

American Burn Association
White Paper

**Surgical Management
of the Burn Wound and
Use of Skin Substitutes**

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About the American Burn Association

The American Burn Association (ABA) and its members dedicate their efforts and resources to promoting and supporting burn-related research, education, care, rehabilitation and prevention. The ABA has over 3,500 members in the United States, Canada, Europe, Asia and Latin America. Members include physicians, nurses, occupational and physical therapists, researchers, social workers, firefighters, and hospitals with burn centers. The American Burn Association was founded in 1967, following a series of national burn seminars sponsored by leading institutions in the field of burn treatment. The ABA sponsors educational programs, fellowships, research, teaching and publications, including the leading peer-reviewed, scientific journal in the burn field, the *Journal of Burn Care and Research* (Richard L. Gamelli, MD, FACS – Editor-in-Chief).

Mission Statement

The American Burn Association is dedicated to improving the lives of everyone affected by burn injury through patient care, education, research and advocacy.

Structure and Governance

The ABA is governed by a Board of Trustees consisting of 14 members who are elected by the general membership of the ABA. The ABA is a non-profit 501(c)3 organization, incorporated in the State of Illinois, and organized for scientific and education purposes.

Activities

The ABA and its members are committed to improving the quality of care provided to burn patients. Our activities include stimulating research in the methods of treating burn injuries, fostering prevention efforts independently and in conjunction with other medical, scientific and safety groups, including major projects supported by FEMA. Other key activities include providing continuing education courses, annual scientific meetings and scientific publications.

We created and administer courses in Advanced Burn Life Support, including the ABLIS Now[®] web-based course, for physicians and other health care and first-responder personnel. We developed national guidelines to optimize burn care and, working with the American College of Surgeons, created a program to provide an operational assessment of individual burn centers and to verify that they comply with the national standards. We established a National Burn Repository and burn registry software, in conjunction with the College, known as National TRACS Burnware. The ABA maintains a Chicago office and Washington, DC representation. Current advocacy efforts include critical collaborative disaster preparedness projects with HHS, federal legislation for improved Medicare coverage of burn patients, preferential reimbursement for verified burn centers and legislative initiatives to support NIH funding for clinical burn care research.

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One can lose only so much of the skin (or any organ) and still survive. James Barrett

*Brown, 1953*¹

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INTRODUCTION

This White Paper has been prepared by the American Burn Association (ABA):

- To serve as an authoritative reference for third party payers and government programs in development of burn care medical policy for claims administration;
- To demonstrate that the medical and surgical treatment of burns is unique and distinct from that for chronic wounds
- To explain that many burn injuries are treated in specialized burn centers by a multidisciplinary team (specially trained surgeons, nurses, therapists, and other care providers) and that many of these centers have undergone ABA verification of their institutional commitment to providing the highest quality burn care; and
- To provide an educational resource that can be used by payer medical/professional and administrative staff as their needs dictate.

Payer Medical Directors and associated professionals will find this paper a valuable source of burn-specific clinical information about burn injuries and

¹ Paraphrase. James Barrett Brown, in discussion following presentation of the paper "Postmortem homografts as 'biological dressings' for extensive burns and denuded areas" Transactions of the American Surgical Association, v. 71 (1953) 340. See Appendix III.

their surgical management to facilitate medical policy development and appropriate adjudication and payment of claims for burn care.

Specifically, this paper provides Medicare and Medicaid Contractors, non-governmental third party payers and interested professionals outside healthcare reimbursement with a current, authoritative clinical reference describing the essentials of

- surgical management of burn injuries,
- use of skin substitutes as treatment for burn wounds and
- care of burn wounds post-acute care discharge.

For all payer classes, this White Paper also

- a) supports the fact that skin substitutes are a standard of care for wound coverage in the treatment of burns;
- b) explains how skin substitutes are uniquely different from dressings; and
- c) provides “medical necessity” information that justifies payment for skin substitute products and their surgical application.

Payer Policies – Problems and Solutions

Payer medical policies define the circumstances under which claims for treatment of certain conditions are paid. This aspect of payer activity is problematic for burn care when a payer policy treats chronic wounds and burn wounds as equivalent clinical entities. This paper provides persuasive evidence that they are fundamentally different entities.

This introductory section illustrates problem areas identified by the ABA. Subsequent sections furnish a more complete discussion of the key distinctions between burns and chronic wounds in order to provide payers with the necessary information to support appropriate medical policy decisions.

Medicare

Medicare payment policies for the care of burn injuries and the use of skin substitutes, many of which have also been adopted by Medicaid state agencies, are inconsistent among Medicare regional administrative Contractors and, in some cases, are fundamentally inappropriate for burn care.

The ABA has confirmed that certain Medicare Contractor local coverage and payment policies for wound care and skin substitutes **lack the following two important components:**

1. final policy provisions that fully and clearly distinguish between the care of **chronic** wounds (which rarely heal permanently) and the highly unique care of **acute burn wounds** (which virtually always heal promptly with appropriate dressings and/or skin grafts), and
2. appropriate clinical input from burn surgeons² during policy development.

As a result, some policies inappropriately blend the two types of wounds and their treatment under a single category, that of chronic wounds. The facts presented in this paper provide contractors with the clinical information needed to implement new or revised policies based on the critically important distinctions between acute burn wounds and chronic wounds.

The following illustrates one of the concerns that arise when a payer considers burns and chronic wounds as similar, if not identical, entities. Some Medicare Contractor policies require a written plan of care as a condition for coverage of “wound” care. This document provides evidence that the acute and rapidly changing nature of burn injury does not permit formulation of a didactic plan of care as required by certain Medicare local

² To the ABA’s knowledge, there are no burn surgeons who are current members of any Medicare Contractor Advisory Committee (CAC) in the nation. To date, the ABA has received no information indicating that burn surgeons have been actively encouraged to become members of any CAC, contrary to the provisions of the CMS Program Integrity Manual, Exhibit 3.1.

policies. Such coverage requirements may be appropriate for chronic wounds (e.g., vascular ulcer of the leg) but are not appropriate for burn wounds and should be revised accordingly in current policies.

This white paper provides support for Contractor policy changes that explicitly acknowledge that burn wounds cannot be equated with chronic wounds and their treatment. Contractors can achieve this goal either a) by exempting burns entirely from a policy or b) by inserting appropriate and unique coverage provisions for the treatment of acute burn injuries.

Non-government Payers

This document is also intended to provide a resource to other third party payers whose policies may involve issues similar to those described under Medicare. It is also a targeted response to specific payer policies that may be industry outliers, for example, in cases where a payer policy excludes payment for an FDA-approved skin substitute with indications for use on burns.

As a further resource for Medicare contractors and non-governmental third party payers, when requested, the ABA will facilitate access to burn surgeon advisory or consultative expertise for the purpose of providing needed expert guidance.³

Every Burn Patient is Unique

Burns are traumatic wounds to normal tissues which heal quickly with local wound care and/or surgical wound closure with skin grafts or skin substitutes. Each burn *patient*, each burn *wound* on a given patient, and each patient's *clinical status* differs from all others. Because of the unique nature of burns, each burn surgeon, acting on the patient's behalf, is the only clinician qualified to determine the appropriate treatment that is medically necessary for the patient in his/her care.

³ Interested parties may contact: John Krichbaum, JD, Executive Director, American Burn Association. 625 North Michigan Avenue, Suite 2550, Chicago, IL 60611. 312/642/9260

Burn Care: A National Resource

The events of September 11, 2001 produced many patients with severe and life-threatening burn injuries. At the request of the [Bush] Administration, Burn center hospitals and burn teams went on standby to meet the national need then and intend to continue to be available for a national emergency in the future. Currently, inappropriate government and commercial third party payment policies threaten to erode and even eliminate these medically necessary resources which must be maintained for the American people, whether they are used on a daily basis or for a mass casualty event.

WOUND CLASSIFICATION - BURNS ARE ACUTE INJURIES

Burn Definition

For the purpose of this paper, a burn is defined as an injury to the skin or other organic tissue primarily caused by thermal or other acute trauma. It occurs when some or all of the cells in the skin or other tissues are destroyed by hot liquids (scalds), hot solids (contact burns), or flames (flame burns). Injuries to the skin or other organic tissues due to radiation, radioactivity, electricity, friction or contact with chemicals are also identified as burns.

Burns versus Chronic Wounds

A burn, irrespective of etiology, is clearly an **acute wound**, as opposed to a **chronic wound**. Evidence-based guidelines from the Wound Healing Society and the Wound Healing Foundation, classify acute wounds as those that repair themselves or can be repaired in an orderly and timely process and those that do not as chronic wounds; that is, chronic wounds have failed to proceed through an orderly and timely process to produce anatomic and functional integrity.^{4,5} Further, the Food and Drug Administration (FDA) categorizes cutaneous wounds as either “burns” or “ulcers”, with ulcers being defined as wounds that have failed to proceed through an orderly and timely series of events to produce a durable, structural, functional, and cosmetic closure.⁶

N.B. Unless otherwise indicated, the comments in the remainder of the White Paper refer specifically to the in-patient treatment of patients with acute burn injuries.

⁴ Lazarus GS, Cooper DM, Knighton DR, Margolis DJ, Pecoraro RE, Rodeheaver G, Robson MC. Definitions and guidelines for the assessment of wounds and evaluation of healing. Arch Dermatol 1994; 130: 489–93.

⁵ Robson MC and Barbul A. Guidelines for the best care of chronic wounds. Wound Rep Reg 2006; 14: 647–8.

