18 (11.9)	17 (7.5)	11 (7.1)
Skin dysfunction/Blister	16 (9.8)	20 (13.2)	38 (16.8)	31 (20.0)
Flu syndrome	15 (9.2)	9 (6.0)	7 (3.1)	8 (5.2)
Osteomyelitis (study wound)	14 (8.6)	13 (8.6)	17 (7.5)	8 (5.2)
Surgeries involving study ulcer[3]	13 (8.0)	21 (13.9)	35 (15.5)	13 (8.4)
Wound enlargement/Skin ulcer (non-study wound)	12 (7.4)	17 (11.3)	30 (13.3)	16 (10.3)
Cellulitis (study wound)	12 (7.4)	14 (9.3)	25 (11.1)	10 (6.5)
Cellulitis (non-study wound)	10 (6.1)	7 (4.6)	15 (6.6)	13 (8.4)
Peripheral edema/Localized swelling	9 (5.5)	7 (4.6)	20 (8.8)	6 (3.9)
Pharyngitis/URI	7 (4.3)	5 (3.3)	13 (5.8)	11 (7.1)
Pain	6 (3.7)	5 (3.3)	24 (10.6)	12 (7.7)
Lab test abnormal-chemistry[4]	6 (3.7)	5 (3.3)	37 (16.4)	31 (20.0)
Skin disorder[5]	5 (3.1)	4 (2.6)	0 (0.0)	0 (0.0)
Osteomyelitis (non-study wound)	5 (3.1)	2 (1.3)	10 (4.4)	6 (3.9)
Wound enlargement/Skin ulcer (study wound)	4 (2.5)	8 (5.3)	12 (5.3)	15 (9.7)
Urinary tract infection	4 (2.5)	1 (0.7)	7 (3.1)	6 (3.9)
Diarrhea	4 (2.5)	5 (3.3)	4 (1.8)	3 (1.9)
Rash	3 (1.8)	2 (1.3)	4 (1.8)	4 (2.6)
Myocardial infarct	3 (1.8)	0 (0.0)	0 (0.0)	4 (2.6)
Fever	3 (1.8)	0 (0.0)	8 (3.5)	3 (1.9)
Allergic reaction	3 (1.8)	1 (0.7)	1 (0.4)	1 (0.6)
Rhinitis	2 (1.2)	1 (0.7)	2 (0.9)	2 (1.3)
Nail disorder	2 (1.2)	3 (2.0)	1 (0.4)	3 (1.9)
Myalgia	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
Joint disorder	2 (1.2)	1 (0.7)	1 (0.4)	0 (0.0)
Headache	2 (1.2)	1 (0.7)	3 (1.3)	3 (1.9)
Gastrointestinal disorder	2 (1.2)	3 (2.0)	0 (0.0)	1 (0.6)
Chest pain	2 (1.2)	1 (0.7)	4 (1.8)	5 (3.2)
Anemia	2 (1.2)	0 (0.0)	4 (1.8)	0 (0.0)
Bronchitis	1 (0.6)	1 (0.7)	7 (3.1)	1 (0.6)
Ecchymosis	1 (0.6)	0 (0.0)	5 (2.2)	0 (0.0)
Sinusitis	1 (0.6)	0 (0.0)	4 (1.8)	3 (1.9)
Neuropathy	1 (0.6)	0 (0.0)	4 (1.8)	0 (0.0)
Nausea	1 (0.6)	2 (1.3)	4 (1.8)	1 (0.6)
Dyspnea	1 (0.6)	1 (0.7)	4 (1.8)	0 (0.0)
Vomiting	1 (0.6)	1 (0.7)	3 (1.3)	2 (1.3)
Sepsis/Septicemia	1 (0.6)	1 (0.7)	3 (1.3)	0 (0.0)
Gastroenteritis	1 (0.6)	0 (0.0)	3 (1.3)	1 (0.6)
Chills	1 (0.6)	0 (0.0)	3 (1.3)	3 (1.9)
Cataract	1 (0.6)	0 (0.0)	3 (1.3)	1 (0.6)
Angina pectoris	1 (0.6)	0 (0.0)	3 (1.3)	3 (1.9)
Wound drainage	0 (0.0)	0 (0.0)	11 (4.9)	5 (3.2)
Cerebrovascular accident	0 (0.0)	0 (0.0)	7 (3.1)	1 (0.6)
Congestive heart failure	0 (0.0)	3 (2.0)	6 (2.7)	1 (0.6)
Cough increased	0 (0.0)	2 (1.3)	5 (2.2)	2 (1.3)
Back pain	0 (0.0)	1 (0.7)	5 (2.2)	4 (2.6)
Peripheral vascular disorder	0 (0.0)	0 (0.0)	4 (1.8)	0 (0.0)
Retinal disorder/Retinopathy	0 (0.0)	0 (0.0)	3 (1.3)	1 (0.6)
Neoplasm[6]	0 (0.0)	0 (0.0)	3 (1.3)	1 (0.6)
Lab test abnormal – urinalysis	0 (0.0)	0 (0.0)	3 (1.3)	2 (1.3)
Cyst	0 (0.0)	0 (0.0)	3 (1.3)	1 (0.6)
Asthenia	0 (0.0)	0 (0.0)	3 (1.3)	0 (0.0)

[1] Infections include all local wound infections, regardless of etiology (e.g. bacterial, fungal), not including osteomyelitis and cellulitis.

[2] Examples of verbatim codes included in this category are: laceration, foreign body in eye, head injury, dislocation of hip, coccyx fracture post fall, skin tear, and burn right index finger.

[3] Surgical procedures to the study ulcer are defined as any procedure (i.e., surgical debridement more extensive than required by protocol, incision and drainage, revision, excision, or amputation) that occurred during the course of the study.

[4] Pilot study codes to "Lab Tests Abnormal" and does not distinguish between Chemistry, Hematology, and Urinalysis.

[5] None of the events reported under "Skin disorder" involved the study ulcer. Under "Neoplasm", none of the events reported involved the study leg for the DERMAGRAFT-treated patients.

7. CLINICAL STUDIES

The pivotal study was a multi-center, controlled randomized clinical trial in which 314 patients were treated with either DERMAGRAFT plus conventional therapy or conventional therapy alone (sharp debridement, saline-moistened gauze, and pressure-reducing footwear). Patients were eligible to be screened if they had a plantar diabetic foot ulcer on the heel or forefoot (including toes) that was $\geq 1 cm^2$ and $\leq 20 cm^2$. At the screening visit, the patients began treatment with sharp debridement and saline-moistened gauze. If the study ulcer had not decreased in size by more than 50% during the next 2 weeks and the patient met all other inclusion and exclusion criteria, the patient was randomized into the study. Key study exclusion criteria included the following: a) the Ankle-Arm Index on the study foot was <0.7; b) the study ulcer was over a Charcot deformity of the mid-foot; c) the study ulcer had sinus tracts or tunnels that could not be completely debrided; d) the study ulcer had increased or decreased in size by >50% during the two week screening period; e) the patient had a serum albumin <2.0g/dl; f) the patient was receiving corticosteroids or immunosuppressive or cytotoxic agents; and g) the study ulcer showed clinical signs of infection.

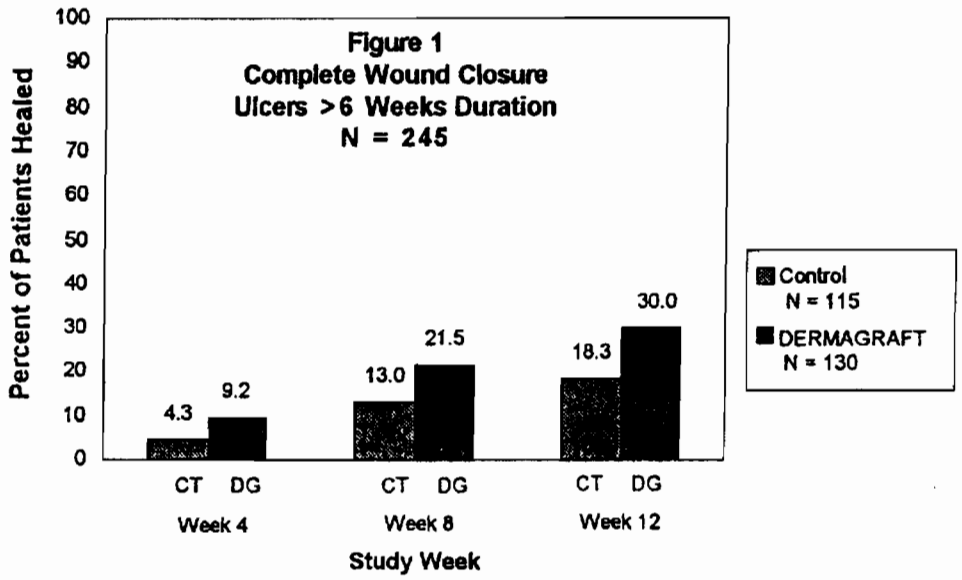
Except for the application of DERMAGRAFT, treatment of study ulcers was identical for patients in both the DERMAGRAFT and Control groups. Patients in the DERMAGRAFT group received up to 8 applications of DERMAGRAFT over the course of the 12-week study. All patients received pressure-reducing footwear and were encouraged to stay off their study foot as much as possible. Total off-weighting (e.g., use of crutches and wheelchairs) was not required by the study protocol. Patients were followed weekly until their study wounds were confirmed healed or they completed the week 12 study visit. At the weekly study visits ulcer tracings were obtained for computer planimetry and photographs of the wounds were taken as a pictorial record of the study ulcer.

The primary endpoint for the pivotal study was complete wound closure by Week 12. Wound closure was defined as full epithelialization without drainage. Furthermore, a determination of wound closure was only made if the wound remained closed at a second, confirmatory visit occurring within 4 weeks of the first assessment of closure. If the wound was not healed at the confirmatory visit, the wound was not deemed closed.

A planned interim analysis was performed during the study that showed a relationship between ulcer duration at the time of screening and incidence of ulcer healing with DERMAGRAFT. Consequently, a modified (after the interim analysis) statistical plan specified that (1) the effectiveness analyses would be based only on the patients with ulcers greater than 6 weeks in duration at the time of the screening visit and (2) the primary endpoint would be analyzed using Bayesian statistical methods. Bayesian methods provide for information obtained during the initial part of a trial to be utilized prospectively in the latter part of the trial to enable overall estimation of measures of effectiveness. The effectiveness data are therefore based on the 245 patients with ulcers of greater than 6 weeks duration. The safety analyses were performed on all 314 patients who were randomized into the study.

The Bayesian analysis concluded that the probability that DERMAGRAFT plus conventional therapy increased the chance of achieving wound closure in patients with ulcers greater than 6 weeks in duration over and above that of conventional therapy alone was 98.4%. Furthermore, there is a 95% probability that the chance of achieving closure in patients with ulcers greater than 6 weeks duration ranges from 22% to 38% in the DERMAGRAFT group and 12% to 26% in the Control group.

Figure 1 presents the proportion of patients who achieved complete wound closure during the course of the study.



Patients reported being ambulatory an average of 8 hours per day.

Patient characteristics, demographics, and healing results by patient category are provided in Table 2.

Table 2
Summary of Complete Wound Closure Results by Patient Category for Patients with Wounds of Greater than 6 Weeks Duration[1]

Category	Number and Percent of Wound Closure by 12 Weeks	
	DERMAGRAFT n/N (%)[2]	Control n/N (%)[2]
Age (years) [3]		
≤55	17/65 (26.2)	14/63 (22.2)
>55	22/65 (33.8)	7/52 (13.5)
Albumin (g/dL) [3]		
≤4.0	24/70 (34.3)	12/67 (17.9)
>4.0	14/59 (23.7)	9/48 (18.8)
Alcohol Use		
Yes	6/37 (16.2)	5/28 (17.9)
No	33/93 (35.5)	16/87 (18.4)
Ankle-Arm Index [3]		
≤1.1	20/70 (28.6)	12/54 (22.2)
>1.1	18/58 (31.0)	9/60 (15.0)
Body Mass Index (kg/m²) [3]		
≤31.1	21/68 (30.9)	14/55 (25.4)
>31.1	18/62 (29.0)	7/60 (11.7)
Diabetes Type		
Type I	8/32 (25.0)	5/27 (18.5)
Type II	31/98 (31.6)	16/88 (18.2)
Gender		
Male	22/90 (24.4)	15/91 (16.5)
Female	17/40 (42.5)	6/24 (25.0)
Hemoglobin A1c (%) [3]		
≤8.5	19/65 (29.2)	13/58 (22.4)
>8.5	20/64 (31.2)	8/56 (14.3)
Mean Hours Non-Weight Bearing [3]		
≤15.7	15/54 (27.8)	13/58 (22.4)
>15.7	21/65 (32.3)	7/47 (14.9)
Number of Ulcers on Study Foot		
1	37/126 (29.4)	20/108 (18.5)
>1	2/4 (50.0)	1/7 (14.3)
Race		
Caucasian	27/90 (30.0)	16/87 (18.4)
Non-Caucasian	12/40 (30.0)	5/28 (17.9)
Smoker		
Yes	8/27 (29.6)	4/17 (23.5)
No	31/103 (30.1)	17/98 (17.3)
Ulcer Area (cm²) [3]		
≤1.5	24/60 (40.0)	15/63 (23.8)
>1.5	15/70 (21.4)	6/52 (11.5)
Ulcer Location		
Forefoot or Toe	33/112 (29.5)	20/102 (19.6)
Heel	6/18 (33.3)	1/13 (7.7)

[1] Data observed at Screening except for Ulcer Area (obtained at the day 0 randomization visit) and Mean Hours Non-weight Bearing (compiled from patient diary information received from Study Weeks 1 through Termination; patients were included if they turned in at least one diary from any post randomization visit).

[2] Note: For individual categories the N will vary based on available patient information.

[3] Cut-off values for each category are based on the overall median value.

The healing results presented in Table 2 above are presented for general information purposes only. Outcome data based on an analysis of one demographic parameter in isolation may not be predictive of wound closure, as multiple factors influence ulcer healing.

Table 3
Summary of Complete Wound Closure Results by Ulcer Duration

Ulcer Duration	Number and Percent of Wound Closure by 12 Weeks	
	DERMAGRAFT n/N (%)	Control n/N (%)
<6 weeks [1]	13/33 (39.0)	15/36 (42.0)
6 –26 weeks	19/68 (27.9)	11/55 (20.0)
>26 weeks	20/62 (32.3)	10/60 (16.7)

[1] These 69 patients with ulcers less than 6 weeks in duration were not included in the primary effectiveness analysis.

