

# Local Coverage Determination (LCD): Wound Care (L35125)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	District of Columbia Delaware Maryland New Jersey Pennsylvania

## LCD Information

### Document Information

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Wound Care

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**Notice Period End Date**

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## **CMS National Coverage Policy**

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for wound care. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for wound care and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site.

### **IOM Citations:**

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
  - Chapter 15, Section 100: Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations.
  - Chapter 16, Section 120: Cosmetic Surgery, Section 130: Charges Imposed by Immediate Relatives of the Patient or Members of the Patient's Household.
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 4, Section 270: Wound Treatment.
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 12, Section 30.6: Evaluation and Management Service Codes – General.
- CMS IOM Publication 100-09, *Medicare Contractor Beneficiary and Provider Communications Manual*, Chapter 5, Correct Coding Initiative.

### **Social Security Act (Title XVIII) Standard References:**

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(D) states that no payment shall be made for any

services that are considered investigational or experimental.

- Title XVIII of the Social Security Act, Section 1862 (a)(10). This section excludes Cosmetic Surgery.

### **Federal Register References:**

- 42 CFR Part 412, FR Doc No: 2013-18956; Volume 78, No. 160, August 19, 2013. Home Health Agency Prospective Payment System.

## **Coverage Guidance**

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

**Notice:** It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

### **History/Background and/or General Information**

This LCD does not address specific wound care procedures described by NCD's and other items such as:

- Hyperbaric Oxygen (HBO) Therapy (See LCD L35021)
- Initial physical therapy or occupational therapy evaluations (See LCD L35036)
- Skin Substitutes for Wound Care (See LCD L35041)
- Electrical Stimulation and Electromagnetic Therapy of Specified Wounds (See NCD 270.1)
- Strapping (See LCD L36423)
- Treatment of burns

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 definition excludes the following:

- Management of acute wounds, or
- The care of wounds that normally heal by primary intention such as clean, incised traumatic wounds, or
- Surgical wounds that are closed primarily and other postoperative wound care not separately covered during the surgical global period.

Various methods to promote wound healing have been devised over time. A method which is unproven by valid scientific literature would be considered not reasonable and necessary. Wound care involves the evaluation and treatment of a wound, including identifying potential causes of delayed wound healing and the modification of treatment when indicated. Wound evaluations may require a comprehensive medical evaluation, vascular evaluation, orthopedic evaluation, functional evaluation, metabolic/nutritional evaluation, and a plan of care. Reduction of pressure and/or control of infection have been shown to facilitate healing and may reduce the need for repeated debridement services.

Medicare coverage for wound care on a continuing basis for a given wound in a given patient is contingent upon evidence documented in the patient's medical record that the wound is improving in response to the wound care being provided. Evidence of improvement may include measurable changes in the following:

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

Wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds. The goal of most chronic wound care should be eventual wound closure with or without grafts, skin replacements, or other surgery (such as amputation, wound excision, etc.). Adjunctive measures include but are not limited to appropriate control of complicating factors such as pressure (e.g., off-loading, padding, appropriate footwear), infection, vascular insufficiency, metabolic derangement and/or nutritional deficiency. While complete healing of the wound may be the primary objective; a secondary desired objective is that, with appropriate management, a wound may reach a state at which its care may be performed primarily by the patient and/or the patient's caregiver with periodic physician assessment and supervision.

In appropriate cases, due to severe underlying debility or other factors such as operability, the goal of wound care provided in outpatient settings may be only to prevent progression of the wound and prevention of prolonged hospitalization.

Active wound care procedures involve selective and non-selective debridement techniques and are performed to remove devitalized tissue and promote healing. The provider is required to have direct (one-on-one) patient contact when performing active wound care management.

The appropriate interval and frequency of debridement depends on the individual clinical characteristics of the patient and the extent of the wound.

It is highly recommended that the treatment plan for a patient who requires frequent repeated debridement be reevaluated to ensure that issues including, but not limited to, pressure reduction, nutritional status, vascular insufficiency and infection control have been adequately addressed. Overall, evaluation of the wound should be performed at a regular frequency to determine whether the individualized treatment goals are being met for the patient.

### **Definition of terms for this policy:**

#### Dressing Changes for Wound Debridement

- Wet dressings: Water and medication may be applied to the skin with dressings (e.g., finely woven cotton or gauze) soaked in solution. Wet compresses, especially with frequent changes, may provide gentle debridement.
- Dry dressings: Used to provide gentle debridement, protect the skin, hold medications against the skin, keep clothing and sheets from rubbing, or keep dirt and air away. Such dressings may also prevent patients from scratching or rubbing the wound.
- Advanced dressings: Used with increasing frequency to provide gentle debridement in the treatment of acute wounds, chronic venous, diabetic and pressure ulcers.
- Dressing changes (removal and subsequent reapplication) alone generally do not require the skills of physicians. They may be performed by physical therapists, occupational therapists, licensed professional

nurses, or wound care nurses.

## Covered Indications

### 1. Medicare would expect that wound care may be necessary for the following types of wounds:

- Surgical wounds that must be left open to heal by secondary intention.
- Infected open wounds induced by trauma or surgery.
- Wounds with biofilm.
- Wounds associated with complicating autoimmune, metabolic, and vascular or pressure factors.
- Open or closed wounds complicated by necrotic tissue and/or eschar.

### 2. Active Wound Care Management

Debridement may be indicated whenever necrotic tissue as well as cellular or proteinaceous debris is present on an open wound in order to keep the wound in an active state of healing. Debridement may also be indicated in cases of abnormal wound healing or repair. The routine application of a topical or local anesthetic does not elevate active wound care management to surgical debridement. Debridement may be categorized as selective or non-selective.

- Wound Care Selective Debridement includes:
  - Removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue by sharp dissection utilizing scissors, scalpel, curettes, and/or tweezers/forceps. This procedure typically requires no anesthesia and generally has no or minimal associated bleeding.
- Wound Care Non-Selective Debridement may include:
  - Mechanical Debridement: This type of debridement is the removal of necrotic tissue by cleansing, or application of a wet-to-dry or dry-to-dry dressing technique. Wet-to-dry dressings should be used judiciously as maceration of surrounding tissue may hinder healing. Generally, dressing changes are not considered a skilled service.
  - Enzymatic Debridement: Debridement with topical enzymes is used when the necrotic substances to be removed from a wound are protein, fiber and collagen. The manufacturer's product insert contains indications, contraindications, precautions, dosage and administration guidelines; it is the clinician's responsibility to comply with those guidelines.
  - Autolytic Debridement: This type of debridement is indicated where manageable amounts of necrotic tissue are present, and there is no infection. Autolytic debridement occurs when the enzymes that are naturally found in wound fluids are sequestered under synthetic dressings.
  - Maggot / larvae therapy: Debridement with medical-grade maggots in wounds.

### 3. Wound Care Surgical Debridements

- Conditions that may require surgical debridement of large amounts of skin may include but are not limited to: rapidly spreading necrotizing process (sometimes seen with aggressive streptococcal infections), severe eczema, extensive skin trauma (including large abraded areas with ground-in dirt), or autoimmune skin diseases.
- Surgical debridement occurs only if material has been excised and is typically reported for the treatment of a wound to clear and maintain the site free of devitalized tissue including but not limited to necrosis, eschar, slough, infected tissue, biofilm, abnormal granulation tissue, etc., and should be accomplished to the margins of viable tissue.
- These procedures can be very effective but represent extensive debridement. They may be complex in nature and may on occasion require the use of anesthesia.

