Noncontact Ultrasound Treatment for Wounds

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

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 débridement. 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 débridement 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 débridement by the removal of yellow slough, fibrin, tissue exudates, and bacteria."[2,] In February 2015, Celleration was acquired by Alliqua Biomedical (Langhorne, PA).

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 débridement 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 ultrasound therapy 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 2014, 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.

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).

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 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

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Policy History

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10/06/2022 Medical Policy Committee review
10/11/2022 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 10/2023

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 2021 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

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CPT is a registered trademark of the American Medical Association.

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.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ 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.

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.