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Medical Policy Manual Medicine, Policy No. 131

Non-Contact Ultrasound Treatments for Wounds

Effective: April 1, 2022

Next Review: February 2023
Last Review: February 2022

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Non-contact ultrasound treatment devices, which administer low-frequency ultrasound with a saline mist, have been proposed for use in wound healing, including pain management and debridement, via the production, vibration, and movement of micron-sized bubbles in the saline and tissue.

MEDICAL POLICY CRITERIA

Non-contact low-frequency ultrasound is considered **investigational** for the treatment of all wounds.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Negative Pressure Wound Therapy in the Outpatient Setting, DME, Policy No. 42
2. Electrostimulation and Electromagnetic Therapy for the Treatment of Wounds, DME, Policy No. 83.09
3. Electromagnetic Therapy Devices, Durable Medical Equipment, Policy No. 83.13

BACKGROUND

Ultrasound is defined as a mechanical vibration above the upper threshold of human hearing

(greater than 20 KHz) and has been used primarily by physical therapists in the megahertz (MHz) range (1–3 MHz) for the treatment of musculoskeletal disorders. Recently, non-contact ultrasound treatment devices, which administer low-frequency ultrasound in the kilohertz range via a saline mist, have been proposed for use in wound healing, including pain management and debridement. Their proposed mechanism of action is the production, vibration, and movement of micron-sized bubbles in the saline and wound tissue.

REGULATORY STATUS

Devices with 510(k) clearance from the US Food and Drug Administration (FDA) include the following:

- The MIST Therapy® System, a non-contact ultrasound device, which uses an ultrasound transducer or wand, by Alliqua Biomeidcal (Langhome, PA).
- The Qoustic Wound Therapy System™ (formerly called model AR1000) by Arobella Medical LLC. In contrast to MIST system, the Qoustic system uses a contact probe to treat wounds.

EVIDENCE SUMMARY

The principal outcomes associated with treatment of wounds, particularly chronic wounds, are complete wound closure (either with or without surgical closure), improvement in the rate or quality of healing (such as the minimization of scarring), treatment of infection, and patient-centered outcomes such as improvements in function or mobility, and minimization of pain.[1, 2] Outcomes relating to the use of a non-contact low-frequency ultrasound devices for the treatment of wounds are best understood when comparing use of a non-contact low-frequency ultrasound device to a sham device among patients with similar wound type (i.e., burn or chronic diabetic ulcer) receiving standardized wound care regimens. Therefore, data from adequately powered, blinded, randomized sham-controlled trials (RCTs) are required to control for bias and determine whether any treatment effect from non-contact low-frequency ultrasound devices provides a significant advantage over standard wound care.

SYSTEMATIC REVIEWS

A Cochrane systematic review (SR) by Cullum (2017) was conducted to evaluate whether venous leg ulcers treated with ultrasound heal more quickly than those not treated with ultrasound.[3] The review included 11 RCTs that compared either high- or low-frequency ultrasound with non-ultrasound comparator treatments of usual care, sham ultrasound, or alternative leg ulcer treatments. The two trials in the SR that evaluated low-frequency ultrasound[4, 5] were considered very low-quality due to risk of bias and imprecision. Results from pooled data analyses were unable to determine whether low-frequency ultrasound affects venous ulcer healing at eight and 12 weeks (N=61, RR 3.91, 95% CI 0.47 to 32.85). Consistent with the results of a previous SR,[6] the authors concluded that it is uncertain whether therapeutic ultrasound (either high- or low-frequency) improves the healing of venous leg ulcers.