Recurrence

In the previous multi-center controlled trial 139 patients were treated with DERMAGRAFT and 142 patients were treated with control. All patients were followed to week 32. Ulcer recurrence (defined as ulcers that healed by week 12 and reopened on or before week 32) was 26% (11/42) for patients in the DERMAGRAFT group and 22% (9/41) for patients in the Control group. Among this group of patients that experienced recurrence, the median time from healing to recurrence was 10 weeks for the DERMAGRAFT group, and 7 weeks for the Control group. These results are reflective of the entire study population, regardless of ulcer duration, and include patients who received DERMAGRAFT that did not meet the final metabolic release criterion.

After this study was completed, the metabolic release criterion for DERMAGRAFT and the intended patient population were modified. Therefore, a retrospective analysis was also performed on a subset of patients with ulcer duration of greater than 6 weeks who received DERMAGRAFT that met the final metabolic release criterion versus Control patients with ulcer duration of greater than 6 weeks. Ulcer recurrence was 18.8% (3/16) for patients in the DERMAGRAFT group and 20.7% (6/29) for patients in the Control group.

Immunology and Persistence Studies

The potential for DERMAGRAFT to elicit an immune response was evaluated by examining the baseline and terminal sera of patients enrolled in a clinical trial for DERMAGRAFT using Western Blot technique. A comparison of pre- and post-immune sera did not indicate an immunologic response to DERMAGRAFT in patients treated with up to 8 pieces of DERMAGRAFT. In investigating the persistence of the product in the wound bed, testing using Y-chromosome [male donor] marker SRY, amplified by a nested PCR technique revealed the presence of DERMAGRAFT cells from biopsies of treated venous ulcers up to 6 months after treatment from a single piece of DERMAGRAFT. Six of 10 patients evaluated at 2 months demonstrated DNA from DERMAGRAFT cells. Three of 10 patients evaluated at 6 months demonstrated DNA from DERMAGRAFT cells. In addition, biopsies of these wounds were evaluated for histologic evidence of an immunologic response to the product. This assessment found no histologic changes suggestive of an immune response to DERMAGRAFT.

8. PATIENT COUNSELING INFORMATION

After implantation of DERMAGRAFT, patients should be instructed not to disturb the ulcer site for approximately 72 hours (three days). After this time period, the patient, or caregiver, should perform the first dressing change. The frequency of additional dressing changes should be determined by the treating physician. Patients should be given detailed instructions on proper wound care so they can manage dressing changes between visits. Compliance with off weight-bearing instructions should be emphasized. Patients should be advised that they are expected to return for follow-up treatments on a routine basis, until the ulcer heals or until they are discharged from treatment. Patients should be instructed to contact their physician, if at any time they experience pain or discomfort at the ulcer site or if they notice redness, swelling, or discharge around/from the ulcer.

9. HOW SUPPLIED

DERMAGRAFT is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single-use application. The clear bag is enclosed in a foil pouch and labeled unit carton.

Caution: DERMAGRAFT is limited to single use application. Do not reuse, refreeze, or sterilize the product or its container.

DERMAGRAFT is manufactured using sterile components and is grown under aseptic conditions. Prior to release for use, each lot of DERMAGRAFT must pass USP Sterility (14-day), endotoxin, and mycoplasma tests. In addition, each lot meets release specifications for collagen content, DNA, and cell viability.

DERMAGRAFT is packaged with a saline-based cryoprotectant. This solution is supplemented with 10% DMSO (Dimethylsulfoxide) and bovine serum to facilitate long-term frozen storage of the product. Refer to the step-wise thawing and rinsing procedures to ensure delivery of a metabolically active product to the wound bed.

10. STORAGE

DERMAGRAFT must be stored continuously at -75°C±10°C.

11. SHELF LIFE

The DERMAGRAFT unit carton is marked with the expiration date of the product. Do not use the product after this date.

12. PEEL-OFF LABEL

Two peel-off labels are provided on the DERMAGRAFT box. One of the peel-off labels should be removed and placed on the patient's chart. This label bears a unique lot number and expiration date that will facilitate the collection of product monitoring information.

13. DIRECTIONS FOR USE

In clinical studies evaluating DERMAGRAFT for the treatment of ulcers in diabetic patients, DERMAGRAFT was applied weekly for up to a total of 8 applications over a 12-week period.

APPLICATION NOTES

- Diabetic foot ulcers must receive adequate sharp debridement, removing any necrotic or hyperkeratinized tissue, leaving a wound bed that meets the clinical criteria for skin grafting prior to application of DERMAGRAFT (i.e., clean, granulating wound bed).
- If extensive bleeding is observed after sharp debridement, the bleeding must be controlled before applying DERMAGRAFT. No topical agents may be used to stop the bleeding.

MATERIALS REQUIRED FOR PREPARATION AND APPLICATION OF DERMAGRAFT

- Water bath/thawing tub (37°C) with lid
- Thermometer
- Sterilized scissors
- Surgical gloves
- Clock or timer
- Sterile normal saline (0.9% sodium chloride) at room temperature
- Permanent ink marker
- Sterilized blunt-end forceps
- DERMAGRAFT rinsing stand
- Dressing supplies

PREPARATION FOR USE

Caution: Do not use DERMAGRAFT after the expiration date.

Caution: Follow all instructions to ensure delivery of metabolically active, living cells to the patient's wound.

Caution: Do not use the product if there is evidence of container damage or if the time on the shipping box has expired.

Caution: Product must remain frozen at -75°C±10°C until ready to thaw. Do not reuse, refreeze, or sterilize this product or its container.

1. For each DERMAGRAFT bag, prepare a 2-Liter water bath or thawing tub containing 2 Liters of water at 34°C to 37°C. Water temperature must not exceed 37°C.

Note: The transfer of DERMAGRAFT from freezer or original shipping container into the 34°C to 37°C water bath must take no longer than 60 seconds to ensure delivery of living cells to the patient's wound.

Note: Do not thaw two pieces of DERMAGRAFT in the same water bath at the same time.

2. Remove the DERMAGRAFT box from either the freezer or the shipping box per the Storage and Transfer Instructions found in the shipping box. Close the freezer door or the shipping box, and then immediately begin the thawing process, as detailed below.

3. Tear the cardboard box open along perforation.

4. Remove the foil pouch from the box.

5. Tear open the foil pouch with your hands at the tear notch.

Note: Do not cut foil pouch with scissors.

6. Remove the clear bag containing DERMAGRAFT. Do not open the clear bag.

Note: During the thawing and rinsing steps, touch the outer margins of the bag only and avoid touching the areas of the bag that come in contact with DERMAGRAFT.

7. Within 60 seconds of removal from the freezer or original shipping container, completely submerge the clear bag in the 34°C to 37°C water. Place the thawing tub lid on the tub during the thawing process to keep the DERMAGRAFT submerged. Water temperature does not need to be monitored from this point. Allow approximately two (2) minutes for thawing. The process is complete when there are no visible ice crystals within the clear bag.

Note: Do not thaw longer than three (3) minutes to ensure delivery of living cells to the patient's wound.

8. Promptly remove the thawing tub lid and remove the clear bag from the water.

9. Handling by the clear bag's outer margins, place the bag into the rinsing stand without touching the areas of the bag that come in contact with DERMAGRAFT.

Note: A thin layer of cells in addition to the DERMAGRAFT may be present inside the clear bag. This is a normal result of the manufacturing process.

10. Secure the clear bag inside the rinsing stand by using the locking clip at the bottom of the stand. Leave the bag in this locked position throughout the rinsing procedure. Immediately begin the rinsing process (Steps 11-14).

Note: Steps 11-14 should be carried out promptly and without interruption to ensure delivery of living cells to the patient's wound.

11. Put on surgical gloves and cut the clear bag open above the cut line with sterilized scissors.

Caution: DERMAGRAFT is packaged with a saline-based cryoprotectant that contains 10% DMSO (Dimethylsulfoxide) and bovine serum. Skin and eye contact with this packaging solution should be avoided.

12. Gently squeeze the solid plastic bar to open the clear bag. Pour the liquid out. Fill the bag up to the plastic bar with room temperature sterile normal saline. Wait for five (5) seconds and then pour out the saline.

13. Refill the clear bag to the bar a second time with room temperature sterile normal saline. Wait for 5 seconds and then pour out the saline.

14. Refill the clear bag to the bar again with room temperature sterile normal saline. Wait for 5 seconds and then pour out the saline. The product has now been rinsed 3 times.

15. Fill the clear bag a fourth time with sterile normal saline and hold. If you are immediately ready to implant the product, hold the product in the saline for a minimum of 5 seconds and then proceed to Step 16. If the patient is not ready or you need to transport the product to the patient, then cap the rinsing stand. DERMAGRAFT may be held in saline up to 30 minutes.

Note: Do not hold DERMAGRAFT at room temperature for more than 30 minutes to ensure delivery of living cells to the patient's wound. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation For Use instructions.

Note: Dispose of all liquid, rinsing solutions, and unused pieces of DERMAGRAFT in accordance with institution or government environmental regulations.

APPLICATION

Caution: Do not use any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with DERMAGRAFT as such preparations may cause reduced viability of DERMAGRAFT.

16. When ready for application, completely drain the clear bag of liquid. Then release the locking clip and remove the bag from the rinsing stand.

17. Holding the clear bag by the outer margins, use a permanent marker to trace the edge of the wound onto the bag either directly or from a separate tracing of the ulcer.

18. Using sterilized scissors, cut the DERMAGRAFT from the edge of the clear bag along the traced lines making allowance for the wound depth, and creating a handling tab to facilitate the implantation of DERMAGRAFT.

19. Carefully peel the plastic from both sides of the DERMAGRAFT using sterilized forceps.

20. Implant the DERMAGRAFT into the debrided ulcer, covering the surface of the wound to just below the epithelial layer. With sterilized scissors trim the excess handling tab.

21. Cover the wound with a non-adherent dressing. Fill, but do not pack the wound with a dressing that provides a moist wound environment.

22. Between routine applications of DERMAGRAFT, it is important to maintain a moist wound environment.

23. After the initial application of DERMAGRAFT, subsequent sharp debridement of the wound should continue as necessary. Subsequent wound preparation should minimize disruption or removal of previously implanted DERMAGRAFT.

24. Following each application of DERMAGRAFT, the first wound dressing change should take place in approximately 72 hours.

Note: If a dressing change is needed prior to 72 hours, the non-adherent dressing layer should be left in place.

DERMAGRAFT® Human Fibroblast-Derived Dermal Substitute
Essential Prescribing Information

Numbers in parentheses ( ) refer to sections in the main part of the product labeling

Device Description

DERMAGRAFT® is a cryopreserved human fibroblast-derived dermal substitute. **(1)**

Intended Use / Indications

DERMAGRAFT is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. DERMAGRAFT should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. **(2)**

Contraindications

- DERMAGRAFT is contraindicated for use in ulcers that have signs of clinical infection or in ulcers with sinus tracts.
- DERMAGRAFT is contraindicated in patients with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution. **(3)**

Warnings

None. **(4)**

Precautions

Caution: Do not use any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with DERMAGRAFT as such preparations may cause reduced viability of DERMAGRAFT.

Caution: Do not reuse, refreeze, or sterilize the product or its container.

Caution: Do not use the product if there is evidence of container damage or if the date and time stamped on the shipping box has expired.

Caution: Do not use DERMAGRAFT after the expiration date.

Caution: The product must remain frozen at -75°C±10°C continuously until ready for use.

Caution: DERMAGRAFT is packaged with a saline-based cryoprotectant that contains 10% DMSO (Dimethylsulfoxide) and bovine serum. Skin and eye contact with this packaging solution should be avoided.

Caution: Always thaw and rinse product according to the Preparation For Use instructions to ensure the delivery of metabolically active, living cells to the patient's wound.

Caution: To ensure the delivery of metabolically active, living cells to the patient's wound do not hold DERMAGRAFT at room temperature for more than 30 minutes. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation for Use instructions.

Caution: The persistence of DERMAGRAFT in the wound and the safety of this device in diabetic foot ulcer patients beyond six months has not been evaluated. Testing has not revealed a tumorigenic potential for cells contained in the device. However, the long-term response to these cells is unknown.

Caution: DERMAGRAFT has not been studied in patients receiving greater than 8 device applications.

Caution: DERMAGRAFT has not been studied in patients with wounds that extend into the tendon, muscle, joint capsule, or bone. DERMAGRAFT has not been studied in children under the age of 18 years, in pregnant women, in patients with ulcers over a Charcot deformity of the mid-foot, or in patients receiving corticosteroids or immunosuppressive or cytotoxic agents. **(5)**

Adverse Events

In clinical studies conducted to date, the overall incidence of reported adverse events was approximately the same for patients who received DERMAGRAFT compared to those who received the CONTROL treatment. **(6)**

Maintaining Device Effectiveness

DERMAGRAFT must be stored continuously at -75°C±10°C. DERMAGRAFT must be thawed and rinsed according to the Preparation For Use instructions. After the initial application of DERMAGRAFT, subsequent sharp debridement of the ulcer should continue as necessary. Additional wound preparation should minimize disruption or removal of previously implanted DERMAGRAFT. **(13)**

Patient Counseling Information

After implantation of DERMAGRAFT, patients should be instructed not to disturb the ulcer site for approximately 72 hours (three days). After this time period, the patient, or caregiver, should perform the first dressing change. The frequency of additional dressing changes should be determined by the treating physician. Patients should be given detailed instructions on proper wound care so they can manage dressing changes between visits. Compliance with off weight-bearing instructions should be emphasized. Patients should be advised that they are expected to return for follow-up treatments on a routine basis, until the ulcer heals or until they are discharged from treatment. Patients should be instructed to contact their physician, if at any time they experience pain or discomfort at the ulcer site or if they notice redness, swelling, or discharge around/from the ulcer. **(8)**

How Supplied

DERMAGRAFT is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single-use application. The clear bag is enclosed in a foil pouch and labeled unit carton.

Caution: DERMAGRAFT is limited to single use application. Do not reuse, refreeze, or sterilize the product or its container.

DERMAGRAFT is manufactured using sterile components and is grown under aseptic conditions. Prior to release for use, each lot of DERMAGRAFT must pass USP Sterility (14-day), endotoxin, and mycoplasma tests. In addition, each lot meets release specifications for collagen content, DNA, and cell viability.

