# Local Coverage Determination (LCD): Wound Care (L37228)

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# Contractor Information

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATE(S) |
|---|---|---|---|---|
| Wisconsin Physicians Service Insurance Corporation | MAC - Part A | 05101 - MAC A | J - 05 | Iowa |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part B | 05102 - MAC B | J - 05 | Iowa |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part A | 05201 - MAC A | J - 05 | Kansas |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part B | 05202 - MAC B | J - 05 | Kansas |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part A | 05301 - MAC A | J - 05 | Missouri - Entire State |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part B | 05302 - MAC B | J - 05 | Missouri - Entire State |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part A | 05401 - MAC A | J - 05 | Nebraska |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part B | 05402 - MAC B | J - 05 | Nebraska |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part A | 05901 - MAC A | J - 05 | Alabama<br>Alaska<br>Arizona<br>Arkansas<br>California - Entire State<br>Colorado<br>Connecticut<br>Delaware<br>Florida<br>Georgia<br>Hawaii<br>Idaho<br>Illinois<br>Indiana<br>Iowa<br>Kansas<br>Kentucky |

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATE(S) |
|---|---|---|---|---|
| | | | | Louisiana<br>Maine<br>Maryland<br>Massachusetts<br>Michigan<br>Mississippi<br>Missouri - Entire State<br>Montana<br>Nebraska<br>Nevada<br>New Hampshire<br>New Jersey<br>New Mexico<br>North Carolina<br>North Dakota<br>Ohio<br>Oklahoma<br>Oregon<br>Pennsylvania<br>Rhode Island<br>South Carolina<br>South Dakota<br>Tennessee<br>Texas<br>Utah<br>Vermont<br>Virginia<br>Washington<br>West Virginia<br>Wisconsin<br>Wyoming |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part A | 08101 - MAC A | J - 08 | Indiana |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part B | 08102 - MAC B | J - 08 | Indiana |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part A | 08201 - MAC A | J - 08 | Michigan |
| Wisconsin Physicians Service Insurance Corporation | MAC - Part B | 08202 - MAC B | J - 08 | Michigan |

# LCD Information

## Document Information

**LCD ID**
L37228

**LCD Title**
Wound Care

**Proposed LCD in Comment Period**
N/A

**Source Proposed LCD**
DL37228

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**Original Effective Date**
For services performed on or after 04/16/2018

**Revision Effective Date**
For services performed on or after 11/01/2019

**Revision Ending Date**
02/08/2020

**Retirement Date**
N/A

**Notice Period Start Date**
03/01/2018

**Notice Period End Date**
04/15/2018

or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

## CMS National Coverage Policy

*Italicized font* -represents CMS national NCD language/wording copied directly from CMS Manuals or CMS Transmittals. Contractors are prohibited from changing national NCD language/wording.

Title XVIII of the Social Security Act; Section 1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. A service must be reasonable and necessary, which includes services which are safe and effective, furnished in the appropriate setting and ordered and/or furnished by qualified personnel.

Title XVIII of the Social Security Act section 1862 (a) (1) (D). This section states that no Medicare payment may be made under part A or part B for any expenses incurred for items or services that are investigational or experimental.

CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Sections
100 - Surgical Dressings. Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations
220 – Coverage of Outpatient Rehabilitation Therapy Services (Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services, Under Medical Insurance and
230 – Practice of Physical Therapy, Occupational Therapy, and Speech-Language Pathology.

CMS IOM Publication 100-03 *Medicare Coverage Determinations (NCD) Manual,* Chapter 1, Part One, Section 20.29: Hyperbaric Oxygen Therapy (Section C, Topical Application of Oxygen).

CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 4, Section
270 – Wound Treatment
270.1 Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds
270.2 Noncontact Normothermic Wound Therapy (NNWT)
270.3 Blood Derived Products for Chronic Non-Healing Wounds
270.6 Infrared Therapy Devices

MLM SE17027 *Clarification of Billing and Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device*

## Coverage Guidance

**Coverage Indications, Limitations, and/or Medical Necessity**

This Local Coverage Determination (LCD) offers coverage indications and guidelines for wound care involving: debridement, electrical stimulation and electromagnetic therapy, negative pressure wound therapy, low frequency non-contact non-thermal ultrasound (MIST Therapy), and topical oxygen therapy (TOT).

For the purposes of this LCD, wound care is defined as care of wounds that are refractory to healing or have complicated healing cycles either because of the nature of the wound itself or because of complicating metabolic and/or physiological factors.

