Medical Coverage Policy | Non-Contact Ultrasound Treatment for Wounds

EFFECTIVE DATE: 09|01|2019
POLICY LAST REVIEWED: 02|07|2024

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Non-contact ultrasound treatment for wounds is considered not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
Non-contact ultrasound treatment for wounds is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for not covered/not medically necessary.

BACKGROUND
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 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.

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.", 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™.

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.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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

RELATED POLICIES

None

PUBLISHED

Provider Update, April 2024
Provider Update, April 2023
Provider Update, June 2022
Provider Update, May 2021
Provider Update, April 2020

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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. Accessed December 29, 2023.

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