

Low-Frequency, Non-Contact, Non-Thermal Ultrasound Therapy (CPT 97610)

Overview

Provider Partners Health Plans considers low-frequency, non-contact, non-thermal ultrasound therapy (CPT 97610) experimental, investigational, and not covered for all indications. Current published evidence does not establish that this treatment improves clinically meaningful outcomes in wound healing compared to standard of care.

However, on appeal, Provider Partners Health Plans will review individual cases in which the provider submits clear documentation demonstrating that the service met all applicable Medicare Administrative Contractor (MAC) Local Coverage Determination (LCD) criteria for medical necessity.

Description

CPT 97610 describes the use of low-frequency, non-contact, non-thermal ultrasound for wound healing. This therapy is intended to promote healing through mechanical stimulation of tissues using acoustic energy delivered through a saline mist.

Clinical Background

Studies of non-contact ultrasound for wound healing have produced inconsistent results. Published clinical trials are generally limited by small sample sizes, lack of appropriate control groups, and absence of long-term outcome data. Systematic reviews have not demonstrated a consistent or clinically meaningful improvement in healing rates, time to closure, or infection prevention when compared to standard wound care practices.

Regulatory Status

The FDA has cleared several non-contact ultrasound devices (e.g., MIST Therapy System) under the 510(k) process as substantially equivalent to predicate devices. FDA clearance does not equate to evidence of clinical efficacy.

Coverage Determination

1. **Non-Covered Service:**

Provider Partners Health Plans does not cover CPT 97610 for any indication because it remains investigational and unproven in demonstrating improved clinical outcomes over standard wound care.

2. **Appeals Review:**

On appeal, Provider Partners Health Plans may consider the service for coverage only if the provider submits medical documentation meeting all LCD criteria. Such documentation must demonstrate:

- Chronic, non-healing wounds refractory to multi-modality conventional care over a 2-month period
- Wounds too painful for, or have contraindications to sharps debridement
- Use as a component of a comprehensive wound management program, not standalone therapy;
- Compliance with any additional MAC documentation requirements.
- Biopsies to rule out malignancy and or studies to rule out osteomyelitis should be obtained for appropriate wounds.

Note: Coverage on appeal does not establish a precedent for future claims and applies solely to the case under review.



Documentation Requirements

Providers must maintain complete clinical records, including wound measurements, treatment plans, and evidence of adherence to standard wound care prior to initiating ultrasound therapy.

Exclusions

This policy does not apply to other forms of therapeutic ultrasound used for musculoskeletal conditions or diagnostic ultrasound services.

Medicare Regulatory Reference

- National Coverage Determination (NCD): None.
- Local Coverage Determinations (LCDs):
 - Novitas Solutions LCD L35125 – *Wound Care Services*
 - First Coast Service Options LCD L37228 – *Wound Care Services*
- Palmetto GBA LCD L34564 – *Wound Care Services*
- Hayes, Inc. Clinical Research Response: *Noncontact Low-Frequency Ultrasound Therapy for Chronic Wounds.*

Summary

While certain Medicare Administrative Contractors describe limited coverage circumstances for CPT 97610, Provider Partners Health Plans has determined that current evidence remains insufficient to demonstrate consistent clinical benefit. Therefore, Provider Partners Health Plans considers this service non-covered under the Medicare Advantage program.

However, Provider Partners Health Plans will review appeals where complete documentation supports that all LCD criteria were fully met for medical necessity.

Policy History/Revision Information

Date	Summary of Changes
2/20/2026	Initial Policy