This policy does not address metabolically active human skin equivalent/substitute dressings, burns, skin cancer or hyperbaric oxygen therapy.

**Debridement**

Debridement is defined as the removal of foreign material and/or devitalized or contaminated tissue from or adjacent to a traumatic or infected wound until surrounding healthy tissue is exposed. This LCD applies to debridement of localized areas such as wounds and ulcers. The mere removal of secretions, cleansing of a wound, does not represent a debridement service.

At least ONE of the following conditions must be present and documented:

- Pressure ulcers, Stage III or IV,
- Venous or arterial insufficiency ulcers,
- Dehiscenced wounds,
- Wounds with exposed hardware or bone,
- Neuropathic ulcers,
- Neuroischaemic ulcers,
- Complications of surgically created or traumatic wound where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment.

**Goals of Debridement:**
Remove devitalized tissue
Decrease risk of infection
Promote wound healing
Prevent further complications

**Debridement may be categorized as selective or non-selective:**

Selective debridement refers to the removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue. Occasional bleeding and pain may occur. The routine application of a topical or local anesthetic does not elevate active wound care management to surgical debridement. Selective debridement includes selective removal of necrotic tissue by sharp dissection including scissors, scalpel, and forceps; and selective removal of necrotic tissue by high-pressure water jet. Selective debridement should only be done under the specific order of a physician.

Wound Care Non-Selective Debridement includes:

- Surgical debridement is excision or wide resection of all necrotic or devitalized tissue, possibly including excision of the viable wound margin. This is usually carried out in the operating room by a surgeon. Anesthesia is usually required. It is frequently used for deep tissue infection, drainage of abscess or involved tendon sheath, or debridement of bone.
- Sharp debridement is the removal of necrotic or foreign material just above the level of viable tissue and is performed in an office setting or at the patient's bedside with or without the use of local anesthesia. Sharp

debridement is less aggressive than surgical debridement but has the advantage of rapidly improving the healing conditions in the ulcer. These typically are the services of recurrent, superficial or repeated wound care.
- Enzymatic Debridement is debridement with topical enzymes used when the necrotic substances to be removed from a wound are protein, fiber and collagen. The manufacturers' product insert contains indications, contraindications, precautions, dosage and administration guidelines.
- Wet to moist dressing: This type of dressing is used to keep the wound moist. This type of dressing is used to remove drainage and necrotic tissue from wounds.

Debridement of the wound(s), if indicated, must be performed judiciously and at appropriate intervals. Medicare expects that with appropriate care and no extenuating medical or surgical complications or setbacks, wound volume or surface dimensions should decrease over time or wounds optimally will demonstrate granulation tissue. Wounds that fail to demonstrate measurable reduction in size at 2 to 4 weeks despite appropriate therapy are unlikely to heal. There is also literature to support that a reduction of less than 40% for venous and less than 50% diabetic ulcers at 4 weeks is an overall predictor of outcome for healing.

Medicare expects the wound care treatment plan to be modified in the event that appropriate healing is not achieved. Debridement should be *performed by a health care professional acting within the scope of his/her legal authority.*

Evidence of improvement includes measurable changes (decreases) of some of the following:

Drainage (color, amount, consistency)
Inflammation
Swelling
Pain
Wound dimensions (diameter, depth, tunneling)
Necrotic tissue/slough

**Use of Evaluation and Management (E/M) Codes in Conjunction with Debridement(s)**

Patients who have chronic wounds may frequently have underlying medical problems that require concomitant management in order to bring about wound closure. In addition, patients may require education, other services, and coordination of care both in the preoperative and postoperative phases of the debridement procedure. An E/M service provided and documented on the same day as a debridement service may be covered by Medicare only 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.

