

PROPOSED/DRAFT Local Coverage Determination (LCD): Wound Care (DL35125)

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Please note: This is a Proposed/Draft policy.

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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
				Colorado
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	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
				District of Columbia
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware
				Maryland
				New Jersey
				Pennsylvania

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Proposed/Draft LCD Information

Document Information

Source LCD ID
[L35125](#)

Proposed LCD ID
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Proposed LCD Title
Wound Care

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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.

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 payable during the surgical global period.

Various methods to promote wound healing have been devised over time. Physicians and health care providers must understand that many of these methods are expensive and unproven by valid scientific literature, and would be considered investigational. 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 record that the wound is improving in response to the wound care being provided. Evidence of improvement includes 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. With appropriate management, it is expected that, in most cases, a wound will reach a state at which its care should be performed primarily by the patient and/or the patient's caregiver with periodic physician assessment and supervision. Wound care that can be performed by the patient or the patient's caregiver will be considered to be maintenance care.

In rare instances, 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.

Active wound care procedures are performed to remove devitalized tissue, promote healing, and involve selective and non-selective debridement techniques. 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 patients 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 pressure reduction and infection control have been adequately addressed.


Definition of terms for this policy:

Dressing Changes for Wound Debridement

- Wet dressings: Water and medication can be applied to the skin with dressings (finely woven cotton, linen, or gauze) soaked in solution. Wet compresses, especially with frequent changes, provide gentle debridement.
- 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. A variety of dressings are available including transparent films, foams, hydrocolloids, and hydrogels.
- Dressing changes (removal and subsequent reapplication) alone do not require the skills of physicians, podiatrists, physical therapists, occupational therapists or wound care nurses and in fact are usually performed by non-physician providers.

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 associated with complicating autoimmune, metabolic, vascular or pressure factors.
 - Open or closed wounds complicated by necrotic tissue and eschar.
2. Active Wound Care Management
Debridement is indicated whenever necrotic tissue is present on an open wound. Debridement may also be indicated in cases of abnormal wound healing or repair. This procedure includes wound assessment; debridement; application of ointments, creams, sealants, and other wound coverings; and instructions for ongoing care. 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 (CPT codes 97597, 97598) includes:
 -  Removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue by sharp dissection including scissors, scalpel, curettes, and tweezers/forceps. This procedure typically requires no anesthesia and there is generally no bleeding associated with it.
- Wound Care Non-Selective Debridement (CPT code 97602) includes:
 - Blunt Debridement: Blunt debridement is the removal of necrotic tissue by cleansing, scraping, chemical application or wet to dry dressing technique. It may also involve the cleaning and dressing of small or superficial lesions. Generally this is not a skilled service and does not require the skills of a physician, podiatrist, therapist, or wound care nurse.
 - 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.
 - Mechanical Debridement: Wet-to-dry or dry-to-dry dressings may be used with wounds that have a high percentage of necrotic tissue. Wet-to-dry dressings should be used cautiously as maceration of surrounding tissue may hinder healing.
 - Jet Hydrotherapy and Wound Irrigation: types of mechanical debridement used to remove necrotic tissue. Jet Hydrotherapy and Wound Irrigation should be used cautiously as maceration of surrounding tissue may hinder healing.
 - Maggot/larvae therapy: Debridement with medical grade maggots in wounds.
- 3. Wound Care Surgical Debridements (CPT codes 11000, 11001, 11004, 11005, 11006, 11008, 11010, 11011, 11012, 11042, 11043, 11044, 11045, 11046, and 11047)
 - Conditions that may require surgical debridement of large amounts of skin include: rapidly spreading necrotizing process (sometimes seen with aggressive streptococcal infections), severe eczema, bullous skin diseases, extensive skin trauma (including large abraded areas with ground-in dirt), or autoimmune skin diseases (such as pemphigus).
 - 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, abnormal granulation tissue, etc., and should be accomplished to the margins of viable tissue. Surgical excision includes going slightly beyond the point of visible necrotic tissue until viable bleeding tissue is encountered in some cases.
 - These procedures can be very effective but represent extensive debridement. They may be complex in nature and may require the use of general 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. Reassessment of a wound maintained by the patient or patient's caregiver is covered as a physician evaluation and management service.
- 5. Negative Pressure Wound Care (NPWT), electrically powered (CPT codes 97605, 97606)