DERMAGRAFT is packaged with a saline-based cryoprotectant. This solution is supplemented with 10% DMSO (Dimethylsulfoxide) and bovine serum to facilitate long-term frozen storage of the product. Refer to the step-wise thawing and rinsing procedures to ensure delivery of a metabolically active product to the wound bed. (9)

Customer Assistance

For product orders, technical support, product questions, reimbursement information or to report any adverse reactions or complications, please call the following number which is operative 24 hours a day:

Smith & Nephew, Inc.
Wound Management Division
Customer Care Center
800-876-1261

Distributed By

Smith & Nephew, Inc.
Wound Management Division
11775 Starkey Road
P.O. Box 1970
Largo, FL 33779-1970

Manufactured By

Advanced Tissue Sciences, Inc.
10933 North Torrey Pines Road
La Jolla, CA 92037-1005

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

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DYSTONIA MEDICAL RESEARCH FOUNDATION

serving all dystonia-affected persons

September 11, 2007

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking

Mr. Kerry Weems
Administrator, Centers for Medicare and Medicaid Services-Designate
U.S. Department of Health and Human Services
Attn: CMS-1392-P
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Mr. Weems:

On behalf of the Dystonia Medical Research Foundation, we are pleased to submit these comments on the proposed Hospital Outpatient Prospective Payment System update for 2008 in general, and particularly on the agency's proposals concerning **Packaged Services** and **Specified Covered Outpatient Drugs**.

The Dystonia Medical Research Foundation (DMRF) was founded over 30 years ago to support research leading to better, more effective treatments for this debilitating and often painful disorder, until a cure is found for all forms of dystonia; to increase awareness and education of and about dystonia; and finally, to support those affected by dystonia, and their families.

Dystonia is a neurological movement disorder that results in abnormal muscle contractions and postures. It affects men, women and children, essentially robbing them of the ability to control their own bodies. It can affect the entire body, or focus on a specific area.

Those who suffer from dystonia rely on numerous therapies to control the symptoms associated with dystonia, a movement disorder that causes muscles to contract and spasm involuntarily. As such, we are concerned by two proposals included in the above referenced rulemaking which could affect the availability of these drugs, and the quality of their delivery.

OPPS: Packaged Services

We generally commend CMS for seeking to improve the OPPS by better aligning hospital incentives with program objectives. However, we have grave concerns about CMS's proposal to package payment for electrical stimulation (HCPCS code 95873) and electromyography (HCPCS code 95874) guidance with chemodenervation procedures (HCPCS codes 64612-64614).

Patients with dystonia frequently receive injections of chemodenervation agents, such as botulinum toxin type A, to block specific muscles that cause involuntary movements and spasms that characterize dystonia. Physicians often use electromyography and electrical stimulation guidance in conjunction with chemodenervation procedures to guide the needle and ensure that the chemodenervation agent is injected in the most appropriate location to achieve the desired outcome.

We are concerned that CMS's proposal to package payment for the electromyography and electrical stimulation guidance services creates inappropriate financial incentives for hospitals to discourage utilization of guidance equipment, even where medically indicated. Hospitals that do not use guidance services will reap a financial windfall for their decision. Also troubling is the notion that hospitals that make the right decision and do not interfere in physician treatment decisions would nonetheless be penalized. While physicians often use guidance with injection procedures, they do not always do so because it is not always medically necessary to use electromyography or electrical stimulation guidance. Under the Proposed Rule, the combined payment amount for the injection and guidance would be substantially less than the total amount presently available when these services are paid separately. In fact, the combined payment amount for the injection and guidance would be approximately 15 percent less than the total amount presently available when these services are paid separately. As such, the hospital that incurs the cost of the guidance procedure will not be adequately reimbursed for the service furnished.

On behalf of the patients we represent, we encourage CMS to reconsider its proposal to package electromyography and electrical stimulation guidance procedures because these guidance procedures do not accompany the chemodenervation procedures in every instance. Specifically, we urge CMS to not package payment for HCPCS codes 95873 and 95874 with HCPCS codes 64612-64614.

OPPS: Specified Covered Outpatient Drugs

In recent years, CMS has set the payment rate to hospitals for physician-injected drugs at 106 percent of the average sales price. This payment has matched the payment for the same drugs furnished in a physician's office. For most drugs, the payment has been adequate to cover hospitals' costs, and the equivalence between the hospital and physician office settings has meant that our members have not had to worry that physicians or hospitals will stop providing the injectable therapies they need.

CMS is now proposing to reduce payment for injectable drugs to 105 percent of average sales price. CMS does not provide adequate justification for this reduction other than to state that this payment amount is consistent with CMS's estimate of hospital acquisition costs. We do not know what payment amount is most appropriate, but we are concerned that a reduction in payments will lead to problems with access if hospitals determine that the payment rate is inadequate to cover their costs.

Moreover, we find it counterintuitive that CMS would pay hospitals less than physician offices for the same drugs when it would seem that hospitals generally have higher overhead costs than physician offices.

CMS only recently began paying hospitals and physician offices the same for injectable drugs. This parity has been welcomed by our members who have been concerned in past years about the affect inadequate reimbursement has on access to therapies. In the past, some patients were shifted from hospital to physician office settings or *vice versa* when Medicare payments in one setting were less than adequate to cover provider costs. The potential to be shifted from one setting to another is troubling to our patients because they have relatively rare disorders and generally rely on the care given by highly specialized treatment centers.

We request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. If CMS believes that hospital costs (total costs including overhead and handling) are lower in the hospital setting than in the physician's office, CMS should collect this data, present it to the public for comment and also consider the potential impact of different payment formulae on patient access before CMS adopts any change in the payment formula.

Thank you for the opportunity to provide comments and for your consideration of our comments. We hope that CMS will follow our recommendations and continue to (1) allow separate payment for HCPCS codes 95873 and 95874 with HCPCS codes 64612-64614, and (2) pay hospitals 106 percent of ASP for physician-injectable drugs.

Sincerely,

Janet L. Hieshetter
Executive Director

Diversified Clinical Services WOUND CARE CENTERS, INC.
Healing Wounds. Changing Lives.

September 13, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

Dear Mr. Weems:

Diversified Clinical Services (DCS) and Wound Care Centers, Inc. (WCCS) welcomes the opportunity to comment on the 2008 Outpatient Prospective Payment System Proposed rule. We manage for our client hospitals, a network of more than 270 Wound Care Centers® that offers a comprehensive array of services for the treatment of chronic wounds, including but not limited to hyperbaric oxygen therapy. Our centers frequently use HBO as an adjunct therapy when standard wound care failed to produce suitable results. They also treat patients that would be covered under the other indications for hyperbaric treatments.

On behalf of our partner hospitals, we have focused our comments on the following areas: Hyperbaric Oxygen Therapy (APC 659), Skin Repair Procedures (APC 134 and APC 135) and the future model for determining the appropriate levels of Evaluation and Management services for specialty clinics, specifically for Wound Care services.

Skin Repair Procedures (APC 134 & 135)

We are addressing the Medicare payment reduction for the Skin Repair Procedures - CPT 15340 and 15341 Apply Cultured Skin Substitutes and CPT codes 15365 and 15366 Apply Dermal Skin Substitutes. These application codes are used by our Wound Care Centers (WCCs). Many of our WCCs treat Medicare beneficiaries for diabetic foot and venous leg ulcers.

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to products, including Apligraf® and Dermagraft. These products are used

Corporate Headquarters: 4500 Salisbury Road, Suite 300, Jacksonville, FL 32216

Phone: 904.962.2365 Facsimile: 904.296.3429

on patients who suffer from chronic ulcers. The treatment of these skin substitutes can prevent amputations for many of the patients that receive services at our partner hospitals. The Proposed Rule would drop the CY 2008 payment amount for the Application of Apligraf and Dermagraft to $132.82. This is a decrease of greater than 55% from final CY 2007 rates. The ability for patients to access this needed product is put at risk with these proposed payment changes.

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

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

Based on this change, the CY 2006 data that was available for the proposed rule may not accurately reflect the true resource costs for applying Apligraf. We have requested that our partner hospitals review their charges if they haven't done so already for skin repair procedures and the charges for CPT codes 15340 and 15341 to include the charges related to for the surgical site preparation which was previously billed under CPT code 15000. The surgical site preparation is now included in the in CPT code 15340 and/or 15341.

We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) rather than using APC 134 (Level II Skin Repair) to best reflect the actual resource cost of applying Apligraf. This grouping is consistent with other skin substitute products.

As you probably know, the Dermagraft product was not available for sale in 2006. Therefore, the cost and related charges were not available for use by CMS to calculate a proper cost to charge ratio in for the 2008 APC rates. Dermagraft was available again for sale to consumers in calendar year 2007. For these reasons, no changes should be made to include the application of this product from a Level III to the proposed Level II Skin Repair category.

We respectively request that CMS consider our comments and make the necessary correction to the APC payment for FY 2008 to allow our partner hospitals can continue the use these product in CY 2008 without a significant reduction in their Medicare reimbursement.

APC 0659 Hyperbaric Oxygen Therapy (HBOT)

We are in support of the proposed increase in the payment rate for HBOT and we believe that CMS is utilizing consistent methodology of utilizing an overall Cost to Charge ratio (CCR) is necessary to yield valid median cost for HBOT services.

HBOT is a well-established and clinically accepted treatment for an ever-increasing number of medical conditions. CMS has already approved HBOT for fifteen covered indications, including diabetic wounds, carbon monoxide poisoning, and decompression sickness, among others. One example of the efficacy and cost-effectiveness of HBOT is its role in the treatment of diabetic wounds. Diabetes is the sixth leading cause of death in the United States, afflicting an estimated seven percent of the U.S. population; and diabetic wounds which disproportionately affect minorities, the elderly, and underprivileged citizens often necessitate amputation of the affected limb. Actually, sixty percent of non-traumatic lower limb amputations are caused by diabetes. HBOT improves patient care by preventing amputations and has been used to save the limbs of thousands of patients, many of whom rely on the Medicare program for their treatments.

We are an active member of the American Association for Wound Care Management (AAWCM). We are aware that they have worked with CMS for several years to address this payment methodology. The Lewin Group has conducted annual surveys and reports to determine an accurate CCR with respect to providing HBOT. The Lewin Group has successfully established and reproduced an accurate CCR for HBOT. AAWCM has shared both the raw data and final results of the Lewin Report with CMS to encourage the adoption of this methodology. We hope CMS will consider this mythology in the near future.

OPPS Drug Administration- Proposed Payment for Hospital Outpatient Visits

We appreciate CMS's perspective on the levels of complexities of various specialty clinics including wound care. While CMS clearly has reviewed several acuity tools and methodology, they rightfully recognize systematic approaches by hospitals to justify evaluation and management levels.

We support the need for a set of national guidelines that will ensure standardized reporting of outpatient hospital visit levels. We believe that specialty clinics should have their own set of guidelines specific to the services offered in those specialty clinics, including wound care. In addition, we support the implementation of a set of national wound care clinic guidelines.

We are aware that the AAWCM is leading the effort to develop an Evaluation and Management model for hospital outpatient wound clinics. AAWCM tested the wound care model previously submitted to CMS and found the model unworkable in a manual form at wound care clinics. AAWCM is developing a tool that can be implemented in a paper-based format, is comprehensive, simple to implement, consistent for use across all wound clinics, captures all facility resources and does not require additional nursing documentation.

The intervention portion of this tool has been successfully tested in several hundred patients in numerous wound clinics. AAWCM is requesting guidance and input on this tool from American Hospital Association (AMA) and American Health Information Management Association (AHIMA) prior to proceeding with the scoring or relative weighting of the interventions and providing the tool and scheduling a meeting to present the materials to the appropriate staff at CMS. It is AAWCM's goal to present this to CMS during calendar 2008. We support this endeavor and are grateful to the willingness of CMS to entertain additional tools to capture all costs realized by hospitals that operate wound care clinics.

If you have any further questions regarding our comments, please contact me jorzali@wccs.com or at (832) 265-3300.

Sincerely,

Julie A. Orzali
Vice President, Reimbursement

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BAPTIST MEMORIAL HEALTH CARE CORPORATION

September 12, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P; Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

In response to your invitation to provide comments regarding the proposed 2008 OPPS changes we are submitting our responses for your consideration.

- **Evaluation and Management**

  In the proposed OPPS changes for 2008, the Centers for Medicare and Medicaid Services (CMS) reinforces the guidelines put forth in the April 7, 2000 final rule. CMS instructed hospitals to continue to report facility resources for clinic and emergency department visits using CPT E/M codes and to develop internal hospital guidelines to determine what level of visit to report for each patient. These internal guidelines should follow the intent of the CPT code descriptors; in that they should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

  We agree with the guidelines proposed in the April 7 OPPS final rule for determining the E & M levels for hospital billing which will allow hospitals to continue using their established internal guidelines. These guiding principles are reflective of the resources utilized by the ED staff and can be applied accurately, objectively and consistently to facilitate the assignment of the appropriate E & M level. We encourage CMS to adopt these guidelines in place of national E/M standard definitions.

- **Injection and Infusions**

  We are thankful that the 2008 OPPS will not change the drug administration codes/rules in a way that would make billing for these services even more complex and burdensome to hospital coders. However, we want to convey to CMS that the current CPT codes and rules put an unreasonable coding-documentation-billing burden on hospitals. The current CPT codes and rules were written for physician services, and they are difficult to apply to hospital ED/outpatient visits. For example, hospital visits usually involve more complex medical situations; therefore, it is difficult for hospital coders to apply the CPT rule that defines the "initial service" as the key or primary reason for encounter (since there is not always one key reason for a hospital encounter). With the greater complexity of medical conditions treated in hospital OP visits, there is often administration of multiple IV drugs and IV fluids, concurrently and/or sequentially. This adds to the difficulty of determining which CPT codes to use for each drug administered, while at the same time applying the rules for concurrent and sequential drugs, only one IVP code per drug, no code for concurrent

hydration, etc. Also, the documentation in hospital medical records is more complex and extensive than that in physician offices. Hospital medical records contain documentation by many more staff members and staff in different departments, leading to greater variations in documentation of drug administration than would be found in physician office records. Moreover, hospital OP visits have a longer length-of-stay than physician office visits, so that it can take hospital coders an inordinate amount of time just to code the drug administration services using so many different CPT codes.

Industry standards do not support capture of all the documentation in the amount of detail required to correctly code the number of hours of infusion that can occur in a hospital visit that spans four to 30 (or more) hours. Hospital coding and nursing staff are already in a current shortage, and the complexity of CPT codes for drug administration has added a staffing burden for hospitals that are struggling to document, code, and bill drug administration services correctly and completely.

