Medical Coverage Policy | Non-Contact Ultrasound Treatment for Wounds



EFFECTIVE DATE: 03 | 01 | 2017 **POLICY LAST UPDATED:** 11 | 07 | 2017

OVERVIEW

Low-frequency ultrasound (US) in the kilohertz (KHz) range may improve wound healing. Several noncontact low-frequency ultrasound (NLFU) devices have received regulatory approval for wound treatment.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Non-contact ultrasound treatment for wounds is covered for BlueCHiP for Medicare members.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial Products

Non-contact ultrasound treatment for wounds is considered **not medically necessary** as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for applicable surgery or when services are not medically necessary.

BACKGROUND

Ultrasound (US) delivers mechanical vibration above the upper threshold of human hearing (greater than 20 KHz). US in the megahertz (MHz) range (1–3 MHz) has been used for the treatment of musculoskeletal disorders, often by physical therapists. Although the exact mechanism underlying its clinical effects is not known, therapeutic US has been shown to have a variety of effects at a cellular level, including angiogenesis, leukocyte adhesion, growth factor and collagen production, and increases in macrophage responsiveness, fibrinolysis, and nitric oxide levels. The therapeutic effects of US energy in the KHz range have also been examined. Although the precise effects are not known, low frequency US in this range may improve wound healing via the production, vibration, and movement of micron-sized bubbles in the coupling medium and tissue.

The mechanical energy from US is typically transmitted to tissue through a coupling gel. Several high-intensity US devices with contact probes are currently available for wound debridement. Recently, low-intensity US

devices have been developed that do not require use of a coupling gel or other direct contact. The MIST TherapyTM System (Celleration, Eden Prairie, MN) delivers a saline mist to the wound with low-frequency US (40 KHz). A second device, the Qoustic Wound Therapy SystemTM (Arobella Medical, Minnetonka, MN), also uses sterile saline to deliver ultrasound energy (35 KHz) for wound debridement and irrigation.

For individuals who have any wound type (acute or nonhealing) who receive noncontact ultrasound therapy, the evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, the service is considered not medically necessary.

CODING

The following code is **covered for BlueCHiP for Medicare members only.** It is considered **not medically necessary for Commercial Products.**

97610 Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, January 2018 Provider Update, February 2017 Provider Update, February 2016 Provider Update, January 2015 Provider Update, July 2013 Provider Update, May 2012 Provider Update, May 2011

REFERENCES

- Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health. Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds -- Developing Products for Treatment. Rockville (MD): Food and Drug Administration; 2006 June.
- Food and Drug Administration. 510(k) Summary K050129. https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf. Accessed November, 2016.
- 3. Food and Drug Administration. 510(k) Summary (K131096). https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131096.pdf. Accessed November, 2016.
- 4. Tricco AC, Antony J, Vafaei A, et al. Seeking effective interventions to treat complex wounds: an overview of systematic reviews. BMC Med. Apr 22 2015;13:89. PMID 25899006
- Driver VR, Yao M, Miller CJ. Noncontact low-frequency ultrasound therapy in the treatment of chronic wounds: a meta-analysis. Wound Repair Regen. Jul-Aug 2011;19(4):475-480. PMID 21649783
- 6. Voigt J, Wendelken M, Driver V, et al. Low-frequency ultrasound (20-40 kHz) as an adjunctive therapy for chronic wound healing: a systematic review of the literature and meta-analysis of eight randomized controlled trials. Int J Low Extrem Wounds. Dec 2011;10(4):190-199. PMID 22184750
- Ennis WJ, Foremann P, Mozen N, et al. Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study. Ostomy Wound Manage. Aug 2005;51(8):24-39. PMID 16234574
- Gibbons GW, Orgill DP, Serena TE, et al. A prospective, randomized, controlled trial comparing the effects of noncontact, low-frequency ultrasound to standard care in healing venous leg ulcers. Ostomy Wound Manage. Jan 2015;61(1):16-29. PMID 25581604
- 9. Prather JL, Tummel EK, Patel AB, et al. Prospective randomized controlled trial comparing the effects of noncontact low-frequency ultrasound with standard care in healing split-thickness donor sites. J Am Coll Surg. Aug 2015;221(2):309-318. PMID 25868409

 White J, Ivins N, Wilkes A, et al. Non-contact low-frequency ultrasound therapy compared with UK standard of care for venous leg ulcers: a single-centre, assessor-blinded, randomised controlled trial. Int Wound J. Oct 2016;13(5):833-842. PMID 25619411

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