

## Non-Contact Ultrasound Treatment of Wounds

Policy Number: PG0219  
Last Review: 07/01/2023

HMO AND PPO  
ELITE (MEDICARE ADVANTAGE)  
MARKETPLACE

### GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

### SCOPE:

☒ Professional  
☐ Facility

### DESCRIPTION:

As the current population ages, chronic, non-healing wounds resulting from diabetes mellitus and peripheral vascular disease are expected to increase. Wounds secondary to trauma and pressure ulcers are also likely to increase within an aging population. Typically, there are four overlapping stages of healing: hemostasis, inflammation, proliferation, and remodeling. In chronic, non-healing wounds, the healing process is interrupted, most commonly during the inflammatory phase. Chronic ulcers heal by secondary intention or from the bottom up, increasing the amount of necrotic tissue, slough, debris, and purulent fluid remaining in the wound, thereby increasing the probability of infection. It is widely thought that to reduce the risk of infection and promote the healing process, chronic, non-healing wounds should undergo adequate debridement or removal of dead tissue, debris, and/or slough from the surface of the wound.

Low-frequency ultrasound is used as an adjunct (supplement) to wound care. A non-contact low-frequency ultrasound device is intended to provide debridement and cleansing to a wound. The device is held 0.5 to 1.5 cm from the wound and saline is delivered to the wound bed, which promotes healing through stimulation of cellular activity. Therapy is usually given in three-to-12-minute sessions, three times per week. This modality is often referred to as "MIST Therapy".

Examples of low frequency ultrasound devices include, but may not be limited to:

- AR1000 Ultrasonic Wound Therapy System
- AS1000 Ultrasound Wound Therapy System
- Jetox™ ND
- MIST Therapy System
- SonicOne O.R.
- SONOCA-185

VERSAJET II Hydrosurgery System

### POLICY:

#### **Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans**

- **Low frequency, non-contact, non-thermal ultrasound (97610) for the treatment of wounds does not require prior authorization when the coverage criteria below is met.**

**COVERAGE CRITERIA:****Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans**

Low frequency, non-contact, non-thermal ultrasound (MIST Therapy) will be considered "reasonable and necessary" wound therapy and therefore eligible for coverage by Paramount when provided as wound therapy 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 debridement but with documented contraindications to sharp or excisional debridement.
- Wounds and ulcers meeting coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care.

**Frequency/Duration**

Low frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided 2-3 times per week to be considered "reasonable and necessary." The length of individual treatments will vary per wound size according to manufacturer recommendations.

Observable, documented improvements in the wound(s) should be evident after 2 weeks or 6 treatments. Improvements would 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.

Paramount will cover up to 6 weeks or 18 treatments with documented improvements of pain reduction, reduction in wound size, improved and increased granulation tissue, or reduction in necrotic tissue. 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 Requirements**

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

In the patient's medical record, there must be clearly documented evidence of the progress of the wound's response to treatment at each physician visit. This documentation at a minimum should include:

- 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.

**CODING/BILLING INFORMATION:**

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

**CPT CODE**

<b>97610</b>	Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care; per day
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**REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 03/30/2009**

Date	Explanation & Changes
<b>04/01/2010</b>	<ul style="list-style-type: none"><li>• Updated</li></ul>
<b>04/01/2011</b>	<ul style="list-style-type: none"><li>• No changes</li></ul>
<b>08/22/2014</b>	<ul style="list-style-type: none"><li>• Removed codes 0183T, S8948, S9055. Added code 97610</li><li>• Low frequency, non-contact, non-thermal ultrasound (97610) for the treatment of wounds is now covered without prior authorization for all product lines</li><li>• Policy reviewed and updated to reflect most current clinical evidence per TAWG</li></ul>

05/09/2017	<ul style="list-style-type: none"> <li>Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee</li> </ul>
12/16/2020	<ul style="list-style-type: none"> <li>Medical policy placed on the new Paramount Medical Policy Format</li> </ul>
02/14/2023	<ul style="list-style-type: none"> <li>Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023</li> </ul>
07/01/2023	<ul style="list-style-type: none"> <li>Medical Policy reviewed and updated to reflect the most current clinical evidence</li> </ul>
03/05/2024	<ul style="list-style-type: none"> <li>Medical Policy placed on the new Paramount Medical Policy format</li> </ul>

**Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to**

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

## REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/>  
Industry Standard Review

Hayes, Inc., <https://www.hayesinc.com/>

Industry Standard Review