Policy

DEPARTMENT: Utilization Management	**POLICY#: UM-019**
TITLE: Wound Care	**VERSION: 6**
APPROVED BY: UM Committee	**APPROVAL DATE:** 8/30/2022, 12/18/2024, 6/5/2025, 12/12/25
	POLICY COMMITTEE APPROVAL DATE:1/12/26
DEPENDENCIES:	

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Purpose

This purpose of this policy is to outline the criteria used to determine the reasonableness and appropriateness of various interventions implemented for wound care. This language is adopted from LCD 37228 Wound Care. For states in which an LCD is not available, this policy services as the guidance appropriateness of services. This policy includes coverage indications and guidelines for wound care involving debridement, negative pressure wound therapy, and low frequency non-contact non-thermal ultrasound (MIST Therapy).

Definitions, Abbreviations, and Acronyms

Acronym	Meaning
LCD	Local Coverage Determination
CMS	Centers for Medicare and Medicaid Services
NPWT	Negative Pressure Wound Therapy
MIST Therapy	Low-Frequency, Non-Contact, Non-Thermal Ultrasound

Policy

Wound care for the purposes of this policy 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.

Debridement

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

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

- Pressure Injury, Stage II, III or IV
- Venous insufficiency ulcers
- Arterial insufficiency ulcers including diabetic lower extremity ulcers
- Dehiscence wounds
- Wounds with exposed hardware or bone
- Neuropathic ulcers
- Neuro-ischemic ulcers
- Diabetic Foot Ulcer(s)
- Complications of surgically created or traumatic wound where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment.

Should deep tissue pressure injury or Stage II injury progress to Unstageable, Stage III or Stage IV requiring debridement then documentation supporting this must be included in the medical record.

Goals of Debridement include:

- Remove devitalized tissue
- Decrease risk of infection
- Promote wound healing
- Prevent further complications

Should deep tissue pressure injury or Stage II injury progress to Unstageable, Stage III or Stage IV requiring debridement then documentation supporting this must be included in the medical record.

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

Medicare expects the wound care treatment plan to be modified in the event that appropriate healing is not achieved.

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

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

Negative Pressure Wound Therapy

Negative Pressure Wound Therapy (NPWT), utilizing either durable or disposable medical equipment, involves the application of controlled or intermittent negative pressure to a properly dressed wound cavity. Suction (negative pressure) is applied under airtight wound dressings to promote the healing of open wounds resistant to prior treatments.

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

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

There should be documented improvements in the wound(s) evident after six MIST treatments. Improvements include documented reduction in pain, necrotic tissue, or wound size or improved granulation tissue. Continuing MIST treatments for wounds demonstrating no improvement after six treatments is considered not reasonable and necessary. No more than 18 services of low frequency, non-contact, non-thermal ultrasound (MIST Therapy) within a six-week period will be considered reasonable and necessary.

Documentation

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

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

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

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

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

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

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

Goals should be specific, measurable, attainable, relevant and time bound. Regarding documentation related to goals, it's expected that the provider will state what the wound should look like when the documented goal is reached. Progress needs to be documented towards these goals and show that goals not being met are being addressed. If goals are not being met and the plan of care is not adjusted or modified to reflect any issues it may be denied.

Utilization Guidelines

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

The beneficiaries who undergo treatment utilizing negative pressure wound therapy, only when medical necessity continues to be met and there is documented evidence of clear benefit from the NPWT treatment already provided.

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

The extent and number of services provided should be medically necessary and reasonable based on the documented medical evaluation of the patient's condition, diagnosis, and plan. Only when medical necessity continues to be met and there is documented evidence of clear benefit from the services provided, should services be continued.

Fluorescent Imaging of Wounds (0598T and 0599T)

Noncontact Real-Time Fluorescent Imaging, such as Moleculight, are intended to aid in the visualization of fluorescent bacteria and measure wound surface area. A MedTech Innovation Briefing published by the National Institute for Health and Care Excellence (NICE 2020) states, “The current evidence is insufficient to support the MolecuLight i:X device when used for identification and management of wounds with bacterial burden or to prove safety and efficacy of the device as a tool for wound care management.” Regarding the current published evidence, the publication notes that sample sizes are small and there are a limited range of outcomes. Additionally, there is a lack of evidence on wound closure times and the effect on antibiotic usage. Multicenter randomized controlled trials are needed to appropriately assess the efficacy and impact of this technology.

Based on the research available, noncontact real-time fluorescent imaging is experimental and therefore not covered by the Plan.

Change Log

Document Version	Major or Minor Revision?	Date	Name	Comments
NEW		8/30/2022	Courtney Gonzales	NEW
2	Minor	11/17/2022	Courtney Gonzales	Addition of Assoc. CPT Codes
3	Major	11/21/2022	Courtney Gonzales	Addition of Biologic Information; CPT Codes
4	Major	12/18/2024	Stefanie Caswell	Alignment with Medicare NCD/LCD, Updating of general information.
5	Minor	6/5/2025	Stefanie Caswell	Addition of coverage criteria based on available literature
6	N/A	12/12/2025	Stefanie Caswell	Annual Review, no changes