We request that CMS consider creating new codes and rules for the 2009 OPPS, to simplify hospital coding of drug administration services. For example, the former Medicare Q-code that was defined as "IV infusion once per visit" was much less time-consuming for hospital coders to report, since it was not necessary for coders to pour over hospital records looking for documentation of all hours of infusion and then calculating the number of hours of multiple medications and IV fluids. In keeping with the spirit of packaging and minimizing APCs as proposed by CMS, it only makes sense to go with an IV infusion "per visit" code, rather than separately coding the first hour, additional hours, sequential hours, and concurrent hours. For hospital drug administration services, a simpler coding structure with simpler rules would help hospitals to more accurately and consistently report these services without great variation from hospital to hospital due to complex coding rules and variations in documentation.

- **Guidance Services, Contrast Media and PET SCANs**

  The CMS 2008 OPPS proposal has far reaching ramifications that make it very difficult to determine the financial impact on our hospitals because of the complex proposal to package payment for the seven categories of supportive ancillary services into the primary diagnostic or treatment procedures with which they are performed.

  We have concerns that when the below procedures with just status indicators (SI) of "Q" are on claims with other procedure codes of "S, T, V, or X" that there would be no payment for these procedures that are "Q" status.

  The process for packaging has not been well tested and may need additional study. For example:

  FDG/PET Example: *In reviewing these changes the results indicate comparable reimbursement from 2007 to 2008.*

  Cardiology Examples:
  We applied the proposed method of packaging to industry standard services. These changes are critical to our 2008 budget and will impact financial reimbursement for years to come.

  We feel the financial impact is unfair and would like the packaging to be delayed to allow reconsideration and then to allow the hospitals time to adjust their budgets. While some hospitals may benefit, others will be hurt significantly by the negative impact.

Scenario	DESCRIPTION	CPT	2008 SI	2007 Reimb	2008 Reimb
Echo with Definity	ECHO 2D	93307	S	$197.64	$419.79
	ECHO DOPPLER	93320	N	$98.18	$0.00
	ECHO COLOR FLOW	93325	N	$98.18	$0.00
	DEFINITY 1 ML	Q9957	N	$61.64	$0.00
			Total	**$455.64**	**$419.79**
TEE	ECHO ESOPHAGEAL	93312	S	$384.21	$536.30
	ECHO DOPPLER	93320	N	$98.18	$0.00
	ECHO COLOR FLOW	93325	N	$98.18	$0.00
			Total	**$580.57**	**$536.30**
EPS,LA, Isuprel	COMP EP STUDY W/INDUCT ARRYTH	93620	Q	$2,107.17	$3,097.37
	W/LEFT ATRIAL RECORDING	93621	N	$2,107.17	$0.00
	PROG STIM PACING AFTER DRUG	93623	N	$2,022.22	$0.00
			Total	**$6,236.56**	**$3,097.37**
EPS,LA, Isuprel, 3 D MAP, SVT Ablation	COMP EP STUDY W/INDUCT ARRYTH	93620	Q	$2,107.17	$3,097.37
	W/LEFT ATRIAL RECORDING	93621	N	$2,107.17	$0.00
	PROG STIM PACING AFTER DRUG	93623	N	$2,022.22	$0.00
	INTRACARDIAC EP 3-D MAPPING	93613	N	$2,022.22	$0.00
	INTRACARDIAC ABLATION SVT	93651	Q	$2,919.31	$5,781.03
			Total	**$11,178.09**	**$8,878.40**

Radiology Examples:

We applied the proposed method of packaging to industry standard services. These changes are critical to our 2008 budget and will impact financial reimbursement for years to come.

We feel the financial impact is unfair and would like the packaging to be delayed to allow reconsideration and then to allow the hospitals time to adjust their budgets. While some hospitals may benefit, others will be hurt significantly by the negative impact.

Scenario	CPT Description	CPT	SI 2008	2007 Reimb	2008 Reimb
1	3D IMAGE PP	76377	N	$94.53	$0.00
	ARCH ANGIO	75650	Q	$1,279.92	$721.14
	CEREBRAL ANGIO	75671	Q	$1,279.92	$721.14
	CAROTID ANGIO	75680	Q	$1,279.92	$721.14
	VERT ANGIO	75685	Q	$1,279.92	$721.14
	1ST ORDER VESSEL	36215	N	$0.00	$0.00
	3RD ORDER VESSEL	36217	N	$0.00	$0.00
	2/3 ORDER VESSEL	36218	N	$0.00	$0.00
	OMNIPAQUE	Q9947	N	$80.94	$0.00
	OMNIPAQUE	Q9949	N	$28.00	$0.00
			TOTAL	**$5,323.15**	**$2,884.56**
2	PERC GASTRO PLCMT	43750	T	$511.26	$552.41
	GASTRIC TUBE PLCMT	74350	N	$104.23	$0.00
	CT ABD LTD	76380	S	$94.53	$106.80
	OMNIPAQUE	Q9949	N	$8.75	$0.00
			TOTAL	**$718.77**	**$659.21**

3	CT BX/ASPIRA BONE	20225	T	$418.49	$555.12
	CT GUIDE NDLE BX	77012	N	$250.94	$0.00
			TOTAL	**$669.43**	**$555.12**
4	CTA AORTA W/BILAT RO	75635	Q	$298.44	$336.41
	OMNIPAQUE	Q9949	N	$35.00	$0.00
			TOTAL	**$333.44**	**$336.41**
5	IVC IMAGE	75825	Q	$584.32	$378.11
	PLCMT IVC FILTER	75940	N	$515.75	$0.00
	INTRO CATH SVC/IVC	36010	N	$0.00	$0.00
	FILTER IVC ANY METH	37620	T	$2,134.71	$2,780.89
	OMNIPAQUE	Q9949	N	$31.50	$0.00
			TOTAL	**$3,266.28**	**$3,159.00**
6	AORTA ABD	75625	Q	$1,279.92	$721.14
	ANGIO EXTREMITY	75716	Q	$1,279.92	$721.14
	PLCMT OCCL DEVICE	G0269	N	$0.00	$0.00
	PLCMT CATH 3RD ORD	36247	N	$0.00	$0.00
	IVUS	37250	N	$2,000.61	$0.00
	IVUS S&I	75945	Q	$151.25	$158.33
	OMNIPAQUE	Q9949	N	$107.45	$0.00
			TOTAL	**$4,819.15**	**$1,600.61**

We request:

CMS delay implementing the packaging of the radiology & cardiology services in 2008.
CMS do additional study of the impact on the facilities.
CMS provide additional information including allowing the provider to fully evaluate the proposal.
CMS provide information regarding which procedures the reimbursement impact has a positive impact that will off set the negative impact as indicated above. Providers need more information on how the reimbursement was reallocated across the APCs from the items whose SI was changed to an "N" status.

- **Intraoperative Services**

In regards to the proposed changes for 2008 OPPS for ***Intraoperative Services****, we believe that certain interactions between the payment status codes for various procedures will result in an inappropriate and harmful allocation of funds relative to cost in a number of situations.*

Quite a few codes are moving from a status T or S (paid fully or discounted payment) to a status Q (paid only when an S, T, V, or X status code is not present). A stated goal of OPPS 2008 is to package payments into fewer CPT codes. An example is taking CPT 93621 (the left atrial component of an EP study) to status N (no payment; fully packaged) and packaging it with CPT 93620 (comprehensive EP evaluation) and/or 93651 (intracardiac ablation) that are both status Q codes. However, the presence of a medically necessary EKG (93005), that's a status S code, on the claim renders the payment for codes 93620 and 93651 nil. Both codes have a much higher payment rate than 93005 and much higher resource usage needs and would seemingly take payment precedence over 93005, but that's not how 2008 OPPS would work and not how we believe it was

intended to work. The net effect is a dramatic loss of payment needed to cover resources used for this procedure. The presence of a medically necessary Chest X-Ray (71010) w/ status code X renders the same effect. The Chest X-Ray is also a very light resource user in comparison to the status Q codes noted above with a much lower payment amount than those codes.

The large financial incentive not to perform an EKG or Chest X-Ray on a visit of this type to allow for payments of the status Q codes would create a reimbursement methodology that may potentially compromise the care of patients.

- **Image Supervision and Interpretation**

Another example of the negative impact exists in the ***Imaging Supervision*** *category. That would be code 75716 (artery x-rays, arms/legs) along with 75625 (contrast x-ray exam of aorta). Both are status Q codes. Both are performed quite often with status S and T procedures (35493, 37205, 93510, 35474 are examples) and thus are not paid resulting in a dramatic and burdensome overall payment decrease. An equally great concern, however, is the dropping of payment for the noted Q status codes when an EKG (93005) is performed on that encounter due to the S payment status of 93005. This also places an equal or greater financial drain on the performing facility creating a financial incentive to not perform a medically necessary procedure in the EKG (93005).*

A further example of this situation in the ***Imaging Supervision*** *category is CPT code 75978 (venous balloon angioplasty) which is a payment Status Q code. This is often performed in concert with CPT codes 75790, G0393, 35476, 75960, 37205, 36879, and 75962. The decrease in payment to zero for the status Q codes in this population is accompanied by an increase in payment for the status S or T codes that are notably less than the decrease in Q status payments thereby creating a great financial burden on the facility.*

We also believe that in situations in which an S,T,V, or X code is normally absent that the typical payment decrease of Q status codes for 2008 causes quite drastic reductions in reimbursement and again is a dramatically noted financial encumbrance.

CPT 75685 is an example of an overwhelming payment decrease for a Q status code often performed along with other Q status codes (75680, 75671, and 75650). These are most often performed with no status S, T, V, or X procedures in a truly diagnostic setting and dramatic drops in payment for these Q status codes for packaging purposes is not made up elsewhere on the patient's roster of billed procedures.

We recommend that CMS consider a reallocation of funds within OPPS packaging situations that lessens the negative impact from the drop in reimbursement for numerous status Q codes from both the Imaging Supervision and Interpretation category and Intraoperative Services category with a lesser decrease in payment (or increase in payment as compared to the current 2008 proposal) to more closely match the increase in reimbursement for many status S or T procedures naturally performed in the same encounter. This would also rectify the overall dramatic decrease in reimbursement on cases with status Q procedures but no status S, T, V, or X procedures.

We also strongly encourage CMS to consider moving CPT code 93005 to a status code of X and simultaneously remove status code X entirely as a qualifier for payment on status Q codes. This would remove the great negative reimbursement effect and the disincentive to perform this and other medically necessary procedures on cases including status Q procedures.

➢ Observation Services

In 2002, the push for observation reimbursement related to access and medical necessity. Primarily, the push revolved around the IOM's recommendations and ED crowding relating to chest pain centers. Within that revision, when adding payment for certain conditions, CMS balanced issues of access, medical necessity potential for abuse, against the need to ensure appropriate payment. In alignment with CMS quality measures, when there is no definitive diagnostic confirmation for AMI, CHF, and Pneumonia, but rather a suspicion of one of these diagnoses, observation is the appropriate level of care.

We wish to comment and make recommendations on the following:

- *Recommend CMS not bundle the reimbursement for observation and continue the current practice to reimburse providers for observation services provided under certain conditions for certain diagnoses;*
- *Recommend CMS to adopt APC Panel's recommendations for expanding the diagnoses for which observation is paid; and*
- *Recommend CMS remove the requirement that the observation status is based on the physician's order and allow hospitals to determine the status based on CMS criteria.*

Not Bundle Observation Service Reimbursement

ED evaluation and management levels are separate and distinct from the care provided in observation and therefore should not be packaged. As noted, only 12% of the cases had a Level 5 ED visit which is a very small percentage; and lower level ED visits are provided to most patients as they move through the system. The minimum requirements for the 3 conditions led also to lower levels of billable E/M services. The physician's intent is for the patient to receive designated diagnostic studies, monitoring and/or interventions, all of which are delivered to patients regardless of whether they are in observation or inpatient status. The status as an inpatient or observation patient affects billing and reimbursement; it has no effect on the patient's care. When patients come to the ED, the entire history of the patient is not always known due to the vast number of physicians/specialists who may be treating a beneficiary. Observation monitoring is no different than inpatient monitoring; in fact observation patients may be intermingled within the inpatient setting.

In the proposed rule, it is stated that the reason for packaging observation is because the facility portion for observation care is supportive and ancillary to other primary services being furnished in the HOPD. Reality is that these other primary services are not being provided in an HOPD and therefore not counted as IP days; and hospitals are not receiving any overhead allocation of staff, etc. Thus, by packaging them with the service, hospitals would not be receiving reimbursement for resources that are being consumed in providing care to the patient.

Adopt APC Panel's Recommendations

With the increased efforts to control costs for healthcare, many insurance companies, as well as Medicare Advantage/HMO plans, are expanding the use of observation services to respond with reduced reimbursement. Observation services help save beneficiary benefit days and enormous out-of-pocket expense for deductibles. CMS has ignored the APC Panel and the IOM recommendation of expanding the conditions for separate OPPS payment to be made for all conditions for which observation is indicated. This is purely a reimbursement rule and not a care directed rule as the

physician is often unaware of the difference between an Inpatient or Observation status for billing purposes. This allows for the potential underutilization of observation or vice versa. Hospitals today are attempting to provide the appropriate care to the beneficiary in accordance with the billing and reimbursement rules. Hospitals strive to provide care to patients in the appropriate levels to provide prompt diagnosis and/or treatment for the presenting condition, thereby, reducing potential harm in any delay of treatment or diagnosis. We recommend that CMS adopt the APC Panel's and IOM's recommendation.

Determine Observation Status Based on CMS Criteria

Observation services require the order of a physician, a facility bed and a clinically trained staff to assess and/or reassess the patient status and need for further care and to provide any treatments that are indicated. The care provided is the same regardless of whether the patient is "deemed" observation or inpatient, so why should reimbursement only be available for inpatient status? These services would be reimbursed under Title XVIII of the Social Security Act in the regulations (42CFR 409.10) if the patient was admitted as an inpatient.

We recommend that CMS not bundle the reimbursement for observation and continue the current practice to reimburse providers for observation services provided under certain conditions for certain diagnoses. Furthermore, we urge CMS to adopt the APC Panel's recommendations for expanding the diagnoses for which observation is paid. Since the patient receives the same care regardless of his/her status, we recommend that CMS remove the requirement that the status be based on a physician's order and allow the hospital to determine the status based on the CMS criteria. This approach would be more consistent with other aspects of Medicare billing/reimbursement rules.

