GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

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 purportedly 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
- Jetoxtm ND
- MIST Therapy System
- SonicOne O.R.
- SONOCA-185
- VERSAJET II Hydrosurgery System

POLICY
Low frequency, non-contact, non-thermal ultrasound (97610) for the treatment of wounds does not require prior authorization.

HMO, PPO, Individual Marketplace, Elite, Advantage
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:

1. Acute or chronic painful venous stasis ulcers, which are too painful for sharp or excisional debridement;
2. Acute or chronic arterial/ischemic ulcers, which are too painful for sharp or excisional debridement;
3. Diabetic or neuropathic ulcers;
4. Radiation injuries or ulcers;
5. Patients with wounds or ulcers with documented contraindications to sharp or excisional debridement;
6. Burns which are painful and/or have significant necrotic tissue;
7. Wounds that have not demonstrated signs of improvement after 30 days of documented standard wound care; or
8. Preparation of wound bed sites for application of bioengineered skin products or skin grafting.

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.

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. Continued treatments beyond 18 sessions per episode of treatment will be considered only upon individual consideration.

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.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>97610</td>
<td>Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care; per day</td>
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TAWG REVIEW DATES: 08/22/2014

REVISION HISTORY EXPLANATION
04/01/10: Updated
04/01/11: No changes
08/22/14: Removed codes 0183T, S8948, S9055. Added code 97610. Low frequency, non-contact, non-thermal ultrasound (97610) for the treatment of wounds is now covered without prior authorization for all product lines. Policy reviewed and updated to reflect most current clinical evidence per TAWG.
05/09/17: Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Industry Standard Review
Hayes, Inc.