Noncontact Ultrasound Treatment for Wounds

Policy # 00808
Original Effective Date: 01/01/2023
Current Effective Date: 11/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Vacuum-Assisted Closure of Chronic Wounds (Negative Pressure Wound Therapy) is addressed separately in medical policy 00132.

Note: Electrostimulation and Electromagnetic Therapy for Treating Wounds is addressed separately in medical policy 00030.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers noncontact ultrasound treatment for wounds to be **investigational.***

Background/Overview

Ultrasound (US) delivers mechanical vibration above the upper threshold of human hearing (>20 kHz). US in the megahertz range (1-3 MHz) has been used to treat 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, collagen production, and increases in macrophage responsiveness, fibrinolysis, and nitric oxide levels. The therapeutic effects of US energy in the kilohertz range have also been examined. Although the precise effects are not known, the 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 the US is typically transmitted to the tissue through a coupling gel. Several high-intensity US devices with contact probes are currently available for wound debridement. Low-intensity US devices have been developed that do not require coupling gel or other direct contact. The MIST Therapy System delivers a saline mist to the wound with low-

frequency US (40 KHz). A second device, the Qoustic Wound Therapy System, also uses sterile saline to deliver US energy (35 KHz) for wound debridement and irrigation.

US is intended as an adjunct to standard wound care. Therefore, the evidence is needed that demonstrates US plus standard wound care provides superior wound closure outcomes compared with standard wound care alone.

The primary endpoints of interest for trials of wound closure are as follows, consistent with 2006 guidance from the U.S. Food and Drug Administration (FDA) for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2005, the MIST Therapy®‡ device (Celleration) was cleared for marketing by the FDA through the 510(k) process "to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates, and bacteria." In February 2015, Celleration was acquired by Alliqua Biomedical (Langhorne, PA). In August 2020, Sanuwave acquired related UltraMIST System assets.

In 2007, the AR1000 Ultrasonic Wound Therapy System (Arobella Medical, Minnetonka, MN) was cleared for marketing by the FDA through the 510(k) process, listing the MIST Therapy®‡ system and several other ultrasonic wound debridement and hydrosurgery systems as predicate devices. The AR1000 system probe uses "contact or noncontact techniques to achieve intended wound therapy modalities to promote wound healing."Indications in the 510(k) summary are listed as "Selective and non-selective dissection and fragmentation of soft and or hard tissue" and "Surgical, excisional or sharp-edge wound debridement (acute and chronic wounds, bums) for the removal of nonviable tissue including but not limited to diseased tissue, necrotic tissue, slough and eschar, fibrin, tissue exudates, bacteria and other matter." This device is now known as the Qoustic Wound Therapy System™‡ (K131096).

Several other devices have been approved as being substantially equivalent to the earlier devices. FDA product code: NRB.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Low-frequency ultrasound in the kilohertz range may improve wound healing. Several noncontact low-frequency ultrasound (NLFU) devices have received regulatory approval for wound treatment.

Summary of Evidence

For individuals who have any wound type (acute or nonhealing) who receive noncontact low-frequency ultrasound therapy (NLFU) plus standard wound care, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The single, double-blinded, sham-controlled randomized trial, which included patients with nonhealing diabetic foot ulcers, had substantial methodologic flaws (eg, high dropout rate, baseline differences between groups) that limit the validity of the findings. In the remaining studies comprising the evidence base, all but 1 RCT comparing NLFU with standard wound care reported improved (statistically significant) results on the primary outcome with NLFU. However, these studies also had several methodologic limitations. Complete healing is the most clinically relevant outcome. None of the RCTs evaluating venous leg ulcers reported complete healing as its primary outcome measure, and none had blinded outcome assessment. Only 1 RCT, which addressed split-thickness graft donor sites, reported on the proportion of patients with complete healing and had blinded outcome assessment. Another limitation of the body of evidence is that some standard of care interventions involved fewer visits than the NLFU intervention, and the differences in intensity of care resulting from this differential in face-to-face contact could partially explain the difference in findings between intervention and control groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the remaining sections in Supplemental Information is to provide reference material regarding existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement and information may not necessarily be used in formulating the evidence review conclusions.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Association for the Advancement of Wound Care
In 2010, the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of pressure ulcers. Noncontact low-frequency ultrasound therapy was included as a potential second-line intervention if first-line treatments did not result in wound healing.