- Negative pressure wound therapy (NPWT) is a method of wound care to manage wound exudates and promote wound closure. The vacuum assisted drainage collection (i.e., NPWT) cleanses the wound by removing fluids and stimulates the wound bed, reduces localized edema and improves local oxygen supply.
 - Electrically powered NPWT (CPT codes 97605, 97606) 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.
 - **Electrically powered NPWT (CPT codes 97605, 97606)** for nonhealing 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, nonhealing ulcer with lack of improvement for at least the previous 30 days despite standard wound therapy**, including the application of moist topical 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:
 - Chronic Stage III or Stage IV pressure ulcer
 - Chronic diabetic neuropathic ulcer
 - Chronic venous ulcer
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 as wound therapy for any of the following clinical conditions:
 - Wounds, burns and ulcers that have failed conventional debridement and meet Medicare coverage for debridement but which are too painful for sharp or excisional debridement.
 - Wounds, burns and ulcers meeting Medicare coverage for debridement but with documented contraindications to sharp or excisional debridement.
 - Wounds, burns and ulcers meeting Medicare coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care.
 - Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided two to three times per week to be considered reasonable and necessary. 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 (CPT codes 29580 or 29581)
- Unna boot is a type of compression dressing used to promote return of blood from the peripheral veins back into the central circulation. When both a debridement is done and an Unna boot is applied only the debridement will be reimbursed. If only an Unna boot is applied and the wound is not debrided, then only the Unna boot application may be eligible for reimbursement.

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 payment 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 or in the absence of abnormal wound healing.

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3. Debridements are considered selective or non-selective unless the medical record supports that a surgical excisional debridement was performed.
 4. Selective debridement should only be provided under a certified plan of care.
 5. **Since the overall goal of care is healing and not palliation, it is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement as outlined in this LCD cannot be shown.**
 6. It would not be expected that an individual wound would be repeatedly debrided of skin and subcutaneous tissue because these tissues typically do not regrow very quickly. Coverage for prolonged, repetitive debridement services will be considered through the redetermination process. The medical record must contain adequate documentation of complicating circumstances to support additional services as reasonable and necessary.
 7. Autolytic debridement is contraindicated for infected wounds.
 8. Debridement of extensive eczematous or infected skin, represented by CPT codes 11000 and 11001 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. **The use of a sharp instrument does not necessarily substantiate the performance of surgical excisional debridement.**
 10. Surgical debridement will be considered not reasonable and necessary when documentation indicates the wound is without infection, necrosis, devitalized, fibrotic, nonviable tissues or foreign matter and has pink to red granulated tissue. When utilized, it is expected that the frequency of debridement will decrease over time.
 11. Wound debridement utilizing experimental or investigational methods is considered not reasonable and necessary. Therefore, it would not be reasonable and necessary to report these services with any CPT code.
 12. Investigational treatments are noncovered by Medicare as not medically necessary. The patient can be requested to pay for investigational treatment under waiver of liability provisions of Medicare law, but an Advance Beneficiary Notice must be obtained for the beneficiary to be liable for such payment.
 13. When performed in conjunction with another wound care service, the dressing change is considered an integral component of that service and is not separately billable.
 14. A wound that shows no improvement after 30 days requires a new approach, which may include a physician reassessment of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing, or a new treatment approach.
 15. Procedures performed for cosmetic reasons or to prepare tissues for cosmetic procedures are statutorily excluded from coverage by Medicare.
 16. Local infiltration, metacarpal/metatarsal/digital block or topical anesthesia are included in the reimbursement for wound care services and are not separately payable.
 17. The following procedures are considered part of an E/M service or wound care management services, and are not separately covered:
 - removal of necrotic tissue by cleansing and dressing, including wet or dry-to-dry dressing changes;
 - cleaning and dressing small or superficial lesions; and
 - removal of coagulated serum from normal skin surrounding an ulcer.
 18. **Disposable non-powered mechanical or single use non-electrically powered NPWT (CPT codes 97607, 97608) for any indication is considered not medically reasonable and necessary.**
 19. NPWT is contraindicated for 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
 - Exposed organs
 20. When both an Unna boot is applied and a wound debridement is performed, the debridement will be reimbursed, if the medical record supports that the service is reasonable and necessary as outlined in this LCD, and the Unna boot application will be denied.
 21. **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 would include documented reduction in pain, necrotic tissue, or wound size or improved granulation tissue.
 22. The following services are considered to be not reasonable and necessary wound debridement services:

- 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.
 - 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 and does not require 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.
23. Wet-to-dry, jet hydrotherapy, or wound irrigations should be used cautiously as maceration of surrounding tissue may hinder healing.
24. Medicare expects that with appropriate care:
- Wound volume or surface dimension should decrease by at least 10 percent per month or
 - Wounds will demonstrate granulation tissue advancement of no less than 1 mm/week.