### 4. Use of Evaluation and Management (E/M) Codes in Conjunction with Surgical Debridements

- 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.

#### 5. Negative Pressure Wound Therapy (NPWT)

- Negative pressure wound therapy (NPWT), utilizing either durable or disposable medical equipment, is a method of wound care to manage wound exudates and promote wound closure. The vacuum assisted drainage collection (i.e., NPWT) may be applied in an effort to cleanse the wound by removing fluids and stimulate the wound bed in order to reduce localized edema and improve local oxygen supply.
- NPWT 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.
- NPWT for non-healing wounds is medically necessary when at least one of the following conditions is met:
  - There are complications of a surgically created wound (e.g., dehiscence, post sternotomy disunion with exposed sternal bone, post sternotomy mediastinitis, or postoperative disunion of the abdominal wall).
  - There is a traumatic wound (e.g., preoperative flap or graft, exposed bones, tendons, or vessels) and a need for accelerated formation of granulation tissue not achievable by other topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments).
  - There is a chronic, non-healing ulcer with lack of improvement despite standard wound therapy, including the application of dressings, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, and weekly evaluations with documentation of wound measurements (i.e., length, width, and depth) in ONE of the following clinical situations:
    - Acute wounds
    - Subacute and dehisced wounds
    - Traumatic wounds
    - Ulcers (such as diabetic or pressure)
    - Chronic Stage III or Stage IV pressure ulcer
    - Chronic diabetic neuropathic ulcer
    - Chronic venous ulcer
    - Flaps and grafts

#### 6. Low-Frequency, Non-Contact, Non-Thermal Ultrasound (MIST Therapy)

- Low frequency, non-contact, non-thermal ultrasound describes a system that uses continuous low-frequency ultrasonic energy to produce and propel a mist of liquid and deliver continuous low-frequency ultrasound to the wound bed. This modality is often referred to as "MIST Therapy."
- Low-Frequency, Non-Contact, Non-Thermal Ultrasound (MIST Therapy) is considered reasonable and necessary wound therapy and therefore eligible for coverage by Medicare when provided for any of the following clinical conditions:
  - Wounds and ulcers which are too painful for sharp or excisional debridement and have failed conventional debridement with documentation supporting the same.
  - Wounds and ulcers meeting Medicare coverage for debridement but with documented contraindications to sharp or excisional debridement.
  - 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) may 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.

#### 7. Application of Paste Boot (Unna Boot) or Application of Multi-Layer Compression System may be useful

adjuncts to wound care management.

## Limitations

1. Wound care should employ comprehensive wound management including appropriate control of complicating factors such as unrelieved pressure, infection, vascular and/or uncontrolled metabolic derangement, and/or nutritional deficiency in addition to appropriate debridement. Medicare coverage for professional wound care procedures requires that all applicable adjunctive measures are also employed as part of comprehensive wound management. Wound care in the absence of such measures, when they are indicated, is not considered to be medically reasonable and necessary.
2. Debridement will be considered not reasonable and necessary for a wound that is clean and free of necrotic tissue/slough.
3. Debridements are considered selective or non-selective unless the medical record supports that a surgical excisional debridement was performed.
4. Debridements are best provided under an individualized plan of care.
5. Wound care may be of a palliative nature. Optimally, the overall goal of care is healing, and it would be neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement leading to healing of the wound as outlined in this LCD cannot be shown. However, if it is determined that the goal of care is not wound healing, which would lead ultimately to wound closure, the patient should be managed following appropriate palliative care standards. Wounds of some Medicare beneficiaries residing in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) may not close, heal, or be amenable to self-care in spite of optimal therapy. In those patients where wound closure, healing, or self-care is not a likely outcome, the goals of wound care may include prevention of hospitalization and improvement in quality of life. As such, due to severe underlying debility or other factors, the goal of wound care provided in these settings may be only to prevent progression of the wound by stabilizing the wound by:
  - minimizing the risk of infection and further progression of the wound;
  - managing the multiple issues that cause patient and family suffering; and
  - optimizing the patient's function and quality of life.
6. Complicating circumstances that support additional wound care services as reasonable and necessary must be supported by adequate medical record documentation.
7. Autolytic debridement is contraindicated for infected wounds.
8. Debridement of extensive eczematous or infected skin is not appropriate for debridement of a localized amount of tissue normally associated with a circumscribed lesion. Examples of this are ulcers, furuncles, and localized skin infections.
9. Surgical debridement will be considered not reasonable and necessary when documentation indicates the wound is without devitalized, fibrotic, nonviable tissue, infection, necrosis, foreign matter, or if the wound has pink to red granulated tissue. When utilized, it is expected that the frequency of debridement will decrease over time.
10. Wound debridement utilizing a method which is unproven by valid scientific literature would be considered investigational and not reasonable and necessary.
11. If a treatment is investigational, under waiver of liability provisions of Medicare law, an Advance Beneficiary Notice must be obtained for the beneficiary.
12. When performed in conjunction with another wound care service, the dressing change is considered an integral component of that service and is not a separately covered service.
13. A wound that shows no improvement after 30 days may require a new approach, which may include a physician reassessment of underlying infection, off-loading, biofilm, metabolic, nutritional, or vascular problems which may inhibit wound healing.
14. Procedures performed for cosmetic reasons or to prepare tissues for cosmetic procedures are statutorily excluded from coverage by Medicare.
15. Local infiltration, metacarpal/metatarsal/digital block or topical anesthesia are included in the reimbursement for wound care services and are not separately covered.



16. The following procedures are considered part of an E/M service and are not separately covered when an E/M service is performed:
  - Removal of necrotic tissue by cleansing and dressing, including wet or dry-to-dry dressing changes,
  - Cleansing and dressing small or superficial lesions, and
  - Removal of coagulated serum from normal skin surrounding an ulcer.
17. NPWT is contraindicated for any of the following wound types/conditions:
  - Necrotic tissue with eschar present,
  - Untreated osteomyelitis,
  - Non-enteric and unexplored fistulas,
  - Malignancy in the wound,
  - Exposed vasculature,
  - Exposed nerves,
  - Exposed anastomotic site, or
  - Exposed organs.
18. Continuing MIST treatments for wounds demonstrating no improvement after six treatments is considered not reasonable and necessary.
  - Observable, documented improvements in the wound(s) should be evident after 2 weeks or 4-6 MIST treatments. Improvements may include documented reduction in pain, necrotic tissue, or wound size; or improved granulation tissue.
19. The following services are considered to be not reasonable and necessary wound debridement services:
  - Removal of necrotic tissue by cleansing or dry-to-dry or wet-to-dry dressing.
  - 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.
  - Paring or cutting of corns or non-plantar calluses.
  - 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, 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.
20. Wet-to-dry dressings, jet hydrotherapy, or wound irrigations should be used cautiously as maceration of surrounding tissue may hinder healing.
21. Jet therapy and wound irrigation for wound debridement must be performed by skilled personnel in order to be considered reasonable and necessary.
22. Medicare expects that with appropriate care:
  - Wound volume or surface dimension should decrease, or
  - Wounds optimally will demonstrate granulation tissue.
23. Debridements of the wound(s) if indicated must be performed judiciously and at appropriate intervals. It is expected that, with appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should decrease overtime. It is also expected the wound care treatment plan is modified in the event that appropriate healing is not achieved.