The AAWC guidelines on the treatment of venous ulcers, updated in 2015, stated that low-frequency ultrasound treatment requires additional evidence before it can be considered an appropriate treatment.

National Institute for Health and Care Excellence
In 2011, the National Institute for Health and Care Excellence published a medical technologies guidance on the MIST Therapy system for the promotion of wound healing. The assessment concluded that "the amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient, at the time of writing, to support the case for routine adoption of the MIST Therapy system in the NHS." This guidance was last reviewed in 2016 with no changes to the recommendations. NICE states that the guidance will be reviewed in the future if there is new evidence that is likely to change the recommendations.

Society for Vascular Surgery, American Venous Forum, American Podiatric Medical Association
In 2014, the Society for Vascular Surgery in collaboration with the American Venous Forum published joint guidelines on the management of venous leg ulcers. The guidelines recommended adjuvant wound therapy options for venous leg ulcers that fail to demonstrate improvement after 4 to 6 weeks of standard wound therapy (strength of recommendation: grade 1; quality of evidence: level B), but recommended against routine ultrasound therapy for venous leg ulcers (strength of recommendation: grade 2; quality of evidence: level B). This guideline is currently archived.

In 2016, the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association published joint guidelines on the management of diabetic foot ulcers. The guidelines recommended adjuvant therapy for diabetic foot ulcers that fail to demonstrate more than 50% wound area reduction after 4 weeks of standard wound therapy. The adjunctive wound therapy options listed in the guidelines included negative pressure therapy, biologics (platelet-derived growth factor, living cellular therapy, extracellular matrix products, amniotic membrane products), and hyperbaric oxygen therapy. Ultrasound therapy was not mentioned as a recommended adjuvant option.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in December 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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[TM] Therapy System: 510(k) Premarket Notification: K050129. https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf.
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.
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): 190-9. 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, Schöpf E, et al. Low-frequency ultrasound treatment of chronic venous leg ulcers in an outpatient therapy. Acta Derm Venereol. Jul 1997; 77(4): 311-4. 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): 221-6. PMID 17415030
10. Beheshti A, Shafigh Y, Parsa H, et al. Comparison of high-frequency and MIST ultrasound therapy for the healing of venous leg ulcers. Adv Clin Exp Med. 2014; 23(6): 969-75. 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): 833-42. 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): 309-18. PMID 25868409
15. Gottrup F, Apelqvist J, Price P. 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): 237-68. 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.
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.
18. National Institute for Health and Care Excellence. Medical technologies guidance (MTG5): The MIST Therapy system for the promotion of wound healing. July 25, 2011; https://www.nice.org.uk/guidance/mtg5/chapter/1-Recommendations.
19. O'Donnell TF, 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. J Vasc Surg. Aug 2014; 60(2 Suppl): 3S-59S. PMID 24974070
20. 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

Policy History

Original Effective Date: 01/01/2023
Current Effective Date: 11/11/2024
10/06/2022 Medical Policy Committee review
10/11/2022 Medical Policy Implementation Committee approval. New policy.
10/05/2023 Medical Policy Committee review

Noncontact Ultrasound Treatment for Wounds

Policy # 00808
Original Effective Date: 01/01/2023
Current Effective Date: 11/11/2024

10/11/2023 Medical Policy Implementation Committee approval. No change to coverage.
10/03/2024 Medical Policy Committee review
10/08/2024 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 10/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Noncontact Ultrasound Treatment for Wounds

Policy # 00808
Original Effective Date: 01/01/2023
Current Effective Date: 11/11/2024

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	97610
HCPCS	NA
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

Noncontact Ultrasound Treatment for Wounds

Policy # 00808
Original Effective Date: 01/01/2023
Current Effective Date: 11/11/2024

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.