



**Missouri Care**

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**WellCare Prescription Insurance**

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**Wound Care**

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4/5/2018, 4/4/2019**

**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**DISCLAIMER**

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on [www.wellcare.com](http://www.wellcare.com). Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

**BACKGROUND**

Wound care includes, but is not limited to ulcers, pressure ulcers, open surgical sites, fistulas, tube sites and tumor erosion sites when the skills of a licensed therapist, qualified wound care nurse, nurse or physician/physician extender are required to safely and effectively provide the care necessary for their treatment. Wound healing involves several factors and is influenced by the severity of the injury. Partial thickness wounds penetrate the epidermis and involve the dermis. A full thickness wound involves the epidermis and dermis and may include subcutaneous tissue, muscle, tendon, and bone.<sup>1</sup>

Covered chronic wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds. Eventual wound closure with or without grafts, skin replacements or other surgery (such as

amputation, wound excision, etc.) should be the goal of most chronic wound care. Medicare payment for professional wound care procedures requires that all applicable adjunctive measures are also employed as part of comprehensive wound management. Such adjunctive measures include but are not limited to appropriate control of complicating factors such as pressure (i.e., off-loading, padding, and appropriate footwear), infection, vascular insufficiency, metabolic derangement and/or nutritional deficiency. Wound care in the absence of such measures, when they are indicated, is not considered to be medically reasonable and necessary. With appropriate management, it is expected that, in most cases, a wound will reach a state at which its care should be performed primarily by the member and/or the member's caregiver with periodic physician assessment and supervision. Wound care that can be performed by the member or the member's caregiver will be considered to be maintenance care.

Standard wound care includes assessment of a member's vascular status and correction of any vascular problems in the affected area, controlling infection, optimization of nutritional status (including glucose control), and debridement by appropriate means to remove devitalized tissue. Members with wounds that are associated with ischemia that has not been evaluated and treated, abscess formation, active infection, exposed tendons or bones, wet or dry gangrene, and or otherwise cannot be treated with local care should have general, vascular and/or orthopedic surgery consultations in their documentation.<sup>2</sup>

#### *Debridement<sup>2</sup>*

Debridements of the wound(s), if indicated, must be performed judiciously and at appropriate intervals. Medicare expects that with appropriate care, wound volume or surface dimension should decrease by at least 10 percent per month or wounds will demonstrate margin advancement of no less than 1 mm/week. Medicare expects the wound-care treatment plan to be modified in the event that appropriate healing is not achieved. Medicare expects fewer than five debridements involving removal of muscle and/or bone debridements to be required for management of most wounds. Payment for prolonged, repetitive debridement services requires adequate documentation of complicating circumstances that reasonably necessitated additional services. Types of active wound care management and procedures are performed to remove devitalized tissue and promote healing, and involve selective and non-selective debridement techniques. Of note:

- *Conservative sharp debridement* is the classical method of selective wound debridement. Conservative sharp debridement is a minor procedure that typically requires no anesthesia. Scalpel, curettes, scissors and tweezers/forceps may be used and only clearly identified devitalized tissue is removed. Generally, there is no bleeding associated with this procedure.
- *Whirlpool* provides a means where a wound can be submerged in water and, if appropriate, an additive agent is used for cleansing. Whirlpool may be covered if medically necessary for the healing of the wound. Generally, whirlpool treatments do not require the skills of a therapist to perform. The skills of a physical therapist may be required to perform an accurate assessment of the member and the wound to assure the medical necessity of the whirlpool for the specific wound type. The skills, knowledge and judgment of a qualified physical therapist might be required when the member's condition is complicated by circulatory deficiency, areas of desensitization, complex open wounds, and fractures. Immersion in the whirlpool to facilitate removal of a dressing would not be considered a skilled treatment modality.
- *Lavage (non-immersion hydrotherapy)* involves the use of an irrigation device, with or without pulsation, to provide a water jet to administer a shearing effect to loosen debris within a wound. Some electric pulsatile irrigation devices include suction to remove debris from the wound after it is irrigated.

Wound care involves evaluation and treatment of a wound including identifying potential causes of delayed wound healing and modifying treatment as directed by the certifying physician. Determining the agent of delayed wound healing such as vascular disease, infection, diabetes or other metabolic disorders, immunosuppression, unrelieved pressure, radiation injury and malnutrition will help determine the course of treatment. Evaluations could include comprehensive medical evaluation, vascular evaluation, orthopedic evaluation and metabolic/nutritional evaluation leading to a plan of care. The plan may include metabolic corrections including dietary supplementation, specialized wound care, pressure relief, use of compression to manage edema,

debridement and reconstruction, rehabilitation therapy, possible general, vascular and/or orthopedic surgery, and antimicrobial agents.

### *Dressings<sup>2</sup>*

A variety of dressings are available and are briefly outlined below:

**Wet dressings.** Water and medication can be applied to the skin with dressings (finely woven cotton, linen, or gauze) soaked in solution. Wet compresses, especially with frequent changes, provide gentle debridement. Wet-dry dressings are considered to be part of the routine nursing care service and not medically necessary for active wound care or debridement.

**Dry dressings.** Used to protect the skin, hold medications against the skin, keep clothing and sheets from rubbing, or keep dirt and air away. Such dressings also prevent members from scratching or rubbing.

**Advanced dressings.** Used with increasing frequency in the treatment of acute wounds, chronic venous, diabetic and pressure ulcers. A variety of dressings are available including transparent films, foams, hydrocolloids, and hydrogels. Dressing changes (removal and subsequent reapplication) alone do not require the skills of physicians, podiatrists, physical therapists, occupational therapists or wound care nurses and in fact are usually performed by non-physician providers. When performed in conjunction with another wound care service, the dressing change is considered an integral component of that service.

### *Professional Organization Recommendations and Guidelines*

The **Agency for Healthcare Research and Quality<sup>3</sup>** published a technology assessment on 57 skin substitutes for treating chronic wounds available in the United States and are regulated by FDA. The assessment broke the products into four groups:

- Human-derived products regulated as HCT/Ps
- Human- and human/animal-derived products regulated through PMA or HDE
- Animal-derived products regulated under the 510(k) process
- Synthetic products regulated under the 510(k) process

A goal of the AHRQ report was to characterize the state of the evidence on skin substitutes as wound care products for chronic wounds. In addition, the report sought to determine the efficacy of skin substitutes in the trials. The following points were published by the AHRQ:

- Eighteen RCTs examining only seven of the skin substitute products identified for this report met the inclusion criteria; twelve studies examined diabetic foot ulcers (DFU) and six examined vascular leg ulcers.
- No studies of pressure ulcers met inclusion criteria; only one RCT of pressure ulcers was identified.
- Of the included studies, none had a high risk of bias and one had an unclear risk of bias, while the others were divided between low (eight studies) and moderate (nine studies) risk of bias.
- No studies reported blinding of the person assessing wound healing.
- All the studies in the evidence base reported some benefit of skin substitutes over the control treatments when number of wounds completely healed was measured between 8 and 16 weeks but the reported results varied widely across studies.
- The strength of the evidence base for evaluating complete wound healing of DFUs at 12 weeks was graded as low for the comparisons of Graftjacket vs. moist wound products, the comparison of Apligraf vs. a nonadherent dressing, for Graftskin vs. saline-moistened gauze, and for Dermagraft vs. saline-moistened gauze. The strength of the evidence for other comparisons for DFUs were graded insufficient, primarily because the overall risk of bias was moderate and/or the reported treatment effect (percentage increase in completely healed wounds) was imprecise. A low grade reflects a low confidence that the evidence reflects the true effect of the skin substitute on complete wound healing as compared to another intervention. Additional evidence is needed before concluding findings.

- Two comparisons were judged to have low strength of evidence for complete wound healing of venous or mixed ulcers at 12 weeks - one comparing Apligraf and compression to compression, and one comparing Oasis Wound Matrix with compression to compression. In each case, the included study was a multicenter trial, had a low risk of bias and reported a precise and direct result. The other comparisons were from studies with moderate risk of bias and imprecise results; these were judged to have an insufficient strength of evidence grade.
- Data on wound recurrence was reported in only seven studies where follow-up was between 6 and 14 months. Recurrence rates varied widely across studies but were comparable between groups within studies.
- Only generally healthy members were enrolled in studies. Members with infected wounds, who used medications that could impede wound healing, had clinically significant medical conditions, significant peripheral vascular disease, malnutrition, or uncontrolled diabetes were excluded.
- No clinical efficacy data from RCTs are available for the large majority of skin substitute products identified.
- Overall applicability of the evidence base is limited to a small number of skin substitutes examining DFUs and vascular leg ulcers and to members in generally good health.
- Various features of study design and conduct as pointed out in this report could be improved in future wound care studies to ensure better study quality and low potential for bias.

The **National Institute for Clinical Excellence**<sup>4</sup> recommends that the choice of debriding agent for difficult to heal surgical wounds should be based on comfort, odor control, other aspects relevant to member acceptability, type and location of wound and total costs. In addition, a structured approach to care (including assessing the member before the operation to identify potential wound healing problems) is required to improve the overall management of surgical wounds. To support this, enhanced education of health care workers, members and caregivers, and sharing of clinical expertise will be required.