⁶ FDA Wound Healing Clinical Focus Group. Guidelines for industry: chronic cutaneous ulcer and burn wounds—developing products for treatment. Wound Rep Reg 2001; 9: 258–68.

Burns and other acute wounds are due to an isolated, non-recurring insult, and are expected to heal within a reasonable period of time, especially when satisfactory medical care is provided. These wounds progress rapidly through an orderly series of healing steps. In some instances, indeterminate depth burn wounds may require a period of wound care and observation until wound demarcation is complete and a decision can be made regarding the necessity of skin grafting. Burn injuries may involve small areas or almost the entire body surface. In the case of extensive third degree burns, multiple staged procedures are required for patient survival and recovery. In contrast, chronic wounds—unlike burns—are most often small, result from very minor skin trauma and heal slowly because of the underlying pathophysiology of the local tissue. These wounds are typically present in patients with progressive medical conditions (such as diabetes mellitus and peripheral vascular disease) which impair oxygen and nutrient delivery to healing tissues and weaken local immunologic defenses. The microbiologic, enzymatic, and inflammatory milieu of burn wounds differs radically from chronic wounds, which support high levels of pathogenic microbes and proteolytic enzymes while maintaining a chronic inflammatory profile.⁷

As acute wounds, the vast majority of burn wounds close by either epithelialization, wound contraction, skin grafting or a combination of these methods. Although most small burns heal (or are surgically closed) within a few weeks, the rest are certainly healed within three months. In contrast, chronic wounds are marked by an absence of progressive epithelialization or reduction in wound size over a protracted period of weeks or months.

Finally, burn wounds are not usually uniform in depth, unlike chronic wounds which have homogeneous cutaneous involvement throughout the wound. For example, a flame burn involving the entirety of an upper extremity may range in depth from full-thickness injury over the dorsum of the hand and the forearm, which were closest in proximity to the flame source, to partial-thickness injury on the upper arm. **Thus, appropriate burn wound care may**

⁷ Schultz GS, Barillo DJ, Mozingo DW, et al. Wound bed preparation and a brief history of TIME. *Int Wound J* 2004; 1: 19-32.

necessitate multiple treatment modalities, each with varying sequencing, for different parts of a burn wound depending on the burn depth of each injured part.

Types of Burns

Cutaneous burns are injuries to the skin caused by the application of heat, cold, or caustic chemicals. When heat is applied to the skin, the depth of injury is proportional to the contact temperature, duration of contact, and the thickness of the skin. The depth of the injury largely determines healing potential and the need for surgical intervention such as skin grafting.

Cold exposure (frostbite) damages the skin and underlying tissues when ice crystals puncture the cells or when they create a hypertonic tissue environment. Blood flow can be interrupted, causing hemoconcentration and intravascular thrombosis with tissue hypoxia.

Chemical burns cause injury to tissues via a wide range of caustic reactions, including radical alteration of pH, disruption of cellular membranes, and direct toxic effects on metabolic processes. In addition to duration of exposure, the chemical nature of the injurious agent (for example, the concentration and pH of an acidic compound) will determine injury severity. Systemic absorption of some chemicals (such as of hydrofluoric acid) can be deadly.

Electrical current causes damage as electrical energy is transformed into thermal energy as the current passes through poorly conducting body tissues. In addition, injury to cell membranes (electroporation) disrupts membrane potential and function. The magnitude of injury depends on the pathway the current follows, the resistance to current flow of the tissues involved, and the strength and duration of current flow.

Burn Depth and Classification

Burn depth is a significant determinant of mortality and the primary determinant of the patient's long-term appearance and functional outcome. Superficial burns (second-degree burns) do not extend entirely through the

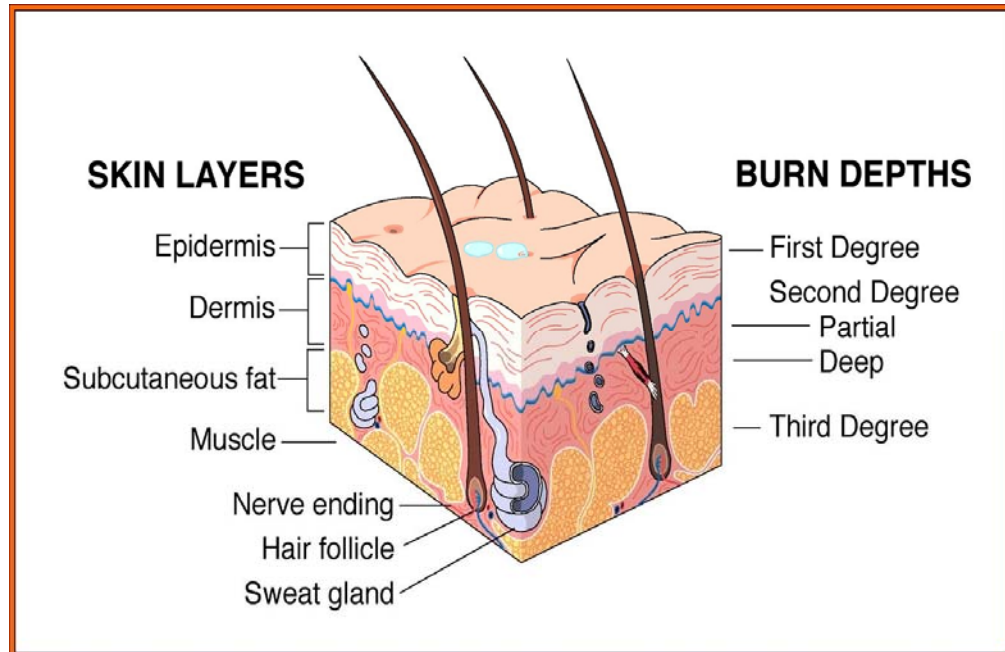
dermis and leave behind epithelial-lined dermal appendages including sweat glands, hair follicles, and sebaceous glands. When dead dermal tissue is removed, epithelial cells migrate from the surface of each dermal appendage to other epithelial cells from neighboring appendages, forming a new, fragile epidermis on top of a thin residual dermal bed. With deeper burns, fewer appendages contribute to healing so the burn takes longer to heal and scarring is more severe.

Second-degree burns that heal spontaneously within 2-3 weeks, facilitated by local wound care alone and without surgery, usually resolve without hypertrophic scarring or functional impairment, although long-term pigmentation changes are common. Burns that require longer than 3 weeks to heal routinely produce hypertrophic scars, frequently lead to functional impairment, and provide only a thin epithelial covering that remains fragile for many weeks or months.

Optimal burn care requires early excision and grafting of all burns that will produce hypertrophic scars (typically those that will not or have not healed within three weeks of the injury) so an accurate estimation of burn depth is crucial. The appearance of the wound—and the apparent burn depth—changes dramatically within the first seven to 10 days. A burn appearing shallow on day 1 may appear considerably deeper by day 3. This demarcation of the burn is a consequence of thrombosis of dermal blood vessels and the death of thermally injured skin cells. Superficial burns may convert to deeper burns due to infection, desiccation of the wound, or the use of vasoactive agents during resuscitation from shock.

Burns are classified according to the depth of tissue injury: epidermal (first-degree), partial-thickness (second-degree), or full-thickness (third-degree). Burns extending beneath the subcutaneous tissues and involving fascia and/or muscle are considered fourth-degree. For coding purposes, burns causing such deep tissue destruction to require amputation or loss of a body part, are termed fifth-degree. Nevertheless, **distinguishing between deeper burns that are best treated by early excision and grafting and shallow**

burns that heal spontaneously is not always straightforward, and many burn wounds have a mixture of superficial and deep burns, making precise classification of the entire wound difficult.



First Degree (Superficial or Epidermal) Burns

These burns involve only the epidermis. They do not blister, but are red and quite painful. Over 2-3 days the erythema and the pain subside. By about day 4, the injured epithelium peels away from the newly healed epidermis underneath, a process which is commonly seen after sunburn.

Second Degree (Partial Thickness) Burns

Partial-thickness burns involve the epidermis and portions of the dermis and can be clinically categorized as either *superficial* partial-thickness or *deep* partial-thickness burns. Superficial partial-thickness burns characteristically form blisters between the epidermis and dermis. Since blistering may not occur for some hours after injury, burns that initially appear to be only epidermal in depth (first degree) may be determined to be partial-thickness burns 12-24 hours later. Most superficial partial-thickness burns heal spontaneously in less than 3 weeks, and do so typically without functional

impairment or hypertrophic scarring. Second degree burns often accumulate a layer of fibrinous exudate and necrotic debris on the surface, which may predispose the wound to heavy bacterial colonization and delayed wound healing, in addition to making more difficult the determination of wound depth by visual inspection.

Deep partial-thickness burns extend into the lower layers of the dermis. They possess characteristics that are distinctly different from superficial or mid-dermal partial-thickness burns. If infection is prevented and spontaneous healing is allowed to progress, these burns will heal in three to nine weeks. However, they invariably cause considerable scar formation. Even with active physical therapy throughout the healing process, hypertrophic scarring is common and joint function is usually impaired. These burns are best treated by excision and grafting. For the patient, a partial-thickness burn that fails to heal within 3 weeks is functionally and cosmetically equivalent to a full-thickness injury.