**The following services may be done during wound care services and can be medically necessary, but they are not considered wound debridement services and wound debridement CPT codes should not be used.**

- Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette), chemical application, or **dry-to-dry** or **wet-to dry** dressing. Generally, dressing changes are not considered a skilled service. The prior dressings are different and distinct from **wet-to-moist** dressings that are used for removal of devitalized tissue from wound(s) for non-selective debridement.
- Washing bacterial or fungal debris from lesions.
- Removal of secretions and coagulation serum from normal skin surrounding an ulcer.
- Dressing of small or superficial lesions.
- Removal of fibrinous material from the margin of an ulcer.
- Paring or cutting of corns or non-plantar calluses. Skin breakdown under a dorsal corn that begins to heal

when the corn is removed, and shoe pressure eliminated is not considered an ulcer that requires debridement unless there is extension into the subcutaneous tissue.
- Incision and drainage of abscess including paronychia, trimming or debridement of mycotic nails, avulsion of nail plates, acne surgery, or destruction of warts.
- Removal of non-tissue integrated fibrin exudates, crusts, biofilms or other materials from a wound without removal of tissue does not meet the definition of any debridement code and may not be reported as such.
- While mechanical debridement is a valuable technique for healing ulcers, it does not qualify as a surgical wound debridement service, and therefore should not be coded as such.
- Scraping the base of the wound bed to induce bleeding, following the removal of devitalized tissue, is not considered to be a separately billable service.
- Removing a collar of callus (hyperkeratotic tissue) around an ulcer is not debridement of skin or necrotic tissue and should not be billed as debridement unless additional partial full skin thickness tissue directly deep to the callus is removed as well.
- Infrared, ultrasound thermal and phototherapy-ultraviolet modalities are not considered debridement services.

**Biophysical Agents**

Biophysical agents or modalities such as electrical stimulation; induced electrical stimulation; negative pressure wound therapy; hyperbaric oxygen; and non-contact, non-thermal ultrasound all add some form of energy to the wound bed to help drive the healing process forward, especially in the compromised tissues of patients who tend to get pressure ulcers.

**Electrical Stimulation and Electromagnetic Therapy**

Please refer to: CMS Publication 100-03, *Medicare National Coverage Determination Manual,* Chapter 1-Part 4, § 270.1 *Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds.*

**Negative Pressure Wound Therapy**

Negative Pressure Wound Therapy (NPWT), utilizing either durable or disposable medical equipment, involves the application of controlled or intermittent negative pressure to a properly dressed wound cavity. Suction (negative pressure) is applied under airtight wound dressings to promote the healing of open wounds **resistant to prior treatments**. Coverage of traditional NPWT (tNPWT) device/unit/type, or supplies is under DME and providers should consult their DME LCD for specific coverage, parameters, and guidelines. For disposable NPWT (dNPWT) devices, this contractor recommends following manufacturer's instructions but, generally be limited to a maximum of 4 applications per 30 days.

NPWT services should not exceed a 120-day period. It is expected a licensed medical professional must directly assess the wound(s) being treated with NPWT and supervise or directly perform the NPWT dressing changes. It is expected there will be an evaluation with documentation of the wound's dimensions and characteristics conducted every 30 days.

NWPT coverage would end, and the pump and/or supplies will be denied as not reasonable and necessary with any of the following, whichever occurs earliest.

1. In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
2. 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.
3. One hundred twenty (120) days (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using NPWT in the treatment of the most recent wound.

**Low Frequency, Non-contact, Non-thermal Ultrasound (MIST Therapy)**

Low frequency, non-contact, non-thermal ultrasound is a system that uses continuous low frequency ultrasonic energy to atomize a liquid and deliver continuous low frequency ultrasound to the wound bed. This modality is often referred to as "MIST Therapy".

There should be documented improvements in the wound(s) evident after six MIST treatments. Improvements include documented reduction in pain, necrotic tissue, or wound size or improved granulation tissue. Continuing MIST treatments for wounds demonstrating no improvement after six treatments is considered not reasonable and necessary. No more than 18 services of low frequency, non-contact, non-thermal ultrasound (MIST Therapy) within a six-week period will be considered reasonable and necessary. Also, Low Frequency, Non-Contact, Non-Thermal Ultrasound treatments would be separately billable if other active wound management and/or wound debridement **is not** performed.

**Topical Oxygen Therapy**

Refer to Change Request (CR) 10220, *Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen.*

**Summary of Evidence**

Despite many recent advances in wound care, the challenge of managing chronic wounds remains complicated by the lack of agreement on clearly defined comprehensive wound care principles and consistently accepted analytical scientific methods to evaluate outcomes.

**Negative Pressure Wound Therapy(NPWT)**
There is moderate evidence in the peer-reviewed published literature to indicate that NPWT using a powered device approved by the U.S. Food and Drug Administration (FDA) is effective for a specific subgroup of patients who have failed a comprehensive, conventional wound therapy program that includes all reasonable, well-established alternative medical treatments. There is also moderate evidence to support the use of this therapy as an alternative to surgery. There is insufficient evidence to support the routine use of NPWT.