For frequency limitations, please refer to the Utilization Guidelines section below.

**Notice:** This LCD imposes frequency limitations as guidelines. 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.

As published in CMS IOM 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed

LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
  - Furnished in a setting appropriate to the patient's medical needs and condition.
  - Ordered and furnished by qualified personnel.
  - One that meets, but does not exceed, the patient's medical needs.
  - At least as beneficial as an existing and available medically appropriate alternative.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

## Summary of Evidence

An article was published in *Wound Repair and Regeneration* on "Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: A multicenter randomized controlled trial" in January 2012 by DG Armstrong, WA Marston, AM Reyzelman, and RS Kirsner. This was a 17-center prospective, randomized controlled clinical trial designed to evaluate the relative impact on wound closure using the "mechanically powered" Smart Negative Pressure (SNaP) Wound Care System (Spiracur, Inc.) vs. the "electrically powered" Vacuum-Assisted Closure (VAC) Therapy System (KCI, San Antonio, TX). One hundred thirty-two (132) patients were enrolled with non-infected, non-ischemic, non-plantar lower extremity diabetic and venous wounds. Eighty-three patients ( $n = 41$  SNaP,  $n = 42$  VAC) completed the study with either healing or 16 weeks of therapy. The study provides evidence that treatment of wounds using a disposable NPWT device (SNaP System) compared to a traditional NPWT device (VAC System) have similar results but have less impact on the patient's quality of life. Potential conflict of interest is that this study was sponsored by Spiracur Inc. and two of the authors received research funding from both Spiracur (SNaP device) and K.C.I. (VAC device). The quality of evidence is low; the strength of recommendation is weak.

"Comparison of high-frequency and MIST ultrasound therapy for the healing of venous leg ulcers" by Beheshti A, Shafiq Y, Parsa H, and Zangivand AA was published in the 2014 *Advances in Clinical and Experimental Medicine*. The aim of the year-long randomized controlled study of 90 patients was to analyze the effect of standard ulcer care alone (compression bandages) with high-frequency ultrasound (HFU) and MIST ultrasound therapy (US) on venous leg ulcers (VLUs). The patients were chosen from patients with VLUs who had received wound care at the hospital outpatient vascular clinic of Shahid Rajaii Hospital. Patients were instructed to contact the clinic monthly and recurrence of VLUs was recorded for six months after complete wound healing. Study results showed no significant differences in recurrence between groups during a six-month follow-up after complete wound healing. All VLUs in the study healed within one year. Recurrence was observed in four cases in the standard group (13.3%); two cases in the HFU group and two cases in the MIST US group (6.6%). The authors stated their results were lower than similar studies but state the 6-month follow-up is very short to truly decide about the potential of prevention of recurrence in patients treated with US therapy. Mean age was 58.5 years (SD 11.6 years). The authors concluded the study showed significant effectiveness of ultrasound therapy, especially MIST therapy, in wound healing as an adjuvant therapy. They noted differences between the two ultrasound therapy groups were not statistically

significant. Exclusion criteria were listed. The design of this study presents limitations including selection bias. The report states the patients were randomized but suggests the study may not have been blinded. Other limitations to this study were a small sample size and inconsistency across studies when comparisons were made. The authors compare the results of their study to other studies of different sample size, different ages, unknown co-morbidities and different wound types. The authors remark that additional work on cost-effectiveness outcomes and planning are greatly needed for the future studies. Note: This study was conducted outside the U.S. and does not largely represent the Medicare population. The quality of evidence is low; the strength of recommendation is weak.

The 2007 *Journal of Palliative Medicine* article by Ferris, Al Khateib, and Fromantin, "Palliative wound care: managing chronic wounds across life's continuum: a consensus statement from the International Palliative Wound Care Initiative," is a consensus statement which recognizes that while most chronic wounds will eventually heal if managed appropriately, some will not. In patients with non-healable wounds, therapies that aim to heal the wound may not be in anyone's best interest. The Initiative recognizes that the expertise and skills in palliative wound care can improve the quality of life of all individuals living with or affected by healing and non-healing chronic wounds and is guided by the philosophy that the opportunity exists to negotiate personalized goals of care to optimize quality of life through an interdisciplinary approach to care. Quality of evidence is low. Strength of recommendation is weak.

The 2015 "Debridement for venous leg ulcers (Review)" by Gethin, Cowman, and Kolbach is a Cochrane Database Systematic Review done through search of a wide range of electronic data bases for randomized control trials (RCTs), either published or unpublished, which compared methods of debridement or compared debridement with no debridement. Ten RCTs were identified involving a total of 715 participants. These studies were selected independently by two review authors who completed all study selection, data extraction and assessment of trial quality; resolution of disagreements was completed by a third review author. Eight RCTs evaluated autolytic debridement and included the following agents or dressings: biocellulose wound dressing (BWD), non-adherent dressing, honey gel, hydrogel (gel formula), hydrofibre dressing, hydrocolloid dressings, dextranomer beads, Edinburgh University Solution of Lime (EUSOL) and paraffin gauze. Two RCTs reported enzymatic preparations and one evaluated biosurgical debridement. No RCTs evaluated surgical, sharp or mechanical methods of debridement, or debridement versus no debridement. The systematic review had the following weaknesses: study results were presented in a narrative form, small populations, heterogeneity of outcomes, and lack of comparability across trials, inconsistent methodology across trials and there was a high risk of bias since most of the RCTs had high risk of bias. The authors conclude there is limited evidence to suggest that actively debriding a venous leg ulcer has a clinically significant impact on healing. The overall small number of participants, low number of studies and lack of meta-analysis in this review precludes any strong conclusions of benefit. Comparisons of different autolytic agents (hydrogel versus paraffin gauze; Dextranomer beads versus EUSOL and BWD versus non adherent dressings) and Larvae versus hydrogel all showed statistically significant results for numbers of wounds debrided. Larger trials with follow up to healing are required. The quality of evidence is low; the strength of recommendation is weak.