Third Degree (Full-Thickness) Burns

Full-thickness burns involve all layers of the dermis and often injure underlying subcutaneous adipose tissue as well. Burn eschar is structurally intact but dead and denatured dermis. Over days and weeks if left *in situ*, eschar separates from the underlying viable tissue, leaving an open, unhealed bed of granulation tissue. Without surgery, they can heal only by wound contracture with epithelialization from the wound margins. Some full-thickness burns involve not only all layers of the skin, but also deeper structures such as muscle, tendon, ligament and bone, and are classified as deep full-thickness or fourth-degree. Grafting may use autologous skin grafts or biologic dressings and skin substitutes or both. (Excision and grafting using biologic dressings or skin substitutes permits closure of extensive burns in stages, with autografting done at a later date; see detailed discussion elsewhere in this paper.) Deep full-thickness burns may require amputation or closure with alternative techniques (such as adjacent tissue transfer or microvascular procedures).

OVERVIEW OF DAILY EVALUATION AND MANAGEMENT

This section provides a brief discussion of the daily inpatient evaluation and management of acute burn wounds, systemic responses to the burn insult, and unrelated comorbidities that may be present.

Burn Wound Care

(Please see “Post-operative Daily Evaluation and Management” section for details of the postoperative care of burn wounds.)

The current standard of care for acute burn wound management involves daily evaluation and management of all non-healed wounds by physicians and/or other members of the burn team. The daily wound care for burn injuries is complex and time-consuming.

Care of Operated and Non-Operated Burn Wounds

Burn care requires a series of ongoing, but separate, interventions until healing of all wounds, whether operated or non-operated, is achieved. Multiple staged and non-staged surgical procedures may be necessary followed by substantial procedural care that was not anticipated at the time of the previous surgical intervention. (For a detailed discussion of these operative interventions, please refer to “Surgical Treatment of Burns” elsewhere in this paper.)

Often, the patient has both operated and non-operated burn wounds at the same time. Non-operated burn wounds require *separate, focused* daily care and treatment apart from that required for the grafted areas. When care and treatment of one or more non-operated wounds is provided during the global period for a previous skin graft, payment is warranted because treatment of these wounds requires physician work that is separate and unrelated to the postoperative care of the skin grafts and donor sites. This situation is comparable to a case involving orthopedic treatment of a patient with a ski injury involving a fractured tibia treated surgically and a simple, non-displaced

fracture of the distal radius that is treated non-surgically. The global surgical period would apply to treatment of the tibial fracture but would be unrelated to the daily evaluation and treatment required for the radius injury. In both cases, the nonoperated burn wounds and the nonoperated radius injury are unrelated to the surgically treated conditions. Further, each is a different, unrelated diagnosis/condition affecting a different body area or anatomic site, for which separate reimbursement is warranted.

Evaluation and Management – Critical Care Services

Critical care services are frequently a necessary component of daily care for patients with extensive or complicated burn injuries. The management of burn patients requires significant attention to pathophysiologic changes caused by the systemic response to the burn injury. Patients need meticulous evaluation and correction of fluid & electrolyte, metabolic, cardiopulmonary, homeostatic and infectious derangements. This labor-intensive daily critical care evaluation and management service is absolutely necessary to achieve satisfactory outcomes.

Care of Unrelated Conditions

Burn patients present with the same comorbid conditions that are encountered in other hospitalized patient populations. Diabetes mellitus, obesity, hypertension, and cardiovascular disease can become an enormous barrier to burn wound healing. Optimal outcomes are only achieved when the burn surgeon also provides careful management of these coexisting, but unrelated, conditions throughout the patient's clinical course. Additional reimbursement for the daily evaluation and management of these unrelated conditions is appropriate, even when they occur within a global period for previous surgery.

SURGICAL TREATMENT OF BURNS

Escharotomy

Definition.—An escharotomy is defined as a surgical incision through burn eschar (necrotic skin). This procedure is usually performed within the first 24 hours of burn injury. Burn eschar has an unyielding, leathery consistency and is characterized by denatured proteins and coagulated vessels in the skin, which are the result of thermal, chemical or electrical injury.

Purpose.—When the burn eschar circumferentially surrounds any body structure (including digits, extremities, abdomen, chest, or neck) the tissues within are subject to increasing interstitial pressures exacerbated by tissue edema that develops during the acute phase of burn resuscitation in the first 48 hours after injury. As the interstitial pressure rises there is initially impairment of venous outflow followed by diminution of arterial inflow. This condition, often termed “compartment syndrome”, will cause dysfunction, ischemia, or necrosis within or distal to that body structure, often within hours.

In the limbs, nerve and muscle death may occur causing permanent functional impairment or even the need for amputation. In the abdomen, the impaired blood supply to the bowels, kidneys and other internal organs results in the rapid onset of hepatic and renal failure, intestinal ischemia, and restriction of diaphragmatic excursion. Compression of the chest by burn eschar worsens pulmonary compliance associated with smoke inhalation injury.

Technique.—Escharotomy (incision through the eschar) releases the constricting tissue allowing the body tissues and organs to maintain their normal perfusion and function. In most cases a single incision is inadequate to provide release of the constricting burn eschar. Escharotomy incisions are routinely performed on both sides of the torso or the medial and lateral sides of each affected limb. For the abdomen and chest, transverse incisions are often required to permit restoration of respiratory movement. The escharotomy procedure is most commonly performed using conscious

sedation at the bedside, in the emergency room, hydrotherapy room, or intensive care unit, but may be done in the operating room if general anesthesia is required.

Subsequent Surgical Excision of the Burn Wound

Escharotomies release the constriction caused by burn eschar but do not remove the eschar. Once the patient is stable enough to be taken to the operating room, generally between the second to seventh days postburn, the burn eschar is excised to the level of viable underlying tissue. (Please see also Burn Wound Excision in a subsequent section.) In some cases, escharotomies are performed through partial thickness burns (second degree burns), which will eventually heal without the need for excision and grafting. Delayed primary closure of escharotomy incisions may produce better functional and cosmetic results than those achieved if the escharotomies are allowed to close by secondary intention.

Debridement of Burn Wounds

Definition—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 (such as curetting, scraping, rongeur, or cutting). The level of debridement is defined by the level of the tissue removed, not the level exposed by the debridement process.

Purpose—Wound healing is optimized when wound surfaces are clean with minimal microbial colonization and necrotic debris present. Debridement cleans the wound and allows it to heal more rapidly with reduced risk of infection. In general, debridement is performed on shallow burns that are expected to heal without the need for skin grafting. In contrast to burn wound excision, the surface of a debrided wound is not ready to support immediate placement of a permanent wound cover.

Technique—Debridement can be accomplished in a number of ways, often using the same surgical instruments used for excision. (This does not include enzymatic debridement of wounds.)

Excision of Burn Wounds

Definition—Excision is a surgical procedure requiring incision through the deep dermis (including subcutaneous and deeper tissues) of open wounds, burn eschar, or burn scars. This entails surgical removal of all necrotic tissue. Burn scars can also be excised in preparation for surgical reconstruction.

Purpose—Excision is typically performed on deep burns that would not heal on their own. The goal is to remove all necrotic and non-viable tissue and to prepare the wound for immediate or delayed wound closure. The skin and subcutaneous tissues are removed followed by wound care (such as application of topical antimicrobials, temporary biologic or synthetic wound covers), immediate or later grafting, flap closure, and other reconstructive procedures. Unlike debridement, excisional techniques create a wound surface that is fully vascularized and ready for application of temporary or permanent skin replacement or substitute.

Technique— Burn debridement (cleaning) and excision (escharectomy) are routinely performed by experienced burn surgeons. Though the techniques and instruments used for debridement and excision are often similar, burn excision is significantly more difficult and requires greater time and physical effort to achieve meticulous burn wound preparation for subsequent grafting with synthetic or biological materials.

The excisional technique may vary but is typically performed in one of two ways: tangential excision (which is usually performed on deep partial thickness burns) and full thickness excision. Tangential excision involves surgical removal of successive layers of the burn wound down to viable dermis. Full thickness excision—often using electrocautery—involves removal of the burn wound down to viable subcutaneous tissue or to fascia.

Either procedure results in a large open area, i.e., a *defect*, which must be covered.

Single- and Multiple-Stage Excision and Grafting

Single-Stage Excision and Grafting

Surgical closure of burn wounds achieves two goals. The first is to facilitate optimal and rapid healing of the wound, minimizing deleterious consequences such as scar contracture while maximizing the best functional and cosmetic outcomes. The second is to ameliorate the adverse influence of the burn wounds on the body's systemic responses, especially the immune and metabolic systems. Meticulous wound preparation and application of skin grafts leads to excellent functional and cosmetic results, but this becomes progressively more difficult in patients with more extensive burn injuries. In life-threatening burns, procedures which improve patient survival by reducing wound infection, hypermetabolism and immunosuppression, assume priority over those which may optimize later functional and cosmetic results.

The single-stage approach to excision and grafting of burn wounds includes seven intraoperative components:

1. Initial decision-making—which is modified as necessary throughout the procedure—including,
 - a. Area(s) to be excised, usually based on the patient's physiologic state⁸ as well as the degree to which the anticipated blood loss⁹ will be tolerated¹⁰.

⁸ Excision of large areas of burns is stressful, and is tolerated poorly by patients with advanced age, other severe injuries (especially smoke inhalation injury and blunt trauma), and pre- or co-existing medical conditions (especially diabetes mellitus or cardiovascular and peripheral vascular disease).

