

Medical Policy

Healthcare Services Department

<p>Policy Name</p> <p>Wound Care (Debridements, Wound Negative Pressure Therapy (Vac Therapy), Surgical Dressings)</p>	<p>Policy Number</p> <p>MP-WC-FP-01-23</p>	<p>Scope</p> <p><input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth</p>								
<p>Service Category</p> <table border="0"> <tr> <td><input type="checkbox"/> Anesthesia</td> <td><input type="checkbox"/> Medicine Services and Procedures</td> </tr> <tr> <td><input type="checkbox"/> Surgery</td> <td><input type="checkbox"/> Evaluation and Management Services</td> </tr> <tr> <td><input type="checkbox"/> Radiology Procedures</td> <td><input type="checkbox"/> DME/Prosthetics or Supplies</td> </tr> <tr> <td><input type="checkbox"/> Pathology and Laboratory Procedures</td> <td><input checked="" type="checkbox"/> <u>Other Wound Wound Care</u></td> </tr> </table>			<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Medicine Services and Procedures	<input type="checkbox"/> Surgery	<input type="checkbox"/> Evaluation and Management Services	<input type="checkbox"/> Radiology Procedures	<input type="checkbox"/> DME/Prosthetics or Supplies	<input type="checkbox"/> Pathology and Laboratory Procedures	<input checked="" type="checkbox"/> <u>Other Wound Wound Care</u>
<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Medicine Services and Procedures									
<input type="checkbox"/> Surgery	<input type="checkbox"/> Evaluation and Management Services									
<input type="checkbox"/> Radiology Procedures	<input type="checkbox"/> DME/Prosthetics or Supplies									
<input type="checkbox"/> Pathology and Laboratory Procedures	<input checked="" type="checkbox"/> <u>Other Wound Wound Care</u>									
<p> </p>										

Service Description**First Coast LCD L37166
Wound Care****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 L36504)
- Therapy and Rehabilitation Services (See LCD L33413)
- Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (See LCD L36377)
- Strapping
- Electrical Stimulation and Electromagnetic Therapy of Specified Wounds (See NCD 270.1)
- Treatment of burns

First Coast LCD define wound care 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 LCD:

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.

Please note that all services described in this policy require prior authorization.

- Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
- Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
- Providers must submit all required and requested documentation for case evaluation and determination.
- The plan may request additional documentation and information not received and or provided initially related to condition and diagnosis for case evaluation and determination. Any additional documentation submitted specifying medical necessity criteria and considered important for case evaluation and determination will be reviewed by Clinical Team utilizing guidelines and regulation criteria.

Medical Necessity Guidelines**First Coast LCD L37166****Wound Care****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 Debridement

- *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. 5. Negative Pressure Wound Care (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.

Limits or Restrictions

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.**

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 (ABN) 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 over time. 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 LCD, 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 Publication 100-08, Chapter 13, Section 13.5.4, 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); and
- 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; and
 - 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.

Reference Information

CMS

First Coast A55818

Billing and Coding: Wound Care

Link: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx>

<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55818&ver=17&bc=0>

CMS

First Coast LCD L37166

Wound Care

Medicare Coverage Database (MCD)

Link: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx>

<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37166&ver=22&bc=0>

CMS

Related NCD's: NCD 270.1, NCD 270.2, NCD 270.3, NCD 270.4, NCD 270.5

Link: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx>

Policy History

Date	Version	Comments
12/07/2023	Draft	New Medical Policy
12/15/2023	Final	Approved by Medical Policy Committee