Recommendations by the **American Diabetes Association** regarding the foot care of diabetics include:<sup>5,6</sup>

- Any new device, dressing, or biological or pharmacological agent should be evaluated in a consistent and rigorous manner and should not be adopted without substantial evidence of its efficacy.
- The reference standard for evaluation of new treatments is the randomized controlled trial, which should consist of a sufficient number of members to obtain adequate statistical power.
- The relevant outcomes, wound healing and the rate of healing, depend upon ulcer severity and the treatment regimen as well as variables such as member compliance.
- Member inclusion and exclusion criteria must be described, including key wound parameters (e.g., area and depth), ulcer duration, and presence of infection, neuropathy, and/or ischemia.
- All members in controlled trials must receive standardized wound care, including off-loading, a defined debridement protocol, and evaluation of member compliance with the protocol.
- Primary study endpoints should include the proportion of members with complete wound healing, as defined by the Wound Healing Society, within a specific time frame. Secondary endpoints include time to healing, velocity of wound healing, rate of recurrence, quality of life, and cost-effectiveness.

In 2006, the **Wound Healing Society** published guidelines on the care of members with arterial insufficiency. Within these guidelines, the WHS stated that "extracellular matrix replacement therapy appears to be promising for mixed ulcers and may have a role as an adjuvant agent in arterial ulcers, but further study is required." Further, the guidelines specified that "despite the existence of animal studies, case series, and a small number of RCTs to support biomaterial use for pressure ulcers, diabetic ulcers, and venous ulcers, there are no studies specifically on arterial ulcers. Therefore, studies in arterial ulcers must be conducted before the recommendation can be made".<sup>5,6</sup>

The WHS also published guidelines for acute wound care. The panel concluded that when an excised burn with a total burn surface area (TBSA) is so large that donor sites for split-thickness skin grafts are not enough, permanent skin substitutes can be used as skin replacement with no fear of rejection. In addition, a WHS panel

advised that nonimmunogenic skin substitutes might also serve as permanent skin replacement with no fear of rejection. Temporary biologic, synthetic, biosynthetic, or bioengineered dressings are not sufficient to provide permanent burn wound closure, but they can allow for the wound to be free of infection until the permanent wound heals completely. Further, 2006 guidelines state that various skin substitutes or biologically active dressings are being developed to provide temporary wound closure of chronic wounds and serve as a source of stimuli (e.g., growth factors) for healing of venous ulcers.<sup>5,6</sup>

The **Association for the Advancement of Wound Care** published a summary algorithm for venous ulcer care that recommends use of dressings that maintain a moist environment. For members with no healing within 30 days, the algorithm recommends biologic dressings, including matrix dressings.<sup>5,6</sup>

Clinical practice guidelines published by the **American College of Foot and Ankle Surgeons** on diabetic foot disorders; the conclusion from the ACFAS is that "although these products are commonly used in clinical practice, they have not yet been conclusively shown to expedite wound healing".<sup>5,6</sup>

The **American Podiatric Medical Association** has given approval for Oasis Wound Matrix.<sup>5,6</sup>

The **American Society of Plastic Surgeons** published guidelines for management of chronic lower extremity wounds. The ASPS advised that appropriate dressings should be used to maintain a moist environment; the ASPS did not support one specific type of dressing material. ASPS further stated that the following be included as possible products for members requiring wound care: bioactive dressings, including topical antimicrobials, bioengineered composite skin equivalent, bilaminar dermal regeneration template and recombinant human growth factor.<sup>5</sup>

The **Wound, Ostomy and Continence Nurses Society** published guidelines on the management of wounds and use of Oasis Wound Matrix product.<sup>5</sup>

## **Electrical Stimulation and Electromagnetic Therapy for Wound Healing**

Chronic wounds, including venous ulcers, diabetic foot ulcers, and pressure sores, are a major public health problem in the United States; the total prevalence of these wounds has been estimated to range from 3 to 6 million. Difficult-to-heal wounds lead to high rates of morbidity and mortality, negative effects on quality of life, and high healthcare costs. While leg and foot ulcers have numerous causes, such as venous disease, arterial disease, mixed venous-arterial disease, diabetic neuropathy, trauma, immobility, and vasculitis, over 90% of chronic lesions are related to venous disease, arterial disease, and neuropathy. Chronic wounds require intervention to promote healing and to prevent infection, progression, and recurrence.<sup>6</sup>

Regardless of the cause, ulcer treatment usually begins with conservative therapies such as pressure relief, sterile dressings, and topical antibiotics. Debridement to remove necrotic tissue may also be necessary. If conservative treatments fail to promote wound healing, surgical treatments such as sclerotherapy of the affected vein, skin flap reconstruction, or amputation of a digit or foot may be necessary. A less invasive approach to management of chronic wounds involves electrical stimulation. This technique typically involves application of one electrode to the skin near the wound and application of a second electrode to saline-moistened gauze placed over the wound. The saline provides a conductive medium that allows electric current to pass directly through the wound. Although electrical stimulation for wound healing may involve electrical potentials as high as 200 volts, the parameters of stimulation such as pulse length or frequency of alternating current are adjusted such that muscle contractions do not occur since contractions could cause pain or disrupt healing.<sup>6</sup>

*Centers for Medicare and Medicaid Services Statement and FDA Regulations*<sup>6</sup>

ES and electromagnetic therapy have been used or studied for many different applications, one of which is accelerating wound healing. ES for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy uses a pulsed magnetic field to induce current. CMS was asked to reconsider its national non-coverage determination for electromagnetic therapy. After thorough review, CMS determined that the results from the use of electromagnetic therapy for the treatment of wounds were similar to the results from the use of ES. Effective July 1, 2004,

Medicare covered electromagnetic therapy for the same settings and conditions for which ES is covered. Medicare will allow either one covered ES therapy or one covered electromagnetic therapy for the treatment of wounds. Electrical stimulation for wound healing is performed with devices similar to those designed to stimulate muscle contractions or to provide transcutaneous electrical nerve stimulation (TENS). These stimulators are regulated by the FDA as Class II devices, and over 500 of these devices have been approved via the FDA 510(k) process.<sup>6</sup>

#### *Professional Organizations*

According to the **American Physical Therapy Association (APTA)**, there is evidence that some forms of electrical stimulation enhance circulation and facilitate wound healing. When the Medicare Coverage Advisory Committee (MCAC) of the Health Care Financing Administration (HCFA) concluded that there was insufficient evidence that electrical stimulation improved healing of chronic wounds, the APTA filed a lawsuit against HCFA and obtained a reversal in the decision concerning non-coverage of this procedure.<sup>7</sup>

The **National Pressure Ulcer Advisory Panel (NPUAP)** presented evidence in 2000 concerning the efficacy of electrical stimulation for treatment of non-healing wounds. In February 2001, the Executive Committee of the organization gave unanimous approval for this use of electrical stimulation. A 2009 update by the NPUAP continued support of electrical stimulation for non-healing wounds.<sup>8</sup>

### **Negative Pressure Wound Therapy**<sup>9-13</sup>

Negative pressure wound therapy (NPWT) is a treatment for acute and chronic wounds that involves the application of subatmospheric pressure to the open wound with the goal of creating a controlled, closed wound amenable to surgical closure, grafting, or healing by secondary intention. NPWT is intended as an adjunct treatment for the healing of nonhealing or slow healing acute or chronic wounds that are refractory to standard treatment.

The morbidity and mortality associated with difficult-to-heal acute and chronic wounds negatively affects the quality of life of these members and incurs high healthcare costs. Difficult-to-heal wounds include acute, subacute, and chronic wounds, such as those resulting from trauma, skin grafting, flap or graft failure, or dehiscence, and open wounds over fractures. Negative pressure wound therapy (NPWT) utilizes subatmospheric pressure to promote wound closure in such wounds. Vacuum-assisted wound closure (V.A.C.® Therapy System), manufactured by Kinetic Concepts Inc. (KCI), was the first NPWT device approved by the Food and Drug Administration (FDA). The NPWT device consists of a noncollapsible evacuation tube embedded in a reticulated polyurethane dressing made of open-cell foam. After thorough wound debridement, the foam dressing is placed within the wound bed and covered by an occlusive dressing to form an airtight seal, and the distal end of the tube is attached to a vacuum unit. Continuous or intermittent negative pressure, the amount of which is determined by the wound type, is applied causing the foam to collapse on itself. When this happens, the resultant forces are distributed equally across the wound surfaces. The theory behind NPWT is that this equal distribution of forces will result in: (1) removal of excess fluid; (2) increased blood flow and decreased bacterial colonization; (3) granulation tissue formation; and (4) partial or complete wound closure with or without the need for additional procedures. The goal of therapy is to convert open wounds into closed, controlled wounds that are amenable to healing by surgery, grafting, or secondary intention.

### **Noncontact Normothermic Wound Therapy (E/I)**

Noncontact normothermic wound therapy (NNWT) using the Warm-Up® Active Wound Therapy system, is a thermal wound care system designed to provide an optimal environment for wound healing. The system utilizes a noncontact wound cover and a warming unit to maintain 100% relative humidity and to produce normothermia in the wound bed. This report will focus on the safety and efficacy of NNWT for the treatment of chronic venous ulcers, stage III and IV pressure ulcers, neuropathic ulcers secondary to diabetes, and ulcers in areas of osteomyelitis. The rationale underlying NNWT is that high moisture levels and physiologic temperatures promote



wound healing. Physiologic temperature increases blood flow to the affected tissue, thereby increasing oxygenation, which increases collagen deposition, scar formation, and antibacterial processes.

There is limited evidence documenting a modest treatment effect of NNWT to promote the healing of venous ulcers, pressure ulcers, and diabetic foot ulcers. However, small study populations, lack of blinding and insufficient statistical analysis compromised the quality of most of the clinical trials. Furthermore, patient selection criteria were not sufficiently defined, and long-term follow-up data evaluating wound stability and recurrence rates were not available from large-scale, randomized controlled trials. One small pilot study investigated NNWT for chronic skin wounds associated with osteomyelitis; this study did not reveal any statistical difference between NNWT and standard care (Hayes, 2003).