⁹ Blood loss during surgical excision of burn wounds is approximately 0.75 ml per square centimeter of burn excised. This can lead to potentially life-threatening hypovolemia if not anticipated and replaced in a timely manner by the anesthesiologist. For example, excision of a 10% TBSA burn in a 70 kg man would be associated with loss of 1350 ml of blood, which is 25% of his total blood volume. Young, healthy patients can withstand this stress, but elderly patients or those with underlying cardiovascular disease cannot sustain adequate organ perfusion even with brisk blood product replacement; the result is hypovolemic shock. (Desai M, Herndon DN, Broemeling L, Barrow RE, Nichols RJ, Rutan RL. Early burn wound excision significantly reduces blood loss. *Ann Surg* 1990; 211: 753-760)

- b. Depth of the excision¹¹, a complex decision involving the anticipated blood loss, the ability of the patient's excised wounds to support the growth of a newly-transplanted skin graft¹², and considerations regarding long-term cosmetic results¹³.
 - c. Location of donor sites, including the thickness of the skin to be harvested¹⁴, the ease of dressing application, and the degree to which the donor site scar will remain masked by clothing in the future¹⁵.
2. Excision of the burn wound, with close monitoring of the patient's vital signs because of intraoperative blood loss.
 3. Achieving hemostasis with electrocautery and topical application of solutions containing vasoconstrictive agents (such as epinephrine or phenylephrine) and/or pro-coagulants (such as thrombin)¹⁶.

¹⁰ Because the excision slices through layers of viable tissue, blood loss is significant, approximating 0.75 ml blood per 1 cm² excised. Large excision procedures are associated with major blood loss which can cause dangerous hypotension.

¹¹ The first level of decision making is whether to perform tangential excision or full-thickness excision of the burns. The next level of decision making focuses on how deep the excision should go, most often based on the degree of bleeding (associated with viable tissue) as well as visual inspection of the exposed tissue (white dermis and yellow fat are viable; discolored tissues and thrombotic blood vessels are not).

¹² For approximately five days following placement of a skin graft, the cells of the transplanted skin survive by imbibing fluid and nutrients and by absorbing oxygen from the excised wound bed while healing is progressing. Thus it is critical that the excised wound bed be completely free of residual necrotic tissue (such as burn eschar), and that bacterial contamination and hematoma formation be minimized. Other factors that influence the success of the graft include peripheral edema and mechanical shearing forces, both of which must be minimized by prescribing bedrest and elevating the grafted extremity after surgery. In addition, splints over joints can reduce the risk of graft loss due to movement.

¹³ Tangential excision is associated with better cosmetic results than full-thickness excision down to muscle fascia because the body contours are maintained by the preservation of subcutaneous fatty tissue.

¹⁴ The thinner the skin graft, the more likely it will adhere and vascularize, and the less likely the donor site will form scars. Thicker skin grafts, on the other hand, are associated with better functional and cosmetic results at the recipient site.

¹⁵ Because an unfortunate minority of patients will form unsightly scars on the donor sites, it is best to place them in areas such as lower back, buttocks or thighs where clothing can hide the scars. Generally the back and scalp have the thickest skin, and thus are ideal sites for graft donation, particularly if multiple harvests are anticipated. Because skin has different shades of color in different anatomic locations, donor sites for cosmetically important areas are often near the recipient site. For example, the ideal donor site for facial grafts is the scalp.

¹⁶ In some cases the area of excision is injected prior to excision with an electrolyte solution containing vasoconstrictive agents to reduce blood loss from the excised wound surface. Hemostasis must be meticulous particularly when sheet skin grafts are applied, because even small hematomas under the graft can lead to graft necrosis and poor outcomes.

4. Harvesting the donor skin (which may be preceded by subcutaneous injection of an electrolyte solution containing vasoconstrictive agents to reduce blood loss, as well as local anesthetics to reduce postoperative pain).
5. Modification/expansion of the skin graft by meshing¹⁷. Expansion is often necessary for patients with extensive burns and/or limited skin graft donor sites.
6. Applying and securing the skin graft to the excised wound bed with some combination of absorbable or nonabsorbable sutures, staples, fibrin glue, synthetic adhesives, and/or tapes¹⁸.
7. Placement of dressings and splints¹⁹ to avoid mechanical shear of the grafts and to maintain proper positioning.

It is clear that single-stage excision and grafting is a complex, time-consuming process, which is often physiologically stressful on the patient and may be poorly tolerated in patients with large burn injuries. It is ideal treatment for small burns in healthy patients.

In addition, graft adherence and vascularization (graft take) following single-stage excision and autografting is less satisfactory in the treatment of large burns. In one study in which conditions were carefully controlled for the purposes of studying a new dermal replacement product²⁰, it was noted that the median graft take in the control group, which was treated within the guidelines described above, was 95%. However, this dropped to 88% (95%

¹⁷ Common mesh ratios include 1:1, 1.5:1, 2:1, 3:1, and 4:1. The larger the ratio, the more area of excised burn wound can be covered by any given piece of donor skin. However, the larger the ratio, the less the wound is actually covered and the more hypertrophic scarring results during the slow process of epithelial cell migration, and the less satisfactory the functional and cosmetic result.

¹⁸ Application of the skin graft can be quite time-consuming, particularly for burns of the face, hands, feet and genitalia where the correct orientation of the grafts and seams critically determine the functional and cosmetic outcome.

¹⁹ Dressings usually include a non-adherent gauze directly on the graft—so it is not displaced during subsequent dressing change—followed by antibiotic-containing dressing. Splints are applied not only to maintain functional positioning or full extension of the joint involved, but also to prevent loss of the fresh grafts from mechanical shearing.

²⁰ Heimbach D, Luterman A, Burke J, Cram A, Herndon D, Hunt J, Jordan M, McManus W, Solem L, Warden G, Zawacki B. Artificial dermis for major burns. A multi-center randomized clinical trial. *Ann Surg* 1988; 208:313-320.

confidence interval 78-98%) in patients with total burn size greater than 60%.²¹ Typically only small areas of the graft are lost, leaving scattered spots which heal by secondary intention and result in unsightly hypertrophic scars. This scattered graft loss can be caused by hematoma formation under the transplanted graft or by inadequate excision of the necrotic tissue. As noted above, the depth of excision is judged on the degree of bleeding and on the visual inspection of the excised bed, both of which require the technical expertise of an experienced burn surgeon.

To summarize, there are two reasons that single-stage excision and grafting may be inappropriate: first, the patient may not tolerate both the extensive blood loss associated with the excision combined with the prolonged operative time necessary to perform all the steps of skin grafting. Second, loss of portions of the grafts may produce unsatisfactory functional and cosmetic results.

Multiple-Stage Excision and Grafting

The alternative to single-stage excision and grafting is to perform the necessary steps in a planned sequence where part of the burn wound is excised initially and the remainder is removed in one or more subsequent operations. This is often done with cosmetically important areas such as the face, as well as with more extensive burns or burns in physiologically less stable patients.

For patients with small burns that are located in functionally and cosmetically important areas, the excision is done on the initial operative day and the freshly excised wound bed is protected with a temporary covering to prevent desiccation and infection²². This is followed in one to two days by harvesting

²¹ Gore DC, Chinkes, D, Heggors J, Herndon DN, Wolf SE, Desai M. Association of hyperglycemia with increased mortality after burn injury. J Trauma 2001; 51:540-544.

²² There are many products available for temporarily covering excised burn wounds. In general, they can be lumped into biological and synthetic products. Biologicals include amniotic membrane (rarely used now), xenograft (usually pigskin), and cadaveric allograft (living related donor allograft is a rarity). Synthetics include products such as Biobrane®, a nylon mesh coated with bovine collagen and pressed with a protective layer of silicon. (Biobrane® is considered a dressing, not a biological; aside from the CPT burn wound care

and placement of the skin autografts. Staged skin grafting of face burns allows inspection for hematomas or inadequately excised areas that would lead to graft loss and can result in nearly 100% graft take.

For patients with physiological challenges that increase the risk of complications with excision, concluding the initial operation after obtaining hemostasis (Step 3 above) reduces the chance of hypotensive complications. Temporary wound coverings can be expeditiously applied because they are prepackaged to simplify placement and because there is less need for careful placement of temporary coverings that will be removed within a few days.

For patients with burns too extensive to be completely excised and grafted in one stage, multiple procedures allow safe removal of the eschar with improved graft take. Most often, the burn eschar is excised on the first few visits to the operating room, and the goal is for complete eschar removal within the first five to seven days after injury. At the next operative procedure, the results of the first excision can be viewed, with further excision being performed and temporary dressings, skin substitutes or skin replacements applied if needed. Sometimes by the time the last areas of burn are being excised on the third or fourth visit to the OR, the first areas of excision are ready for permanent autografting. The other advantage of staging the excision and grafting procedures is that donor sites are given time to reepithelialize between harvesting sessions.

codes for dressing change [16020, 16025, 16030], application of Biobrane® is not reportable with a CPT billing code. Application of this product is not to be reported as application of a skin substitute.) All of these products need to be changed on a regular basis, usually every five to seven days, to prevent incorporation of the product into the wound bed and to reduce the risk of infection or rejection. Repeat allografting is also performed when allografted sites begin to undergo rejection. Eventually, all allografted sites require autografting.

Case Study: Acute Care of Burn Wounds

The following *Case Study* describes the typical sequence of operative procedures for a patient with a 75% TBSA third degree burn. Applicable CPT billing codes and ICD-9 diagnosis codes are included to demonstrate the nature and scope of the provided services and the medical necessity for the services.

