Anthem

Medical Policy

Subject: Low-Frequency Ultrasound Therapy for Wound Management
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Description

This document addresses the use of low-frequency, non-contact, non-thermal ultrasound therapy for wound management.

Note: Please see the following related document for additional information:

- CG-DME-48 Vacuum Assisted Wound Therapy in the Outpatient Setting

Position Statement

Investigational and Not Medically Necessary:

Use of low-frequency, non-contact, non-thermal, ultrasound therapy is considered**investigational and not medically necessary** for all applications.

Rationale

The use of low-frequency, non-contact, non-thermal ultrasound has been proposed as a supplement to wound therapy. The premise is to promote wound healing through cleansing and debridement of the wound bed.

Ennis and colleagues (2005) reported on a prospective, randomized, double-blinded, controlled, multicenter study to evaluate the safety and efficacy of non-contact, low-frequency ultrasound therapy compared to a sham device for the treatment of diabetic foot ulcers. There were 133 participants enrolled. All participants received at least one ultrasound or sham treatment and were included in the intent-to-treat population. There were 78 participants lost during the study for various reasons leaving 55 participants available for the final evaluation. Treatment was either active with 40 KHz ultrasound delivered by a saline mist or a sham device which delivered a saline mist without the use of ultrasound. At 12 weeks of care, 40.7% of wounds healed in the ultrasound therapy group compared to 14.3% in the sham group. There were 193 adverse events reported for the 133 participants. There was no statistically significant difference between the two treatment groups and 160 of the adverse events were not related to the treatment or sham devices. There were several instances of confusion and protocol violations surrounding treatment with the sham device. In this study, comparison was made between ultrasound to a sham device. Further research is necessary to show improvement of net health outcome and that ultrasound is as beneficial as established alternatives (as this study compared ultrasound to a sham device).

In a prospective, randomized controlled trial, Kavros and colleagues (2007a) assigned 35 individuals with non-healing leg and foot ulcers, due to chronic critical limb ischemia, to standard wound care, and another 35 to standard care plus low-frequency, non-contact, non-thermal ultrasound therapy. The primary endpoint of the study was to evaluate progression of wound healing at 12 weeks. After 12 weeks, there were 22/35 participants who achieved greater than 50% wound healing in the ultrasound group and 10/35 participants who achieved greater than 50% wound healing in the standard care only group. Technique of wound measurement is subject to error. And in this study there is no information about complete wound healing or improvement of net health outcomes of the study participants.

Another study by Kavros and colleagues (2007b) evaluated the effects of non-contact, low-frequency ultrasound on recalcitrant lower leg and foot ulcers. In this open-label, nonrandomized, baseline-controlled, single-center clinical case series there were 51 individuals included with chronic non-healing wounds of the lower leg or foot of 3 to 18 months duration. All individuals first received the standard of care protocol, which included aggressive medical management, moist wound healing, off-loading and compression when appropriate and aggressive routine debridement when clinically appropriate. During the standard care phase, participants were followed on a weekly basis. When the study investigator determined the wounds were no longer progressing, participants were then switched to or had the ultrasound therapy added to their treatment regimen. While receiving ultrasound therapy, participants were treated 3 to 5 times per week. The percentage of wound reduction in the standard of care group was 37.3% ± 18.6% over a treatment period of 9.8 ± 5.5 weeks. The percentage of wound reduction in the ultrasound group was 94.9% ± 9.8% over a treatment period of 5.5 ± 2.8 weeks. There was no wound closure noted during the baseline standard care period. During the ultrasound treatment period, 26 of the wounds proceeded to closure. The authors acknowledge that some degree of bias was possible, due to the baseline-controlled study design, and that further clinical and basic science study of this technology is warranted.

Another author commented about the challenges of conducting randomized controlled trials of wound healing noting that:

> In general, designing clinical studies for wound healing is difficult, and surrogate endpoints might enable trials to be constructed with valid outcomes measures, other than total closure. Many randomized controlled clinical wound care studies have failed to deliver the outcomes anticipated by pre-clinical work, an observation that warrants further study on the need for better methods of quantifying the debridement process, in order to accurately compare study results (Margolis 2004).

In a 2014 study by Beheshti and colleagues, 90 participants with venous leg ulcers were randomized to receive standard treatment (consisting of compression therapy) and high frequency ultrasound, standard treatment and low-frequency, non-contact, non-thermal ultrasound therapy, or standard treatment alone. Study endpoints included the mean time duration of wound healing, edema, pain, size of ulcers and recurrence rate of the ulcers. In the two ultrasound groups, therapy was administered 3 times per week until the wound healed. Monthly visits following therapy were completed with ulcer size, pain and edema recorded. Mean time duration of complete wound healing was 8.13 months in the standard treatment group, 6.10 months in the high frequency ultrasound group, and 5.70 months in the low-frequency, non-contact, non-thermal ultrasound group. Edema was mild to severe in all groups at the first visit following treatment. After 4 months, the edema was less in both ultrasound groups when compared to the standard treatment group; however the difference of edema between the two ultrasound groups was not significant. Pain degree was found to be decreased in the ultrasound groups compared to the standard treatment group, but no significant differences were found between the two ultrasound groups. Six months following treatment, the venous leg ulcers recurred in 4 participants in the standard treatment group, and 2 participants in each of the ultrasound groups. Although the authors noted improvement in edema, a decrease in pain and less recurrence in the ultrasound groups when compared to compression therapy, there were no significant differences between the high

frequency ultrasound and the low-frequency, non-contact, non-thermal ultrasound groups. With no significant differences between high-frequency ultrasound and low-frequency, non-contact ultrasound therapy groups, reasonable conclusions about the effect of the low-frequency outcomes are lacking and there is no information provided showing improvement of net health outcomes.