We appreciate the opportunity to provide these comments and thank you for your consideration.

Sincerely,

William A. Griffin
Vice President of Corporate Finance

September 12, 2007

Edward T. Karlovich
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Via: UPS Delivery and
http://www.cms.hhs.gov/eRulemaking

ATTENTION: CMS-1392-P

RE: CMS-1392-P
Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year (CY) 2008 Payment Rates; Proposed Rule (Vol., 72, No. 148), August 2, 2007

Dear Sir or Madam:

On behalf of the University of the Pittsburgh Medical Center (UPMC) we are submitting one original and two copies of our comments regarding the Center for Medicare and Medicaid Services (CMS) proposed rule (Federal Register / Vol. 72, No. 148 / August 2, 2007 pages 42627 - 43130) "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; ... Proposed Rule". We are also submitting these comments electronically to http://www.cms.hhs.gov/eRulemaking.

The following is a detailed explanation of UPMC concerns and issues with the OPPS CY 2008 proposed rule.

Section "OPPS: Packaged Services"

Issue 1: Proposed Packaging Approach (FR page 42652)

***Proposed CY 2008 Rule*:** CMS is proposing a shift in OPPS payment from the concentrated effort over the past seven years of identifying and refining service-specific payment for services rendered to patients to a more encounter or episode-of-care-based payment approach. CMS considers this proposed packaging (and bundling) approach a first step toward "value-based purchasing" which is a performance-based payment model rather than a volume-based payment model. CMS believes this shift is necessary as the implementation of OPPS has not slowed outpatient spending or volume growth. MedPAC confirmed that much of the growth in service volume from 2003 to 2005 resulted from increases in the number of

services per beneficiary who received care, rather than from increases in the number of beneficiaries served. CMS indicates that by expanding the packaging of supportive ancillary services and by bundling payment for multiple independent services into a single OPPS payment an incentive will be created for hospitals to monitor and adjust service volumes and resource efficiencies themselves. To start this process CMS is proposing in CY 2008 to package (by HCPCS) the payment for dependent services, in seven categories, into the payment for the independent services with which they are furnished. The seven service categories are as follows:

- Guidance services
- Image processing services
- Intraoperative services
- Imaging supervision and interpretation services
- Diagnostic radiopharmaceuticals
- Contrast media
- Observation services

Response: While UPMC believes in providing better quality services at fair and reasonable prices, we are concerned that CMS is accelerating too hastily in the direction of an outpatient episode-based payment system. It is apparent in reading the proposed rules and background materials that CMS has begun to shift its OPPS payment approach in CY 2008 from identifying and establishing accurate service-specific payments toward an episode-based payment system. CMS considers the proposed seven category packaging approach (noted above) as a first step towards an episode-based payment system process. CMS also acknowledges that they believe an episode-based payment system will help alleviate the "tremendous growth in OPPS volumes and expenditures" of approximately ten percent growth per year, by encouraging providers to use resources more effectively. See Federal Register (FR) excerpts below, from FR of 8-2-2007:

> (FR page 42649) – "During the evolution of the OPPS over the past 7 years, significant attention has been concentrated on service specific payment for services furnished to particular patients, rather than on creating incentives for the efficient delivery of services through encounter or episode-of-care-based payment. Overall packaging included in the clinical APCs has decreased, and the procedure groupings have become smaller as the focus has shifted to refining service-level payment."
>
> (FR page 42649) – "As illustrated in Table 5, total spending has been growing at a rate of roughly 10 percent per year under the OPPS, and the Medicare Trustees project that total spending under the OPPS will increase by more than $3 billion from CY 2007 through CY 2008 to nearly $35 billion."

UPMC believes that caution is critical and that CMS should not be attempting to establish outpatient quality and efficiency payment rates, through packaging and bundling of services, before both hospitals and physicians are adequately prepared

for these planned and significant payment changes. As CMS mentioned this proposed packaging approach is the first step in a total reversal of seven years of APC refinement of more accurate service payments toward an episode-based payment approach that appears to be budget driven. This proposed and planned payment approach described by CMS will soon place providers in severe financial risk with outpatient payment system modifications that are not simple, predictable or stable for providers. We believe a more cautious approach is necessary, requiring issues to be resolved before CMS proceeds with an episode or value-based driven OPPS payment system. We would urge CMS not to adopt these proposed packaging steps at this time. Issues such as best-treatment approaches and APC bench-marks; establishment and availability of good outpatient quality measures and availability of peer group data; provider risk floors; physician monitoring education; hospital staff training; beneficiary education; are all concerns that should be addressed. Another issue that needs to be considered by CMS is medical liability costs. The growth of physician medical malpractice liability costs and settlements encourages physicians to practice "defensive medicine". This could cause physicians to perform more tests and procedures in order to reduce exposure to lawsuits. Since this proposed rule contains no incentives for physicians to limit service volumes the hospital is at risk for this additional cost. We believe CMS needs to take a more global approach and provide some physician incentives to address this concern without placing the full responsibility on the provider as Medicare moves towards an episode-based payment system. In addition the simultaneous implementation of significant outpatient payment system reform at a time when providers are required to adapt to a new inpatient MS-DRG system places a tremendous burden on limited hospital resources and the quality improvement managers. We would urge CMS to postpone implementation of the seven packaged and bundled service categories and continue the current payment methodology for those service categories in question for a minimum of one year. We believe the above questions and provider risk concerns should be resolved by CMS and national healthcare organizations before the proposed packaging approach payment modifications are implemented.

Issue 2: "Proposed Development of Composite APCs" (FR page 42677)

***Proposed CY 2008 Rule*:** CMS is proposing the development of a composite APC, and a change in the definition of "service" for purposes of payment under OPPS. CMS proposes "to view a service, in some cases, as not just the diagnostic or treatment modality identified by one individual HCPCS code but as the totality of care provided in a hospital outpatient encounter that would be reported with two or more HCPCS codes for component services." As with packaging CMS believes that the payment approach for CY 2008 OPPS needs to create incentives for hospitals to provide services more efficiently than under the current OPPS, especially considering the significant growth in outpatient volume and spending.

Two specific sets of services identified by CMS for composite APCs are:

"Low dose rate (LDR) prostate brachytherapy" and
"Cardiac electrophysiologic evaluation and ablation services"

Response: As discussed in our packaging response, UPMC cannot support the development of composite APC's at this time and urges CMS to withdraw this proposal until the packaging questions and provider risk issues can be resolved.

Section "OPPS: Partial Hospitalization"

Issue 3: Partial Hospitalization (FR page 42691)

Proposed CY 2008 Rule: CMS proposed to adopt for CY 2008 an alternate method for computing the partial hospitalization program (PHP) median per diem costs. Under this new costing method, partial hospitalization per diem payments would drop from its CY 2007 rate of $233.37 to $178.00 in CY 2008. This is a proposed rate reduction of approximately (24%). CMS describes below how they propose to alter their current computation method to arrive at the proposed methodology. They also indicate how they have considered this alternative computation method during the past two years but rejected it because the method for producing median costs were too low to cover the costs of the PHP program which they believed typically spanned 5 to 6 hours. At this time CMS also indicated that over 65% of the CMHC data reflects "low unit days" of 3 or less hours of service and is included in the proposed rate of $178 per day. CMS Proposed methodology states:

> (FR page 42692) – "Our current method for computing per diem costs is as follows: we use data from all hospital bills reporting condition code 41, which identifies the claim as partial hospitalization, and all bills from CMHCs. We use CCRs from the most recently available hospital and CMHC cost reports to convert each provider's line-item charges as reported on bills to estimate the provider's cost for a day of PHP services. Per diem costs are then computed by summing the line-item costs on each bill and dividing by the number of days of PHP care provided on the bill. These computed per diem costs are arrayed from lowest to highest and the middle value of the array is the median per diem cost.
>
> We have developed an alternate way to determine median cost by computing a separate per diem cost for each day rather than for each bill. Under this method, a cost is computed separately for each day of PHP care. When there are multiple days of care entered on a claim, a unique cost is computed for each day of care. All of these costs are then arrayed from lowest to highest and the middle value of the array would be the median per diem cost.
>
> We believe this alternative method of computing a per diem median cost produces a more accurate estimate because each day gets an equal weight towards computing the median. We have considered this alternative method for several years, but in light of the volatility of the data, we have not believed it would provide a reasonable and appropriate median per diem cost. In light of the stabilizing trend in the data, and in light of the robustness of recent data analysis, we now believe it is appropriate to propose the adoption of this method."

Response: UPMC does not support the adoption of this proposed alternative costing methodology for the partial hospitalization per diem rate (APC 0033) and we do not

support the proposed Partial hospitalization rate of $178 per day for CY 2008 for the reasons indicated below:

As CMS has stated above and on various pages of the proposed rule, the volatility of the CMHC cost and charge data and its significant fluctuation over the years places the reliability of the CMHC data in doubt and produces cost levels that are too low to cover the expected PHP program cost per day based on 5 or 6 hours of service. See excerpts below:

> (FR page 42691) – "In the CY 2006 and CY 2007 OPPS updates, the data have produced median costs that we believe were too low to cover the cost of a program that typically spans 5 to 6 hours per day."
>
> (FR page 42690) – "Historically, the median per diem cost for CMHCs greatly exceeded the median per diem cost for hospital-based PHPs and has fluctuated significantly from year to year, while the median per diem cost for hospital-based PHPs has remained relatively constant ($200-$225). We believe that CMHCs may have increased and decreased their charges in response to Medicare payment policies."
>
> (FR page 42692) – "We have considered this alternative method for several years, but in light of the volatility of the data, we have not believed it would provide a reasonable and appropriate median per diem cost."

At this time we still believe the cost projections could be flawed due to inaccurate CMHC data, inappropriate default Cost-to-Charge Ratios (CCRs) or possibly the comparison of half day rates to our full day costs. Currently our internal computations reflect a partial hospitalization program per diem cost of approximately $273.43 per day for our facility; however our programs typically span between 5 and 6 hours per day. The CMS computations indicate significant CMHC "low unit days" of three or less hours per day. In fact CMS indicates that the CMHC data is more than 64% of "low unit days". Assuming the $178 rate is based on approximately 3 hour days, a five hour (or full day) rate should be approximately $296. At this time we urge CMS to consider the following:

1. Establish Partial program per diems for full day (between 4 and 6 hours of care) and for half day (2 to 3 hours for a half day rate), since it is obvious that the majority of CMHCs and many hospital-based programs are not performing the same level of care or treatment that CMS originally expected. If more accuracy is necessary then several rate levels could be established based on the actual treatment hours performed. This would help alleviate the disparity between partial program payments and cost for providers trying to meet Medicare's full day treatment levels of between 4 and 6 hours. We would recommend full day rates of $297 ($178 / 3 * 5 hrs) and half day rates of $178 (based on your current analysis).
2. Withdraw the alternative costing methodology proposal since a large portion of its costs and rates are based on CMHC data which historically has been inconsistent and inaccurate. CMS did not provide any cost / rate data comparing the current or original partial program rate methodology to the proposed alternative

methodology. Instead CMS just reported its alternative methodology using CMHC data which it has rejected for several years as inaccurate due to extreme fluctuations between calendar years. We would urge CMS to exclude the CMHC data from the rate computations as unreliable, and use hospital-based partial program data only, until accurate CMHC PHP data and accurate CCRs are available.

3. Require fiscal intermediaries (FIs) to work with hospitals and CMHC providers to establish separate Partial Hospitalization Program lines on their appropriate Medicare cost reports (i.e. Hospital CMS-2552-96) to arrive at real CCRs for partial hospitalization programs rather than the default Psychiatric, Clinic or overall outpatient CCRs lines currently being used by CMS to estimate partial program costs. We suspect that nationally the cost-to-charge ratios for the partial hospitalization programs are being understated by applying overall CCRs and or clinic CCRs which penalize the most structured, clinically intensive partial programs which generally provide four or more services per day. The need for more accurate CCRs is clearly demonstrated by the repeated cost fluctuation and required use of default cost centers by CMS, in the computation of partial program rates. Therefore it is time the cost report data lines are updated to an adequate detail level. A separate Partial Hospitalization Program cost center should be established.
4. Begin to include CMHC data from the CMS-2088-92 cost reports in the Healthcare Cost Report Information System (HCRIS). The inclusion of this data would provide full transparency for industry review and analysis.
5. Analyze the group psychotherapy APC to better understand the reasons for the decline in the APC rate over the last couple of years.

Our partial hospitalization program and others who are working to provide the most structured, and clinically intensive programming, cannot sustain another 24% payment reduction (as proposed) on top of the 15% and 5% rate reductions taken in the last two years, without a severe service reduction. Cumulatively these rate reductions of 44% leave an inadequate partial payment rate of $178 compared to our current costs of approximately $273. We urge CMS to implement our partial hospitalization program recommendations as noted above so service reductions or program closings will not be necessary. With fewer partial hospitalization programs Medicare would surely face increased inpatient hospitalizations and higher overall Medicare expenditures.

Section: "OPPS: Device-Dependent APCs"

Issue 4: Proposed Payment for Devices when Devices are Replaced with Partial Credit to the Hospital (FR page 42723)

Proposed CY 2008 Rule: CMS has indicated that they believe hospitals should report occurrences of devices being replaced under warranty or when given a partial credit so that CMS may be able to identify systematic failures of devices or device problems

through claims analysis and CMS can make appropriate payment adjustments in these cases. At this time CMS is proposing to establish a new HCPCS "partial credit modifier" to be reported on cases in which the device credit is equal to 20 percent or greater of the cost of the new replacement device. Medicare will then apply a payment reduction of 50 percent of the full offset rate established for select APCs (21) on select HCPC devices (31) for CY 2008.

(Note: The proposed APCs affected by this proposed rule are shown in Table 38 page 42726 and the proposed devices for which the full or partial credit modifiers must apply are shown on Table 39 page 42727).

Response: At this time we urge CMS to withdraw this proposed rule, as it is not always apparent from the manufacture at the time of billing what percentage discount (if any) will be given on a replacement device. In some instances the device has to be returned to the manufacture for examination before any discount decision is made. Other venders make determinations based on unexpired warranty periods. However, the official determination by the manufacturers is not always known or available at the time of surgery or billing.

In addition we believe that any manufacture discount that a hospital would receive would already be included in its annual hospital cost-to-charge- ratios (CCRS) and would already be factored into the annual APC weighting changes. As such we do not believe this proposed rule change is necessary.