Chang (2017) published a SR on the use of low-frequency ultrasound as an adjunct therapy for chronic wound healing.[7] Of the 25 studies that met selection criteria, four studies were not included due to low quality. The SR did not include meta-analyses due to study heterogeneity and the narrative synthesis did not provide complete information on the range of comparative effects. More than four ultrasound modalities and six wound etiologies were evaluated. Only

two studies reported follow-up data, and this follow-up was a short timeframe of 3 months. The authors concluded that while the data supporting the use of low-frequency ultrasound as adjunctive therapy to wound healing is promising, there is not enough high-quality evidence to draw conclusions about its efficacy beyond standard care, a conclusion that is consistent with previous reviews of the relevant literature.[8, 9]

RANDOMIZED CONTROLLED TRIALS

There have been a number of published unblinded RCTs comparing non-contact low-frequency ultrasound with standard wound care alone in addition to the ones discussed in the SRs above.[10-16] All of the RCTs used MIST therapy and, other than two trials that did not report a funding source, all were industry funded.[13, 15] One study addressed diabetic foot ulcers, the population included in the Ennis 2005 RCT, discussed above.[17] Four RCTs included patients with venous leg ulcers and one RCT evaluated treatment of split thickness graft donor sites. All studies except one, on split thickness graft donor sites, included patients with non-healing wounds; eligibility criteria included wounds that had not healed after at least four weeks. Three studies reported that patients and providers were not blinded but outcome assessment was blinded.[10-12] The other studies did not mention blinding. Standard care interventions varied somewhat but generally consisted of wound cleaning, noncontact dressings, compression and, if deemed necessary by providers, debridement. Two studies mentioned following national guidelines for the standard care intervention.[10, 12] Prather did not describe the standard care intervention, and Beheshti reported only that compression was used.[11, 13] Study characteristics and findings are summarized in Table 1 below.

Table 1. RCTs Comparing Low-Frequency Ultrasound to Standard Care

Study	Initial N Final N	Wounds included	Interventions	Primary Outcome	Outcome Assessment Single-Blinded	Results
Beheshti (2014)	N=90 N=90	Venous leg ulcers (≥4 wk)	NLFU: 3×/wk until healed (same protocol for HFU) SOC: Compression therapy (visit frequency not reported)	Time to wound healing (months)	NR	NLFU + SOC: 5.70 (SD=1.57) HFU + SOC: 6.10 (SD=1.47) SOC: 8.13 (SD=1.40) 3 groups: p<0.001 HFU vs NLFU: p=0.22
Gibbons (2015)	N=81 N=74	Venous leg ulcers (≥30 d)	NLFU: 3×/wk for 4 wk SOC: 3×/wk for 4 wk	Percent wound area reduction at 4 wk	Yes	NLFU + SOC: -61% (SD=28.9%) SOC: -45% (SD=32.5%) p=0.002
Olyaie (2013)	N=90 N=90	Venous leg ulcers (≥4 wk)	NLFU: 3×/wk for 3 mo or until healed (same protocol for HFU) SOC: 3×/wk for 3 mo or until healed	Time to wound healing (months)*	NR	NLFU + SOC: 6.65 (SD=1.59) HFU + SOC: 6.86 (SD=2.04) SOC: 8.50 (SD=2.17)

Study	Initial N Final N	Wounds included	Interventions	Primary Outcome	Outcome Assessment Single-Blinded	Results
						3 groups: p=0.001 HFU vs NLFU: p not reported
Prather (2015)	N=31 N=27	Split-thickness graft donor sites	NLFU: 1×/wk for 5 consecutive days (after 2-wk run-in period) SOC: 1×/wk for 5 consecutive days (after 2-wk run-in period)	Time to wound healing (days)	Yes	NLFU + SOC: 12.1 (SD=6.0) SOC: 21.3 (SD=14.7) p=0.04
White (2015)	N=36 N=36	Venous leg ulcers (≥6 wk)	NLFU: 3×/wk for 8 wk (after 2-wk run-in period) SOC: >1 visit per week for 8 wk	Percent wound area reduction at 13 wk	Yes	NLFU + SOC: -46.6% (SD=38.1%) SOC: -39.2% (SD=38.0%) p=0.565

HFU: high-frequency ultrasound; NLFU: noncontact low-frequency ultrasound; NR: not reported; SOC: standard of care.
* Reported this outcome; did not specify primary outcome.