Although NPWT appears effective and its superiority to conventional techniques has been demonstrated, there are still some critical concerns concerning its efficacy. Because its mechanisms of action remain partly unclear and because there are still some gaps between evidence-based data and the excellent clinical results, further prospective, randomized, ideally blinded studies are needed.[1]

**Low Frequency, Non-contact, Non-thermal Ultrasound (MIST Therapy)**
A 2011 meta-analysis, three randomized-control trials. 444 patients with various chronic wounds.
It found 85% wound-area reduction in a mean of 7 weeks, wound-volume reduction of 80% at a mean of 12 weeks, and 42% complete wound closure at 12 weeks. By comparison, a meta-analysis of standard-of-care treatment found only 24% complete wound closure at 12 weeks.
Thus, Noncontact, Low Frequency Ultrasound (NLFU) achieves almost twice the healing of the standard treatment.[2]

**Topical Oxygen Therapy(TOT)**

Because of the difficulties in obtaining reliable wound measurements, wound closure is an important and measurable goal, and we agree with the FDA that complete wound closure is the most objective and clinically meaningful endpoint. Studies were weighted stronger when randomized and with controls, and when study end-points or patient selection did not change during the study. The review of the literature that was conducted for TOT is summarized below.

Azimian's paper was a sample of 100 hospitalized adult patients were recruited to this single blinded multi-center study and were randomly assigned to an intervention or control group. Patients in the intervention group received transdermal wound oxygen therapy (TWOT). TWOT consisted of the direct application of humidified high-pressure oxygen via disposable catheter, at a rate of 10 liters per minute, to the wound site for 20 minutes, three times a day for 12 days. The authors concluded that transdermal wound oxygen therapy could effectively promote the healing of pressure wounds on the sacral and ischial areas of the body. However, due to the relatively small study sample, they recommended larger studies be pursued.

Blackman's paper describes a controlled, single site study of a prospective comparison of the healing rates of chronic diabetic foot ulcers (DFUs) treated with either topical wound oxygen therapy ($TWO_2$) or advanced moist wound therapy (AMWT). Only 28 patients were included in the trial. The authors concluded that the wounds of study patients treated with $TWO_2$ were significantly more likely to heal and in a shorter period than those treated with AMWT, and that well designed randomized controlled trials to confirm the efficacy of $TWO_2$ were needed.

The goal of this prospective, randomized study, reported by Driver was to evaluate the efficacy of the use of transdermal continuous oxygen therapy (TCOT) in patients with nonhealing diabetic foot wounds by following wound healing and biological markers of tissue response. Eligible patients were randomized either to the intervention group (n = 9) or control group (n=8) by a block randomization scheme. TCOT provided a continuous delivery of 99.8% pure oxygen by cannula at a rate of 3 mL/hour directly to the wound site. The manufacturer of the TCOT device supported this study. The authors concluded that the clinical efficacy of TCOT was established, as there was a significant difference in percent volume reduction in wound size for the TCOT group compared to the control group. No wounds completely healed during the study.

Niederauer 2015 reports a planned interim analysis of a randomized, balanced, double blind, sham controlled, parallel group clinical trial performed to evaluate use of a device providing the continuous diffusion of oxygen (CDO) to diabetic foot ulcers (DFU) compared to treatment of the ulcers with standard moist wound therapy (MWT).

The full sample size of the study is anticipated to be 84 subjects. With this report of the results of the first 50% of subjects who completed a twelve-week course of treatment (n=42). The primary outcome of the investigation is complete wound closure defined as complete reepithelization with no drainage. Those in the sham group received no oxygen to the wound but did receive standard of care MWT. Patients were followed for twelve weeks or until wound closure, whichever came first. Dressing change frequency depended on rate of exudate and varied from 2-12 times per week.

Upon analysis of the data, the investigators excluded any subject that had fast wound healing between the screening and visit number one.

As the study progressed, the authors found it necessary to have regular conference calls with investigators to provide emphasis on the proper principles of moist wound therapy, and the number of dressing changes.

Any subject who withdrew from the study, for any reason, was excluded from the statistical analysis. This study reported on the first 42 subjects (active group: n = 21; sham group, n= 21) to complete the study per protocol. The authors reported that they found no significant and beneficial treatment effect in the active arm of the study.