Section: "OPPS: Specified Covered Outpatient Drugs"

Issue 5: Proposed Payment for Specified Covered Outpatient Drugs (FR page 42733)

***Proposed CY 2008 Rule*:** CMS indicated their proposal to pay for acquisition and overhead costs of non-pass through separately payable drug and biologicals under the OPPS at ASP + 5 percent for CY 2008, while in CY 2007 and CY 2006 CMS maintained payment rates at ASP + 6 percent.

Response: At this time we do not support your proposal to reduce the drug and biological payment levels below the current ASP + 6 percent, for several reasons. They include:

1. Current calculation problems:
   a. ASP is based on the price that manufacturers charge distributors, including any prompt pay discounts. These prices and discounts often are not passed along to providers but are included in the calculation of the ASP.
   b. ASP is based on sales to all entities, including group purchasing organizations and large hospital systems on one end of the spectrum

and one-physician oncology practices on the other. It means that many hospitals, particularly the smaller ones without purchasing power, will purchase drugs above ASP.

c. There appears to be a two-quarter lag in the calculation of ASP, meaning that reimbursement is based on prices that are six-months old. Since manufacturers typically raise prices two to three times per year, there is potential for hospitals to suffer losses each time they administer drugs. Even as a large volume buyer, UPMC currently pays greater than ASP for many of our most highly utilized drugs and, in some cases, pay greater than ASP + 6%.

2. Inconsistent payment rates across settings. This proposal would result in lower payment for drugs and biologicals provided in hospital outpatient departments (proposed ASP + 5 percent) than for the same drugs and biologicals furnished in a physician office setting (paid ASP + 6 percent). We do not support the proposed hospital rate reduction to a level lower than what is paid to physicians and urge CMS not to reduce payment below the current rate of ASP + 6 percent.

Section "OPPS: Specified Covered Outpatient Drugs"

Issue 6: Pharmacy Overhead Carve out (FR page 42735)

***Proposed CY 2008 Rule*:** CMS has proposed the following pharmacy overhead carve out for FY2008:

> (FR page 42735) "We are proposing to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead charge on an uncoded revenue code line on the claim beginning in CY 2008. This proposed change, from a CY 2007 policy where hospitals include pharmacy overhead in their charges for the drug or biological to a CY 2008 policy of including the pharmacy overhead charges on an uncoded revenue code line, would allow us to package pharmacy overhead costs for drugs and biologicals into payment for the associated procedure, likely a drug administration procedure, in future years when the CY 2008 claims data become available for rate setting. We are proposing to apply this policy to the reporting of charges for all drugs and biologicals, including contrast agents, irrespective of the item's packaged or separately payable status for the CY 2008 OPPS. We are not proposing to apply this policy to the reporting of overhead charges for radiopharmaceuticals given the explicit instructions they gave hospitals beginning in CY 2006 to include the charges for radiopharmaceutical overhead and handling in the charges for the radiopharmaceutical product. This proposal would not change our current policy of packaging payment for pharmacy overhead with payment for another item or service. Rather, in

future years it would only change the types of items or services with which pharmacy overhead is packaged."

Response: We do not support the adoption of the pharmacy overhead charge carve out as proposed for CY 2008 for the following reasons:

- Charge Identification & Capture – There would be an enormous administrative reporting burden on department managers, billing staff and accountants to identify and split the current charge for all drugs and biologicals into two separate charge fees, one for the cost of the drug, another for the pharmacy overhead charge.
- Billing System Updates – Generating a separate, uncoded line item for pharmacy overhead would require significant updates to the current billing system. This change would affect all payers and require software modifications in order to rebundle or roll "pharmacy overhead" back into the drug charge for other payers and would double the size of our drug service lines.
- Create Other Payer Problems – This will create massive confusion and billing problems for all other third-party and secondary payers who would now see all drug and biologicals split into two separate fees (Drug charge" and "pharmacy overhead" as requested by Medicare) plus a third charge for "Drug Administration fee".

We again believe that the adoption of this proposed rule would create more confusion and problems for the beneficiaries and all other third parties and urge that it not be adopted. Instead we would propose a cost report modification to capture the drug and overhead cost separately. A suggested approach could be as follows:

We suggest CMS modify the current hospital cost reports by splitting the "pharmacy" line and "Drugs Sold to Patient" lines into two lines, one line to capture drug costs and the other for all other costs. The line splits could be labeled "Pharmacy - drug costs" and "Pharmacy – All Other Costs" while the Drugs Sold to Patients line could be split as "Drugs Sold to Patients - Drug cost only" and "Drug Sold to Patients – All Other Costs & Overhead". The cost reports could then provide CMS with the proper portion of drug cost versus all other direct and indirect pharmacy overhead costs. CMS or the provider could then pro-rate their Drug charges between these two Drugs Sold to Patients lines to arrive at the overall cost to charge ratios. (Note: While the CCRs would be identical for each of the drugs sold to patient lines, CMS could then use the cost reports to determine the portion of drug costs versus all other pharmacy overhead costs).

We believe cost report modification (with the FI's assistance) is the less complex approach rather than providing CMS with the overall hospitals "drug costs" and "pharmacy overhead" splits that they are trying to collect.

Section "OPPS: Proposed Hospital Coding and Payments for Visits"

Issue 7: Proposed Hospital Coding and Payments for Visits (FR page 42751)

Proposed CY 2008 Rule: CMS has not proposed national visit reporting guidelines for clinic visits or Emergency Room visits in CY 2008, instead CMS is proposing to allow hospitals to continue to use their own internal guidelines for visit reporting. CMS identified six original guiding principles and five additional principles that a provider's internal guidelines on visit reporting should follow. In addition CMS requested provider comments on whether a need for national guidelines still exists or if the current system where hospitals create and apply their own internal guidelines to report visits is more practical and appropriately flexible for hospitals.

CMS also proposed eliminating the five Office consultation HCPCS codes (99241 through 99245) and indicated that providers use the existing new or established patient visit codes to appropriately describe the service provided.

Response: Due to the obvious difficulty in developing a national coding guidance acceptable to most parties from the various E/M coding models, we prefer to keep our own internal guidelines for the reporting of E/M services. As such we do not support any change at this time. We do support the elimination of Office consultations codes as unnecessary and believe the existing office visit codes should suffice.

Section "OPPS: Observation Services"
Issue 8: Observation Services (FR page 42674)

Proposed CY 2008 Rule: CMS has indicated that they believe it is appropriate to package payment for all observation services reported with HCPCS code G0378 "Hospital observation service per hour" into the primary APC service beginning in CY 2008. CMS indicates that observation services are ideal for packaging because they are always provided as a support service in conjunction with other independent separately payable hospital outpatient services such as emergency department visit, surgical procedure, or another separately payable service.

Response: We do not support the CMS proposal to package "all observation services" into the medical condition with which it was provided. We believe that the previous approach utilized by CMS during CY 2007 was the correct approach. That approach recognized:

- Medicare beneficiaries must have access to medically necessary observation care.
- Observation payments made only for beneficiaries actually receiving observation care services.

- Observation care payment is restricted to clinically appropriate observation care.
- Observation is limited to medical conditions which would benefit from the observation care by avoiding significant morbidity and mortality issues by an inappropriate discharge to home while at the same time avoiding unnecessary inpatient admissions.
- Establishment of additional criteria, tests, physician determinations, minimum and maximum hours of observation.
- Establishment of Outpatient Claim Edit (OCE) logic to recognize all required elements for separate payment processing and to recognize required packaging criteria.
- Observation services are generally performed on all patients after a surgical procedure and for that reason observation services were properly recognized as packaged for that surgical procedure.

As can be seen above, the previous approach recognized that some observation care was appropriate for separate payment as determined from clinical and financial analysis in prior years for specific Medicare patient populations. However the current proposal to package "all observation services" as part of other APC payments clearly overpays some claims for services not received and underpays other claims for observation services that were received. In addition, we believe this packaging approach could lead to many more inpatient admissions for patients with chest pain, congestive heart failure or asthma. It might also place some patients at higher risk if they are discharged to home earlier than would have occurred under the previous payment methodology. For these reasons we would urge CMS to maintain the current observations payment process and not package "All observation services" as proposed.

Section: "Quality Data"

Issue 9: Proposed Hospital Outpatient Measures – Five Emergency Department (ED) AMI Measures (FR page 42800)

***Proposed CY 2008 Rule*:** CMS proposes to establish a separate Hospital Outpatient Quality Data reporting program (HOP QDRP) and is proposing ten quality measures that are appropriate for measuring hospital outpatient quality of care. These ten measures reflect consensus among affected parties, and are set forth by one or more of the national consensus building entities. Five measures relate to Emergency Department (ED) and five others relate to hospital outpatient settings.

Response: UPMC suggests that a separate reporting system for hospital based outpatient services will add costs to the total infrastructure as new systems and resources will need to be hired to train to take on this new responsibility. In addition we believe there are no approved outpatient vendors of choice, with functional

reporting systems, as ORYX is still evaluating their participation. This is leaving hospitals in a difficult position with little time for resolution. We do have an existing system for collecting and reporting inpatient measures to CMS with trained personnel and we encourage CMS to consider utilizing the existing infrastructure to save valuable hospital resources particularly for the Emergency Department (ED) measures proposed as the medical records for outpatients in the ED have the same processes for review and abstraction as the inpatient records. While this is a possibility for ED measures we would still need additional staff and resources for this option.

Issue 10: Proposed Hospital Outpatient Measures – Five Additional Non-Emergency Department AMI Measures (FR page 42800)

Proposed CY 2008 Rule: CMS has also proposed 5 additional quality measures (beyond the ED measures) for hospital outpatient clinic settings.

Response: These five additional (non-ED) measures will be a burden in terms of cost and the time to implement and train on the methods and systems required to collect and submit information. We encourage CMS to consider delaying these 5 (of the total 10) measures until a system for collecting and reporting can be evaluated and existing electronic systems can be modified to collect this data as a by-product of the care process. Hospital based clinics have much less of a medical records infrastructure and staff, and taking on additional abstraction and systems work, which has not yet been clearly defined could be problematic. UPMC urges a delay in the reporting of these outpatient non-ED quality measures to allow for appropriate planning and for national testing. CMS proposed a very aggressive timeline to implement a new data collection process for the outpatient setting. We believe the development of a new data collection mechanism where there is not a process currently in place will be very costly. UPMC suggests a three year phase-in approach allowing sufficient time for the ambulatory measures to be collected.

Issue 11: Thirty Additional Hospital Outpatient Measures for Subsequent Years (FR page 42801)

***Proposed CY 2008 Rule*:** CMS is seeking public comment on thirty additional measures, beyond the 10 measures identified above. These measures are being considered for use in assessing the care of services provided by hospital outpatient settings, for the determination of CY 2010 and subsequent calendar year payments.

Response: UPMC encourages CMS to consider the lack of operational outpatient data collection processes, at this time. Premature requests for more outpatient measures before processes can be established and functional should not be considered. Organizations with only manual processes and records will have a very challenging time and will incur additional costs to find the appropriate cases to perform chart review for multiple measures, reviewing inclusion and exclusion

criteria and evaluating other factors in the chart. For example, to identify a medication reconciliation measure, the rule proposes that the measure is the "Percentage of patients aged 65 and older discharged from any inpatient facility and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medications list in the medical record documented". While this may be a very good clinical measure, the logistics of the data collection may be better suited once a more mature electronic environment exists across care continuum. UPMC does not believe these additional measurements should be considered at this time due to the unresolved collection and reporting problems discussed above.

Issue 12: Diabetes Care Outcome Measurement (FR page 42800)

***Proposed CY 2008 Rule*:** CMS requests comments on their rationale for choosing a diabetes outcome measure.

Response: UPMC believes the diabetes measure is difficult for providers due to the socio-economic status of many of our patients and their inability or unwillingness to adhere to the prescribed care. Providers should not be held accountable for diabetic patients who are not being treated for primary care and are only receiving specialty care from other clinics.

Conclusion

We appreciate the opportunity to submit these comments on your proposed changes on the "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY2008 Payment Rates...Proposed Rule" and hope they are considered before any final rules are published.

If you have any questions regarding our comments please telephone Paul Stimmel at (412) 623-6719.

Sincerely,

Ed Karlovich (ee)

Edward Karlovich
Chief Financial Officer
Academic and Community Hospitals

CC: Lewandowski, C.
Stimmel, P.
System CFO's

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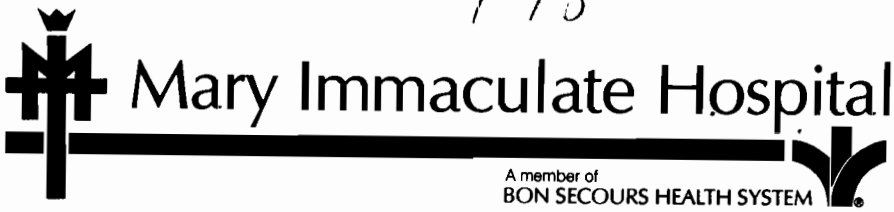

September 7, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and CY 2008 Payment Rates

Dear Mr. Kuhn,

On behalf of Mary Immaculate Hospital, I welcome the opportunity to comment on the August 2, 2007 proposed OPPS rule. Mary Immaculate is a 110-bed acute-care medical center located in Newport News, VA. Our Emergency Department cares for over 35,000 patient encounters annually.

Our comments address the proposed packaging of observation services, and other proposed changes affecting hospital observation services. Also, these comments focus on coding for payment of Emergency Department and clinic visits, including national guidelines for the coding of these visits.

OPPS: Observation Services

CMS proposes to package payment for CY 2008, including all observation care reported under HCPCS code G0378 (hospital observation services, per hour); payment would be packaged as part of the payment for the separately payable services with which the observation service is billed.

We oppose the proposed packaging of observation services for chest pain, congestive heart failure and asthma. The costs and resource utilization for such patients are obviously much higher than those for patients requiring only a given level of Emergency Department visit service. Patients requiring observation care for the three conditions in question have a higher acuity and their length of stay is prolonged. Further, our hospital which specializes in the care of patients with cardiac problems and/or asthma would find themselves severely disadvantaged under the proposed packaging because the costs they incur in providing observation services for patients with these conditions would not be adequately covered if not paid separately. **In summary, we urge CMS to maintain separate payment for observation services provided to patients with chest pain, congestive heart failure and asthma.**

In light of its proposed packaging of all observation services, CMS concludes that there is no need to accept the Ambulatory Payment Classification (APC) Panel's recommendations to add two diagnoses (syncope and dehydration) to the list of diagnoses for which observation care would be separately payable or consider other possible additions. **We urge CMS to reconsider the APC Panel's recommendations with respect to syncope and dehydration. We also encourage CMS to consider the potential need to add other conditions to the list in the future.**

2 Bernardine Drive, Newport News, Virginia 23602-4499 757/886-6000 Fax 757/886-6751

Mary Immaculate Hospital
A member of CHESAPEAKE HEALTH SYSTEM

OPPS: Hospital Coding and Payments for Visits

We are very satisfied with a **problem-based** facility coding approach and therefore analyzed the August 2, 2007 CMS OPPS proposal with great care.