In 2015, "A Prospective, Randomized, Controlled Trial Comparing the Effects of Noncontact, Low-frequency Ultrasound to Standard Care in Healing Venous Leg Ulcers" was published in *Ostomy Wound Management* by Gibbons, Orgill, Serena, et al. This article is a prospective, randomized, controlled, multicenter (22 U.S. sites) trial was conducted to compare percent wound size reduction, proportions healed, pain, and quality-of-life (QOL) outcomes in patients randomized to standard care (SC) alone or SC and 40 kHz noncontact, low-frequency ultrasound (NLFU) treatments 3 times per week for 4 weeks. One hundred, twelve (112) eligible participants with documented venous stasis, a VLU greater than 30 days' duration, measuring 4 cm<sup>2</sup> to 50 cm<sup>2</sup>, and demonstrated arterial flow were enrolled. Of these, 81 (72%) reduced less than 30% in size during the 2-week run-in study phase and were randomized (SC, n = 40; NLFU+SC, n = 41). Median age of participants was 59 years; 83% had multiple complex comorbidities. After 4 weeks of treatment, average wound size reduction was 61.6% ± 28.9 in the NLFU+SC compared to 45% ± 32.5 in the SC group (P = 0.02). Reductions in median (65.7% versus 44.4%, P = 0.02) and absolute wound area (9.0 cm<sup>2</sup> versus 4.1 cm<sup>2</sup>, P = 0.003) as well as pain scores (from 3.0 to 0.6 versus 3.0 to 2.4, P = 0.01) were also significant. NLFU therapy with guideline-defined standard VLU care should be considered for healing VLUs not responding to SC alone. The results of this study warrant further research on

barriers to healing and the changes occurring in the tissue of the wound to explore theories that the microenvironment impacts wounds that do not heal despite provision of guideline-defined care. This study was sponsored by Celleration, Inc. The authors consulted on study design, protocol development, and study oversight. The authors remained blinded throughout the study. A limitation of this study was that the investigators and participants were not blinded to treatment group assignment. The study was limited to participant-reported measures such as QOL and VAS pain scores. A second limitation was the treatment groups did not have the same required frequency of treatment visits. Another limitation was that there was a short-term (7-week) follow-up with a final ulcer measurement performed at the last study visit, 11 weeks post randomization. The quality of evidence is low; the strength of recommendation is weak.

In 2004, Gupta, Baharestani, Baranoski, et al. published "Guidelines of Managing Pressure Ulcers with Negative Pressure Wound Therapy" in *Advances in Skin & Wound Care*. In this article, a consensus panel of experienced wound care clinicians reviewed the mechanism of action and research basis for Negative Pressure Wound Therapy (NPWT). After answering key questions about NPWT, an algorithm was developed to assist clinicians in decision making for use of NPWT with Stage III/IV pressure ulcers. Therapy with NPWT lasted for a mean of 35 days (range: 3-124 days). Panel members believe the role of NPWT as an adjunctive therapy should be validated. The guideline states the numbers should be interpreted cautiously, however, because of discrepancies in methodology. Limitations include multiple studies with variable criteria, and/or with study size, duration, population undefined. Some conclusions are not statistically substantiated. This guideline was limited to "FDA-cleared NPWT device (V.A.C. Therapy System)" and funded by a NPWT manufacturer. The quality of evidence is low; the strength of recommendation is weak.

In 2005, *Home Health Care Management & Practice* published "Palliative wound care at the end of life" by Hughes, Bakos, O'Mara, et al. This source purports that providing wound care, although often curative, is also palliative. It further states that patients nearing the end of their lives may benefit from the curative aspects of wound care and makes the following assertions. Palliative care supports the health care needs of dying patients by focusing on alleviating symptoms. Although wound care can be both healing and palliative, it can impair the quality of the end of life for the dying if it is done without proper consideration of the patient's wishes and best interests. Wound care may be optional for dying patients. This article discusses the ethical responsibilities and challenges of providing wound care for surgical wounds, pressure ulcers, and wounds associated with cancer as well as wound care in home health compared to end of life. Quality of evidence is low. Strength of recommendation is weak.

"Use of a Portable, Single-use Negative Pressure Wound Therapy Device in Home Care Patients with Low to Moderately Exuding Wounds: A Case Series" by Hurd, Trueman, and Rossington was published in *Ostomy Wound Management* in 2014. This case report is an 8-week study to evaluate outcomes of using a single-use NPWT system for the treatment of exuding wounds. Data was retrospectively abstracted from 326 patient medical records. The mean age of patients treated was 57 years (median 61 years, range 17 to 91 years) with mixed etiologies: 53 pressure ulcers, 21 venous leg ulcers, 16 diabetic foot ulcers, 15 traumatic wounds, and 221 surgical wounds. There were 228 with complete wound closure within 8 weeks of treatment. The mean wound area at baseline was 20 cm<sup>2</sup> (median 14 cm<sup>2</sup>, range 0.1–99 cm<sup>2</sup>). Mean wound volume at baseline was 45 cm<sup>3</sup> (median 31 cm<sup>3</sup>, range 0–269 cm<sup>3</sup>). At the baseline visit, 180 and 116 patients (91%) had low or moderate levels of exudate, respectively. Although the portable device is indicated for low to moderately exuding wounds, a small number of patients showed scant (12, 4%) and large (18, 6%) levels of exudate, met local protocols for accessing NPWT, and were deemed to be suitable for inclusion in the evaluation in the opinion of the treating physician. The majority of patients (218, 68%) discontinued treatment with portable NPWT as a result of their wound healing within the 8-week evaluation period. The proportion of wounds completely healed during the 8-week evaluation was higher in surgical wounds (167 out of 219, 76%) than in nonsurgical wounds (51 out of 104, 49%); 30 patients (9%) discontinued treatment as a result of the study period ending. An additional 21 patients (7%) discontinued therapy due to hospitalization and nine (3%) due to doctor's orders. Twenty-six patients (26, 8%) discontinued treatment due to excessive exudate. Excessive exudate was more commonly reported during treatment in nonsurgical than in surgical wounds (14 out of 104 [13%] versus 12 out of 219 [6%], respectively). Device-related reasons for discontinuation were loss of seal

(10, 3.1%) and poor compliance (i.e., patient removed device or asked for it to be removed; six [1.9%]). Poor compliance was reported more commonly in nonsurgical wounds, although the numbers remained small (five out of 104, 5%). For five patients, reason for discontinuation was unknown or unreported; there was one death. Healing rates in the portable (disposable) and traditional NPWT groups were similar (approx. 10%/week). The mean reduction in wound area per week was similar in both groups (11% /week, median = 10, range 0–66.7 for portable NPWT compared to 10%/week, median = 9.4, range 1.7–31.7 for conventional NPWT). Patient satisfaction for dressing performance was 97%. Eighty-nine (89) percent who used the conventional NPWT (n=539) had an open surgical wound with moderate or high levels of exudate. The findings of this evaluation suggest the single-use; portable device may redefine access to NPWT for patients with low exudating wounds. The decision to use conventional or portable, single-use NPWT devices should start with wound characteristics such as size and exudate levels. However, other criteria may be taken into account — particularly, the patient’s mobility, lifestyle, and ability to adhere to a treatment regimen. The design of this study presents inherent limitations, including selection bias. This evaluation considered only patients eligible for NPWT treatment according to local protocols, and nurses chose to use portable NPWT on those patients who were most likely to benefit. The comparison with the retrospectively collected data provides some context but no control. In addition to the limitations of evaluating retrospectively collected data, the patient population and wounds previously managed with conventional NPWT were very different from those managed with the portable device. Randomized, controlled clinical studies are needed to compare the portable NPWT device to other treatment modalities indicated for these wounds with respect to wound outcomes, cost-effectiveness, and patient quality of life. The quality of evidence is low; the strength of recommendation is weak.