However, in a series of subsequent analyses, the authors found that among subjects with wound size of at least 1.5 $cm^2$ and who experienced wound closure and excluding subjects who experienced fast closure between Screen and Visit 1 (Active n=9; Sham n=3), the average number of days to closure was significantly lower among the active group than the sham group. However, stratification was then used and at the median randomization date, wound closure was found to be significantly increased in those individuals in the active group seen after the median randomization date. The authors concluded that this interim analysis suggested improved healing with CDO versus MWT for slower to close, larger chronic wounds.

Niederauer (2017) followed up on the interim report (2015) that was published in *Wound Medicine*, with the protocol being amended to change the minimum baseline wound size and run-in rate of wound closure inclusion/exclusion criteria. Subjects that failed these criteria were removed from the study. Sixty-six of 146 subjects were now dropped or excluded from the study after randomization. The authors stated that the results of this study suggest that CDO over a wound, leads to significantly higher rates of closure and faster time to closure compared to similarly treated patients receiving standard therapy provided along with a sham device.

In a paper by Tawfick, a parallel group observational comparative study was used to examine the safety and efficacy of topical wound oxygen ($TWO_2$) versus conventional compression dressings in the management of refractory nonhealing venous ulcers. Here patient preference determined group allocation. The ulcer healing time among wounds treated with $TWO_2$ was shorter regardless of the duration or size of the ulcer. During the twelve-month follow up, none of the 37 healed $TWO_2$ ulcers showed signs of reoccurrence, while five of the thirteen healed ulcers by compression did. The authors concluded that $TWO_2$ produced superior outcomes to compression therapy in the treatment of refractory venous ulcers by achieving shorter healing times and reducing recurrence rates. They also noted that a randomized controlled trial was underway to study the benefits of $TWO_2$.

Yu's paper reports a pilot randomized controlled trial to compare a continuous topical oxygen delivery system to standard best practice in patients with nonhealing DFUs. Patients were randomized into either a group which received topical oxygen as well as standard of care (SOC) (n=10) or into a nonplacebo control group which received standard of care alone (n = 10). The study was performed for eight weeks. One subject in the continuous topical oxygen group dropped out; and the results of one subject in the control group were discarded as an outlier, due to the large size of the wound. (n=18 total). The authors concluded that though this study was underpowered, it demonstrated that topical oxygen applied continuously to a chronic wound, can have a great effect on healing.

**Analysis of Evidence**
**(Rationale for Determination)**

*Level of Evidence*
Quality –Moderate
Strength – Limited
Weight – Limited

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# General Information

**Associated Information**

**Documentation**
The medical record must clearly show that the criteria under Coverage Indications, Limitations, and /or Medical

Necessity have been met. The medical record must include a certified plan of care containing a treatment plan with goals, physician follow-up, the expected frequency and duration of the skilled treatment, and the potential to heal. With continuation of a treatment plan, there needs to be ongoing evidence of the effectiveness of the plan, including diminishing area and depth of the ulceration, resolution of surrounding erythema and /or wound exudates, decreasing symptomatology, and overall assessment of wound status (such as stable, improved, worsening, etc.) documented. Appropriate modification of treatment plan, when necessitated by failure of wounds to improve, must be demonstrated. The record must document complicating factors for wound healing as well as measures taken to control complicating factors when debridement is part of the plan. Medical records must be made available to Medicare upon request.

The patient's medical record must contain clearly documented evidence of the progress of the wound's response to treatment at each visit. This documentation must include, at a minimum:

- Current wound volume (surface dimensions and depth).
- Presence (and extent of) or absence of obvious signs of infection.
- Presence (and extent of) or absence of necrotic, devitalized or non-viable tissue or other material in the wound that is expected to inhibit healing or promote adjacent tissue breakdown.

When debridement is reported, the debridement procedure notes should demonstrate tissue removal (i.e., skin, full or partial thickness; subcutaneous tissue; muscle and/or bone), the method used to debride (i.e., hydrostatic, sharp, abrasion, etc.) and the character of the wound (including dimensions, description of necrotic material present, before and after debridement; and after debridement the description of tissue removed (including amount in sq. cm, degree of epithelialization, etc.). Procedure notes should also include the severity of tissue destruction, undermining or tunneling, necrosis, infection or evidence of reduced circulation.

When performing debridement of a single wound, report depth using the deepest level of tissue removed. In multiple wounds, sum the surface area of those wounds that are at the same depth, but do not combine sums from different depths. See current CPT Book for coding guidance.