In a 2019 randomized, double-blind, sham control, single-center study by Rastogi and colleagues, the authors reported on the efficacy of noncontact, low-frequency airborne ultrasound therapy in participants with neuropathic, clinically infected or noninfected diabetic foot ulcers. There were 60 participants enrolled in the study with 58 participants completing the study. The included participants had a foot ulcer of at least 2 cm^2 in size. The therapy duration was for 28 days; daily for an initial 6 days followed by twice a week for the next 3 weeks. Both study participants and investigators were blinded to the treatment as the ultrasound devices were coded by the manufacturers. The primary outcome measure was the percentage of participants with greater than 50% decrease in the ulcer area. Secondary outcomes were the percentage of participants with complete wound healing and percentage decrease in wound area at the end of the study. In the ultrasound therapy group, there was a greater than 50% reduction in wound area observed in 33 of 34 participants (97.1%). There were 8 participants (23.5%) who had a complete wound closure. The duration of the wound was 15.8 ± 11.2 weeks. One participant had less than 50% wound healing. In the sham group, there was a greater than 50% reduction in wound area observed in 19 of 26 participants (73.1%). There were 3 participants (11.5%) who had a complete wound closure. The duration of the wound was 12.1 ± 10.9 weeks. Seven (7) participants had less than 50% wound healing. There was a progressive reduction in wound size in both groups when compared to baseline. However, limitations of this study include the short follow-up period and single-center study design. The authors note that additional randomized, sham-control studies with longer follow-up times are needed to corroborate the results of this study with improvement in net health outcome.

In a 2017 systematic review by Chang and colleagues, the authors reported on 25 studies which examined efficacy of low-frequency ultrasound for wound debridement. While the authors noted that the use of low-frequency ultrasound as an adjunctive therapy in the treatment of chronic wounds is supported, the majority of the evidence is limited by study designs. In the articles reviewed, the authors noted eight different types of ultrasound debridement tools which led to uncertainty regarding the effectiveness and mechanism of action of each tool and the lack of well-designed clinical trials.

A 2023 meta-analysis by Chen and colleagues reported on the efficacy of low-frequency ultrasound as an added treatment for chronic wounds. There were 17 studies included. Studies were included if they were prospective, observational, randomized controlled trials, retrospective studies, and study participants had chronic wounds, with interventions based on low-frequency ultrasound, and compared the low-frequency ultrasound to standard care. Sample sizes ranged from 8 to 81 subjects among the studies. From the studies, there were 412 participants who received low-frequency ultrasound and 187 of those participants received low-frequency, low-intensity non-contact ultrasound for venous leg wound ulcers compared to 193 participants who received sham treatment for venous leg wound ulcers. At greater than 3-month follow-up, those who received the low-frequency, low-intensity, non-contact ultrasound had significantly lower non-healed venous leg wound ulcers and a higher percentage of venous wound area reduction compared to those who received sham treatments. The authors note potential for selection bias due to studies excluded from the meta-analysis, small sample sizes, and lack of information whether the results were related to gender, age, and ethnicity. They advise the analysis of outcomes should be used with caution.

Current published literature does not materially prove the use of low-frequency, non-contact ultrasound improves net health outcomes. There is a lack of studies reporting complete wound healing as the primary outcome. Varying outcomes, study methodologies, and treatments make it difficult to generalize the findings of the current literature.

Background/Overview

In 2004 and 2005 the United States Food and Drug Administration (FDA) cleared an ultrasound wound cleaning system through the 510(k) marketing process (The MIST Therapy System, [Celleration, Inc. Eden Prairie, MN]). The ultrasound device is indicated to promote wound healing without the use of a coupling gel or other direct contact. Wound healing is reportedly achieved by wound cleansing and maintenance debridement through the removal of yellow slough, fibrin, tissue exudates and bacteria. A saline mist is delivered to the wound via low-frequency non-contact ultrasound. Potential risks to health that may be associated with this device were identified by the FDA as: delayed wound healing, thermal damage, inflammation/foreign body response, infection and electrical shock (FDA, 2005). There are several low-frequency non-contact ultrasound devices cleared through the 510(k) process.