All but one of the RCTs in Table 1 had statistically significantly better results on the primary outcome with low-frequency ultrasound compared with standard care. However, studies had methodological limitation. In terms of outcome assessment, complete healing is generally considered the most clinically relevant outcome; a 50% reduction in wound area over time and time to heal are also considered to be acceptable outcomes.[18] A reduction of less than 50%, or wound area reduction without a predefined cutoff is not considered acceptable. The largest number of trials included patients with venous leg ulcers. None of these RCTs had blinded outcome assessment and reported complete healing or one of the other acceptable outcomes as the primary outcome measure. Only one RCT in Table 1, on split thickness graft donor sites, met both of these criteria.[11] Another limitation of the body of evidence is that some of the standard care interventions involved fewer visits than the NLFU intervention and nonspecific effects of this differential in face-to-face contact could partially explain the difference in findings between intervention and control groups.

NONRANDOMIZED STUDIES

A number of nonrandomized studies described experiences of MIST therapy-treated wound patients.[19-35] Although these studies contribute to the body of knowledge by providing direction for future research, evidence from these studies does not permit conclusions due to methodological limitations, such as non-random allocation of treatment and lack of appropriate control groups.

PRACTICE GUIDELINE SUMMARY

ASSOCIATION FOR THE ADVANCEMENT OF WOUND CARE

The 2015 update of the Association for the Advancement of Wound Care (AAWC) guideline on treatment of venous ulcers stated that “low-frequency ultrasound may support healing, reduce pain and improve QOL of non-healing venous or mixed etiology venous ulcers” (moderate

strength of rating), but also cautions that limited evidence supports enduring benefit or parameters of application.[36]

In 2010, the Association for the Advancement of Wound Care (AAWC) published a guideline on care of pressure ulcers.[37] Non-contact ultrasound therapy was included as a potential second-line intervention if first-line treatments did not result in wound healing, although the strength of the evidence supporting this decision was low (Level C), indicating a lack of sufficient studies on this topic.

AMERICAN COLLEGE OF PHYSICIANS

The American College of Physicians developed a guideline based on evidence on the comparative effectiveness of treatments of pressure ulcers in 2015.[38] The review of the evidence for therapeutic ultrasound for pressure ulcers concluded that this treatment was similar to controls. Ultrasound is not mentioned in the recommendations.

SOCIETY FOR VASCULAR SURGERY, AMERICAN VENOUS FORUM, AMERICAN PODIATRIC MEDICAL ASSOCIATION

The Society for Vascular Surgery in collaboration with the American Venous Forum published joint guidelines on the management of venous leg ulcers in 2014.[39] The guidelines recommended adjuvant wound therapy options for venous leg ulcers that fail to demonstrate improvement after four to six weeks of standard wound therapy (strength of recommendation: grade 1; quality of evidence: level B), but suggested against routine ultrasound therapy for venous leg ulcers (strength of recommendation: grade 2; quality of evidence: level B).

The Society for Vascular Surgery in collaboration with the American Podiatric Medical Association published joint guidelines on the management of diabetic foot in 2016.[40] The guidelines recommended adjuvant therapy that for diabetic foot ulcers that fail to demonstrate more than 50% wound area reduction after four weeks of standard wound therapy. The adjunctive wound therapy options listed in the guidelines are negative pressure therapy, biologics (platelet-derived growth factor, living cellular therapy, extracellular matrix products, amniotic membrane products), and hyperbaric oxygen therapy. Ultrasound therapy is not mentioned as a recommended adjuvant option.

SUMMARY

There is not enough research to show that non-contact low-frequency ultrasound improves health outcomes for the treatment of wounds. In addition, no practice guidelines recommend non-contact low-frequency ultrasound, for wound healing. Therefore, the use of non-contact low-frequency ultrasound is considered investigational for the treatment of all wounds.

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CODES

Codes	Number	Description
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
HCPCS	None	

Date of Origin: *April 2008*