The Hurd, Rossington, Trueman, et al., comparison article published in *Advances in Wound Care* in 2017 is a retrospective cohort study consisting of a Canadian institution wide audit of basic, anonymized data derived of records from patients with postsurgical wounds. A total of 1,107 patients were analyzed, 808 of whom were treated with the RENASYS NPWT system (Smith & Nephew) and 299 of whom were treated with the V.A.C. system (KCI, Inc.). The two groups were well matched in terms of their demographics and baseline wound characteristics. The majority of the wounds were postsurgical wounds that had developed complications. The limitations of the study were variable treatment protocols, subjective and objective end points measured and high risk of bias. The findings of this analysis suggest that the RENASYS NPWT system and V.A.C. therapy offer similar levels of performance in the management of challenging wounds. Wound area reductions over the course of the evaluation period were almost identical in both treatment groups and the overall rates of wound closure and the time to achieve predefined treatment goals were comparable. Nanocrystalline silver (ACTICOAT Flex 3) was used successfully as an adjunct to either NPWT system. This retrospective, naturalistic analysis is believed to be the largest case series of NPWT patients presented to date and as such is a valuable complement to the existing evidence base on this therapy. Potential conflicts of interest may include author honorarium and assistance with data interpretation and manuscript preparation from Smith & Nephew. The quality of evidence is moderate; the strength of recommendation is strong.

Krug, Berg, Lee, et al. had “Evidence-Based Recommendations for the Use of Negative Pressure Wound Therapy in Traumatic Wounds and Reconstructive Surgery: Steps towards an International Consensus” published in 2011 in *Injury*. In addition to developing recommendations, the panel sought to clarify treatment goals that can be achieved using NPWT. It is increasingly recognized that NPWT can be used to achieve a variety of treatment goals, which will vary according to the patient and wound characteristics. Currently, there is a propensity to believe that the only valuable end-point with regards to wound management is complete wound closure. However, the advent of NPWT has introduced the concept that other treatment goals may act as staging posts along the path towards complete closure, which may be useful end-points in any clinical trial. A total of 208 papers met the inclusion/exclusion criteria were identified through the systematic review. Recommendations were developed according to a modification of the SIGN (Scottish Intercollegiate Guidelines Network) classification system. This classification system is designed to reduce variation in practice and outcome through the development and dissemination of clinical guidelines containing recommendations for effective practice based on current evidence. Areas assessing NPWT use include surgical repair of soft tissue traumatic wounds to provide temporary wound cover, interim use of NPWT to progress a wound from that of a complex wound which may require complex surgical closure (such as a microsurgical free flap) to a

smaller and simpler wound which may be adequately managed with a simpler procedure. Also assessed include cases in which wound closure by secondary intention may be a viable option, Gustilo open fractures, burns, skin grafts and flaps. The resulting evidence base is therefore weaker than the wide-spread adoption of NPWT would suggest. In light of this, consensus becomes an important part of recommendation generation. Potential conflicts may include this review was funded by Smith and Nephew. Quality of evidence is low. Strength of recommendation is moderate.

Lau, Tatsioni, Balk, et al., prepared "Usual care in management of chronic wounds: A review of the recent literature" for ARHQ in 2005. This is a systematic review of randomized controlled trials from 1997 to 2004, the authors extracted information about the background care given to control groups to identify treatment modalities that represent the standard of care. A total of 148 RCTs were selected, the largest number of trials were on venous ulcer, followed by diabetic ulcers and pressure ulcers. Just one trial addressed arterial ulcers. The review had some limitations: Inconsistency across studies, large degree of variation in the reporting of basic wound treatment modalities and variation in the duration of usual care. The review does not address outcomes. It has a low risk of bias. Relevant conclusions from the authors were there is little evidence to indicate which dressings or topical agents are the most effective in the treatment of chronic wounds and that there is evidence that hydrocolloid dressings are more effective than wet to dry dressings in the treatment of pressure sores. In the treatment of venous ulcers non adherent dressings are as effective as hydrocolloid dressings beneath compressive bandages. There is no evidence to support the use of systemic agents for chronic wound healing. Topical agents may be helpful in chronic wound care but further research is required. Compression is more effective than no compression in healing leg venous ulcers. The quality of evidence is high. The strength of recommendation is strong.

The 2013 "International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers" in *Wounds International* was compiled by an expert panel of endocrinologists, podiatrists, and rehabilitation specialists. The guideline offers a global wound care plan for practitioners which includes a series of steps for preventing complications through active management combined with appropriate patient education and integrated approach to care. Factors to consider for dressing choice "must begin with a thorough patient and wound assessment" and include location of the wound, extent of the wound (size/depth), amount and type of exudate, the predominant tissue type on the wound surface, condition of the periwound skin, compatibility with other therapies, wound bioburden and risk of infection, avoidance of pain and trauma at dressing changes, quality of life and patient well-being. Regularly reviewing of patient's wound and dressing is vital. Adjunctive treatments such as NPWT may be considered, if appropriate, where wound not healing. Limitations are that information was collected from Europe and the United Kingdom. The target population was patients with diabetic foot ulcers. Statistics vary and the information appears to be not universally applicable across healthcare systems to Medicare beneficiaries. Also, healthcare providers are not necessarily equally trained and patient access to care varies widely depending on region. The guideline was supported through an educational grant from B Braun (a German medical and pharmaceutical device company). The quality of evidence is low; the strength of recommendation is weak.

A 2014 article in *Advances in Wound Care*, "A Multicenter Randomized Controlled Trial Comparing Treatment of Venous Leg Ulcers Using Mechanically Versus Electrically Powered Negative Pressure Wound Therapy," discusses a 13 center non-blinded prospective randomized controlled clinical trial designed to evaluate the relative impact on wound closure using a MP NPWT system (SNaP Wound Care System; Spiracur, Inc., Sunnyvale, CA) versus an EP NPWT system (V.A.C. Therapy System; KCI). The article does not identify the initial population enrolled in the study it just addresses the 40 (n = 19 MP NPWT, n = 21 EP NPWT) patients that completed the study. Each subject was randomly assigned to treatment with either MP NPWT or EP NPWT and evaluated for 16 weeks or complete wound closure. The study had the following weaknesses: small sample, subject and investigator blinding was not performed. There were significant differences in the mean initial wound size between the control and the experimental groups, differences on dressing changes between groups. There was a high risk of performance, detection and publication bias. The study concluded that in this group of venous ulcers, wounds treated with MP NPWT demonstrated greater improvement and a higher likelihood of complete wound closure than those treated with EP NPWT. Potential bias includes this study was sponsored by Spiracur Inc. Also, two authors received research funding from both Spiracur (SNaP device) and

other authors consulted for KCI (VAC device). The quality of evidence is low; the strength of recommendation is weak.