Active debridement must be performed under a treatment plan as any other therapy service outlining specific goals, duration, frequency, modalities, an anticipated endpoint, and other pertinent factors as they may apply. Departure from this plan must be documented.

Documentation for debridement exceeding Utilization Guidelines must include a complete description of the wound, progress towards healing, complications that have delayed healing and a projected number of additional treatments necessary.

Appropriate evaluation and management of contributory medical conditions or other factors affecting the course of wound healing (such as nutritional status or other predisposing conditions) should be addressed in the record at intervals consistent with the nature of the condition or factor.

Photographic documentation of wounds immediately before and after debridement is recommended for prolonged or repetitive debridement services and maybe requested by this contractor for payment of claims.

When wound care is provided by the Physical Therapist, for both in and out patient wound care, the medical record is required to have the following documentation:

- Physician order(s) for physical therapy (PT)/wound care services.

- Initial evaluation of PT/wound care services.
- Wound characteristics such as diameter, depth, color, presence of exudates or necrotic.
- Previous wound care services administered including date and modalities of treatment.
- Plan of treatment for PT/wound care services.
- Weekly progress notes to include current wound status, measurements (including size and depth), and the treatment provided.
- Description of instrument used for selective or sharp debridement (i.e. forceps, scalpel, scissors, tweezers, high-pressure water jet, etc.).
- Certification/recertification for PT/wound care services.
- Actual minutes provided to support each timed service/HCPCS provided.

**Utilization Guidelines**

Prolonged, repetitive debridement services require adequate documentation of complicating circumstances that reasonably necessitated additional services. The record must clearly document the failure of wounds to improve to support the medical necessity for removal of muscle and/or bone for complicated management of wounds.

Coverage of traditional Negative Pressure Wound Therapy (tNPWT) device/unit/type, or supplies is covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)), and providers should consult their DME LCD for specific coverage, parameters, and guidelines.

For disposable NPWT (dNPWT) devices, this contractor recommends following manufacturer's instructions but, generally be limited to a maximum of 4 applications per 30 days.

Negative Pressure Wound Therapy services should not exceed a 120-day period. There should be no more than 4 dressing changes per wound per month for the majority of wounds. With dNPWT, there should be a maximum of 4 new disposable NPWT per month. It is expected there will be an evaluation with documentation for a wound(s) every 30 days. The beneficiaries who undergo treatment utilizing negative pressure wound therapy, only when medical necessity continues to be met and there is documented evidence of clear benefit from the NPWT treatment already provided.

The number of debridements and NPWT for a wound within the context of a palliative treatment plan (i.e., when wounds are not expected to heal or when patients are in an end-of-life situation) would be expected to be of a limited frequency and duration consistent with that of palliative care.

The extent and number of services provided should be medically necessary and reasonable based on the documented medical evaluation of the patient's condition, diagnosis, and plan.
Only when medical necessity continues to be met and there is documented evidence of clear benefit from the services provided, should services be continued. When services are performed in excess of anticipated peer norms based on data analysis, the services may be subject to medical review.

**Sources of Information**

N/A

**Bibliography**

Agency for Healthcare Research and Quality (AHRQ). (2013, May). Pressure ulcer treatment strategies: comparative effectiveness. *Effective Health Care Program. 90*:1-24.

Agency for Healthcare Research and Quality (AHRQ). (2009, May). Negative pressure wound

therapy devices. *Technology Assessment Program* 1-59.

Alumia, A. (Sept./Oct. 2013) Improving outcomes with noncontact low-frequency ultrasound. *Wound Care Advisor*. 2(5):17-202 http://woundcareadvisor.com/wp-content/uploads/2013/09/BP_IMPROVE_S-O13.pdf

Azimian J, Nayeri ND, Pourkhaleghi E, Ansari M. Transdermal Wound Oxygen Therapy on Pressure Ulcer Healing: A Single-Blind Multi-Center Randomized Controlled Trial. Iran Red Crescent Med J. 2015; 17(11): e20211. doi:10.5812/ircmj.20211. PMID: 26734476

Baharestani, M.M., Berger, T., M., Bolton, L.L., & et al. (2010, Oct 1). Association for the Advancement of Wound Care guideline of pressure ulcer guidelines. *Agency for Healthcare Research and Quality. National Clearinghouse Website*.

Bell, A.L., & Cavorsi, J. (2008, Dec). Noncontact ultrasound therapy for adjunctive treatment of nonhealing wounds: A retrospective analysis. *Physical Therapy. 88*(12):1517-1524.

