AmeriHealth Caritas Ohio

Low-frequency ultrasound therapy for wound management

Clinical Policy ID: CCP.1532

Recent review date: 10/2024

Next review date: 2/2026

Policy contains: low-frequency ultrasound, MIST system, wound management

Coverage policy

Low-frequency ultrasound therapy for wound management is considered experimental/investigational and not clinically proven.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Advanced wound dressings.
Compression bandaging.
Systemic antibiotic therapy.
Wound debridement.

Background

Wounds are a common occurrence, especially in certain populations, such as the elderly. While many wounds heal in the short term, some are difficult to treat, and thus become chronic; treatment of these wounds can be lengthy. Among these difficult-to-treat wounds are burns, diabetic foot ulcers, leg ulcers, pressure ulcers, and surgical wounds (National Institute for Health and Care Excellence, no date specified).

Treatments for the more challenging wounds can include advanced wound dressings, compression bandaging, wound debridement, and antibiotic therapy for patients with infection (National Institute for Health and Care Excellence, 2011).

As wounds do not always resolve, ways to supplement standard treatments have been developed. One of these is use of low-frequency, non-contact, non-thermal ultrasound that cleanses and debrides the wound bed without any direct contact. This treatment has the potential to cure wounds, relieve pain, decrease pigmentation, and lessen odor (Alkahtani, 2017).

The MIST Therapy System (Celleration, Inc., Eden Prairie, MN) is a non-contact, low-energy device that delivers continuous ultrasonic energy to atomize saline and delivers a continuous mist to the treatment site to promote wound healing. Specifically, MIST treats wounds by removing yellow slough, fibrin, tissue exudates, and bacteria. In 2005, government officials granted 501(k) premarket approval to use MIST (U.S. Food and Drug Administration, 2005).

The MIST system includes a generator, single-use applicator, and sterile saline bottle. Treatment occurs three times a week, when a wound's dressings are changed. Treatment duration is typically five to seven minutes (National Centers for Health and Care Excellence, no date specified).

While the precise mechanism of low-frequency ultrasound for wounds is not fully understood, recent research has shown the treatment enriches genes involved in regulation of cell metabolism, proliferation, and immune cell signaling. Impact on cellular behavior on wounds can be observed as early as one week after treatment begins (Boerman, 2023).

Findings

A 2011 guideline on use of the MIST system to promote wound healing states that while the device shows promise in complex wounds that often are difficult to heal, the amount and quality of research is insufficient to support routine use. The guideline's conclusion has not been altered since it was published (National Institute for Health and Care Excellence, 2011).

The Institute's guideline cited 10 published studies as a basis for its recommendation. However, only two of these were randomized, and just three of 10 had sample sizes greater than 70 subjects. Heterogeneity of wounds also is an obstacle to high-quality studies, as is absence of information on recurrence of chronic wounds (National Institute for Health and Care Excellence, 2011).

A guideline from the Wound Healing Society stated lack of randomized trials and variability in settings used in studies make it difficult to support low-frequency ultrasound in arterial ulcers (Federman, 2016). The Society's guideline on venous ulcers says ultrasound can be considered while wound healing fails to progress, but assigns it a Level III recommendation, as technique, settings, and treatment duration are not established (Marston, 2016). Ultrasound is not mentioned in Society guidelines on diabetic foot ulcers and pressure ulcers.

A Cochrane review selected two randomized trials (n = 61) that compared low-frequency ultrasound with no ultrasound used for venous ulcers for 8 to 12 weeks. The quality of evidence was very low, and the difference between the two groups was not statistically significant (Cullum, 2017).

Results of several randomized, controlled studies on efficacy of low-frequency ultrasound therapy have been published. The most recent (Rastogi, 2019), was a double-blind, single-center review (n = 60) of patients with diabetic foot ulcers > 2 square centimeters, treated for 28 days. Compared to sham treatment, the proportion of patients with at least a 50% decrease in ulcer area was superior for the ultrasound group (97.1% versus 73.1%). Compared to baseline, both groups showed progressive reduction in wound size.

A meta-analysis of eight randomized, controlled trials of patients with venous stasis and diabetic foot ulcers found low-intensity ultrasound improved outcomes within five months of treatment. However, authors note data quality may be suspect due to significant biases (Voigt, 2011).

A systematic review of 25 studies (n = 850) included four (n = 489) that made up nearly 60% of all patients in the review; each of the four addressed MIST therapy. Because 21 of 25 studies had low-level evidence and 16 of 25 studies had 20 or fewer patients, authors suggest using the treatment on a larger scale (Chang, 2017).

A meta-analysis of two studies (n = 173) found no difference in the percent of adult diabetic foot ulcerations that healed whether patients were treated with non-surgical sharp debridement or low-frequency ultrasonic debridement (Michailidis, 2018).

A meta-analysis of 17 studies determined patients treated with low-frequency ultrasound therapy for diabetic foot wound ulcers and venous leg wound ulcers (n = 187) had significantly fewer non-healed cases after three months compared with standard therapy (sharp debridement or sham treatment (n = 426). Authors advise caution due to small sample sizes in some studies (Chen, 2023).

A literature review concluded that while ultrasound is superior to standard care for wound debridement, findings of efficacy of low-level (versus high-level) ultrasound are mixed. Authors point to lack of standard treatment protocols, limits to trial design, and data consistency as barriers to research (Kavros, 2018).

In 2024, we found a review article low-frequency ultrasound therapy shows promise as a treatment for wound healing, particularly for leg ulcers. The article states that low-frequency ultrasound ranging from 30 to 40 kilohertz has demonstrated efficacy in wound healing and has been applied with good results in leg ulcers. Low-frequency ultrasound is typically used directly on the skin around the wound for five to 10 minutes, with a topical gel applied between the skin surface and the applicator. The review notes that low-frequency ultrasound has been approved by the Food and Drug Administration as an adjuvant therapy for wound healing. However, the authors caution that while low-frequency ultrasound has potential applications in wound healing, there is a lack of clinical studies on its effects in wound healing or scar prevention outside of leg ulcers. They emphasize the need for further randomized clinical trials and established protocols to fully evaluate its effectiveness (Fernández-Guarino, 2023).

References

On September 10, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “low-frequency ultrasound,” “MIST system,” and “wound management.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

10/2023: initial review date and clinical policy effective date: 11/2023

10/2024: Policy references updated.