O'Donnell TF, Passman MA, Marston WA, et al., had "Management of venous ulcers: Clinical practice guidelines of the Society for Vascular Surgery® and the American Venous Forum" in the *Journal of Vascular Surgery* in 2014. This is an evidence synthesis, Clinical Practice Guideline developed based on the grading of recommendation assessment, development, and evaluation (GRADE) system. When evidence is lacking, the committee relied on case series supplemented by the best opinion of panel of experts and the recommendation was labeled [BEST PRACTICE]. Such "best practices" from a guideline has obvious advantages but implementation can be a challenge. Focus on "best outcomes for the most reasonable health care dollar" stimulated SVS and AVF to develop and promote a unified set of guidelines for treatment of chronic diseases, such as VLUs. This guideline is presented from the Society for Vascular Surgery and the American Venous Forum. Venous Ulcer Guidelines Committee was divided into six sub-committee sections. The overall committee developed a series of key clinical questions to guide the overall approach for the guideline development; each section team determined the need for a systematic and meta-analysis review which was then agreed on by the entire committee. All guidelines were developed by building on existing guidelines with a complementary literature search by the section sub-committee. It was agreed that the studies reviewed should be published in peer-reviewed journals. The following studies were reviewed: Edinburgh study, a multi-center study of Polish patients, a cross-sectional study in France, the Bonn Vein Longitudinal Study by German Ministry of Health. The sample size of the studies varied widely from 84-40,000 participants. The sample age was unknown or not consistently reported. The guideline is intended for specialists who treat vascular disease and wounds limited to venous leg ulcers. The guideline mentions that future research design should include patient-centered outcomes measures which need to be incorporated into trial design. There is insufficient evidence to generalize to the Medicare population. The quality of evidence is low; the strength of recommendation is weak.

Rhee, Valle, Wilson, et al., with Johns Hopkins Evidence-base Practice Center, prepared a Technology Assessment report, "Negative Pressure Wound Therapy Technologies for Chronic Wound Care in the Home Setting," for the AHRQ. Johns Hopkins University conducted research to systematically review the efficacy and safety of negative pressure wound therapy (NPWT) for treatment of chronic wounds in the home setting. The focus of this review was use of NPWT in the home population, thus the results are not necessarily applicable to other health care settings in which NPWT may be used. Two independent reviewers screened search results. Studies examined the use of NPWT in patients with chronic wounds, including venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers, and mixed etiology chronic wounds. Comparative trials were used that followed subjects in the home setting. The group was unable to draw conclusions about the efficacy or safety of NPWT for the treatment of chronic wounds in the home setting due to insufficient evidence. Though NPWT has been used across the wound care spectrum, significant research gaps remain. Standardization of wound care research protocols, such as providing consistency in comparator groups, robust randomized study designs, larger trials, and common definitions of outcomes, would be helpful in providing evidence to inform decisions about the use of NPWT. A very nice summary of the strength of the body of evidence comparing NPWT with other wound care treatments is summarized in Table 5. Pre-defined critical outcomes, those essential for decision making in wound care, were determined to evaluate the strength of evidence. For each of these five critical outcomes, across all wound etiologies, the strength of the evidence is insufficient to draw conclusions on the effectiveness and safety of NPWT compared with other wound care treatments. There were few studies addressing each outcome for each wound etiology; for several outcomes, no studies were identified. Most of the studies were observational studies of poor quality. Only one study was an RCT, and it was judged to be fair quality. The strength of evidence domain of directness was downgraded by the reviewer because some studies used inappropriate control group or used surrogate markers for outcomes. Reviewers were rarely able to evaluate consistency. There were not enough studies to use funnel plots to determine if there was reporting bias. Publication bias may be of concern. Five of the studies reported funding from industry, while Yao et al. did not report funding source. The RCT had a small sample size, and therefore, imprecise results. Some of the observational studies reported limited data on outcomes. Previous systematic reviews on NPWT noted in Table 8 provide a nice summary of systematic reviews on NPWT in various environments. Given the mixture of wound etiologies, and the lack of details about the patients in each of the studies, it was difficult to generalize the results to the overall population.

The populations studied all had chronic wounds, and since the chronic wound treatment modalities can be used across the age spectrum, the data we found could be applicable to the Medicare population with moderate generalizability at best. Quality of evidence is low. Strength of recommendation is weak.

Sullivan, Snyder, Tipton, et al., with ECRI Institute published a revised "Negative Pressure Wound Therapy Devices: Technology Assessment Report" in 2009. Over 1400 items were submitted by stakeholders and all were reviewed for relevance. None of the submissions were studies directly comparing different NPWT devices/systems. Submissions included systematic reviews, comparison studies, and uncontrolled case series. In 40 comparison studies, it was found that all of the controlled trials involved the evaluation of one NPWT device, the V.A.C® manufactured by Kinetic Concepts Inc. (KCI). None of the 40 comparison studies met the design and conduct requirements to be considered high quality, only seven studies could be considered moderate quality, and the majority of studies (82%) were rated low quality. AHRQ noted conclusions made in the TA agreed with the systematic reviews examined; the reviews indicated the majority of evidence on NPWT was of poor quality. The TA indicates the most commonly reported adverse events associated with NPWT are pain, bleeding, and infection. Of the 37 studies reporting events, seven (19%) studies described NPWT as a safe treatment. Fewer complications were reported in the NPWT-treated patients than in those receiving other wound therapies in 19 (51%) studies and similar complications were reported in 8 (22%) studies. The TA noted important study features were not typically reported such as concealment of allocation, reporting of randomization methods and use of power analysis to ensure adequate study size, blinding patients and especially wound assessors, and reporting of complete wound healing data to insure the internal validity of study results. No study included in the TA reported that the physicians were blinded to treatment assignment, and only 12% of the studies reported blinding of outcome assessors. In only 7% of studies was there concealment of allocation to treatment, one of the most crucial elements of any randomized controlled trial with failure typically resulting in selection bias. The TA noted the findings could not be transferred from one wound type to another so numerous high quality studies of several different wound types would be necessary in order to determine if any one NPWT system or component provides a significant therapeutic distinction over another. The TA stated the strongest evidence of efficacy will come from properly designed and conducted RCTs that can be replicated by independent research units. The quality of evidence is low; the strength of recommendation is weak.

In 2013, the *Journal of American Medical Association (JAMA) Dermatology* published "Frequency of Debridements and Time to Heal; A Retrospective Cohort Study of 312,744 Wounds" by Wilcox, Carter and Covington. The stated desired objective in this article was to investigate healing outcomes and debridement frequency in a large wound data set. This is a retrospective cohort study. Data was collected from 525 wound care centers from June 1, 2008, through June 31, 2012, using a web-based clinical management system. A referred sample of 154,644 patients with 312,744 wounds of all causes (of an initial data set of 364,534 wounds) participated. A total of 47.1% were male. Median age was 69 years (age range, 19-112 years), with 59.2% having one wound. Eligibility criteria included age older than 18 years, receiving at least 1 debridement, and having been discharged from the system. Advanced therapeutic treatment was ineligible. Because of incomplete, questionable, or ineligible data, 57,190 wounds were not included. Most wounds were diabetic foot ulcers (19.0%), venous leg ulcers (26.1%), and pressure ulcers (16.2%). Debridement (removal of necrotic tissue and foreign bodies from the wound) occurred at different frequencies. Wound healing was defined as complete epithelialization with dimensions at 0x0x0cm. A total of 70.8% of wounds healed. The median number of debridements was 2 (range, 1-138). Frequent debridement healed more wounds in a shorter time (P less than .001). In regression analysis, significant variables included male sex, physician category, wound type, increased patient age, and increased wound age, area, and depth. The odds ratio varied considerably for each variable. The authors concluded the more frequent the debridements, the better the healing, (in spite of noting that the median number of debridements required is two). Although limited by retrospective data, this study's strength was the analysis of the largest wound data set to date. Potential bias is a conflict of interest as the review was obtained from and conducted by a for-profit wound care company and some authors are employed by a for-profit wound care company. Limitations of the study include the use of retrospective data and the statistical analysis. Further analysis will be necessary to determine the precise effect size due to debridement frequency because certain causes will have unique factors come into play. They conclude that the issue remains that there has not yet been an adequately powered retrospective trial to test the efficacy of debridement of wounds. Quality of



evidence is low. Strength of recommendation is weak.