Our currently implemented **problem-based** approach results in a visit level distribution reflecting resource use. Consistent results demonstrated across our outpatient and Emergency Department settings speaks to the standardized characteristics of the problem-based approach.

Our current problem-based approach is easy to learn and simple to use. The ease of use is demonstrated by the fact that the system methodology is consistent despite multi-level use by RNs, coders and department clerks.

Despite our satisfaction with our current problem based approach, we continue to support the development and implementation of national coding guidelines for outpatient services. There is a need for standardization and consistency in the definition and reporting of facility resource utilization. With the absence of national guidelines, there are many different types of guidelines in use by multiple entities. For example, we are seeing an emerging trend for payers to develop their own coding/audit guidelines and apply them to services coded using other methodologies. If this trend continues, hospitals will have to develop payer specific guidelines to meet each payer's specific compliance expectations. This will pose an administrative burden to hospitals and companies providing coding services to multiple entities. National guidelines could undoubtedly provide a means for addressing this problem.

We appreciate the opportunity to provide comments and do hope that these comments will be reflected upon in depth and considered with the weight and importance they deserve.

Sincerely,

Valerie Sommer, RN
ED Nurse Manager
Mary Immaculate Hospital
2 Bernardine Dr.
Newport News, VA. 23602

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Arizona Hospital and Healthcare Association

September 11, 2007

Mr. Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital OPPS and CY 2008 Payment Rates

Dear Mr. Kuhn,

Thank you for the opportunity to comment on the proposed outpatient prospective payment system (OPPS) rule for CY 2008. I submit these comments on behalf of the Arizona Hospital and Healthcare Association (AzHHA). AzHHA and its members are concerned about the negative several of the proposed provisions will have on the ability of hospitals to care for Medicare beneficiaries. These provisions include: (1) changes to the Critical Access Hospital Conditions of Participation; (2) changes to cardiac rehabilitation billing; (3) payment for medical devices; (4) observation services; and (5) payment for drugs and biologicals.

Critical Access Hospital Medicare Conditions of Participation

One and half million Arizonans who reside in rural areas of the state receive healthcare services from approximately twenty-five sole community and critical access hospitals (CAHs), exclusive of tribal and Indian Health Service facilities. These services are spread over nearly 100,000 square miles. Because of the large distances between Arizona's rural healthcare providers, this population is particularly vulnerable to reductions in services. For this reason, it is imperative that the Centers for Medicare and Medicaid Services (CMS) continue to support the services provided by CAHs and not place these hospitals in jeopardy. To our dismay, this is exactly what the proposed CY 2008 OPPS changes would do.

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www.azhha.org

Under the proposed regulation, a CAH-operated provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008 must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). If a necessary provider CAH violates this requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

Because access to primary care is particularly limited in rural Arizona, 55 areas have been designated as primary care health services shortage areas, 33 of which have a score of greater than 14. Arizona CAHs have responded to the needs of their communities by providing -- in many cases -- the only primary care available. Under Arizona law, these primary care clinics are licensed as outpatient treatment centers (OTCs) and operate federally as rural health clinics (RHCs). Without the provision of these primary care and other OTC services, Medicare beneficiaries in rural Arizona would be required to travel many miles to receive treatment, placing their health at risk.

The changes proposed by the CY 2008 OPPS regulation will negatively impact Medicare beneficiaries by disincentivizing CAHs from building or replacing necessary satellite facilities. While it appears the intent of CMS is to address market saturation and infringement with respect to necessary provider CAHs, the regulations may have unintended consequences. At this point it is not clear whether the regulation applies to RHCs, whether it applies to on-campus clinics of a necessary provider CAH, and whether all CAHs are subject to the regulation, if they open up a clinic within 35/15 miles of another hospital.

We strongly urge CMS to eliminate the CAH provider-based facility restrictions of the proposed regulation or alternatively clarify that these do not apply to RHC, on-site facilities or non-necessary provider CAHs.

Cardiac Rehabilitation

CMS proposes billing cardiac rehabilitation services in hourly increments, as opposed to the current per session increments utilized since the mid-1980s. The current CPT codes will be replaced by G codes representing one hour of service. We are specifically concerned that the descriptor used for the new G codes, "Physician service, cardiac rehab with (and without) ECG monitoring," could be

misinterpreted by Medicare contractors as requiring a physician to directly deliver the care or be in attendance during each service episode. Medicare administrative contractors and fiscal intermediaries could use this interpretation to develop restrictive policies requiring the physical attendance of a physician during the delivery of care, similar to requirements imposed by Medicare in the past, and which have been recently revised.

AzHHA is also concerned with the implementation costs that providers could incur. Many hospitals' billing software only facilitates the creation of one set of billing parameters for each procedure. Because many managed care payers will not accept Medicare's G codes or hourly billing, but will continue to require providers to report per session with CPT codes, hospitals will need to bill Medicare differently than other payers. This could result in the need to manually change claims before billing and increase the likelihood of billing errors, potentially causing problems with denials from secondary payers who do not model CMS billing practices.

We urge CMS to clarify that the proposed regulations does not require the physical attendance of a physician during the delivery of care. In addition, we urge CMS to consider an alternative to changing billing regulations solely for the purpose of gathering informational data when the current method has been in place for such a long time and has remained stable and reliable.

Payment for Medical Devices

CMS proposes a reduction in APC payment and beneficiary co-payment when hospitals receive a partial credit toward the replacement of a medical device listed in Table 39 of the proposed rule. Payments for these APCs would be reduced by half of the amount of the offset that would apply if the device were replaced at no cost or with full credit. This policy would apply only if the amount of the device credit is at least 20 percent of the cost of the new replacement device.

In its summary statement of the rule, CMS argues that "this policy is necessary to pay equitably for these services when the hospital receives a partial credit for the cost of the device being implanted." AzHHA strongly disagrees with the statement that this rule would "pay equitably" for services. Although this change would positively impact Medicare and possibly some providers, it would be detrimental to providers who typically receive a large number of cases with credits ranging near 20 percent.

Moreover, there is virtually no data available to providers regarding the number of devices this rule could affect annually. Providers are unable to compare their own data with national averages to identify areas with higher frequencies of device failure or other discernable negative patterns, which could potentially help providers choose a device that would be beneficial for the patient and cost effective on a long term basis.

We are also concerned about the different reporting requirements for outpatient and inpatient device credits. The rule proposes partial credits of 50 percent or greater for inpatient devices and partial credits of 20 percent or greater for outpatient devices. Creating a system to identify credits correctly according to patient type will be operationally difficult. Among our concerns is the risk for reporting errors due to differences in the minimum percentage of credit required to be reported based on patient type. There is little time to evaluate and modify current systems used for implementation of the full device/no cost rule instituted for the CY 2007 OPPS.

We urge CMS to publish any data specific to the number of cases reported nationally since the 2007 rule became final, to consider increasing the OPPS final rule to equal the inpatient rule of reporting reduced costs of 50 percent or greater with the FB modifier for CY2008, and to evaluate the effects of this change before instituting the 20 percent requirement.

Observation Services

CMS proposes packaging payment for all observation care, reported under HCPCS code G0378 (Hospital observation services, per hour), into the separately payable services with which they are billed. CMS believes packaging observation services would help address its concerns about increased OPPS spending. CMS has also expressed concern that the current criteria for separate payment for observation services, which requires that observation services must last a minimum of 8 hours, provides disincentives to hospitals to make timely decisions with regard to patients' placement after observation care ends. CMS believes that packaging would contribute to more efficient use of observation services and improve the flow of patients through emergency departments.

While AzHHA understands CMS' concern with billing under observation code G0378 and the desire for more efficiency, we disagree with the decision to package all observation services provided under HCPCS code G0378. There are many patients who meet the guidelines for continuous observation monitoring, and for whom hospitals will receive reduced payments for their care and treatment.

AzHHA urges CMS to reconsider its decision to institute packaging of observation in cases of care extended beyond 24 hours for patients who do not meet Interqual criteria for inpatient admission, but who continue to exhibit symptoms which could be associated with a life threatening condition that would prevent the hospital from safely discharging the patient.

Payment for Drugs and Biologicals

CMS proposes that hospitals report pharmacy overhead charges to provide data for possible future payment changes. Hospitals would be required to remove the overhead cost from the price charged for drugs and biologicals and report it on a separate revenue code line. The policy would apply to all drugs, biologicals, and contrast agents irrespective of the item's packaged or separately payable status for CY 2008.

AzHHA is concerned about the requirement to report overhead as an uncoded revenue code line. We request CMS to clarify the meaning of "un-coded revenue code line." Does CMS intend providers to bill with two separate lines on the UB04 for "each medication", "total overhead" per claim, or "total overhead per day" for claims with multiple dates of service? Billing multiple lines could create claims with several pages just for pharmacy for Medicare outpatients who receive multiple medications that span several dates of service. This also presents the issue that most billing software is limited in the number of billable lines per claim. Additionally, hospital's Charge Description Masters (CDM) would need to reflect these changes in reporting overhead costs, requiring that each charge in the CDM with associated overhead would have to be modified to comply with the two line requirement. Considering the size of these areas, this would also be a large undertaking for completion before the 2008 implementation.

AzHHA urges CMS to eliminate the proposed reporting requirements for pharmacy overhead charges or alternatively delay implementation so that hospitals have time to put appropriate systems in place.

Conclusion

In summary, AzHHA commends CMS for their efforts to provide accurate claims payments to providers and supports CMS in reducing Medicare spending identified as incorrect or wasteful. But we urge CMS to further consider the implications of making the proposed changes. The number of changes in this rulemaking, including the recalculated wage index, restructured APC payments, packaged services, additional bundled procedures, and quality reporting requirements would result in a 2 percent market basket reduction for CY2009 for those providers who fail to comply. Additionally, we are concerned with the limited amount of time providers will have to implement and evaluate the needed modifications prior to the January 1 effective date. Several Arizona hospitals have conferred with vendors and operational system directors and determined that completing modifications to meet CMS' requirements would be very difficult and would leave little time for testing prior to implementation. They also project significant additional labor costs related to the changes.

We urge CMS to consider the complicated modifications and the financial cost the proposed rule could cause providers and their ability to continue to provide patient care in compliance with CMS standards. We further ask CMS to reconsider proposing all of the proposed changes for CY2008 with effective dates of January 1st, and to allow providers more time to complete modifications, upgrade systems, and implement and evaluate processes that will ensure their ability to comply with Federal Standards.

We appreciate the opportunity to comment on the proposed rule. If you have any questions or would like further information regarding our comments, please call me.

Sincerely,

John R. Rivers, FACHE
President and Chief Executive Officer

Kentucky
Rural Health Association
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September 13, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Dept of Health and Human Services
Attn: CMS-1392-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Weems:

CMS proposes to clarify that if a CAH operates a provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). CMS believes that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. In the case of a necessary provider CAH that violates the proposed requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

Further, CMS' proposal will have detrimental effects on all CAHs, not just necessary provider CAHs. Two CAHs could be 40 miles apart, but their provider-based entities could be within 20 miles of the other hospital in a town midway in between the CAHs. This rule would prevent either hospital from serving this town through a provider-based entity.

This regulation is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Moreover, CMS' policy would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas.

As the President and CEO of the Kentucky Rural Health Association, I appreciate your consideration of this matter.

Sincerely,

Susan Starling

Susan Starling, President
KRHA

SS/rm

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Redlands Community Hospital

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P.O. Box 3391
Redlands, CA 92373-0742
909-335-5500
Fax 909-335-6497

September 13, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir:

I am writing you today in opposition to the proposed revisions and policy changes to the hospital outpatient prospective payment system (OPPS). Number one issue that is of particular concern to Redlands Community Hospital is the policy and payment changes to reimbursement for partial hospitalization programs (PHP.)

Hospital based PHP have provided more services per day when compared to community mental health centers (CMHC.) Assumptions that were made during a CMS survey in CY 2008 analysis were inaccurate. In fact in 66% of the time, more than four services were provided per day unlike CMHS where these services were provided only 34% of the time.

We take our job of caring for our psychiatric patients, often time our most vulnerable patients, very seriously. Any changes to policies or rate could have a negative impact on patients by placing a financial strain on an area in healthcare that is already under-funded and under-valued when it comes to the positive life changing results of such care.

Under the proposed rules, we could see a reduction of reimbursements by nearly 25% or a loss of over $140,000. This type of substantial hit to an important community health program could have a catastrophic effect on the ability of the hospital to continue providing these services to some of our most needy patients.

I urge you to reconsider the proposed revisions and policy changes to the OPPS program.

Yours truly,

James R. Holmes
President/CEO

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MARCUM
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September 13, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Dept of Health and Human Services
Attn: CMS-1392-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Weems:

CMS proposes to clarify that if a CAH operates a provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). CMS believes that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. In the case of a necessary provider CAH that violates the proposed requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

Further, CMS' proposal will have detrimental effects on all CAHs, not just necessary provider CAHs. Two CAHs could be 40 miles apart, but their provider-based entities could be within 20 miles of the other hospital in a town midway in between the CAHs. This rule would prevent either hospital from serving this town through a provider-based entity.

Our goal is to develop an after hours clinic in a poor and underserved county. This area has 27% of its residents living below the poverty level and they do not have a hospital. The CMS regulation will prevent us from being able to provide a Provider Based Rural Health Clinic (PBRHC). This proposal is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Moreover, CMS' policy would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas.

As the President and CEO of Marcum and Wallace Memorial Hospital, I appreciated your consideration of this matter.