Definitions

The MIST Therapy System: This device consists of an equipment component (an ultrasonic generator and transducer) and a disposable component (sterile applicator). The sterile disposable applicator is attached to the generator's transducer and has been designed to accept a pre-packaged sterile bottle of saline. Generally, treatment consists of three sessions per week, during which time the nurse or therapist holds the device near the wound while ultrasonic energy generated by the device atomizes the saline and delivers a continuous mist to the treatment site. The disposable applicator contains an on/off valve that controls the flow of sterile saline to the ultrasound transducer surface. This device is designed to deliver low levels of ultrasound energy to the wound bed by means of the generated mist without direct contact of the device with the wound, thereby avoiding possible contamination.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code for all indications or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

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

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Beheshti A, Shafigh Y, Parsa H, Zangivand AA. Comparison of high-frequency and MIST ultrasound therapy for the healing of venous leg ulcers. Adv Clin Exp Med. 2014; 23(6):969-975.
2. Bell AL, Cavorsi J. Noncontact ultrasound therapy for adjunctive treatment of nonhealing wounds: retrospective analysis. Phys Ther. 2008; 88(12):1517-1524.
3. Chang YR, Perry J, Cross K. Low-frequency ultrasound debridement in chronic wound healing: a systematic review of current evidence. Plast Surg (Oakv). 2017; 25(1):21-26.
4. Chen H, Yu Z, Liu N, et al. The efficacy of low-frequency ultrasound as an added treatment for chronic wounds: A meta-analysis. Int Wound J. 2023; 20(2):448-457.
5. 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. 2005; 51(8):24-39.
6. 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; 19(8):437-446.
7. Gehling ML, Samies JH. The effect of noncontact, low-intensity, low-frequency therapeutic ultrasound on lower-extremity chronic wound pain: a retrospective chart review. Ostomy Wound Manage. 2007; 53(3):44-50.
8. Hinchliffe RJ, Valk GD, Apelqvist J, et al. A systematic review of the effectiveness of interventions to enhance the healing of chronic ulcers of the foot in diabetes. Diabetes Metab Res Rev. 2008; 24 Suppl 1:S119-S144.
9. 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; 21(9):416-423.
10. Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with non-contact, low-frequency ultrasound: the Mayo Clinic experience, 2004-2006. Adv Skin Wound Care. 2007a; 20(4):221-226.
11. 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. 2007b; 97(2):95-101.
12. Keltie K, Reay CA, Bousfield DR, et al. Characterization of the ultrasound beam produced by the MIST therapy, wound healing system. Ultrasound Med Biol. 2013; 39(7):1233-1240.
13. Margolis D. The swings and roundabouts of randomized controlled studies in wound healing. Int J Low Extrem Wounds. 2004; 3(1):4-6.
14. Ramundo J, Gray M. Is ultrasonic mist therapy effective for debriding chronic wounds? J Wound Ostomy Continence Nurs. 2008; 35(6):579-583.
15. Rastogi A, Bhansali A, Ramachandran S. Efficacy and safety of low-frequency, noncontact airborne ultrasound therapy (Glybetac) for neuropathic diabetic foot ulcers: a randomized, double-blind, sham-control study. Int J Low Extrem Wounds. 2019; 18(1):81-88.
16. Samies J, Gehling M. Acoustic pressure wound therapy for management of mixed partial- and full-thickness burns in a rural wound center. Ostomy Wound Manage. 2008; 54(3):56-59.
17. Serena T. Wound closure and gradual involution of an infantile hemangioma using a noncontact, low-frequency ultrasound therapy. Ostomy Wound Manage. 2008; 54(2):68-71.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration 510(k) Premarket Notification Database. Celleration MIST Therapy System Summary of Safety and Effectiveness. No. K032378. Rockville, MD: FDA. June 25, 2004. No. K050129. May 2005. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf. Accessed on July 6, 2023.

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MIST Therapy System

Qoustic Wound Therapy System™

SonicOne®

UltraMIST®

Ultrasound, low-frequency wound therapy

Wound management, ultrasound MIST therapy

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	08/11/2022	MPTAC review. Updated Rationale and Index sections.
Reviewed	08/12/2021	MPTAC review. Updated Rationale, Background/Overview, References, and Index sections.
Reviewed	08/13/2020	MPTAC review.
Reviewed	08/22/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	11/02/2017	MPTAC review. Updated References section. The document header wording updated from “Current Effective Date” to “Publish Date.”
Reviewed	11/03/2016	MPTAC review. Updated Rationale and References sections.
Reviewed	11/05/2015	MPTAC review. Updated Rationale and References. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated References.
Reviewed	11/14/2013	MPTAC review. Updated Index. Updated Coding section with 01/01/2014 CPT changes; removed 0183T deleted 12/31/2013.
Reviewed	11/08/2012	MPTAC review. Updated Rationale and References.
Reviewed	11/17/2011	MPTAC review. Updated Rationale, Background/Overview, References, and Index. Removed Websites for Additional Information.
Reviewed	11/18/2010	MPTAC review. Description, Rationale, Background/Overview, References and Index updated.
Reviewed	11/19/2009	MPTAC review. No change to stance. References were updated.

Reviewed	11/20/2008	MPTAC review. No change to stance. References were updated.
New	11/29/2007	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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