A 25 year old man (1.8 m² body surface area [BSA]), otherwise healthy, sustains third degree burns over 75% (13,500 cm²) BSA after falling into a vat of sodium hydroxide. He has deep chemical burns of his feet, legs, trunk, arms and hands²³. Stable after his initial burn resuscitation, he is taken to the OR for the first time on day two (PBD 2) for excision and placement of allograft on his hands and arms (approximately 15% TBSA; 2700 cm²)²⁴. Two days later (PBD 4) he is returned for excision and allografting of a different anatomic area, the chest and abdomen (15% TBSA; 2700 cm²)²⁵. At that time, the excised burns and allografts performed on PBD2 were evaluated. There were several areas of necrosis, so the allograft was removed, areas of the wounds were re-excised, and new allograft was placed²⁶. In addition, acellular dermal replacement (Integra[®]) was applied to the forearms (500 cm²)²⁷.

Two days later (PBD6) he undergoes excision and allografting of the back and buttocks (15% TBSA; 2700 cm²)²⁸. Previously excised and grafted areas on the anterior trunk and upper extremities were examined, and repeat excision and allografting was performed on several areas of the chest and abdomen²⁹. The excised and allografted areas on the upper extremities, however, were in excellent condition, including the areas on the forearms treated with Integra[®]. New allograft was applied to the arms, and split-thickness autografting of the hands was done, using skin harvested from unburned areas on the upper arms and meshed at a 1.5:1 ratio³⁰.

²⁴ ICD-9 codes 942.39, 943.39, 944.38, and 945.39.

²⁴ CPT codes 15002, 15003, 15004, 15005, 15300, 15301, 15320, 15321.

²⁵ CPT codes 15002, 15003, 15300, 15301.

²⁶ CPT codes 15002, 15003, 15300, 15301.

²⁷ CPT codes 15170, 15171

²⁸ CPT codes 15002, 15003, 15300, 15301.

²⁹ CPT codes 15002, 15003, 15300, 15301.

³⁰ CPT codes 15120, 15121, 15300, 15301.

On PBD8, he is once again taken back to the OR for excision and allografting of the legs and feet (30% TBSA; 5400 cm²)³¹. With this procedure, the burn wound has now been completely excised. Repeat excision and allografting is also done on the back³². Autografting is done on the chest, using skin from unburned areas in the lower abdomen and groins meshed at a 3:1 ratio³³. The previously applied allograft, which has begun to undergo rejection, is excised from the arms and abdomen and replaced with new allograft³⁴.

Two days later on PBD 10 he undergoes inspection of the recently excised and allografted areas on the lower extremities, some of which require further excision; new allograft is applied to the legs and feet at that time³⁵. Using skin from the buttocks which is meshed at a 3:1 ratio, autografting is done to areas of the upper back³⁶. New allograft is applied to the lower back, abdomen, and arms³⁷. The autografts of the hands and chest are noted to be in excellent condition, and are cleaned of all necrotic debris³⁸.

Following this procedure, he develops ventilator-associated pneumonia. For five days his pulmonary function is too poor to permit return to the OR, but on PBD 16 he is taken for inspection and replacement of all areas of allograft³⁹. In addition, the donor sites on the upper arms (previously used for the hand autografts) as well as those on the lower abdomen and groins (used for the chest autografts) have now reepithelialized, and are ready for harvesting again. Autografts harvested from these donor sites are now meshed at a 3:1 ratio and used to cover the arms, including the areas treated with Integra^{®40}.

By PBD 20 the donor sites on the buttocks—previously used for autografts to the upper back—are now ready for repeat harvesting.

³¹ CPT codes 15002, 15003, 15004, 15005, 15300, 15301, 15320, 15321.

³² CPT codes 15002, 15003, 15300, 15301.

³³ CPT codes 15100, 15101.

³⁴ CPT codes 15300, 15301.

³⁵ CPT codes 15002, 15003, 15004, 15005, 15300, 15301, 15320, 15321.

³⁶ CPT codes 15100, 15101.

³⁷ CPT codes 15300, 15301.

³⁸ CPT code 16030.

³⁹ CPT codes 15300, 15301, 15320, 15321.

⁴⁰ CPT codes 15100, 15101.

Autografting at a 3:1 ratio is done to the lower back⁴¹. Allografts are also changed during this procedure⁴².

On PBD 26 the donor sites on the upper arms and lower abdomen are closed and ready for harvesting again. Meshing the autograft at a 3:1 ratio, wounds on the abdomen and right thigh are now covered⁴³.

Donor sites on the buttocks are ready for reharvesting on PBD 29. Meshed at a 3:1 ratio, this skin is used to cover the right lower leg and foot⁴⁴. Remaining areas of allograft on the left lower extremity are changed at this time⁴⁵.

On PBD 40 the patient returns to the OR for the last time, during which the remaining wounds on the left leg and foot are covered using autograft harvested from previously used donor sites⁴⁶. This completes the acute phase of excision and grafting.

⁴¹ CPT codes 15100, 15101.

⁴² CPT codes 15300, 15301, 15320, 15321.

⁴³ CPT codes 15100, 15101.

⁴⁴ CPT codes 15100, 15101, 15120, 15121.

⁴⁵ CPT codes 15300, 15301, 15320, 15321.

⁴⁶ CPT codes 15100, 15101, 15120, 15121.

BURN WOUND COVERAGE

Burn wound coverage is a unique surgical process. Simple, small burn wounds are excised and covered by either a full thickness skin graft, in which the donor site is primarily closed, or by a split-thickness skin graft. Even though it seems a simple procedure, the surgeon must first choose the thickness to harvest the graft. He will then decide whether to mesh the graft (which would allow the drainage of fluid from beneath) or apply it as a sheet graft without perforations. The thicker the graft, the less it will contract, yet the more difficult it is to obtain 100% engraftment and the more difficult it is for the donor site to heal.

As the extent of the burn increases, the operative procedures and decision-making become more complex. Early excision of burn wounds improves patient survival. However, excision alone without grafting leaves an open wound that must be covered in order to prevent infection, decrease fluid losses, and reduce the risk of scar contractures.

Skin Substitutes and Skin Replacements

Definitions⁴⁷

Skin substitute [commercial product]: 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.

Skin replacement: A tissue or graft that permanently replaces lost skin with healthy skin.

Temporary Wound Coverage

Temporary skin substitutes are used when the wound is too extensive to be closed in one stage because there is not enough donor skin available, because the patient is too ill to undergo the creation of another wound that

⁴⁷ American Medical Association. *CPT Assistant*. Skin Replacement Surgery and Skin Substitutes. Volume 16, October 2006.

results when skin is harvested from a donor site, because there is a question regarding the viability of the recipient bed, or because of a concern regarding potential infectious complications. The gold standard temporary skin substitute is cadaver **allograft**.⁴⁸

James Barrett Brown, whose 1953 observation opens this White Paper,⁴⁹ popularized allograft use as early as 1942⁵⁰ and today it is the most often used temporary biological wound covering for excised burn wounds when sufficient autograft skin is not available or when autografting is clinically not indicated.⁵¹ Allograft will adhere and induce vascularization on an appropriately prepared wound bed. It will decrease the loss of fluids, proteins, and electrolytes and drying of the recipient bed. It also decreases bacterial contamination, diminishes pain, improves the patient's ability to participate in all types of therapy, is a marker for the ability of the wound to accept an autograft, and promotes wound healing in partial thickness wounds. In some patients, cultured keratinocytes can be applied onto the vascularized allodermis once the alloepidermis has been removed.^{52,53}

Allograft adherence depends on meticulous wound bed preparation. If the allograft does not adhere, the wound bed must be re-excised and the wound covering reapplied. Allograft is obtained from skin banks accredited by the American Association of Tissue Banks to ensure quality and safety. Allograft may be used as fresh, refrigerated tissue or as frozen tissue, which is thawed immediately prior to use.⁵⁴ Optimal thawing will prevent the formation of ice

⁴⁸ Living-related allograft is rarely used, and is limited to transfer of skin between identical twins.

⁴⁹ "One can lose only so much of the skin (or any organ) and still survive." See Appendix III for full text of Dr. Brown's discussion.

⁵⁰ Brown JB and McDowell F: Massive repair of burns with thick split thickness skin grafts: Emergency "dressings" with homografts. *Annals of Surgery* 1942; 115: 658-74.

⁵¹ Hansborough, John: *Wound Coverage with Biologic Dressings and Cultured Skin Substitutes*; p 21; Austin, Texas: R.G. Landes Company, 1992.

⁵² Cuono C, Landgon R, McGuire J. Use of cultured epidermal autografts and dermal allografts as skin replacement after burn injury. *Lancet* 1986; 1: 1123-4.

⁵³ Hickerson W, Compton C, Fletchall S, et al. Cultured epidermal autografts and allodermis combination for permanent burn wound coverage. *Burns* 1994; 20: S52.

⁵⁴ An alternative approach is using fresh allograft, which has adherence and vascularity properties superior to those of frozen allograft. However, the disadvantage is that the fresh

crystals in the allograft skin, which decreases its viability. The application of all temporary skin substitutes requires similar painstaking attention to technique although that for allograft is perhaps the most demanding.

Other temporary skin substitutes are used to provide transient wound coverage and to create a physiologically homeostatic environment. **Skin Xenografts**—also termed heterografts—were first described in 1880 by Lee⁵⁵, and may be obtained from various animals, although pigs are the most common donors. Xenograft (pigskin) is used at many institutions in the same manner as allograft (see above). Zawacki also showed that necrosis in the zone of stasis (the damaged but potentially viable area of thermally injured tissue surrounding irreversibly necrotic skin) could be avoided by optimal treatment of the wound with a biologic dressing such as xenograft.⁵⁶ Thus application of xenograft on a debrided mid-dermal burn might prevent/obviate the need for excision and autografting.