At this time, there is insufficient evidence available to support the use of non-contact radiant heat bandage devices in the treatment of any classification of wounds. While the evidence regarding this therapy includes several randomized clinical trials published in the medical literature, the sample sizes of these studies have been too small to adequately evaluate the efficacy of this treatment method. Additionally, the current outcomes of several available studies did not find a significant difference between non-contact radiant heat bandage therapy and standard therapy. Additional larger-scale studies are warranted before adequate data is available to make an educated assessment of this technology. As such, NNWT is considered experimental and investigational and NOT a covered benefit for the treatment of ulcers and other wounds.

### **Ultrasound Therapy for Wound Healing (Mist Therapy™)<sup>14-18</sup>**

Chronic wounds, including venous ulcers, diabetic foot ulcers, and pressure sores, are a significant health problem in the United States, affecting approximately 1% of adults. Difficult-to-heal wounds lead to high rates of morbidity and mortality, negative effects on quality of life, and lengthy periods of medical care. Although leg and foot ulcers have numerous causes, such as malfunctioning veins, diseased arteries, mixed venous-arterial disease, nerve damage due to diabetes, trauma, or immobility, over 90% of the lesions are related to venous disease, arterial disease, and nerve damage. Another common type of chronic wound is pressure sores, which develop due to soft tissue breakdown at sites of repeated or prolonged contact between underlying bone and external surfaces. Regardless of the cause, chronic wound treatment usually begins with conservative therapies (e.g., pressure relief, sterile dressings, topical antibiotics). Debridement to remove dead or severely damaged tissue may also be necessary. If conservative treatments fail to promote wound healing, surgical treatments may be necessary (e.g., closure of a malfunctioning vein, transplantation of tissue from another site to cover the wound, amputation of a digit or foot).

The Mist Therapy™ System has been developed to provide simultaneous cleansing and debridement of wounds. Treatment with this device involves holding an ultrasonic handset 1 cm away from the wound and applying a saline solution to the handset, generating a saline mist that is designed to carry low levels of ultrasonic energy into the wound. According to the device manufacturer, this treatment promotes healing of acute, traumatic, and chronic wounds by stimulating cellular activities that contribute to healing and by cleaning the wound surface. Under normal circumstances, members undergo Mist Therapy on an outpatient basis in 3 sessions per week and 3 to 12 minutes of treatment per session, depending on wound size.

Results of the available studies provide preliminary evidence that, as a supplement to standard wound care, Mist Therapy improves healing of chronic diabetic foot ulcers and of chronic ulcers due to insufficient lower limb blood flow. In an RCT that examined wound healing in 55 patients who underwent up to 12 weeks of Mist Therapy for diabetic foot ulcers, this therapy was associated with a statistically significant improvement in wound healing. Complete healing was achieved by 41% of patients who underwent true Mist Therapy versus 14% of patients who underwent placebo therapy. For patients who had wounds due to insufficient lower limb blood flow, another RCT found that Mist Therapy was associated with a statistically significant improvement in partial wound healing. After 12 weeks of treatment, > 50% wound healing occurred for 63% of patients who underwent Mist Therapy versus 29% of patients who underwent standard wound care alone. Although these results are promising, these RCTs were relatively small (n=55 to 70 evaluable patients) and no other controlled trials of Mist Therapy were identified to confirm the efficacy of this treatment for diabetic foot ulcers and ulcers due to insufficient lower limb blood flow. Furthermore, the latter RCT used 50% rather than 100% wound healing as the measure of success and did not

report whether any patients achieved complete wound healing. There is currently insufficient evidence to support the effectiveness of ultrasound therapy in the management of members with chronic wounds.

## **POSITION STATEMENT**

Wound Care **is considered medically necessary** for arterial insufficiency related wounds, VSUs and DFUs. Wounds should:

- Require non-selective or selective debridement to facilitate healing or due to necrotic tissue; **OR**,
- Require complex dressings; **OR**,
- Show documentation of signs of infection or risk factors for infection (e.g., diabetes mellitus, moderate dose of steroids, frail, elderly, poor nutrition, ischemia, venous insufficiency, etc.); **OR**,
- Surgical wounds that must be left open to heal by secondary intention; **OR**,
- Infected open wounds induced by trauma or surgery; **OR**,
- Wounds associated with complicating autoimmune, metabolic, vascular or pressure factors; **OR**,
- Open or closed wounds complicated by necrotic tissue and eschar.

Wound Care may be provided in the office setting, outpatient hospital or at home.

In rare instances, the goal of wound care provided in outpatient settings may be only to prevent progression of the wound, which, due to severe underlying debility or other factors such as inoperability, is not expected to improve. In this case the focus of the care should be to transition the patient for self-care or to the patient's care giver for continued care of the wound if feasible based on the patient and/or caregiver's cognitive ability to perform wound self-care. In such cases, this would clearly be documented in the member's clinical record.

### **Pressure Ulcer and Wounds (Decubitus Wounds) in Adults<sup>8,9</sup>**

The National Pressure Ulcer Advisory Panel guidelines state that reduction and relief and strategies to maintain tissue tolerance. The panel did not consider interventions unless they were supported by two or more clinical studies or were recommended in current clinical practice. Pressure ulcers usually occur over bony prominences and are graded or staged to classify the degree of tissue damage observed. The staging of pressure ulcers recommended for use by this panel is consistent with the recommendations of the National Pressure Ulcer Advisory Panel as derived from previous staging systems proposed by Shea (1975) and the International Association for Enterostomal Therapy (IAET, 1988). The staging is as follows:

- Stage I.** Nonblanchable erythema of intact skin; the heralding lesion of skin ulceration.  
Note: Reactive hyperemia can normally be expected to be present for one-half -to three-fourths as long as the pressure occluded blood flow to the area (Lew is and Grant, 1925).
- Stage II.** Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.
- Stage III.** Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
- Stage IV.** Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures (e.g., tendon or joint capsule).  
Note: Undermining and sinus tracts may also be associated with Stage IV pressure ulcers.

Staging definitions recognize these assessment limitations:

- Identification of Stage 1 pressure ulcers may be difficult in members with darkly pigmented skin.
- When eschar is present, accurate staging of the pressure ulcer is not possible until the eschar has sloughed or the wound has been debrided.

### **Evaluation and Improvement**

Clinical Coverage Guideline

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Evaluations could include comprehensive medical evaluation, vascular evaluation, orthopedic evaluation and metabolic/nutritional evaluation leading to a plan of care. The plan may include metabolic corrections including dietary supplementation, specialized wound care, pressure relief, use of compression to manage edema, debridement and reconstruction, rehabilitation therapy, possible general, vascular and/or orthopedic surgery, and antimicrobial agents. In order to be covered under Medicare, a service must be reasonable and necessary. Among the requirements for a reasonable and necessary service are that the service be safe and effective, furnished in the appropriate setting, and ordered and/or furnished by qualified personnel.<sup>1,2</sup>

It is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement cannot be shown as long as the overall goal of care for the specific member is healing and not palliation. It is, however, anticipated that at least one of the following metrics would be addressed with palliative care, and the reason(s) for palliative care would be clearly documented and discussed with the member (or member's representative). **Evidence of improvement includes measurable changes in at least some of the following:**<sup>2</sup>

- Drainage
- Inflammation
- Swelling
- Pain and/or tenderness
- Wound dimensions (surface measurements, depth)
- Granulation tissue
- Necrotic tissue/slough
- Tunneling or undermining

**A wound that shows no improvement after 30 days may require a new approach, which should include a physician reassessment of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing, or a new treatment approach.** In rare instances, the goal of wound care provided in an outpatient setting may be only to prevent progression of the wound, which, due to severe underlying debility or other factors such as inoperability, is not expected to improve.<sup>2</sup>

Initial requests for office and outpatient hospital wound care are authorized for a total of three weekly (3) visits. After 3 approved weekly treatments, additional documentation, including pre-and post-debridement wound measurements, detailed descriptions of wound (including photographs of member's wound) as well as clinical documentation by physician to support need for ongoing treatment (such as continuing decrease in wound size), may be requested to authorize.

Ongoing authorizations for office and outpatient hospital are approved for up to 3 weekly visits and will require a separate authorization request from provider.

For home-based wound care treatments, up to 12 weekly visits may be authorized for initial treatment with an initial submitted authorization. A separate wound care authorization request is required for ongoing treatment and also may be approvable up to 12 weekly visits with supporting documentation.

## **Therapy Specific Criteria**

Criterion for the following types of Wound Care are listed below:

- Active Wound Care Management
- Electrical Stimulation and Electromagnetic Therapy for Wound Healing
- Hyperbaric and Topical Oxygen Wound Therapies
- Negative Pressure Wound Therapy
- Topical Oxygen Wound Therapy
- Ultrasound Therapy for Wound Healing (Mist Therapy™)

Active wound care procedures are performed to remove devitalized tissue and promote healing, and involve selective and debridement techniques.<sup>2</sup>

## **Active Wound Care Management**

**Wound Care Selective.** Debridement will not be considered a reasonable and necessary procedure for a wound that is clean and free of necrotic tissue or in the absence of abnormal wound healing. Selective debridement should only be provided under a certified plan of care.

Outpatient therapy services shall be furnished under a plan established by:

- A physician / non-physician practitioner (NPP) (consultation with the treating physical therapist, occupational therapist, or speech-language pathologist is recommended. Only a physician may establish a plan of care in a Comprehensive Outpatient Rehabilitation Facility (CORF); **OR**
- A physical therapist who will provide the physical therapy services; **OR**
- An occupational therapist who will provide the occupational therapy services; **OR**
- A speech-language pathologist who will provide the speech-language pathology services.

