

Clinical Policy: Low-Frequency Ultrasound Therapy for Wound Management

Reference Number: CP.MP.139

Last Review Date: 01/19

[Coding Implications](#)

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Description

Low-frequency ultrasound debridement is a noncontact debridement method that provides simultaneous cleansing and debridement of wounds. It is generally performed at a 5 mm - 15 mm distance from the wound surface. A device uses ultrasound technology to atomize saline, delivering a continuous mist to the treatment site. Multiple passes over the wound are made with the treatment head of the device for a predetermined treatment session. This can accelerate the wound healing process by removing the necrotic tissue, fibrosis, exudate, and bacteria with minimum bleeding and pain.

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that low-frequency ultrasound wound therapy is considered **investigational**. This treatment continues to be evaluated in clinical studies. However, current peer reviewed literature is inconclusive at this time.

Background

The treatment of chronic and difficult to heal wounds presents many clinical challenges. To ensure proper healing, the wound bed needs to be well vascularized, free of devitalized tissue, clear of infection, and moist. Surgical debridement is the most appropriate choice for removing large areas of necrotic tissue and is indicated whenever there is any evidence of infection (cellulitis, sepsis). Surgical debridement is also indicated in the management of chronic non-healing wounds to remove infection, handle undermined wound edges, or obtain deep tissue for culture and pathology.¹

Noncontact, low-frequency ultrasound debridement devices have been proposed as adjunctive treatment of a variety of wounds including, but not limited to, acute, traumatic, chronic, and dehisced wounds. Several devices have received FDA approval, including but not limited to, The Mist Therapy System (Alliqua Biomedical), Qoustic Wound Therapy System (Arobella Medical, LLC), SonicOne Ultrasonic Wound Debridement System (Misonix Inc.) and Sonoca TM 180/1 96 Wound Care System. Evidence for the use of these devices to treat wounds is limited and consist of studies that lack adequate sample sizes. Results at this time are inconclusive.

A Cochrane database review of randomized control trials (RCTs) comparing ultrasound with no ultrasound in wound care identified two trials evaluating low frequency ultrasound. The trials reported healing at different time points. Both trials reported no evidence of a difference in the proportion of ulcers healed with ultrasound compared with no ultrasound. Both trials were significantly underpowered. The reviewers concluded there is no evidence of a benefit associated with low frequency ultrasound.² Several other small randomized controlled trials that compared patients treated with non-contact low-frequency ultrasound therapy in addition to standard

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wound care reported that outcome measures favored non-contact low-frequency ultrasound therapy in addition to standard wound care over standard wound care alone. However, the differences were not statistically significant.^{3,4} A small RCT of 35 patients who received MIST Therapy plus the standard of wound care (treatment group) compared to 35 patients who received the standard of wound care alone (control group) for 12 weeks or until fully healed reported that a significantly higher percentage of patients treated with the standard of care plus MIST Therapy achieved greater than 50% wound healing at 12 weeks than those treated with the standard of care alone (63% vs 29%).⁵ Additional research with larger randomized trials is necessary in order to demonstrate that low frequency ultrasound is beneficial for health outcomes in patients with wounds.

Society for Vascular Surgery and the American Venous Forum.

The Committee suggests against ultrasonic debridement over surgical debridement in the treatment of venous leg ulcers. (Grade 2, Level of Evidence C)⁷

National Institute of Health Care Excellence (NICE)

The National Institute of Health Care Excellence (NICE) concluded, “The MIST Therapy system shows potential to enhance the healing of chronic, “hard-to-heal,” complex wounds, compared with standard methods of wound management. However, the amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient to support the case for routine adoption of the MIST Therapy system. Comparative research is recommended to reduce uncertainty about the outcomes of patients with chronic, “hard-to-heal,” complex wounds treated by the MIST Therapy system compared with those treated by standard methods of wound care.”⁶ In June 2016, NICE reviewed the guidance again and decided not to update it, noting new relevant evidence has been published but it is inconclusive.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

| HCPCS Code | Description |
|------------|-------------|
| N/A | |

ICD-10-CM Diagnosis Codes that do NOT Support Coverage Criteria

| ICD-10 CM Code | Description |
|----------------|-------------|
| ALL | |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|-----------------------------------|-------|---------------|
| Policy developed | 01/17 | 02/17 |
| References reviewed and updated | 01/18 | 01/18 |
| References reviewed and updated | 01/19 | 01/19 |

