

Medical Coverage Policy | Non-Contact Ultrasound Treatment for Wounds



EFFECTIVE DATE: 03|01|2017
POLICY LAST UPDATED: 08|07|2018

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 Therapy™ 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 System™ (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, November 2018

Provider Update, January 2018

Provider Update, February 2017

Provider Update, February 2016

Provider Update, January 2015

REFERENCES

1. 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.
2. Food and Drug Administration. MIST™ Therapy System: 510(k) Premarket Notification: K050129. https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf. Accessed January 2, 2018.
3. Food and Drug Administration. 510(k) Summary: 510(k) -AR1000 Series K131096, Arobella Medical, LLC. 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131096.pdf. Accessed January 2, 2018.
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
5. 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
6. 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
7. Peschen M, Weichenthal M, Schopf E, et al. Low-frequency ultrasound treatment of chronic venous leg ulcers in an outpatient therapy. *Acta Derm Venereol*. Jul 1997;77(4):311-314. PMID 9228227
8. Chang YR, Perry J, Cross K. Low-frequency ultrasound debridement in chronic wound healing: a systematic review of current evidence. *Plast Surg (Oakv)*. Feb 2017;25(1):21-26. PMID 29026808
9. Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with noncontact, low-frequency ultrasound: the Mayo clinic experience, 2004-2006. *Adv Skin Wound Care*. Apr 2007;20(4):221-226. PMID 17415030
10. Beheshti A, Shafiqh Y, Parsa H, et al. Comparison of high-frequency and MIST ultrasound therapy for the healing of venous leg ulcers. *Adv Clin Exp Med*. Nov-Dec 2014;23(6):969-975. PMID 25618125

11. Olyaie M, Rad FS, Elahifar MA, et al. High-frequency and noncontact low-frequency ultrasound therapy for venous leg ulcer treatment: a randomized, controlled study. *Ostomy Wound Manage.* Aug 2013;59(8):14-20. PMID 23934374
12. 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
13. 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
14. 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
15. Gottrup F, Apelqvist J, Price P, et al. Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management. *J Wound Care.* Jun 2010;19(6):237-268. PMID 20551864
16. Association for the Advancement of Wound Care (AAWC). Guideline of Pressure Ulcer Guidelines. 2010; <https://s3.amazonaws.com/aawc-new/memberclicks/AAWCPressureUlcerGuidelineofGuidelinesAug11.pdf>. Accessed January 2, 2018.
17. Association for the Advancement of Wound Care (AAWC). International Consolidated Venous Ulcer Guideline (ICVUG) 2015 (Update of AAWC Venous Ulcer Guideline, 2005 and 2010). 2015; <https://aawconline.memberclicks.net/assets/appendix%20c%20guideline%20icvug-textformatrecommendations-final%20v42%20changessaved18aug17.pdf>. Accessed January 2, 2018.
18. O'Donnell TF, Jr., Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery (R) and the American Venous Forum. *J Vasc Surg.* Aug 2014;60(2 Suppl):3s-59s. PMID 24974070
19. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg.* Feb 2016;63(2 Suppl):3s-21s. PMID 26804367

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