The plan may be entered into the patient's therapy record either by the person who established the plan or by the provider's or supplier's staff when they make a written record of that person's oral orders before treatment is begun.

Therapy may be initiated by qualified professionals or qualified personnel based on a dictated plan. Treatment may begin before the plan is committed to writing only if the treatment is performed or supervised by the same clinician who establishes the plan. Payment for services provided before a plan is established may be denied.

NOTE: It is acceptable to treat under two separate plans of care when different physician's/NPP's refer a patient for different conditions. It is also acceptable to combine the plans of care into one plan covering both conditions if one or the other referring physician/NPP is willing to certify the plan for both conditions. The Treatment Notes continue to require timed code treatment minutes and total treatment time and need not be separated by plan. Progress Reports should be combined if it is possible to make clear that the goals for each plan are addressed. Separate Progress Reports referencing each plan of care may also be written, at the discretion of the treating clinician, or at the request of the certifying physician/NPP, but shall not be required by contractors.

## **Electrical Stimulation and Electromagnetic Therapy for Wound Healing**

### **Applicable To:**

- Medicaid – All Markets
- Medicare – All Markets
- Medicaid – Florida (CMS Health Plan - CHIP)

The use of electrical stimulation (ES) and electromagnetic therapy **are considered medically necessary** for the treatment of the following types of chronic non-healing wounds:

- Stage III or IV pressure ulcers; OR,
- Arterial ulcers; OR,
- Diabetic ulcers; OR,
- Venous stasis ulcers

The use of ES and electromagnetic therapy **is considered medically necessary** only after 30 days of standard wound care has failed (The 30 day period may begin when the wound is acute). Standard wound care includes:

- Optimization of nutritional status
- Debridement by any means to remove revitalized tissue
- Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings
- Necessary treatment to resolve any infection that may be present
- Frequent repositioning (usually every two hours) of a member with pressure ulcers
- Offloading of pressure and good glucose control for diabetic ulcers
- Establishment of adequate circulation for arterial ulcers

- Use of compression system for members with venous ulcers

ES and electromagnetic therapy **is considered NOT medically necessary** in the following circumstances:

- As an initial treatment modality; OR,
- Measurable signs of healing have not been demonstrated within a 30-day period of treatment\*
- Treatment is used in an unsupervised setting (home use) as this has not been found to be medically reasonable and necessary

\* Signs of improvement include decrease in wound size (surface area or volume), amount of exudates, or amount of necrotic tissue.

ES or electromagnetic therapy **must be** discontinued when wound demonstrates 100% epithelialized wound bed.

### **Negative Pressure Wound Therapy**

#### **Applicable To:**

- Medicaid – All Markets
- Medicare – All Markets
- Medicaid – Florida (CMS Health Plan - CHIP)

#### **NEGATIVE PRESSURE WOUND THERAPY (Initial Coverage)**

Negative pressure wound therapy (NPWT), and related pumps and supplies, **is/are considered medically necessary** when the following criteria are met:

The member has:

- A chronic Stage III or IV pressure ulcer; **OR**,
- Neuropathic (e.g. diabetic) ulcer; **OR**,
- Venous or arterial insufficiency ulcer; **OR**,
- Chronic (being present for at least 30 days) ulcer of mixed etiology.

A complete wound therapy program described by criterion 1 and criteria 2, 3, **OR** 4 (depending on type of wound) should have been tried or considered and ruled out prior to application of NPWT.

- For ulcers or wounds, the following components of a wound therapy program **MUST** include a minimum of **ALL** of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:
  - Documentation in the member's medical record of evaluation, care, and wound measurements by a licensed medical professional; **AND**,
  - Application of dressings to maintain a moist wound environment; **AND**,
  - Debridement of necrotic tissue if present; **AND**,
  - Evaluation of and provision for adequate nutritional status.
- For Stage III or IV pressure ulcers :
  - Member has been appropriately turned and positioned; **AND**,
  - Member has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis; **AND**,
  - Member's moisture and incontinence have been appropriately managed.
- For neuropathic (diabetic) ulcers:
  - Member has been on a comprehensive diabetic management program; **AND**,
  - Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.
- For venous insufficiency ulcers:

- Compression bandages and/or garments have been consistently applied; **AND**,
- Leg elevation and ambulation have been encouraged.

#### ***OTHER EXCLUSIONS FROM COVERAGE***

An NPWT pump and supplies **is NOT medically necessary and NOT a covered benefit** if ONE OR MORE of the following are present:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted; **OR**,
- Untreated osteomyelitis within the vicinity of the wound; **OR**,
- Cancer malignancy present in the wound; **OR**,
- The presence of a fistula to an organ or body cavity within the vicinity of the wound; **OR**
- Inpatient treatment of wounds where post-surgical care includes NPWT and ordered by treating physician.

#### **NEGATIVE PRESSURE WOUND THERAPY (Continued Coverage)**

*For wounds and ulcers described above, once placed on an NPWT pump and supplies, in order for coverage to continue a licensed medical professional MUST do the following:*

- On a weekly basis at home, in the outpatient clinic or outpatient hospital setting, the wound(s) being treated with the NPWT pump shall be assessed.
- On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

NOTE: If criteria are NOT fulfilled, continued coverage of the NPWT pump and supplies will be denied **as NOT medically necessary**.

#### **NEGATIVE PRESSURE WOUND THERAPY (End of Coverage)**

For wounds and ulcers described under A or B above, an NPWT pump and supplies will be denied as NOT medically necessary with ANY of the following, whichever occurs earliest:

- Criteria C1-C2 cease to occur; **OR**,
- In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued; **OR**,
- Any measurable degree of wound healing has failed to occur *over the prior month*. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound; **OR**,
- Four months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using NPWT pump in the treatment of the most recent wound; **OR**,
- Once equipment or supplies are no longer being used for the member, whether or not by the physician's order.

**NPWT Pumps.** NPWT pumps must be capable of accommodating more than one wound dressing set for multiple wounds on a member. Therefore, more than one pump billed per member for the same time period **is NOT medically necessary and will be denied**.

**Supplies.** Coverage is provided up to a maximum of 15 dressing kits per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change. Coverage is provided up to a maximum of 10 canister sets per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). For high volume exudative wounds, a stationary pump with the largest capacity canister must be used.

**Licensed Health Care Professional.** For the purposes of this coverage guideline, a licensed health care professional may be:

- A physician; **OR**,

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- Physician's assistant; **OR**,
- Registered nurse; **OR**,
- Licensed practical nurse; **OR**,
- Physical therapist.

### **Noncontact Normothermic Wound Therapy (E/I)**

**Applicable To:**

- Medicaid – All Markets
- Medicare – All Markets
- Medicaid – Florida (CMS Health Plan - CHIP)

Noncontact Normothermic Wound Therapy (NNWT) **is considered experimental and investigational and NOT a covered benefit** for the treatment of chronic ulcers and other wounds.

### **Ultrasound Therapy for Wound Healing (Mist Therapy™)<sup>32</sup>**

**Applicable To:**

- Medicaid – All Markets
- Medicare – All Markets
- Medicaid – Florida (CMS Health Plan - CHIP)

Low-frequency, non-contact ultrasound therapy for wound healing and reduction of chronic wound pain **is considered medically necessary** when the following are met:

- Wounds and ulcers meeting Medicare coverage for debridement but which are too painful for sharp or excisional debridement; **OR**
- Wounds and ulcers meeting Medicare coverage for debridement but with documented contraindications to sharp or excisional debridement; **OR**
- Wounds and ulcers meeting Medicare coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care.

Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided two to three times per week to be considered "reasonable and necessary. Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided two to three times per week to be considered "reasonable and necessary." The length of individual treatments will vary per wound size.

Observable, documented improvements in the wound(s) should be evident after six treatments. Improvements include documented reduction in pain, necrotic tissue, or wound size or improved granulation tissue. Continuing treatments are not covered for wounds demonstrating no improvement after six treatments.

Medicare will cover up to 18 treatments (MIST Therapy) to wounds with documented improvements of pain reduction, reduction in wound size, improved and increased granulation tissue, or reduction in necrotic tissue. Coverage for continuing treatments beyond 18 sessions will be considered only upon individual consideration.

**Notice:** This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

### **Exclusions**

Low-frequency, non-contact ultrasound therapy **is considered experimental / investigational** for all indications not listed above due to a lack of established efficacy in the medical literature.

## LIMITATIONS AND EXCLUSIONS

Wound care **is not medically necessary** for any of the following:

- Products other than those listed above under *Approved Products*.
- A superficial wound, less than 0.2mm in depth (i.e., abrasion, road rash, etc.), without documentation of signs of infection.
- A small-uncomplicated wound (0.5 cm. square) in a member without documentation of risk factors for infection (e.g., diabetes mellitus, moderate dose of steroids, frail, elderly, poor nutrition, ischemia, venous insufficiency, etc.) or signs of infection.
- There is no documentation of the continued need for debridement, or current wound infection, or complex wounds or dressings.
- The management of acute wounds; the care of wounds that normally heal by primary intention, such as clean, incised traumatic wounds; surgical wounds, which are closed primarily; and other uncomplicated postoperative wound care.
- Debridement of the wound(s) if there is no necrotic, devitalized, fibrotic, or other tissue or foreign matter present that would interfere with wound healing.
- Procedures performed for cosmetic reasons or to prepare tissues for cosmetic procedures.
- Wound care performed in a non-specialized office setting or by the member or the member's caregiver.