The 2008 “Principles of best practice: Vacuum assisted closure: recommendations for use. A Consensus Document” is World Union of Wound Healing Societies’ Initiative. This is a consensus expert opinion drawn from selected clinical evidence (RCTs, Retrospective match group analysis, Randomized Controlled Crossover Studies, Randomized Controlled Pilot Studies, Retrospective Controlled Studies and Data Compilation from published literature). It has an unclear risk of bias. VAC therapy must be used as part of an individualized, comprehensive treatment plan and is indicated for both acute and chronic wounds. VAC therapy can be considered for deep complex wounds, for post-surgery wounds and, occasionally, for superficial wounds in addition to standard treatments. For patients with ischemic wounds, referral to a vascular surgeon should be considered prior to VAC therapy. Under ideal conditions (especially in the absence of infection), well perfused wounds will respond quickly (i.e., within one week) with evidence of granulation tissue formation. This can be used to test vascularity and suitability of VAC therapy. VAC therapy can be used in a number of ways to manage the complex diabetic foot wound, post-surgery diabetic foot wounds and superficial diabetic foot wounds. It is recognized that compression therapy is regarded as the first-line treatment for venous leg ulcers. However, there is a role for VAC therapy in inflammatory or complex therapy-resistant leg ulcers that are unsuitable for compression. The use of portable VAC systems may also allow ambulatory patients to be treated at home and can reduce the need for hospitalization. In patients with inflammatory ulcers, VAC therapy can be used to enhance wound bed preparation before definitive surgical closure or delayed secondary healing. VAC therapy is recommended as a first-line treatment for grade/stage 3 and 4 pressure ulcers in certain situations and should be used as part of a comprehensive treatment plan. VAC therapy should be considered as a first-line treatment for dehisced sternal wounds following cardiac surgery. This can be used as a bridge to definitive surgical closure or to achieve delayed primary closure or flap reconstruction and closure. The guideline also recommends VAC therapy is in the treatment of: open abdominal wounds, in the treatment of complex traumatic wounds. Finally it states that further research is needed to increase understanding of the therapeutic effects of VAC therapy to give clinicians stronger arguments to support its use. In particular, future trials should focus on the generation of level 1 evidence and further comparative data for specific indications. This will help to clarify the potential for VAC therapy in different wound types and to enhance clinical decision making in various population groups. The quality of evidence is low; the strength of recommendation is moderate.

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

Wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds. The literature on wound care is virtually without limit; yet, in spite of the volume of research conducted, there exists a tremendous diversity of opinion in the literature. Clinical trials, consensus panel reports, and practice patterns reflect considerable differences among clinicians. The appropriate interval and frequency of debridement depends on the individual clinical characteristics of the patient and the extent of the wound. 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. Given the varied nature and diversity of options available to the clinician, this LCD does not impose strictly defined frequency limitations as such on wound care debridements, palliative care wound treatments, application of negative pressure wound therapy with the exception of services rendered for low frequency, non-contact, non-thermal ultrasound (MIST Therapy).

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 prepay or post pay medical review.

# Coding Information

## Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

CODE	DESCRIPTION
012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
018x	Hospital - Swing Beds
022x	Skilled Nursing - Inpatient (Medicare Part B only)
023x	Skilled Nursing - Outpatient
071x	Clinic - Rural Health
073x	Clinic - Freestanding
074x	Clinic - Outpatient Rehabilitation Facility (ORF)
075x	Clinic - Comprehensive Outpatient Rehabilitation Facility (CORF)
077x	Clinic - Federally Qualified Health Center (FQHC)
083x	Ambulatory Surgery Center
085x	Critical Access Hospital

## Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

**Note:** The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual (IOM) Pub. 100-04, *Medicare Claims Processing Manual*, for further guidance.

CODE	DESCRIPTION
027X	Medical/Surgical Supplies and Devices - General Classification
036X	Operating Room Services - General Classification
042X	Physical Therapy - General Classification

CODE	DESCRIPTION
043X	Occupational Therapy - General Classification
044X	Speech-Language Pathology - General Classification
045X	Emergency Room - General Classification
049X	Ambulatory Surgical Care - General Classification
051X	Clinic - General Classification
052X	Freestanding Clinic - General Classification
0623	Medical/Surgical Supplies and Devices - Surgical Dressings
0761	Specialty Services - Treatment Room
0977	Professional Fees - Physical Therapy
0978	Professional Fees - Occupational Therapy
0982	Professional Fees - Outpatient Services
0983	Professional Fees - Clinic

### CPT/HCPCS Codes

#### Group 1 Paragraph:

**Note:** Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

#### Group 1 Codes:

CODE	DESCRIPTION
11000	Debride infected skin
11001	Debride infected skin add-on
11004	Debride genitalia & perineum
11005	Debride abdom wall
11006	Debride genit/per/abdom wall
11008	Remove mesh from abd wall
11010	Debride skin at fx site
11011	Debride skin musc at fx site
11012	Deb skin bone at fx site
11042	Deb subq tissue 20 sq cm/<
11043	Deb musc/fascia 20 sq cm/<
11044	Deb bone 20 sq cm/<
11045	Deb subq tissue add-on

CODE	DESCRIPTION
11046	Deb musc/fascia add-on
11047	Deb bone add-on
29580	Application of paste boot
29581	Apply multlay comprs lwr leg
97597	Rmvl devital tis 20 cm/<
97598	Rmvl devital tis addl 20cm/<
97602	Wound(s) care non-selective
97605	Neg press wound tx </=50 cm
97606	Neg press wound tx >50 cm
97607	Neg press wnd tx </=50 sq cm
97608	Neg press wound tx >50 cm
97610	Low frequency non-thermal us

### ICD-10 Codes that Support Medical Necessity

#### Group 1 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

No procedure code to diagnosis code limitations are being established at this time.