Blackman E, Moore C, Hyatt J, Railton R, Frye C. Topical Wound Oxygen Therapy in the Treatment of Severe Diabetic Foot Ulcers: A Prospective Controlled Study. Ostomy Wound Manage. 2010; 56(6): 24-31. PMID: 20567051

Burke, T.J. (2006, May). The effect of monochromatic infrared energy on sensation in subjects with diabetic peripheral neuropathy: a double-blind, placebo-controlled study. *Diabetes Care 29*(5):1186. A response to Clifft et al. Accessed 11/03/2015.

Cole, P.S., Quisberg, J., & Melin, M.M. (2009, Mar/Apr). Adjuvant use of acoustic pressure wound therapy for treatment of chronic wounds. *Journal of Wound, Ostomy, and Continence Nursing. 36*(2):171-177.

Department of Health and Human Services. (2014). *Negative Pressure Wound Therapy Technologies For Chronic Wound Care in the Home Setting – Technology Assessment Program* (Project ID: WNDT0913) Rockville, Maryland

[1]Division of Plastic Surgery and Reconstructive Surgery, Medical University Graz, et al Negative pressure therapy: theory and practice. Diabetes Metab Res Rev. 2012 Feb;28 Suppl 1:72-7. doi: 10.1002/dmrr.2243.

[2]Driver, V.R., Yao, M., & Miller, C.J. (2011, Jun). Noncontract low-frequency ultrasound therapy in the treatment of chronic wounds: A meta-analysis. *Wound Repair and Regeneration. 19*(4): 475-480.

Driver VR, Yao M, Kantarci A, Gu G. Park N, Hasturk H. A Prospective, Randomized Clinical Study Evaluating the Effect of Transdermal Continuous Oxygen Therapy on Biological Processes and Foot Ulcer Healing in Persons with Diabetes Mellitus. Ostomy Wound Manage. 2013; 59(11): 19-26. PMID: 24201169

Escandon, J., Vivas, A.C., Perez, R., Kirsner, R., & Davis, S. (2012, Oct). A prospective pilot study of ultrasound therapy effectiveness in refractory venous leg ulcers. *International Wound Journal. 9*(5):570-578.

Flanagan M (2003) Wound measurement: can it help us to monitor progression to healing? *J Wound Care* **12(5)**: 189–94

Fonder, M.A., Lazarus, G.S., Cowan, D.A., Aronson-Cook, B., Kohli, A.R., & Mamelak, A.J.
(2008, Feb). Treating the chronic wound: A practical approach to the care of nonhealing wounds and wound care dressings. *Journal of the American Academy of Dermatology. 58*(2): 185-206.

Gray, M., Black, J.M., Baharestani, M.M., Bliss, D.Z., Colwell, J.C., Goldberg, M., et al.
Moisture-Associated Skin Damage: Overview and Pathology *Journal of Wound, Ostomy and Continence Nursing*. 2011;38(3):233-241. Wound Care Literature Review 2011

Haan, J., & Lucich, S. (2009). A retrospective analysis of acoustic pressure wound therapy:
effects on the healing progression of chronic wounds. *Journal of the American College of Certified Wound Specialists. 1*:28-34.

Honaker, J.S., Forston, M.R., Davis, E.A., Wiesner, M.M., & Morgan, J.A. (2013, Feb). Effects of noncontact low-frequency ultrasound on healing of suspected deep tissue injury: a retrospective analysis. *International Wound Journal. 10*(1):65-72.

Hurd, T., Trueman, P., & Rossington, A. (2014, Mar). Use of a portable, single-use negative pressure wound therapy device in home care patients with low to moderately exuding wounds: a case series. O*stomy Wound Management. 60*(3):1943-2720.

International Consolidated Venous Ulcer Guideline (ICVUG) 2015
(Update of AAWC Venous Ulcer Guideline, 2005 and 2010) Retrieved from: https://aawconline

Krokowicz, L., Borejsza-Wysocki, M., Mackiewicz, J., Iqbal, A., Drews, M. (2014, Jan.).
10 years of Negative Pressure Wound Therapy [NPWT]: Evolution of Indications for its Use.
*Negative Pressure Wound Therapy* 1(1):27-321
http://researchpub.org/journal/npwt/number/vol1-no1/vol1-no1-6.pdf

Niederauer MQ, Michalek JE, Armstrong DG. Interim results for a prospective, randomized, double-blind multicenter study comparing continuous diffusion of oxygen therapy to standard moist wound therapy in the treatment of diabetic foot ulcers. Wound Med. 2015: 8; 19–23. http://dx.doi.org/10.1016/j.wndm.2015.03.005.