## PRODUCTS

Wound care continues to change as newer treatment and newer protocols and modalities are developed and recommended based on Evidence Based Medicine (EBM) and frequent subject matter expert review. Hence, when determining medical necessity, the products used for wound care will be the most efficacious for treating the member's wound(s). Products, treatment and procedures shall reflect the coverage specified by this Clinical Coverage Guidelines (CCG) and medical necessity. Items contained in this section are subject to change pending any changes to rules and regulations set forth by the Centers for Medicare and Medicaid Services, United States Food and Drug Administration or other related government organizations

### **General Guidelines and Evidence for Skin Substitutes Cellular and/or Tissue Based Products (CTPs)**

Biologic cell-based dressings are composed of a live-cell construct that contains at least one layer of live allogenic cells. Cell-based dressings can be used when traditional dressings have failed or are deemed inappropriate.<sup>24</sup> One study suggested that advanced biologics should be used when chronic wounds fail to heal at an appropriate rate of closure, (e.g., 55 percent reduction in wound area within four weeks of treatment).<sup>21</sup> Cell-based dressings are ideal for the treatment of chronic ulcers because additional cells and growth factors are added to a deficient wound-healing environment. Accelerated wound healing reduces the risk of wound infection.

Cell-based therapies may use epidermal and dermal elements. Other therapies focus on dermal elements such as collagen and fibroblasts, which prevent wound contraction and provide greater stability.<sup>22</sup> Apligraf combined with compression therapy has been found to improve healing of venous stasis ulcers compared with compression therapy.<sup>16</sup> Clinical rejection has not been reported. Cell-based therapies have also been studied in patients with diabetes.<sup>21-24</sup> In one study of 208 patients with non-infected neuropathic ulcers, weekly application of Graftskin for four weeks improved the rate of complete wound healing compared with usual care (56 versus 38 percent).<sup>24</sup> Other studies have shown Dermagraft to be superior to standard care in the healing of diabetic foot ulcers.<sup>28,39</sup>

Acellular matrices serve as a scaffold, which may assist in forming some of the structure, components, and signaling mechanism to assist in healing and regeneration. Some of these include AlloDerm, which is made of decellularized allogenic dermal component, and Integra, which is a bovine collagen-based dermal matrix.

### **General Limitations of Coverage for Cellular and/or Tissue Based Products (CTPs)**



- Timing, frequency, and number of reapplications of CTPs should be appropriate for the material used and clinical condition of the member. Medicare does not expect to see routine application of maximally allowed numbers of skin substitutes/replacements per wound and will monitor and evaluate claim data regarding numbers of applications per member and per wound.
- During a course of treatment, repeat applications of CTPs is not considered medically reasonable and necessary when previous applications was unsuccessful. Unsuccessful treatment is defined in this situation as increase in size or depth of a wound or ulcer, or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation or epithelialization and no progress toward closing) since the previous application.
- Retreatment of healed ulcers is not considered medically reasonable and necessary. Retreating the wound with the same CTP product is not indicated for ulcers for which an initial course of treatment with the same CTP was unsuccessful. An unsuccessful course of treatment is defined in this case as incomplete healing following maximal numbers of applications and/or maximal duration of treatment time indicated by the FDA label of the individual product and/or this LCD.
- CTPs are contraindicated in members with inadequate control of underlying conditions or exacerbating factors, or other contraindication (e.g., uncontrolled diabetes, active infection, active charcot arthropathy of the ulcer extremity, and/or vasculitis).
- Skin substitutes are contraindicated in members with known hypersensitivity to any component of the specific skin substitute (e.g, allergy to bovine).
- In vitro and in vivo histology studies have shown that Apligraf<sup>®</sup> either degrades or its cell viability is reduced when the device is exposed to the following cytotoxic agents: Dakin's solution, Mafenide acetate, Scarlet red dressing, Tincoban, Zinc sulfate, Povidine-iodine solution, Chlorhexidine, or Polymixin/Nystatin. The use of Apligraf<sup>®</sup> with these solutions will be considered not medically reasonable and necessary, and will result in denial of reimbursement.
- Any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with Dermagraft<sup>®</sup> may reduce the viability of the product. The use of Dermagraft<sup>®</sup> in conjunction with these solutions will be considered not reasonable and necessary and will result in denial of reimbursement.
- Treatment of any ulcer will typically last no more than 12 weeks. For diabetic foot ulcers, if after 9 weeks of treatment, and 3 applications of the CTP, satisfactory healing progress is not noted, then re-application of the CTP is not recommended and other treatment modalities must be considered.
- For venous stasis ulcers, if after 12 weeks of compression treatment and the appropriate number of applications of the CTP, a 50 percent or greater improvement is noted and documented, then one or more subsequent re-applications of the CTP will be considered for Medicare coverage. Otherwise, re-application of the CTP is not recommended and will not be reimbursed and other treatment modalities should be considered.
- Re-treatment within one year of completion of any given course of skin substitute for venous stasis ulcers is not covered.

## **Covered Products**

WellCare considers the products listed below as medically necessary for the treatment of wounds; coverage is considered experimental and investigational for indications not listed, including those that are not consistent with labeling by the U.S. Food and Drug Administration (FDA).

**Alloderm**

- For use in conjunction with breast reconstructive surgery.

**Apligraf**<sup>®2</sup>

Apligraf<sup>®</sup> is considered reasonable and medically necessary when criterion 1 **OR** 2 is met.

1. *For standard therapeutic compression for venous stasis ulcers (VSUs), all of the following must be met:*
  - Only for ulcers that have failed to respond to documented conservative measures of greater than four (4) weeks in duration, that have at minimum included regular dressing changes, debridement of necrotic tissue and standard therapeutic compression. A “failed response” is defined as an ulcer that has increased in size or depth, or for which there has been no change in baseline size or depth and no sign of improvement or indication that improvement is likely, such as granulation, epithelialization, or progress toward, closing. Documentation of response, or lack thereof, requires measurement of the ulcer at baseline, following cessation of conservative or conventional management. Documentation should also include measurement of the ulcer immediately prior to the placement of Apligraf<sup>®</sup>.
  - Only when adequate treatment of the underlying disease process(es) contributing to the ulcer, e.g., hypertension, is provided and documented in conjunction with the treatment; **AND**
  - Only for ulcers that are free of infection, redness, drainage, underlying osteomyelitis, surround cellulitis, sinus tracts or tunnels, eschar or any necrotic material that could interfere with the adherence of Apligraf<sup>®</sup> and wound healing.
2. *For standard diabetic foot ulcer (DFU) care for neuropathic DFUs, all of the following must be met:*
  - Only if the patient has the current medical diagnosis of either Type I or Type II diabetes mellitus;
  - Only if the patient does not have a current HbA1C reading exceeding 12%;
  - Only for full thickness ulcers of greater than three weeks in duration, which extend through the dermis but without tendon, muscle, capsule or bone exposure;
  - Only when adequate treatment of the underlying disease process(es) contributing to the ulcer, e.g., diabetes is provided and documented in conjunction with treatment; **AND**
  - Only for ulcers located on the foot or toes that are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material that could interfere with the adherence of Apligraf<sup>®</sup>, and the process of wound healing.

**For both VSUs and DFUs all of the following must also be satisfied and documented:**

- The patient must have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (presence of acceptable peripheral pulses and/or Doppler toe signals and/or ankle-brachial index [ABI] of 0.65 or greater in limb undergoing the procedure); **AND**
- DET treatment must be used in conjunction with following standard conservative measures:
  - Use of pressure-reducing footwear;
  - A non-weight bearing regiment;
  - Debridement of necrotic and callused tissue when necessary; and
  - Acceptable methods of wound care, such as saline moistened dressings.

The patient must be competent and/or have the support system required to participate in follow-up care associated with treatment of the wound with Apligraf<sup>®</sup>.

NOTE: Apligraf requires medical director review.

#### Contraindications, Exclusions and Limitations

- Payment for Apligraf<sup>®</sup> is limited to 3 applications per ulcer, though 5 applications of Apligraf<sup>®</sup> to a single wound are usually unnecessary but may be approved with additional information and request for authorization.
- Continued reapplication of Apligraf<sup>®</sup> when the treatment is unsuccessful after 30 days of treatment.

The use of Apligraf<sup>®</sup> on ulcers with any of the following conditions is considered not medically necessary:

- cellulitis;
- osteomyelitis;
- necrotic ulcer;
- draining wound;
- bone exposed- wound bed; or
- clinically significant wound healing impairment due to uncontrolled diabetes.

#### **Dermagraft<sup>®2</sup>**

Dermagraft<sup>®</sup> use is considered medically necessary in the following conditions and when used with standard diabetic foot ulcer care for neuropathic diabetic foot ulcers (DFUs):

- Only if member has a current medical diagnosis of Type I or Type II of diabetes mellitus;
- Only if member does not have a current HbA1C reading exceeding 12%;
- Only for full thickness ulcers that have been in existence for greater than six weeks;
- Only for ulcers which have failed to respond to documented conservative treatment measures of greater than six weeks;
- Only for ulcers located on the foot or toes that are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, sinus tracts or tunnels, eschar or any necrotic material that could interfere with the adherence of Dermagraft<sup>®</sup>, and process of wound healing;
- Only for ulcers which extend through the dermis but without tendon, muscle, capsule or bone exposure;
- The member must have adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in limb undergoing the procedure.

Dermagraft<sup>®</sup> treatment must be used in conjunction with following standard conservative measures:

- Use of pressure-reducing footwear;
- A non-weight bearing regimen;
- Debridement of necrotic and callused tissue when necessary;
- Acceptable methods of wound care, such as saline moistened dressings; and
- The member must be competent and/or have the support system required to participate in follow-up care associated with treatment of the wound with Dermagraft<sup>®</sup>.