#### Group 1 Codes:

ICD-10 CODE	DESCRIPTION
XX000	Not Applicable

### ICD-10 Codes that DO NOT Support Medical Necessity

#### Group 1 Paragraph:

N/A

#### Group 1 Codes: N/A

### Additional ICD-10 Information

N/A

# General Information

## Associated Information

### Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The most accurate and specific diagnosis code(s) must be submitted on the claim. The patient's medical record should indicate the specific signs/symptoms and other clinical data supporting the diagnosis code(s) used. It is expected that the physician will document the current status of the wound in the patient's medical record and the patient's response to the current treatment.
5. The patient's medical record must contain clearly documented evidence of the progress of the wound's response to treatment at each physician 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.
  - Other material in the wound that is expected to inhibit healing or promote adjacent tissue breakdown.
6. Identification of the wound location, size, depth, and stage by description must be documented and may be supported by a drawing or photograph of the wound. Photographic documentation of wounds at initiation of treatment as well as either immediately before or immediately after debridement is recommended. This may be of particular benefit for documentation as an adjunct to written documentation of reasonable and necessary services, which require prolonged or repetitive debridement (especially those that exceed 5 debridements per wound).
7. Medical record documentation for debridement services must include the type of tissue removed during the procedure as well as the depth, size, or other characteristics of the wound and must correspond to the debridement service submitted. A pathology report substantiating depth of debridement is encouraged when billing for the debridement procedures involving deep tissue or bone.
8. In addition, except for patients with compromised healing due to severe underlying debility or other factors, documentation in the medical record must show:
  - There is an expectation that the treatment will substantially affect tissue healing and viability, reduce or control tissue infection, remove necrotic tissue, or prepare the tissue for surgical management.
  - The extent and duration of wound care treatment must correlate with the patient's expected restoration potential. If wound closure is not a reasonable goal, then the expectation is to optimize recovery and establish an appropriate non-skilled maintenance program. Alternatively, palliative care of the patient and wound may be provided to diminish the probability of prolonged hospitalization, etc. If it is determined that the goal of care is not wound closure, the patient should be managed following appropriate covered palliative care standards.
9. Service(s) must include an operative note or procedure note for the debridement service(s). This note should include the following:
  - Medical diagnosis.
  - Indication(s) and medical necessity for the debridement.
  - Type of anesthesia used, if and when used.
  - Wound characteristics such as diameter, depth, undermining or tunneling, color, presence of exudates or necrotic tissue.

- Level/depth of tissue debrided and a description of the types(s) of tissue involved and the tissue(s) removed.
  - Vascular status, infection, or evidence of reduced circulation.
  - Narrative of the procedure to include the instruments used. When debridements are reported, the debridement procedure notes must 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, description of tissue removed, degree of epithelialization, etc.) before and after debridement.
  - Patient specific goals and/or response to treatment.
  - Immediate post-op care and follow-up instructions.
  - The presence or absence of necrotic, devitalized, fibrotic, or other tissue or foreign matter must be documented in the medical record when wound debridement is performed.
10. The medical record must include a plan of care containing treatment goals and physician follow-up. 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. Appropriate modification of treatment plans, when necessitated by failure of wounds to heal, must be demonstrated. A wound that shows no improvement after 30 days may require a new approach. Documentation of such cases may include a physician reassessment of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing, or a new treatment approach.
  11. 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 medical record at intervals consistent with the nature of the condition or factor.
  12. Documentation must support the use of skilled personnel with the use of jet therapy and wound irrigation for wound debridement.
  13. Documentation for low frequency, non-contact, non-thermal ultrasound (MIST Therapy) services should include documented improvements of pain reduction, reduction in wound size, improved and increased granulation tissue, or reduction in necrotic tissue. The services should be medically necessary based on the provider's documentation of a medical evaluation of the patient's condition, diagnosis, and plan.

### **Utilization Guidelines:**

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds. The appropriate interval and frequency of debridement depends on the individual clinical characteristics of the patient and the extent of the wound. 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.

With the above in mind, only a minority of beneficiaries who undergo debridements for wound care appear to require more than eight total surgical excisional debridement services involving subcutaneous tissue, muscle/fascia, or bone in a 360 day period, (five debridements of which involve removal of muscle/fascia, and/or bone) in order to accomplish the desired objective of the treatment plan of the wound. Only when medical necessity continues to be met and there is documented evidence of clear benefit from the debridements already provided, should debridement services be continued beyond this frequency or time frame.

Also with the above in mind, of the beneficiaries who undergo treatment utilizing negative pressure wound therapy, only a minority appears to require more than 6 NPWT services in a 120 day period to accomplish the desired

objective of the treatment plan of the wound. Only when medical necessity continues to be met and there is documented evidence of clear benefit from the NPWT treatment already provided, should NPWT services be continued beyond this frequency or time frame.

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.

Low frequency, non-contact, non-thermal ultrasound (MIST Therapy) may be provided 2-3 times per week to be considered 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.

Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient's medical record. When services are performed in excess of anticipated peer norms, based on data analysis, the services may be subject to prepay or post pay medical review.

### **Sources of Information**

N/A

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Novitas Solutions, Inc. – JL Local Coverage Determination (LCD) L35139: Wound Care.

Novitas Solutions, Inc. – JL Article A53001: Wound Care.

Other Contractor Local Coverage Determinations

First Coast Service Options, Inc. JN LCD L33566: Wound Debridement Services.

Contractor Medical Directors

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## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/09/2017	R7	<p>LCD revised and published on 11/09/2017 effective for dates of service on and after 11/09/2017 to add the following Revenue Codes: 0982 and 0983.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"><li>• Other (Inquiry)</li></ul>
11/09/2017	R6	<p>LCD posted for notice on 09/21/2017. LCD becomes effective for dates of service on and after 11/09/2017.</p> <p>01/19/2017 DL35125 Draft LCD posted for comment.</p>	<ul style="list-style-type: none"><li>• Creation of Uniform LCDs With Other MAC Jurisdiction</li><li>• Automated Edits to Enforce Reasonable &amp; Necessary Requirements</li></ul>
10/01/2015	R5	<p>LCD revised and published on 08/11/2016 to add several sources from a reconsideration request for larval therapy. The content of this policy has not been changed in response</p>	<ul style="list-style-type: none"><li>• Reconsideration Request</li></ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		to the reconsideration request. The CPT Group 1 codes have been reformatted without change in coverage.	<ul style="list-style-type: none"> <li>Other (Clarification)</li> </ul>
10/01/2015	R4	Removed ICD-10 Group 2 area as there were no codes in that group.	<ul style="list-style-type: none"> <li>Other (Annual Review)</li> </ul>
10/01/2015	R3	LCD revised and published 10/16/2015. Procedure code to diagnosis code limitations have been removed from the policy effective for dates of service on and after 10/01/2015.	<ul style="list-style-type: none"> <li>Other (Inquiry)</li> </ul>
10/01/2015	R2	LCD revised and published on 10/08/2015 to remove Diagnosis Group 2 for HCPCS codes G0281 and G0329 and Refer to the NCD for coverage.	<ul style="list-style-type: none"> <li>NCD Supplementation</li> </ul>
10/01/2015	R1	LCD revised and published on 01/23/2015 to reflect the annual CPT/HCPCS code updates. HCPCS codes G0456 and G0457 have been deleted and therefore removed from the LCD. CPT codes 97607 and 97608 have been added to the LCD. For the following CPT/HCPCS code(s) either the short description and/or the long description was changed: 97605 and 97606. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document.	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

Article(s)

A55578 - Response to Comments: DL35125, Wound Care

LCD(s)

L35041 - Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds

L35094 - Services That Are Not Reasonable and Necessary

DL35125

- (MCD Archive Site)

### 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

270.2 - Noncontact Normothermic Wound Therapy (NNWT)

270.5 - Porcine Skin and Gradient Pressure Dressings

270.4 - Treatment of Decubitus Ulcers

**Public Version(s)**

Updated on 11/03/2017 with effective dates 11/09/2017 - N/A

Updated on 09/15/2017 with effective dates 11/09/2017 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

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## **Keywords**

N/A