Niederauer M, Michalek J, Armstrong D. A Prospective, Randomized, Double-Blind Multicenter Study Comparing Continuous Diffusion of Oxygen Therapy to Sham Therapy in the Treatment of Diabetic Foot Ulcers. *J Diabetes Sci Technol.* 2017; 1-9.

Photography in Wound Documentation: Fact Sheet from Wound Ostomy and Continence Nurses Society January 2, 2012

U.S. Food & Drug Administration, UPDATE on Serious Complications Associated with Negative Pressure Wound Therapy Systems: FDA Safety Communication. Date issued: February 24, 2011.

Sheehan, P., Jones P., Caswlli, A., Giurini, and J., Veves. Percent Change in Wound Area of Diabetic Foot Ulcers Over a 4-Week Period Is a Robust Predictor of Complete Healing in a 12-Week Prospective Trial. Diabetes Care 2003 Jun; 26(6): 1879-1882. https://doi.org/10.2337/diacare.26.6.1879

Synder, R.J., Cardinal, M., Dauphinée, D.M., Stavpsky, J. A post-hoc analysis of reduction in diabetic foot ulcer size

at 4 weeks as a predictor of healing by 12 weeks. *Ostomy Wound Manage*. 2010 Mar 1;56(3):44-50.

Steed, D. L., Attinger, C., Colaizzi, T., Crossland, M., Franz, M., Harkless, L., Johnson, A., Moosa, H., Robson, M., Serena, T., Sheehan, P., Veves, A. and Wiersma-Bryant, L. Guidelines for the treatment of diabetic ulcers. *Wound Rep Regen* 2006; 14:680–692. doi:10.1111/j.1524-475X.2006. 00176.x

Tawfick WA, Sultan S. Does Topical Wound Oxygen (TWO2Offer an Improved Outcome Over Conventional Compression Dressings (CCD) in the Management of Refractory Venous Ulcers (RVU)? A Parallel Observational Comparative Study. Eur J Vasc Endovasc Surg. 2009 Jul; 38(1):125-32. doi: 10.1016/j.ejvs.2009.03.027. Epub 2009 May 22. PMID: 19464933.

The Management of Diabetic Foot: A Clinical Practice Guideline by the Society for Vascular Surgery in Collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg 2016*; special supplement published February 2016.

Yu J, Lu S, McLaren A, Perry JA, Cross KM. Topical oxygen therapy results in complete wound healing in diabetic foot ulcers. Wound Repair Regen. 2016. doi: 10.1111/wrr.12490. PMID: 27733020.

# Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|---|---|---|---|
| 11/01/2019 | R3 | Content has been moved to the new template. | • Revisions Due To Code Removal |
| 03/28/2019 | R2 | 03/28/2019 Removed national policy language from the sections: Electrical Stimulation and Electromagnetic Therapy and Topical Oxygen Therapy due to Change Request (CR)10901 Local Coverage Determinations (LCDs). Typographical error corrected. Review completed 03/05/2019. | • Other (Review) |
| 04/16/2018 | R1 | Corrected Title in companion Article A55909 | • Other |

# Associated Documents

**Attachments**

N/A

**Related Local Coverage Documents**

Article(s)

A55909 - Billing and Coding: Wound Care

A55910 - Response to Comments: Wound Care (DL37228)

**Related National Coverage Documents**

NCD(s)
270.3 - Blood-Derived Products for Chronic Non-Healing Wounds
270.1 - Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds
270.6 - Infrared Therapy Devices
270.2 - Noncontact Normothermic Wound Therapy (NNWT)
270.4 - Treatment of Decubitus Ulcers

**Public Version(s)**

Updated on 12/17/2019 with effective dates 02/09/2020 - N/A
Updated on 11/14/2019 with effective dates 11/01/2019 - 02/08/2020

Updated on 03/19/2019 with effective dates 03/28/2019 - 10/31/2019
Updated on 02/21/2018 with effective dates 04/16/2018 - 01/23/2020
Updated on 02/20/2018 with effective dates 04/16/2018 - N/A

# Keywords

- Debridement
- Electrical Stimulation
- Electrical Therapy
- MIST
- Wound