Frequency is limited to eight applications per ulcer. As long as reasonable healing progress is noted, reapplication may continue to a maximum of 8 applications in 12 weeks. Continued reapplication of Dermagraft<sup>®</sup> when the treatment is unsuccessful after two applications as evidenced by increased wound size over two successive weeks is not medically necessary. Retreatment of the same ulcer using Dermagraft<sup>®</sup> within one year following the last successful or unsuccessful treatment is considered not medically necessary.

#### Contraindications, Exclusions and Limitations

The use of Dermagraft<sup>®</sup> on ulcers with any of the following conditions is considered not medically necessary:

- cellulitis;
- osteomyelitis;

- necrotic ulcer;
- draining wound;
- bone exposed-wound bed; or
- clinically significant wound healing impairment due to uncontrolled diabetes.

Dermagraft® is contraindicated for use in members with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution. It should not be used on wounds that have signs of clinical infections. Survival of the dermal substitute decreases significantly when the 24 steps noted in the FDA labeling are not followed, therefore the 24 steps must be followed and documented.

### **Dermapure**<sup>32</sup>

DermaPure® is a human cellular repair matrix used in the treatment of chronic and acute wounds and considered reasonable and medically necessary for chronic and acute wounds that have failed to respond to conservative measures.

#### **Contraindications, Exclusions and Limitations**

- Five applications per ulcer.
- Continued reapplication when the treatment is unsuccessful after 12 weeks of treatment, retreatment of an ulcer following an unsuccessful course of treatment or retreatment of a successfully treated healed ulcer will not be considered medically necessary.

### **Epifix**<sup>32</sup>

Epifix® is considered reasonable and necessary in the wound management for members with neuropathic diabetic foot ulcers (DFUs) when the following criteria are met and documented in the member's medical record:

- Only if the member has the current medical diagnosis of either Type I or Type II diabetes mellitus
- Only if the member does not have a current HbA1c reading above 12%
- Only for partial or full thickness ulcers of greater than four weeks in duration, with documented failure of prior treatment to heal the wound
- Ulcer extends through the dermis, with or without tendon, muscle, capsule or bone exposure
- Ulcer must exhibit no signs of infection

Member must have adequate circulation to the affected extremity, as evidenced by one of the following during the past 60 days:

- TcPO<sub>2</sub> with results  $\geq 30$ mmHG; **OR**
- ABI with results of  $\geq 0.7$  and  $\leq 1.2$ ; **OR**
- Doppler arterial waveforms which are triphasic or biphasic at the ankle of the affected leg.

The following conservative measures must be in place:

- Debridement of necrotic tissue;
- Offloading bearing regimen;
- Use of pressure-reducing footwear.

#### **Contraindications, Exclusions and Limitations**

The use of EpiFix® on ulcers with any **one** of the following conditions is considered not reasonable and necessary and will result in a claim denial:

- Osteomyelitis

- Cellulitis
- Necrotic tissue
- Draining wound
- Exposed bone
- Active infection at wound site
- Members who are currently receiving radiation therapy or chemotherapy
- Members with an allergy to Gentamicin or Streptomycin
- Members whose index diabetic foot ulcer is greater than 25 cm<sup>2</sup>
- Treatment of the ulcer greater than twelve (12) weeks

#### Utilization Guidelines

Treatment with EpiFix® occurs weekly, and is expected to last up to twelve (12) weeks. Updated wound measurements will be required after 3rd application to determine medical necessity of ongoing therapy. Reapplication of EpiFix® within one week for the same ulcer is considered not reasonable and necessary, and will not be reimbursed.

Re-treatment within one year following the last successful application with EpiFix® is considered not reasonable and necessary, and will not be reimbursed.

Re-treatment of an ulcer following the unsuccessful treatment where it consisted of two (2) failed EpiFix® applications is considered not reasonable and necessary, and will not be reimbursed.

#### ***Grafix Prime***<sup>56</sup>

Grafix Prime is considered reasonable and necessary in the wound management for members with diabetic foot ulcers. Application of a skin substitute graft for lower extremity DFU and VLU will be covered when the following conditions are met and documented as appropriate for the individual patient:

- Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks.
- Presence of a chronic, non-infected venous stasis ulcer with failure to respond to documented conservative wound-care measures (outlined below) for greater than 4-6 weeks with documented compliance.
- Conservative wound care measures include, but are not limited to:
  - Comprehensive patient assessment (history, exam, ABI (Ankle-Brachial Index) & diagnostic test as indicated) and implemented treatment plan.
  - For patient with DFU-assessment of type I vs. II Diabetes Mellitus and management history with attention to certain comorbidities (vascular disease, neuropathy, osteomyelitis); review of the current blood sugars/ HgbA1c, diet and nutritional status, activity level, physical exam that includes assessment of skin and wound, ABI (Ankle-Brachial Index), check of off-loading prosthetics or shoes for signs of abnormal wear.
  - For patient with VLU- assessment of history (prior ulcers, thrombosis risks), physical exam (edema, skin changes), ABI (Ankle-Brachial Index), and duplex scan to confirm CEAP classification (Clinical-Etiology-Anatomy-Pathophysiology (\*CEAP) classification categorizes chronic venous disorders to facilitate communication between physicians, to serve as a basis for standardized reporting during scientific analysis of management alternatives, and to identify segments of venous incompetence amenable to vein ablation therapies.
  - Implemented treatment plan as indicated
    - debridement
    - pressure relief [repositioning schedule, etc. for DFUs/VLUs; prior and on-going compression therapy (e.g. static compression includes compression hosiery (>20 mm HG) and compression bandages) for VLUs

- infection control
  - management of exudate- maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.).
  - Patient is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to planned skin replacement surgery, or has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation.
- Applied to ulcers that have failed to respond to documented conservative wound-care measures. “Failed response” is defined as an ulcer that has increased in size or depth, or no change in baseline size or depth or no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing). Documentation of response requires measurements of the initial ulcer, measurements at the completion of at least four weeks DFU (4-6 weeks for VLU) of conservative wound-care measures and measurements immediately prior to placement of the skin substitute graft. For VLUs, completion of conservative wound-care measures must include 4-6 weeks and on-going compression therapy.
  - A skin replacement surgery is considered an advanced treatment modality (not a conservative wound care measure). Pre-service record specifically addresses circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and must reference specific interventions that have failed based on the prior wound evaluation. Such record should include updated medication history, review of pertinent medical problems that may have arisen since the previous wound evaluation, and explanation of the planned skin replacement surgery with choice of skin substitute graft product. The procedure risks and complications should also be reviewed and documented.

#### *Limitations*

- One specific skin substitute graft product will be allowed for the episode of skin replacement surgery wound care (defined as 12 weeks from the first application of a skin substitute graft) assuming its use is not in conflict with FDA assessments and assuming there is one related wound.
- Switching products in a 12-week episode of skin replacement surgery wound care or application of a product beyond 12-weeks is not expected.
- Repeat applications of skin substitute grafts are not considered medically reasonable and necessary when a previous application was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing).
- Application of skin substitute grafts are contraindicated and noncovered in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindication (e.g., uncontrolled diabetes, active infection, active charcot arthropathy of the ulcer extremity, active vasculitis).
- Application of skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g, allergy to bovine).
- Per CPT definition, injected skin substitutes are not used with skin replacement surgery application codes and will be denied. Such products are bundled into other standard management procedures if medically necessary and not separately payable.
- Use of surgical preparation services (CPT codes 15002, 15003, 15004, and 15005) in conjunction with routine, simple and/or repeat application of skin substitute grafts is not reasonable and necessary and will be denied accordingly.
- Most repeat applications of skin replacement materials will not require separate debridement procedures. Such procedures may be subject to pre or post payment medical review. If documentation does not support cross contamination requiring extended cleansing and removal of appreciable amounts of devitalized tissue was performed, the service will be denied.
- Removal of current graft and/or simple cleansing of wound is included in the skin replacement surgery application codes. Active wound care management (CPT code 97602) procedures should never be reported.



- Application procedure and associated supply must be coded correctly. The units of service must be reported correctly. The units of service billed for the supply must be accounted for in the medical record (i.e., amount used, amount discarded and reason for the discarded amount). Only a reasonable amount of wastage (discarded amount) is covered.
- Though arterial insufficiency ulcers, pressure sores, traumatic wounds, mixed ulcers, and post-surgical wounds are not directly addressed by this LCD, the comprehensive patient assessment and treatment plan requirement would apply to any patient with lower extremity ulcers/chronic wounds. Diagnosis coding to avoid the applications of this policy is abuse.
- The patient must be under the care of a qualified Physician/ NPP for their underlying chronic condition. Skin replacement surgery services must be performed by a qualified physician/NPP within their scope of practice.

**Graftjacket Regenerative Tissue Matrix** <sup>32</sup>

GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair will be considered medically necessary for the following indications:

- Augmentation of repairs of large rotator cuff tears or ruptured calcaneal tendons; **OR**
- Treatment of neuropathic diabetic foot ulcers (DFU) with all the following conditions:
  - Member has a current medical diagnosis of either Type I or Type II diabetes mellitus; **AND**
  - Member does not have a current HbA1C reading exceeding 12%; **AND**
  - Full thickness ulcers of greater than three weeks duration that extend through the dermis but without tendon, muscle, capsule or bone exposure; **AND**
  - Underlying disease process(es) contributing to the ulcer (e.g., diabetes, is adequately treated and documented); **AND**
  - Ulcers are located on the foot or toes and are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels or tracts, eschar or any necrotic material that could interfere with the adherence of GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair and the process of wound healing; **AND**
  - Member must have adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb undergoing the procedure.

GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair must be used in conjunction with the following standard conservative measures:

- Pressure-reducing footwear;
- Non-weight bearing regimen;
- Debridement of necrotic and callused tissue when necessary; **AND**
- Acceptable standard methods of wound care, such as saline moistened dressings.

The member must be competent and/or have the support system required to participate in follow-up care associated with treatment of the wound with GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair. The use of GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair on ulcers with any of the following conditions is considered not medically necessary:

- Cellulitis
- Osteomyelitis
- Necrotic ulcer
- Draining wound
- Bone exposed wound bed
- Clinically significant wound healing impairment due to uncontrolled diabetes, poor nutrition and/or general medical condition
- Autoimmune connective tissue disease.

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Contraindications, Exclusions and Limitations

GRAFTJACKET® matrix is contraindicated for use in any patient who is sensitive to any of the antibiotics listed on the package or polysorbate 20.

Payment for GraftJacket® is limited to 1 application per ulcer.

Note: Treatment with GraftJacket® is usually expected to last no more than 12 weeks and to involve a maximum of 2 applications for any ulcer that initially qualifies for treatment.

**Oasis Wound Matrix**<sup>32</sup>

OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix will be considered medically necessary for **any** of the following indications:

- Partial and full thickness wounds
- Pressure ulcer
- Venous stasis ulcers (VSUs) – when ALL the following conditions are met:  The venous stasis ulcer has been present for greater than one month duration;
  - The venous stasis ulcer has failed to respond to documented conservative measures of at least four weeks duration. A “failed response” is defined as an ulcer that has increased in size or depth, for which there has been no change in baseline size or depth and no sign of improvement or indication that improvement is likely, such as granulation, epithelialization, or progress towards closing;
  - Documentation of response or lack thereof requires measurement of the ulcer at baseline and at completion of at least four weeks of standard conservative management. Documentation should also include measurement of the ulcer immediately prior to the placement of OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix and before each additional weekly placement;
  - Conservative methods of wound care include wound tissue hydration with saline, non-adherent dressings, moisture-donating or absorptive dressing (depending on amount of exudate), and compression wraps.
- Chronic vascular ulcers
  - Ankle Brachial Index (ABI) when applicable must be greater than 0.7 mm HG, in the affected limb being treated.
- Neuropathic diabetic foot ulcers (DFUs) - when ALL the following conditions are met:
  - The member is currently under management for either Type I or Type II diabetes mellitus;
  - The non-healing diabetic foot ulcer has been present for greater than one month and has a viable wound bed with granulation tissue present;
  - Standard conservative wound care measures have been tried. Conservative measures include removal of mechanical stress, debridement of necrotic tissue if present, and saline moistened dressings;
  - The ulcer is located on the foot or toes and there is no exposed bone, tendon, or fascia.
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, wound dehiscence).

OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix should be used only in cases where the member is competent and/or has a support system to participate in the follow-up care associated with its use.

Contraindications, Exclusions and Limitations

OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix is contraindicated in members with the following history or conditions and would be considered not medically necessary:

- Rheumatoid arthritis;

- Radiation therapy to the ulcer site;
- Uncontrolled congestive heart failure;
- Severe arterial disease;
- Recipient of corticosteroids or immunosuppressive therapies;
- Collagen vascular disease;
- Malnutrition (albumin);
- Known allergy to porcine-derived products;
- Ulcers that are clinically infected;
- Uncontrolled diabetes (HgbA1c > 12%);
- Previous organ transplant recipient;
- Members undergoing hemodialysis;
- Wounds with signs of cellulitis, osteomyelitis, or necrotic or avascular ulcer beds;
- For ulcers with exposed bone, tendon, or fascia;
- Insufficient blood supply to the ulcer (TcPO<sub>2</sub>@ < 30 mm Hg, toe or ankle brachial index < 0.7 mm Hg);
- Active Charcot joint disease or Sickle Cell disease.

The application of OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix to human wounds requires reapplication every five to seven days. Once correctly applied, the wound should be assessed every five to seven days and if appropriate, additional applications of Oasis® should be performed.

If wounds/ulcers managed with OASIS® Wound Matrix or OASIS® Ultra Tri-Layer Matrix do not evidence a measurable response after 12 weeks of applications, future applications are considered not medically necessary

### **Orcel**

- To aid in the treatment of healing donor site wounds in those with burns; **OR**
- For members with dystrophic epidermolysis bullosa undergoing hand reconstruction surgery to close and heal wounds created by the surgery, including those at donor sites.

### **PriMatrix**<sup>32</sup>

PriMatrix® is considered reasonable and medically necessary for partial and full-thickness venous wounds.

#### **Contraindications, Exclusions and Limitations**

- Adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in limb undergoing the procedure full thickness ulcers of at least 3 weeks in duration and extend through dermis.
- Non-covered for retreatment of the same ulcer using PriMatrix® following unsuccessful course of treatment.
- No coverage for retreatment of a successfully treated, healed ulcer.

### **Theraskin**<sup>32</sup>

Theraskin® is considered reasonable and medically necessary for venous ulcers located on foot and toes free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material.

#### **Contraindications, Exclusions and Limitations**

- Adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in limb undergoing the procedure.
- Full thickness ulcers of at least 3 weeks in duration and which extend through dermis.

- No coverage retreatment of the same ulcer using Theraskin® following an unsuccessful course of treatment.
- No coverage for retreatment of a successfully treated, healed ulcer.

### TransCyte

- For use as a temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in persons who require such a covering before auto-graft placement; **OR**
- For the treatment of mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without auto-grafting.

## CODING

### General Notes

Per CMS, the evaluation and treatment may occur and are both billable either on the same day or at subsequent visits. It is appropriate that treatment begins when a plan is established.<sup>2</sup>

When providing and billing surgical debridements, the surgical debridement service is to include: the pre-debridement wound assessment, the debridement, and the post-procedure instructions provided to the member on the date of the service. When a "reasonable and necessary" Evaluation and Management (E&M) service is provided and documented on the same day as a debridement service, it is payable by Medicare when the documentation clearly establishes the service as a "separately identifiable service" that was reasonable and necessary, as well as distinct, from the debridement service(s) provided.<sup>2</sup>

Documentation is required for **each visit and procedure**. A lack of documentation will result in a denial due to lack of sufficient medical information in order to make an appropriate medical necessity determination.

### Covered CPT Codes

- |              |  |
|--------------|--|
| <b>15131</b> | Derm autograft T/A/L add-one   |
| <b>15271</b> | Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area   |
| <b>15272</b> | Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof; list separately in addition to code for primary procedure   |
| <b>15273</b> | Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children   |
| <b>15274</b> | Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure) |
| <b>15275</b> | Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area   |
| <b>15276</b> | Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)                    |
| <b>15277</b> | Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children   |
| <b>15278</b> | Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each   |

- additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
- 20240^^** Biopsy, bone, open; superficial (eg, sternum, spinous process, rib, patella, olecranon process, calcaneus, tarsal, metatarsal, carpal, metacarpal, phalanx)
- 20245** Biopsy, bone, open; deep (eg, humeral shaft, ischium, femoral shaft)
- 97032** Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
- 97605** Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
- 97606** Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
- 29581** Application of multi-layer compression system; leg (below knee), including ankle and foot
- 97014** Application of a modality to 1 or more areas; electrical stimulation (unattended)
- 97032** Electrical stimulation, manual, attended, 15 minutes, one or more areas
- 97597** Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session total wound(s) surface area; first 20 sq cm or less
- 97598** Each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure)
- 97610** Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day
- 97605** Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters)
- 97606** Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters)

NOTE: Report correct HCPCS code separately if two or more drugs or biologicals mixed together Two or more mixed does not constitute a "new" drug C9399 is for FDA approved drugs and biologicals for which a HCPCS code had not been assigned.

NOTE: C Codes apply to the Missouri Medicaid market only.

^^ Authorization needed for POS 11 only in the Hawaii market only.

# Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1-2 levels). Vascular studies include patient care required to perform the studies, supervision of the studies and interpretation of study results with copies for patient records of hard copy output with analysis of all data, including bidirectional vascular flow or imaging when provided. The use of a simple hand-held or other Doppler device that does not produce hard copy output, or that produces a record that does not permit analysis of bidirectional vascular flow, is considered to be part of the physical examination of the vascular system and is not separately reported. The Ankle-Brachial Index (or ABI) is reportable with 93922 or 93923 as long as simultaneous Doppler recording and analysis of bidirectional blood flow, volume plethysmography, or transcutaneous oxygen tension measurements are also performed.