How do burn surgeons decide whether to use allograft or xenograft?

The decision is multifactorial, determined by the viability of the skin substitute, desired outcomes, cost-effectiveness, anticipated time of coverage needed, patient preference, and surgeon experience and preference.

Biobrane[®] is a silicone membrane pressed onto a flexible nylon fabric which has been coated with porcine dermal collagen. Used as a temporary wound cover, it is considered a dressing by the FDA and CPT Editorial Panel.

Transcyte[®], a related product, is not a dressing. It is classified as a temporary skin substitute and is composed of Biobrane[®] and cultured newborn human fibroblasts, which secrete growth factors and matrix proteins onto the wound surface. TransCyte[®] must be applied to a clean wound bed

allograft must be procured, processed, shipped and delivered within 48 hours of application, limiting the practicality of its use.

⁵⁵ Lee, EW: Zoografting in a burn case. Boston Med Surg 1880; 103:260.

⁵⁶ Zawacki, BE: Reversal of capillary stasis and prevention of necrosis in burns. Annals of Surgery 1974; 180: 98-102

and monitored closely because it is prone to infection. It can be used in ways similar to allograft and xenograft.

Permanent Wound Coverage

A **full-thickness skin graft** contains all components of the skin: epidermis, dermis, hair follicles and nerve endings. The most important advantage of full-thickness grafts is decreased scar formation; however, because there is no dermis to regenerate epithelial coverage, the donor site of a full-thickness skin graft must be closed either with primary direct closure or with a split-thickness skin graft; local advancement of skin flaps is a rarely used option. Full-thickness grafts are thus usually used to cover small, functionally and cosmetically important areas (such as eyelids and digits).

The **split-thickness skin graft** is the most common method used to achieve permanent wound coverage. It includes the entire epidermis but the dermal layer is split by the dermatome blade. With thicker split-thickness grafts, more dermis is transferred with the skin graft (such as 15/1000 of inch or greater). This reduces the risk of scar formation at the recipient site, but it takes longer for the donor site to heal. Furthermore, the thicker the graft, the more likely the donor site will heal with a scar and the less likely the donor site may be reharvested for further grafts.

There is enough unburned skin available for use as donor site that thick split-thickness skin grafts can be used with impunity for treatment of small to moderate sized burns (under 20% TBSA). However, for burns over 40% TBSA it is difficult to harvest enough skin using each donor site only once. There are many areas—such as the face, neck, hands, feet, and perineum—that are generally not used as skin graft donor sites. It is also technically difficult to harvest skin from the area around the elbows, knees and ankles. Thus approximately 15-20% of the body surface is rarely harvested, forcing repeat use of other areas for donor skin. When the donor sites are harvested at 12/1000 inch or less, they may be reharvested provided they heal without infection.

There are a number of commercially available products to facilitate permanent wound coverage. **Acellular human dermal allograft (Alloderm®)** is devoid of epidermis and must be covered by a thin split-thickness autograft at the time of the initial operation; however, it replaces a portion of the missing dermis on the newly covered wound, thus reducing postoperative scarring. Another permanent wound coverage product is a **dermal regenerative template (Integra®)** constructed with bovine collagen and shark chondroitin sulfate with a silicone surface layer. This is applied to an excised wound bed that is well vascularized and free from infection, and provides wound coverage much like other skin substitutes; however, after the template becomes vascularized, it forms a neodermis (usually within 10 days to three weeks) and when the silicone layer is removed, an epidermal autograft (< 0.008 inch thickness) can be applied. This intermingling of autograft on a biosynthetic neodermis is permanent, unlike the wound coverage provided by temporary skin substitutes. This approach may be lifesaving and provides quality skin coverage.

Cultured epidermal autograft (CEA; Epicel®), also referred to as “test tube” skin, was introduced by Rheinwald & Green in 1975⁵⁷ and is often employed to provide permanent skin coverage for patients with extensive burns. This product has limitations including sensitivity to infection and the lack of a dermis, which leads to fragility of the healed skin and severe scarring. However, the short- and long-term results of CEA application can be improved by the use of a sandwich technique, in which CEA is applied over a vascularized allogeneic dermis, Integra®, or Alloderm®. A review of 301 cases of burns treated with CEA has shown that the success rate improves from 53% to 83% if the CEA is applied to a well-vascularized dermal bed.⁵⁸ This dermis is created by utilizing the dermal templates noted above, or by using allograft that is allowed to engraft and removing the epidermis after the dermis is vascularized.

⁵⁷ Rheinwald, JG, Green H. Serial cultivation of strains of human epidermal keratinocytes: the formation of keratinizing colonies from single cells. *Cell* 1975; 6: 331-334.

⁵⁸ Hickerson W, Bishop, J, Love R: Cultured epidermal autografts: the current status in Scott-Conner C, ed. *Problems in General Surgery*: JB Lippincott: volume II, Number 4, 1994: 747-752.

Table of Indications for Integra and Alloderm Wound Covers

	Integra	Alloderm
FDA-approved indications	<ul style="list-style-type: none"> • Postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. • Treatment of scar contractures 	Full thickness burns
Description	Acellular bilayer dermal replacement composed of cross linked bovine tendon collagen and chondroitin-6-sulfate.	Human allodermis
Permanent epidermal coverage	No—temporary silastic covering	No
Indications	Permanent wound coverage	Permanent wound coverage
Biologically active	Yes	Yes

Wound coverage to tissue damaged by thermal, chemical, electrical or radiation effects is a complex process which is technically very challenging. These multiple, staged procedures often have to be accomplished in critically ill patients prone to numerous complications including infections, hematological and other systemic problems. Although skin coverage for other illnesses or injuries may borrow techniques from those utilized in burn care, rarely does the coverage for other wounds involve the complexity of that for the coverage of acute burn wounds.

POST-OPERATIVE DAILY EVALUATION AND MANAGEMENT

Operated Burn Wounds

Despite the most attentive precautions in the operating room, many patients will return to the burn intensive care unit with hypothermia which is treated by increasing the ambient temperature of the patient’s room and positioning portable heating units over the patient’s bed. As the patient’s body

temperature begins to rise towards normal, vasoconstriction in the periphery abates and the patient becomes tachycardic, hypovolemic and oliguric. The hypovolemia of re-warming can be anticipated and treated with the infusion of additional crystalloid fluids run through a fluid warmer.

In most cases, the post-operative care of burn patients following excision and grafting is uncomplicated. Any fluid and electrolyte replacements are corrected and adequate nutritional intake is assured. Many patients can begin a regular diet the morning following surgery unless they are ventilator-dependent. Continuation and/or resumption of enteral feedings begins in critically ill patients as soon as there is evidence of bowel function. Combinations of short- and long-acting narcotics and benzodiazepines are used for pain relief and sedation.

The dressings and splints are typically removed on the fourth or fifth day following skin grafting; they may, however, be reapplied for a more lengthy period of time in order to maintain proper positioning. Physical and occupational therapy resumes at this time, and patients are encouraged to resume as much independent activity as possible. For patients with smaller burns, discharge typically occurs within 48 hours of removing the dressings.

Many options are available for postoperative care of skin grafts. Grafts and donor sites should be kept clean, moist and covered. After discharge, patients return weekly to the outpatient clinic until all wounds, including donor sites, have reepithelialized and satisfactory progress is being made in therapy. Monthly or bimonthly visits for up to six months are necessary to ensure that patients achieve optimal restoration of functional capabilities, including range of motion, strength and endurance, and return to their pre-injury work status.

Care of Burn Wounds Unrelated To Previously Operated Wounds

Not all burn wounds require surgical intervention. Superficial second degree burns will close within two weeks and require only moist antimicrobial dressings. These second degree burns need to be monitored closely by

experienced nurses and burn doctors since infections such as cellulitis are common and can result in extension of the depth of the burn. In addition, the progress of patients in physical and occupational therapy must be monitored, and pain medications frequently adjusted. For these reasons, daily evaluation and management of non-operatively treated burn wounds merits recognition in the reimbursement process.

Unrelated Conditions

Thermal injuries result in perturbation of many systemic processes. Metabolic rate is increased, sometimes to double that of the uninjured healthy person. Because of increased metabolism, carbon dioxide production is greatly increased, resulting in the need for augmented minute ventilation. The immune system is impaired, and bacterial and fungal infections are common. Management of pain and anxiety are challenging because of the magnitude of physical discomfort and emotional distress.

Many patients with extensive thermal injuries, inhalation injuries or multiple comorbid conditions require intensive care in specialized units. ICU care includes management of fluids and electrolytes, assessment of airway, management of mechanical ventilators, establishment and evaluation of nutritional supplementation, and monitoring and treatment of infectious processes. The physician skills required for the management of these complex patients comes only with residency and fellowship training programs that emphasize critical care. The surgical skills needed to treat burn patients in the perioperative period are related but not identical to the requisite critical care skills. For this reason, billing for critical care services during the 90 day global period for skin grafting is a legitimate and well-recognized service for the treatment of medical conditions unrelated to the management of the postoperative burn wound.

POST-DISCHARGE BURN WOUND MANAGEMENT

Discharge and Follow Up

Following discharge from the hospital, the condition of the burn patient ranges from fully independent at home to completely dependent in a skilled nursing facility. At the point of discharge the patient is typically breathing without continuous ventilatory support, is hemodynamically stable, and is showing no signs of sepsis. However, there may be resolving conditions still requiring treatment, such as infections, open wounds, and the need for nutritional support. Some patients are discharged on intravenous antibiotics; others finish their prescribed courses with oral agents. Most burn patients still have open wounds or donor sites at the time of discharge; more discussion follows below. Some are still receiving enteral feedings through feeding tubes, often because they have not successfully passed a swallowing evaluation. The resolution of these issues may require three months or more, and progress is monitored in the outpatient clinic or at the rehabilitation/skilled nursing facility.