Sincerely,

Susan Starling
President/CEO

Timothy Ravenscroft
President
Tel 978.671.8100 Fax 978.436.7521 timothy.ravenscroft@bms.com

September 12, 2007 153 cc: Herbert Kuhn

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS – 1392 – P
Comments on CMS Proposed Rule on Hospital Outpatient Prospective Payment System for 2008

HOPPS: Payment for Diagnostic Radiopharmaceuticals (RPs) and Nuclear Medicine APCs

Dear Mr. Weems:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to comment on the radiopharmaceutical (RP) and nuclear medicine sections of the proposed rule on the Medicare hospital outpatient prospective payment system (HOPPS) for 2008. 72 Fed. Reg. 42,628 (August 2, 2007). BMSMI is one of the largest manufacturers of RPs in the United States and its products include radiopharmaceuticals for cardiac, neurologic, pulmonary, and other diagnostic imaging procedures important for Medicare patients.

The Centers for Medicare and Medicaid Services (CMS) has proposed very significant 2008 changes in payment for diagnostic RPs that could have an adverse impact on the quality of care for Medicare patients. CMS's proposed changes may over-pay for some products, under-pay other RPs, and could create improper financial incentives for hospitals and physicians to reprioritize patients' clinical needs, select the cheapest priced RP, which could result in lower quality care. Below, we provide a summary of our comments and recommendations, followed by a more detailed analysis.

A. Summary

1. CMS should consider continuing to pay for diagnostic radiopharmaceuticals (RPs) separately from the nuclear medicine procedures.

2. For 2008, payment for diagnostic RPs should be based on CMS's paid claims data with edits/trims that remove inaccurate data for RPs. Such payment should be based on mean calculated cost, consistent with CMS standard methods using CMS's paid claims data from hospitals. CMS could adjust that payment with an add-on for overhead and pharmacy handling costs, to achieve payment that accurately reflects the average acquisition cost.

Bristol-Myers Squibb Medical Imaging 331 Treble Cove Road North Billerica MA 01862 Tel 800.362.2668 www.bmsmi.com

3. Separate payment for diagnostic RPs will ensure that physicians select the radiopharmaceutical that best meets the patients' medical needs and will support high quality care and access by Medicare beneficiaries.

4. Separate payment will also ensure that Medicare payments in the hospital outpatient setting for Cardiolite®, (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) and other diagnostic RPs and nuclear medicine procedures are consistent with statutory standards and preserve resource and clinical homogeneity in the APCs.

5. Moreover, in 2008, CMS should consider paying for the highest priced therapeutic radiopharmaceuticals using estimated average acquisition cost (EAAC), as reported by the manufacturer of the specific radiopharmaceutical. In 2009, CMS should consider extending an EAAC method to all therapeutic and diagnostic radiopharmaceuticals.

6. New radiopharmaceuticals should also qualify as new drugs eligible for pass-through payment. Pass-through payment for these new radiopharmaceuticals should be based on established Medicare payment standards, (e.g., Average Wholesale Price) and following completion of the pass-through payment, CMS could use mean calculated cost, edited hospital claims data, EAAC, and consider external cost data, including survey data, to correct for any potential charge compression.

7. CMS should edit hospital reported claims data to ensure that any claims used for nuclear medicine procedure APC or radiopharmaceutical APC rate setting are accurate.

B. Detailed Analysis

1. Problems with CMS's Proposal to Package Diagnostic Radiopharmaceuticals

BMSMI believes there are significant policy, data, and legal challenges with CMS's proposal to package payment for diagnostic radiopharmaceuticals into the payment for nuclear medicine procedure APCs. First, there are radiopharmaceuticals with different clinical and cost features that CMS intends to pay under the same APC. This will overpay some products and underpay others. Packaging radiopharmaceuticals creates serious financial barriers for hospitals and physicians that could block the selection of radiopharmaceuticals based on the patients' clinical needs.

For example, BMSMI makes Cardiolite® (A9500 technetium Tc99m sestamibi), which is one of three different radiopharmaceuticals proposed to be bundled into APCs 398 and 377 (Level I Cardiac Imaging at $346 and Level II/III Cardiac Imaging – at $765.25).

-- Varying product prices can lead to a lack of homogeneity

As noted in the chart below, there are three quite different radiopharmaceuticals with varying prices that CMS proposes to bundle into two APCs. Please note that these three RPs are different chemical entities and there are significant differences in the FDA-approved clinical indications for these RPs.

HCPCS	Descriptor	2006 Mean Unit Cost[1]
A9500	Technetium sestamibi	$84.97/dose
A9503	Technetium tetrofosmin	$74.20/dose
A9505	Thallium	$25.76/mCi or approx. $100 per patient test assuming 3.8 mCi dose

Physicians and/or hospital outpatient departments may select combinations of myocardial perfusion radiopharmaceuticals that could vary in cost from $75 to $170, per myocardial imaging procedure. Paying separately for the radiopharmaceutical preserves the resource and clinical homogeneity in the procedure APCs.

BMSMI also manufactures Neurolite®, (A9557 technetium Tc99m bicisate) with 2006 unit cost of $270. CMS proposes to bundle this radiopharmaceutical into APCs 403 and 402, with proposed payment levels of $212 and $563. Clearly, these APC payment levels for the procedures do not adequately account for the cost of the radiopharmaceutical.

2. CMS Packaging of Add-on Procedures Exacerbates Problems

CMS is also proposing to bundle certain cardiac add-on procedures in cardiac imaging: (78478 – heart wall motion, 78480 – heart function add-on, and 78496 – heart first pass add-on) into APC 377. The selection of add-on procedures can trigger widely varying resource costs and may undermine the clinical and resource homogeneity of the nuclear medicine APCs, especially the cardiac imaging APCs.

3. Flaws in Restructured Cardiac Imaging APCs

CMS is also proposing to restructure Level I Cardiac Imaging so that it would contain 14 procedures that differ widely clinically and in terms of resources. This Level I Cardiac Imaging APC would have all radiopharmaceutical costs packaged. Keeping separate payment for radiopharmaceuticals would contribute to an APC that was clinically homogenous and similar with respect to resources, as the statute requires (See Social Security Act, section 1833(t)(2)(B).

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1 See CMS Tables 3 and 4, Radiopharmaceuticals With a Mean Unit Cost Increase/Decrease between 2005 and 2006, presented by CMS to APC Advisory Panel Meeting (March 7, 2007).

4. No Authority to Bundle/Package Radiopharmaceuticals

CMS proposes to bundle/package diagnostic radiopharmaceuticals suggesting that they are "supplies". FDA regulates radiopharmaceuticals as drugs. Equally if not more important, the Medicare HOPPS statute consistently recognizes all radiopharmaceuticals as drugs and specified covered outpatient drugs. See, for example, Social Security Act section 1833(t)(14)(B). Under this authority, CMS has treated radiopharmaceuticals as drugs for reimbursement under HOPPS. CMS does not have the authority to differentiate radiopharmaceuticals from other drugs and bundle diagnostic radiopharmaceuticals into the procedure APC merely based on the characterization that they are supplies. Radiopharmaceuticals, including diagnostic radiopharmaceuticals, qualify as "specified covered outpatient drugs" (SCODs) and should be covered separately and paid consistently with the statutory standard for average acquisition cost, and accounting for the unique overhead/pharmacy handling costs needed to provide radiopharmaceuticals safely.

5. Packaging Violates Two-Times Rule

Packaging of all the various cardiac imaging radiopharmaceuticals and add-on procedures would, in our opinion, violate the "two-times" rule. CMS has moved all the CPT codes previously in Level II and Level III Cardiac Imaging (except CPT 78465) into Level I Cardiac Imaging. CMS has essentially created a new Level II Cardiac Imaging APC, with a proposed payment level of $765.25, containing only one primary procedure (CPT 78465 – Myocardial perfusion imaging; tomographic (SPECT), multiple studies (including attenuation correction when performed), at rest or stress (exercise and/or pharmacologic), with or without quantification). This Level II Cardiac Imaging APC is intended to pay for various combinations of primary and add-on procedures, radiopharmaceuticals, and cardiac stress agents.

Different combinations of add-on procedures can be performed. Packaging all the radiopharmaceuticals (at low and high costs) and add-on procedures into the same APC would trigger widely varying resources that violate the "two-times" rule. A "simple" myocardial SPECT procedure, done with thallium and no add-on procedures, would use significantly lower resources, compared to a "complex" myocardial SPECT procedure with Cardiolite® and multiple add-on procedures. In like fashion, the consolidation of all the remaining cardiac imaging procedures from two into one APC (Level I Cardiac Imaging) "force-fits" many different procedures with widely varying resources into one payment level. Comparing the resources of the different procedures in the proposed consolidated cardiac imaging APCs clearly demonstrates a violation of the "two-times" rule. Further, we do not believe this is a justification or explanation for exempting this APC from the "two-times" standard. Retaining separate payment for radiopharmaceuticals would contribute to more uniform and homogeneous resources in the newly configured APCs.

6. Recent changes not yet in effect – loss of data

CMS has recently implemented (2007 will be the first full year) distinct revenue codes for diagnostic and therapeutic radiopharmaceuticals. Hospitals have not yet fully implemented these revenue codes into billing practices. The payment for radiopharmaceuticals as a packaged unit risks the hospitals abandoning separate charging for these drugs. That, in turn, can lead to loss of key data about radiopharmaceuticals and fundamentally inaccurate data for

purposes of further weighting and payment adjustments. Deficient data could trigger improperly low payment and barriers to appropriate use. Packaging under these circumstances may not only be problematic but perhaps also premature.

7. Improper incentives

Packaging could most likely create unforeseen and unwanted financial incentives so that hospitals could select a specific radiopharmaceutical based on lowest cost rather than selecting the product that produces high quality care and is clinically most appropriate for the patient's particular medical needs.

With separate payment for each diagnostic radiopharmaceutical, physicians and hospitals choose the radiopharmaceutical that makes the most clinical sense. Packaging triggers a heightened sensitivity to product payment differences, which would not be consistent with quality care.

8. Edits to Hospital Claims Data

On September 6, 2007, the APC Advisory Panel recommended that CMS implement special edits to hospital claims data for nuclear medicine procedures and radiopharmaceuticals. BMSMI supports this recommendation. One specific edit would be to put CPT code 83017 on the by-pass list. This would correct methodological and data flaws that are resulting in improper payment for cardiac imaging APCs. Cardiac imaging often requires multiple procedures. Multiple procedure data are being lost and thus values for cardiac imaging are undervalued.

C. Recommendations

1. CMS should continue to pay separately for diagnostic radiopharmaceuticals, including Cardiolite®, and other myocardial perfusion imaging agents.

2. In 2008, payment for Cardiolite® and other myocardial perfusion imaging agents should be based on mean calculated costs from CMS's paid claims data and with any edits or trims in that data to remove inaccurate hospital data. CMS should adjust those payment amounts to include an appropriate amount covering the unique overhead and handling costs for safe preparation, administration and disposal of radioactive isotopes. This will be the most accurate proxy for hospital average acquisition costs, the statutory standard.

3. In 2008, CMS should also begin to accept from the manufacturers of high priced therapeutic radiopharmaceuticals an estimated average acquisition cost (EAAC). Since radiopharmaceutical manufacturers do not have average sales prices (ASP), manufacturers should begin a new process of estimating the acquisition cost, and reporting this amount to CMS as a basis for payment. Looking ahead to 2009, as the methods for estimating EAAC for radiopharmaceuticals are better developed, this method could be expanded for other radiopharmaceuticals, including diagnostic radiopharmaceuticals. We strongly urge CMS that since such estimates do not have the same precision as conventional ASP calculations, that manufacturers only be

held to an appropriate standard (for example: reasonable efforts to accurately estimate) for such EAAC reporting.

4. CMS should apply similar hospital billing standards to radiopharmaceuticals that are required for other drugs. That is, hospitals should be required to separately report the charge for the radiopharmaceutical, and also pharmacy overhead, and handling costs, as part of the RP charge. This will enable CMS to develop accurate data and appropriate payment for handling costs. MedPAC established that radiopharmaceuticals have the highest overhead costs, and CMS data do not yet capture nor pay for radiopharmaceutical overhead and handling costs.

BMSMI strongly encourages CMS to adopt the recommendations made above. In so doing, HOPPS payment will better support high quality care for Medicare beneficiaries. We would welcome the opportunity to discuss these recommendations in greater detail. Should you have any questions, please contact Jack Slosky, Ph.D., FASNC, at jack.slosky@bms.com or (978) 671-8191.

Thank you for your consideration.

Sincerely,

T Ravenscroft

Timothy Ravenscroft
President
Bristol-Myers Squibb Medical Imaging

Cc: Herbert B. Kuhn
Carol Bazell, M.D. (CMS)
American College of Cardiology
American College of Radiology
American Society of Nuclear Cardiology
Council on Radionuclides & Radiopharmaceuticals
Nuclear Medicine APC Task Force
Society of Nuclear Medicine

C. CRAIG KARRASCH, D.P.M., F.A.C.F.A.S.
Podiatric Medicine, Foot Surgery
- Sports Medicine -

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Diplomate, American Board of Podiatric Surgery
Diplomate, American Board of Podiatric Orthopedics
Fellow American College of Foot and Ankle Surgeons
Fellow American College of Foot Orthopedists

September 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

RE: **Comments on CMS-1392-P; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (High-Energy Extracorporeal Shock Wave Therapy).**

To Whom It May Concern:

As a physician providing High Energy Extracorporeal Shock Wave Technology (ESWT) to my patients with Plantar Fasciitis in a surgical facility, I am writing to urge the Center for Medicare Services **not** to adopt the proposed Payment Indicator for High-Energy ESWT. Although the final rule on ambulatory surgery center payments recognizes the appropriate site of service as a facility setting, the proposed 2008 payment schedule suggests that the procedure should be performed mostly in the physician office setting. An ambulatory surgical center is my preferred location to perform this procedure. Further, unless the appropriate payment indicator is recognized, Medicare beneficiaries will be denied access to meaningful and effective treatment. Therefore, I request the agency retain the Payment Indicator ("G2") for CPT code 28890, as published in the final 2008 ASC rule.

Moving CPT Code 28890 to Payment indicator "P3" will reduce payment to such a level that the ASCs will not be able to offer this procedure, effectively denying Medicare beneficiaries access to this effective treatment at this important site of service. As a result, a less effective or more costly option will have to be used to treat these patients. I would like to ensure my patients are treated with the best possible option in the most appropriate setting.

Patients being treated with this procedure requires an anesthetic other than a local; preferably a general to receive its maximum efficacy & safety. This alone, added to the fact that many Medicare patients have coexisting conditions that need monitoring, should let you know the appropriate place for ESWT to be done is in either a hospital outpatient suite or an ASC.

Thank you for your consideration in this matter,

C Craig Karrasch DPM FACFAS

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