### **Covered HCPCS Level II ® Codes**

- A6550** Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
- A7000** Canister, disposable, used with suction pump, each
- C5271** Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm;  
first 25 sq cm or less wound surface area
- C5272** Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm;

- each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary proced.)
- C5275** Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
- C5276** Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
- C5273** Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
- C5274** Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
- C5277** Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
- C5278** Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
- C9399** Unclassified drugs or biologicals
- E0761** Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
- E0769** Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
- E2402** Negative pressure wound therapy electrical pump, stationary or portable
- G0281** Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care
- G0282\*** Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
- \*(This Code is Non-Covered by Medicare)
- G0329** Electromagnetic therapy, to one or more areas for chronic stage iii and stage iv pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care
- G0456** Negative pressure wound therapy, (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area less than or equal to 50 sq cm
- G0457** Negative pressure wound therapy, (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area greater than 50 sq cm
- K0743** Suction pump, home model, portable, for use on wounds
- K0744** Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches or less
- K0745** Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches
- K0746** Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches
- Q4116** Alloderm, per square centimeter



### **Covered HCPCS Codes (Products)<sup>33</sup>**

<b>Q4101</b>	Apligraf, per square centimeter
<b>Q4102</b>	Oasis Wound Matrix, per square centimeter
<b>Q4106</b>	Dermagraft, per square centimeter
<b>Q4107</b>	Graftjacket, per square centimeter
<b>Q4110</b>	Primatrix, per square centimeter
<b>Q4121</b>	Theraskin, per square centimeter
<b>Q4124</b>	Oasis Ultra Tri-Layer Wound Matrix, per square centimeter
<b>Q4131</b>	Epifix, per square centimeter
<b>Q4116</b>	Alloderm, per square centimeter

### **Covered ICD-10-CM Codes**

<b>E08.40 - E08.49</b>	Diabetes mellitus due to underlying condition with neurological complications
<b>E08.51 - E08.59</b>	Diabetes mellitus due to underlying conditions with circulatory complications
<b>E09.40 - E09.49</b>	Drug or chemical induced diabetes mellitus with neurological complications
<b>E09.51 - E09.59</b>	Drug or chemical induced diabetes mellitus with circulatory complications
<b>E10.40 - E10.49</b>	Type 1 diabetes mellitus with neurological complications
<b>E11.40 - E11.49</b>	Type 2 diabetes mellitus with neurological complications
<b>E10.51 - E11.59</b>	Type 1 diabetes mellitus with circulatory complications
<b>E11.51 - E10.59</b>	Type 2 diabetes mellitus with circulatory complications
<b>E11.621</b>	Type 2 diabetes mellitus with foot ulcer
<b>E11.622</b>	Type 2 diabetes mellitus with other skin ulcer
<b>E13.40 - E13.49</b>	Other specified diabetes mellitus with neurological complications
<b>E13.51 - E13.59</b>	Other specified diabetes mellitus with circulatory complications
<b>I70.25</b>	Atherosclerosis of native arteries of other extremities with ulceration
<b>I70.261 - I70.269</b>	Atherosclerosis of native arteries of extremities with gangrene
<b>I73.9</b>	Peripheral vascular disease, unspecified
<b>I83.011 - I83.019</b>	Varicose veins of right lower extremity with ulcer
<b>I83.021 - I83.029</b>	Varicose veins of left lower extremity with ulcer
<b>I83.211 - I83.219</b>	Varicose veins of right lower extremity with both ulcer and inflammation
<b>L79.401 - L79.429</b>	Non-pressure chronic ulcer of heel and midfoot
<b>L97.501 - L97.529</b>	Non-pressure chronic ulcer of other part of foot
<b>L89.013</b>	Pressure ulcer of right elbow, stage III
<b>L89.014</b>	Pressure ulcer of right elbow, stage IV
<b>L89.023</b>	Pressure ulcer of left elbow, stage III
<b>L89.024</b>	Pressure ulcer of left elbow, stage IV
<b>L89.113</b>	Pressure ulcer of right upper back, stage III
<b>L89.114</b>	Pressure ulcer of right upper back, stage IV
<b>L89.123</b>	Pressure ulcer of left upper back, stage III
<b>L89.124</b>	Pressure ulcer of left upper back, stage IV
<b>L89.133</b>	Pressure ulcer of right lower back, stage III
<b>L89.134</b>	Pressure ulcer of right lower back, stage IV
<b>L89.143</b>	Pressure ulcer of left lower back, stage III
<b>L89.144</b>	Pressure ulcer of left lower back, stage IV
<b>L89.153</b>	Pressure ulcer of sacral region, stage III
<b>L89.154</b>	Pressure ulcer of sacral region, stage IV
<b>L89.213</b>	Pressure ulcer of right hip, stage III
<b>L89.214</b>	Pressure ulcer of right hip, stage IV
<b>L89.223</b>	Pressure ulcer of left hip, stage III
<b>L89.224</b>	Pressure ulcer of left hip, stage IV
<b>L89.313</b>	Pressure ulcer of right buttock, stage III

L89.314	Pressure ulcer of right buttock, stage IV
L89.323	Pressure ulcer of left buttock, stage III
L89.324	Pressure ulcer of left buttock, stage IV
L89.43	Pressure ulcer of contiguous site of back, buttock and hip, stage III
L89.44	Pressure ulcer of contiguous site of back, buttock and hip, stage IV
L89.513	Pressure ulcer of right ankle, stage III
L89.514	Pressure ulcer of right ankle, stage IV
L89.523	Pressure ulcer of left ankle, stage III
L89.524	Pressure ulcer of left ankle, stage IV
L89.613	Pressure ulcer of right heel, stage III
L89.614	Pressure ulcer of right heel, stage IV
L89.623	Pressure ulcer of left heel, stage III
L89.624	Pressure ulcer of left heel, stage IV
L89.813	Pressure ulcer of head, stage III
L89.814	Pressure ulcer of head, stage IV
L89.893	Pressure ulcer of other site, stage III
L89.894	Pressure ulcer of other site, stage IV
L97.112 - L97.119	Non-pressure chronic ulcer of right thigh
L97.122 - L97.129	Non-pressure chronic ulcer of left thigh
L97.212 - L97.219	Non-pressure chronic ulcer of right calf
L97.222 - L97.229	Non-pressure chronic ulcer of left calf
L97.312 - L97.319	Non-pressure chronic ulcer of right ankle
L97.322 - L97.329	Non-pressure chronic ulcer of left ankle
L97.412 - L97.419	Non-pressure chronic ulcer of right heel and midfoot
L97.422 - L97.429	Non-pressure chronic ulcer of left heel and midfoot
L97.512 - L97.519	Non-pressure chronic ulcer of other part of right foot
L97.522 - L97.529	Non-pressure ulcer of other part of left foot
L97.812 - L97.819	Non-pressure chronic ulcer of other part of right lower leg
L97.821 - L97.829	Non-pressure chronic ulcer of other part of left lower leg
L97.912 - L97.919	Non-pressure chronic ulcer of unspecified part of right lower leg
L97.922 - L97.929	Non-pressure chronic ulcer of unspecified part of left lower leg
L98.411 - L98.499	Non-pressure chronic ulcer of skin, not elsewhere classified
L98.412 - L98.419	Non-pressure of buttock
L98.422 - L98.429	Non-pressure chronic ulcer of back
L98.492 - L98.489	Non-pressure chronic ulcer of skin of other sites
T81.31XD - T81.31XS	Disruption of external operation (surgical) wound, not elsewhere classified
T81.33XD - T81.33XS	Disruption of traumatic injury wound repair
T81.4XXD - T81.4XXS	Infection following a procedure
T81.89XD - T81.89XS	Other complications of procedures, not elsewhere classified

## Topical Oxygen Wound Therapy

### Applicable To:

- Medicaid – New York

Topical Oxygen Wound Therapy **is considered medically necessary and a covered benefit for New York Medicaid ONLY when criteria 1 and ANY of criteria 2-6 of the New York Medicaid TOWT guidelines are met:**

1. A complete wound therapy program as applicable, depending on the type of wound, has been attempted prior to application of TOWT, including:

- a. Documentation in the member's medical record of evaluation, care, compliance and wound measurements by the treating physician, **AND**,
  - b. Application of dressings to maintain a moist wound environment , **AND**,
  - c. Debridement of necrotic tissue if present, **AND**,
  - d. Evaluation of and provision for adequate nutritional status.
2. Stage IV pressure ulcers:
- a. The member has been appropriately turned and positioned, **AND**,
  - b. The member has used a support surface for pressure ulcers on the posterior trunk or pelvis (not required if the ulcer is not on the trunk or pelvis), **AND**,
  - c. The member's moisture and incontinence have been appropriately managed.

**OR,**

3. Neuropathic (for example, diabetic) ulcers:
- a. The member has been on a comprehensive diabetic management program, **AND**,
  - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities,

**OR,**

4. Venous insufficiency ulcers:
- a. Compression bandages and/or garments have been consistently applied, **AND**,
  - b. Leg elevation and ambulation have been encouraged.

**OR,**

5. For non-healing surgically created or traumatic wounds, documentation of medical necessity for accelerated formation of granulated tissue as a result of which cannot be achieved by other topical wound treatments,

**OR,**

6. A chronic (being present for at least 30 days) ulcer of mixed etiology.

**An initial prior authorization will be granted for a maximum of 16 days in a 28 day period, as treatment is 4 days on, 3 days off.**

### **Non-Covered Indications**

**Oxygen Wound Therapy** is considered **investigational, not medically necessary, medically contraindicated** and **not covered** for all other indications, including but not limited to, the following:

1. The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
2. Untreated osteomyelitis within the vicinity of the wound;
3. Cancer present in the wound;
4. The presence of a fistula to an organ or body cavity within the vicinity of the wound; **OR**
5. Stage I, II or III pressure ulcers.

#### **Covered CPT Code**

**99183** Physician attendance and supervision of hyperbaric oxygen therapy, per session

**Covered HCPCS Codes** - when criteria 1 and any of criteria 2-6 noted above are met:

**A4575** Topical hyperbaric oxygen chamber, disposable

**E0446** Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

**G0277** Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval

**E1390** Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate

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## MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
4/4/2019, 4/5/2018 9/7/2017	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> <li>• Approved by MPC. Removed Hyperbaric Oxygen Therapy from guideline, will defer to InterQual for reviews. Also changed policy name from “Wound and Burn Care” to “Wound Care”.</li> </ul>
12/3/2015	<ul style="list-style-type: none"> <li>• Approved by MPC. Inclusion of <i>Noncontact Normothermic Wound Therapy (E/I): HS-052</i> (retired). Inclusion of coverage of Graft Prime for diabetic foot wounds (see LCD 36013).</li> </ul>
7/9/2015	<ul style="list-style-type: none"> <li>• Approved by MPC. New.</li> </ul>