Open wounds are present in nearly all patients discharged from burn centers. These may be second degree burns which are being allowed to epithelialize on their own without surgery. There may also be unhealed donor sites that were created for split-thickness autografting. In addition, many third degree burns that have been grafted do not have 100% graft take (adherence and vascularity leading to viable incorporation of the graft), and there may be areas of granulation tissue that eventually heal by secondary intention (horizontal migration of epithelial cells and contraction of the wound). These open areas of third degree burns may be small (1-2 mm) or much larger. Most wounds require daily care which may range from 1 to 3 dressing changes daily. The following *Case Study* illustrates how patients may be treated in an outpatient clinic for third degree burns without definitive wound closure. This might also apply to patients whose medical comorbidities preclude any operative intervention.

Case Study: Burn Wound Care Post Acute Care Discharge

An 83 year old man is admitted for treatment of 10% TBSA third degree burns of the right chest and abdomen, sustained when his shirt caught on fire while he was smoking.

He presented to the hospital in stable condition, awake and alert, without signs of smoke inhalation injury or hemodynamic compromise. His past medical history was significant for myocardial infarction two years prior to the burn.

During his hospitalization he was evaluated by the cardiologist, who deemed him to be at moderate risk of complications from surgery. This was explained to the patient and his family, who nonetheless agreed with plans for surgical excision and grafting. During the operative procedure, the patient became hypotensive. At that point in the operation, all of the burn had been excised, but only half of it had been grafted. The operation was concluded prematurely, leaving half the wound covered only with antibiotic dressings. After surgery, changes in the electrocardiogram and in cardiac enzymes confirmed that he had an intraoperative myocardial infarction. He was nonetheless stable, and within seven days was ready for discharge. Because of his intraoperative MI, he was considered high risk for another cardiac event during anesthesia, and all agreed that the remaining open wounds should be allowed to heal on their own.

Following discharge, he returned weekly to burn clinic, where dressings were changed by the clinic nurses and the wounds evaluated by the physician in attendance. During each clinic visit, there was inspection of the grafted area, the donor site, and the third degree burn which was being allowed to heal by secondary intention, including necessary modification of the treatment plan. At home his wounds were cleansed and inspected daily, with an application of new dressings. Over the course of the next three months, the remaining open wound contracted and epithelialized.

As the wounds are healing, other challenges appear. Pruritus (itching) is a nearly ubiquitous problem for burn survivors, occurring in healed second degree burns or donor sites, or in grafted areas. Pruritus can range from minor irritation to significant interference with daily activities. Pruritus can exacerbate the patient's negative perception of chronic pain, can cause insomnia, and can add to depression. Treatment of pruritus is multifaceted and includes pharmacologic approaches (typically antihistamines) as well as non-pharmacologic techniques (such as massage and application of cold).

Chronic pain is a difficult challenge for many burn survivors. Pain occurs in the scar tissue or in the underlying muscles and joints affected by weeks of disuse. Active participation in physical and occupational therapy often exacerbates the need for pain medications. Narcotics are not satisfactory long-term solutions to this type of chronic pain, and other options are usually explored (such as neurontin and TENS units). Management of chronic pain requires a significant commitment of time by the treating physician.

Restoration of function is one of the major goals of treatment for burn injuries. It requires a multidisciplinary effort, utilizing physical and occupational therapy in addition to evaluation and treatment by experienced physicians. Scar management hinges on range of motion exercises and compression of the scar tissue by compression garments. Both of these approaches require monitoring on a regular basis (at least monthly), and patient outcomes are often improved when compliance can be monitored by frequent follow-up visits. Reconstructive surgery may be required to restore function to the injured body part.

Thus the comprehensive care of the burn survivor often extends for months, if not years. Typical length of follow-up after discharge is 12 months; some patients are followed for two or more years. Children are typically followed until they have completed their growth into adulthood.

Conclusion

This reference work, published by the American Burn Association and authored by a number of experienced burn surgeons in active practice, is the first and only definitive and authoritative resource of burn-specific information primarily developed for Medical Directors in government health care programs and in the third party payer private sector.

This White Paper provides the salient facts needed to understand that burns are a unique clinical entity that requires knowledge of burn pathophysiology and expertise in the surgical management of burn wounds, and that the decision-making varies in each individual burn case. The White Paper addresses the management of the burn patient from the initial inpatient admission to a burn unit through the post acute care discharge phase of care. Such burn care can often require multiple surgical interventions and intense ongoing evaluation and management. Of major importance, the White Paper includes detailed discussions of wound excision and debridement, temporary and permanent wound covers such as skin substitutes and grafts, and relevant case studies. In summary, this is an authoritative reference on the management of burn injuries that is an essential, practical tool which can be used by Medical Directors when setting medical policy for claims payment.

APPENDICES

APPENDIX I

Glossary

Acute: having a rapid onset, severe symptoms and short course; not chronic

Allograft (homograft): graft of tissue between individuals of the same species

Apoptosis: fragmentation or disintegration of a cell into membrane-bound particles that are then eliminated by phagocytosis

Autograft: graft transferred from one area of a patient's body to another area of the same patient.

BSA: body surface area

Chronic: persisting for a long period of time with little change; opposite of acute

Clysis: administration or injection of fluid into the body by other than the oral or intravenous route

CMS: Center for Medicare Services, Department of Health and Human Services of the United States

Conversion: process of progressive necrosis, in depth and width of a burn following initial injury; process in which burn depth increases due to progressive apoptosis, e.g., from partial thickness to full thickness, hours or days after the initial injury.

CPT: *Current Procedural Terminology*, annual publication of the American Medical Association listing thousands of billing codes for identification and billing of healthcare services and procedures.

Cutaneous: referring to the skin

Demarcation: the boundary between the burn wound and the peripheral unburned skin. Also, the observation of a distinct boundary between a partial-thickness wound and a wound which is full-thickness (that may not have been clinically detectable earlier after the burn injury)

Desquamate: a normal process in which the cornified layer of the epidermis is sloughed off in fine scales. In the context of burns, an accelerated process of peeling of the epidermis and loss of deeper layers of the skin.

Desiccation: process of drying out

Enzymatic: pertaining to enzymes. Enzymes are proteins produced by living cells that catalyze (increase the speed of) reactions within cells.

Epithelial: pertaining to or composed of epithelium, the covering of the external and internal organs and lining of the internal passageways of the body.

Erythematous: pertaining to redness or inflammation of the skin or mucous membranes caused by congestion of the capillaries

Eschar: a slough (area of necrotic tissue), crust or dry scab resulting from a burn.

Escharectomy: the surgical removal of dead soft tissue (eschar) from a burn wound.

Etiology: study of causes of disease

Heterogeneous: consisting of dissimilar elements or parts; derived from different individuals or species

Hypermetabolism: abnormally increased rate of metabolic activity

Hypertrophic scar: abnormal area of scarred tissue that replaces normal tissue at the site of an injury due to an increase in the size of the area's constituent cells

ICD-9-CM: International Classification of Diseases, 9th Revision, Clinical Modification. A three-volume publication of the World Health Organization modified for use in the United States that lists codes and nomenclature for conditions, diseases, and health care encounters as well as surgical procedures.

Indolent: slow growing

In situ: in its original place

Local coverage and payment policies: terms commonly used to describe Medicare's written formal medical policies, termed Local Coverage Determinations (LCDs) that stipulate the conditions under which certain diagnostic or therapeutic procedures and services are covered and payable.

Mechanical shearing: in relation to burns, a cut or tear in tissue or a graft due to a physical force or strain placed on the area.

Meshing: the process of creating small openings across the length and breadth of a harvested piece of skin to be used for grafting so that the graft can be expanded or stretched to cover a burn wound recipient site.

Milieu: environment

Pathogen: microorganism capable of producing disease.

PBD: post burn day

Peripheral vascular disease: an abnormal condition that affects the blood vessels outside the heart and brain and often involves a narrowing of vessels that carry blood to the legs, arms, stomach or kidneys. Causes can include obesity, smoking, and numerous metabolic disorders (e.g., diabetes) and involve structural changes in the blood vessels such as inflammation and resulting tissue damage, ulceration, etc.

Proteolytic: pertaining to the breakup of protein molecules by hydrolysis

Sebaceous gland: one of many small oil-secreting glands located in the dermis, often lying adjacent to hair follicles.

Skin appendages: referring to the hair follicles, sweat glands, and sebaceous glands in the skin

Skin replacement: 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.

TBSA: total body surface area; in burn care, referring to the total body surface area affected by second and third degree burns or to the total body surface area treated

Third party payer: a health insurer or health care claims administration organization

Vasoconstrictive: causing narrowing of blood vessels

Vasodilation: dilation or widening of the lumen of blood vessels

Xenograft (heterograft): a graft between two different species (e.g., animal to human)

APPENDIX II

Burn Center Referral Criteria⁵⁹

A burn center may treat adults, children, or both.