References

1. Armstrong DG, Meyr AJ. Basic principles of wound management. Eidt JF, Mills JL, Bruera E, Berman RS (Eds.) In: UpToDate, Waltham, MA. Accessed Dec 14, 2018.
2. Cullum NA, Liu Z. Therapeutic ultrasound for venous leg ulcers. Cochrane Database Syst Rev. 2017, Issue 5. Art. No.: CD001180.
3. Ivins N, Wilkes A, et al. Non-contact low-frequency ultrasound therapy compared with UK standard of care for venous leg ulcers: a single-center, assessor-blinded, randomized controlled trial. *Int Wound J.* 2016 Oct;13(5):833-42.
4. 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.* 2013 Aug;59(8):14-20.
5. 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.* 2007 Apr;20(4):221-6.
6. The National Institute for Health and Care Excellence. The MIST Therapy system for the promotion of wound healing. Medical technologies guidance [MTG5] Published date: July 2011. Accessed Dec 14, 2018.
7. O'Donnell TF Jr, Passman MA, Marston WA, et al. Management of venous leg ulcers : clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. Aug 2014.
8. Hayes Health Technology Brief. Noncontact Low-Frequency Ultrasound Using the MIST Therapy System (Celleration Inc.) for Treatment of Venous Leg Ulcers. June 2016. Accessed Dec 14, 2018.
9. Hayes Health Technology Brief. Noncontact Low-Frequency Ultrasound Using the MIST Therapy System (Celleration Inc.) for Treatment of Lower Extremity Arterial and Diabetic Foot Ulcers. June 2016. Accessed Dec 14, 2018.
10. 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.* 2015 Jan;61(1):16-29.
11. Yao M, Hasturk H, Kantarci A, et al. A pilot study evaluating non-contact low-frequency ultrasound and underlying molecular mechanism on diabetic foot ulcers. *Int Wound J.* 2014 Dec;11(6):586-93.
12. Driver VR, Yao M, Miller CJ. Noncontact low-frequency ultrasound therapy in the treatment of chronic wounds: a meta-analysis. *Wound Repair Regen.* 2011 Jul-Aug;19(4):475-80.

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13. Kavros SJ, Liedl DA, Boon AJ, et al. Expedited wound healing with noncontact, low-frequency ultrasound therapy in chronic wounds: a retrospective analysis. *Adv Skin Wound Care*. 2008 Sep;21(9):416-23.
14. Kavros SJ, Schenck EC. Use of noncontact low-frequency ultrasound in the treatment of chronic foot and leg ulcerations: a 51-patient analysis. *J Am Podiatr Med Assoc*. 2007 Mar-Apr;97(2):95-101.
15. Ennis WJ, Valdes W, Gainer M, Meneses P. Evaluation of clinical effectiveness of MIST ultrasound therapy for the healing of chronic wounds. *Adv Skin Wound Care*. 2006 Oct;19(8):437-46.
16. Berlowitz D. Clinical staging and management of pressure-induced skin and soft-tissue injury. Berman RS, Schmader KE (Eds.) In: *UpToDate*, Waltham, MA. Accessed Dec 14, 2018.
17. Alguire PC, Mathes BM. Medical management of lower extremity chronic venous disease. Eidt JF, Mills JL (Eds.) In: *UpToDate*, Waltham, MA. Accessed Dec 14, 2018.
18. Akbari Sari A, Flemming K, Cullum NA, Wollina U. Therapeutic ultrasound for pressure ulcers. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Art. No.: CD001275.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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