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

Notice: This LCD imposes frequency limitations. 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.

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[Proposed/Draft Process Information](#)

Synopsis of Changes

Changes Fields Changed

N/A N/A

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 and may be supported by a drawing or photograph. Photographic documentation of wounds immediately before and after debridement is recommended for prolonged or repetitive debridement services (especially those that exceed five debridements per wound). Photographic documentation is required for payment of more than five extensive debridements (beyond skin and subcutaneous tissue) 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 shall be submitted when billing for the debridement procedure described by CPT code 11044.** In addition, except for patients with compromised healing due to severe underlying debility or other factors, documentation in the medical record must show:
 - **The status of the wound is such that the treatment is expected to make a significant practical improvement in the wound in a reasonable and generally predictable period of time.**
 - 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 patient's expected restoration potential must be significant in relation to the extent and duration of treatment required in achieving this potential. If wound closure is not a reasonable goal, then the expectation is to optimize recovery and establish an appropriate non-skilled maintenance program.
8. 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 type(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 debridement of wounds is performed.
9. 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 requires 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.**

10. 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.
11. Documentation must support the use of skilled personnel with the use of jet therapy and wound irrigation for wound debridement in order to be considered reasonable and necessary.
12. 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.

Utilization Guidelines

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

Debridements will be limited to eight total services per year for any of the debridement codes listed in this LCD (CPT codes 11000, 11004-11006, 11010-11044, 97597 and 97598). Of the eight debridements, no more than five debridements involving removal of muscle and/or bone (CPT codes 11043, 11044) per year will be considered reasonable and necessary. Services beyond these limits may be considered through the redetermination process when supported in the medical record.

No more than 6 NPWT (CPT codes 97605-97606) services in a four month period will be considered reasonable and necessary. NPWT services exceeding this frequency may be covered upon redetermination only when medical necessity continues to be met as previously outlined and there is documented evidence of clear benefit from the NPWT treatment already provided.

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.

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

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

Sources of Information and Basis for Decision

Contractor is not responsible for the continued viability of websites listed.

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Other Contractor Local Coverage Determinations

Novitas Solutions, Inc. – JH Local Coverage Determination (LCD) L35125: Wound Care.

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

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

Contractor Medical Directors

Open Meetings/Part B MAC Contractor Advisory Committee (CAC) Meetings

Meeting Date	Meeting Type	Meeting State(s)	Meeting Information
01/26/2017	Open Meeting	<ul style="list-style-type: none">ArkansasColoradoDelawareDistrict of ColumbiaLouisianaMarylandMississippiNew JerseyNew MexicoOklahomaPennsylvaniaTexas	The open meeting is a joint meeting for both JL and JH. The meeting will be held at the Mechanicsburg office of Novitas Solutions, Inc. at 2020 Technology Parkway, Mechanicsburg, PA 17050.

Comment Period Start Date
01/19/2017

Comment Period End Date
03/09/2017

Released to Final LCD Date
N/A

Reason for Proposed LCD

- Automated Edits to Enforce Reasonable & Necessary Requirements
- Creation of Uniform LCDs With Other MAC Jurisdiction

Proposed Contact
Novitas Solutions Medical Policy Department
Union Trust Building Suite 600
501 Grant Street
Pittsburgh, PA 15219-4407
DraftLCDComments@novitas-solutions.com [Back to Top](#)

[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.

- 011x Hospital Inpatient (Including Medicare Part A)
- 012x Hospital Inpatient (Medicare Part B only)
- 013x Hospital Outpatient
- 018x Hospital - Swing Beds
- 021x Skilled Nursing - Inpatient (Including Medicare Part A)
- 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) Publication 100-04, *Medicare Claims Processing Manual*, for further guidance.

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

CPT/HCPCS Codes

Group 1 Paragraph: Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT books.

Group 1 Codes:

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
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
97606 Neg press wound tx >50 cm
97610 Low frequency non-thermal us

Group 2 Paragraph: The following are non-covered services.

Group 2 Codes:

97607 Neg press wnd tx
97608 Neg press wound tx >50 cm

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 Codes Description

XX000 Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity N/A

ICD-10 Additional Information

N/A

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[Associated Documents](#)

Attachments N/A

Related Local Coverage Documents LCD(s) [L35041 - Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds](#) [L35021 - Hyperbaric Oxygen \(HBO\) Therapy](#) [L35094 - Services That Are Not Reasonable and Necessary](#) [L36423 - Strapping](#)

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](#) [Back to Top](#)

[Keywords](#)

N/A [Back to Top](#) Read the [LCD Disclaimer](#)