Burn injuries that should be referred to a burn center include the following:

1. Partial-thickness burns of greater than 10% of the total body surface area
2. Burns that involve the face, hands, feet, genitalia, perineum, or major joints
3. Third-degree burns in any age group
4. Electrical burns, including lightning injury
5. Chemical burns
6. Inhalation injury
7. Burn injury in patients with preexisting medical disorders that could complicate management, prolong recovery, or affect mortality
8. Any patients with burns and concomitant trauma (such as fractures) in which the burn injury poses the greatest risk of morbidity or mortality. In such cases, if the trauma poses the greater immediate risk, the patient's condition may be stabilized initially in a trauma center before transfer to a burn center. Physician judgment will be necessary in such situations and should be in concert with the regional medical control plan and triage protocols.
9. Burned children in hospitals without qualified personnel or equipment for the care of children
10. Burn injury in patients who will require special social, emotional, or rehabilitative intervention

⁵⁹ American College of Surgeons, Committee on Trauma. "Guidelines for the Operation of Burn Centers." In *Resources for Optimal Care of the Injured Patient*, 2006; 14: 79-86.

APPENDIX III

James Barrett Brown Paraphrase

In the discussion following a paper "Postmortem homografts as 'biological dressings' for extensive burns and denuded areas," James Barrett Brown said, "Dr. Evans spoke about the death rate. Skin, as everybody knows, is an organ. It is not just epithelium. The silly idea of having a little, tiny graft having epithelium come out permanently to cover a body, doesn't mean anything. They look horrible, and won't bear up; you have to have a full complement of skin. You have to have the derm of the skin to make a final covering surface. Along with that you can only lose so much of the skin and the patient dies, just as you can only lose so much heart or lung or liver."⁶⁰

⁶⁰ Quote from Transactions of the American Surgical Association, v. 71 (1953), page 340

APPENDIX IV

Correct Coding and Payment for Burn Excision and Grafting Following National Guidelines for CPT Primary and Add-on Secondary Codes

The purpose of this Appendix is provide coding, reporting, and claim interpretation guidelines for burn excision and grafting fully consistent with HIPAA¹ and AMA/CPT guidelines.

In the *Case Study* entitled “Acute Care of Burn Wounds,” the applicable CPT billing codes for the procedures described in the case study are listed in footnotes to demonstrate the nature and scope of the provided services. In a number of footnotes, relevant primary and related “add-on” codes for the burn excision and graft application procedures apply. To conserve space, units of service for each code that are normally required on claims were omitted in the footnotes.

The applicable guidelines are listed below along with two examples which illustrate proper coding and reporting methods. Units of service are shown as they should be entered on and adjudicated for claims. (The paper claim form, CMS-1500 (08-05) layout, is used in each example.)

¹ According to the HIPAA Final Rule published August 17, 2000, establishing CPT as one of the standard code sets for claims submission, health plans must accept CPT codes and modifiers by October 16, 2003. “However, the health plan is not required to pay the claim merely because the health care provider submitted it in standard format, if other business reasons exist for denying the claim (for example, the service for which the claim is being submitted is not covered).” (Federal Register Vol. 65, No. 160, Thursday, August 17, 2000 Final Rule. Health Insurance Reform: Standards for Electronic Transactions.)

AMA/CPT Guidelines for Add-on Codes

CPT 2009: Introduction (excerpt)

Some of the listed procedures are commonly carried out in addition to the primary procedure performed. These additional or supplemental procedures are designated as add-on codes with the symbol + and they are listed in Appendix D of the CPT codebook. Add-on codes in *CPT 2009* can be readily identified by specific descriptor nomenclature that includes phrases such as “each additional” or “(List separately in addition to primary procedure).”

The add-on code concept in *CPT 2009* applies only to add-on procedures or services performed by the same physician. Add-on codes describe additional intra-service work associated with the primary procedure (eg, additional digit[s], lesion[s],...)

Add-on codes are always used in addition to the primary service or procedure code and must never be reported as a stand-alone code. All add-on codes found in the CPT codebook are exempt from the multiple procedure concept (see modifier 51 definition in Appendix A).

Source: American Medical Association. *CPT 2009*. Chicago: American Medical Association, 2008.

CPT codes for excision and grafting of burns are listed under the subheading “Skin Replacement Surgery and Skin Substitutes” in the Integumentary system subsection of the Surgery section of CPT. Codes 15002-15005 are used to report excision of burns and other specific lesions. Codes 15040-15431 are used to report application of various types of grafts. These code descriptors specify the anatomic site(s) on which each procedure is performed, with two codes typically assigned to each group of anatomic sites. The first code is the primary code and the second is an add-on code used in those instances when additional work is performed by the same physician at the same operative intervention. For example:

15002 Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar..., trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children

+15003 each additional 100 sq cm **or part thereof**, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure
[Emphasis added])

Code 15002 is used to report the primary procedure. Code 15003 is the related add-on code that is used when the additional work described in 15003 is performed at the same operative intervention. **The units of service for each primary code in the code range 15002-15431 will always be 1. The units of service for each add-on code in the range 15002-15431 will always be the multiple of the numeric quantity stated in the add-on code plus a quantity of 1 for any additional part thereof.** For example, burn wound excision of 950 sq cm on the trunk would be assigned code 15002 (Units of Service = 1) and add-on code 15003 for the additional work over and above the first 100 sq cm in 15002 (Units of Service = 9 for 850 sq cm excision). In another example for a 130 sq cm excision on the trunk, code 15002 would be reported for the first 100 sq cm (Units of Service = 1) and code 15003 for the remaining 30 sq cm (Units of Service = 1).

CPT Guidelines for Excision and Graft Codes (*excerpt*)

When square centimeters are indicated [in primary codes], this refers to 1 sq cm up to the stated amount. Add-on codes begin with the next sq cm (eg 130 sq cm would be coded using a code for the first 100 sq cm and an add-on code for the next 30 sq cm).

[Payer Guidelines with Examples](#)

Two cases are presented, each illustrating the appropriate method for listing burn procedures on a claim. The first is the Case Study for Acute Care of Burns described earlier in this paper and the second is for excision of a burn followed by application of CEA to the excised burn wound.

These case studies incorporate several critically important guidelines that should be followed during payer claim adjudication:

- Add-on codes are always to be distinguished from primary codes in that they are always secondary procedures and, as such, have been assigned relative values that have been reduced from the relative values that would be assigned to a primary code. Add-on codes are never primary procedures and can never stand alone.
- As secondary procedure/codes with already reduced value and payment amounts, no additional payment reduction is required or appropriate.
- Claims for add-on codes should never be submitted with modifier 51 because it would be redundant and could inappropriately trigger a further and incorrect reduction in payment from the already reduced value set in payer fee schedules.
- Payers should disregard modifier 51 any time it is submitted with an add-on code and, instead, allow payment at the relative value already set for the add-on code multiplied by the number of units of service reported for the respective add-on code.
- Therefore, payers should never apply the multiple procedure reduction to any add-on codes.
- When it is necessary to report an add-on code, it should be listed on a separate line, once only, with the number of units for that code entered in the Units field of the claim form. Similarly, when it is necessary to adjudicate an add-on code and it is reported as just described, it should be paid accordingly based on the number of units of service entered on the single line where the code is entered.

Case Study: Acute Care of Burns

(Surgical procedures only are listed. Refer to the Case Study narrative for descriptions. To conserve space, certain columns on the CMS-1500 (08-05) have been omitted. Claim form columns are shaded.)

Dates of Service	Procedures, Services, Supplies	Days or Units	
Postburn Day (PBD) 2	Surgical preparation of arms & forearms [2700 sq cm] 15002 [primary code]	1	1 st 100 sq cm
“	15003 [add-on code]	26	Each add'l 100 sq cm or part thereof (2600 sq cm)
“	Surgical preparation of bilateral hands [500 sq cm] 15004 [primary code]	1	1 st 100 sq cm
“	15005 [add-on code]	4	Each add'l 100 sq cm or part thereof (400 sq cm)
“	Allograft application to arms & forearms [2700 sq cm] 15300 [primary code]	1	1 st 100 sq cm
“	15301 [add-on code]	26	Each add'l 100 sq cm or part thereof (2600 sq cm)
“	Allograft application to bilateral hands [500 sq cm] 15320 [primary code]	1	1 st 100 sq cm
“	15321 [add-on code]	4	Each add'l 100 sq cm or part thereof (400 sq cm)

Example 2: Coding Burn Excision Followed by Application of Acellular Dermal Replacement and Later Grafting of Tissue Cultured Epidermal Autografts (CEA)

(Surgical procedures only are listed. To conserve space, certain columns on the CMS-1500 (08-05) have been omitted. Claim form columns are shaded.)

Dates of Service	Procedures, Services, Supplies	Days or Units	
Postburn Day (PBD) 4	Surgical preparation of anterior & posterior torso [3500 sq cm] 15002 [primary code]	1	1 st 100 sq cm
“	15003 [add-on code]	34	Each add'l 100 sq cm or part thereof (3400 sq cm)
Postburn Day (PBD) 5	Application of acellular dermal replacement to torso [3500 sq cm] 15170 [primary code]	1	1 st 100 sq cm
“	15171 [add-on code]	34	Each add'l 100 sq cm or part thereof (3400 sq cm)
Postburn Day (PBD) 35	Application of tissue cultured epidermal autografts to anterior & posterior torso [3500 sq cm] 15150 [primary code]	1	1 st 25 sq cm
“	Application of tissue cultured epidermal autografts to anterior & posterior torso 15151 [add-on code]	1	Add'l 1-75 sq cm
“	Application of tissue cultured epidermal autografts to anterior & posterior torso 15152 [add-on code]	34	Each add'l 100 sq cm or part thereof (3400 sq cm)