

FEP 2.01.79 Noncontact Ultrasound Treatment for Wounds

Effective Date: April 15, 2018

Related Policies:

1.01.16 Negative Pressure Wound Therapy
2.01.57 Electrostimulation and Electromagnetic Therapy for the Treatment of Chronic Wounds

Noncontact Ultrasound Treatment for Wounds

Description

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.

FDA REGULATORY STATUS

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 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.”³ 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, burns) 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.”³ This device is now known as the Qoustic Wound Therapy System™.

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

POLICY STATEMENT

Noncontact ultrasound treatment for wounds is considered **investigational**.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FEP 2.01.79 Noncontact Ultrasound Treatment for Wounds

RATIONALE

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 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 the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Association for the Advancement of Wound Care

In 2010, the Association for the Advancement of Wound Care published guidelines on care of pressure ulcers.¹⁶ Noncontact low-frequency ultrasound therapy was included as a potential second-line intervention if first-line treatments did not result in wound healing.

The Association 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.¹⁷

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 2014.¹⁸ 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).

The Society for Vascular Surgery in collaboration with the American Podiatric Medical Association published joint guidelines on the management of diabetic foot in 2016.¹⁹ 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.

FEP 2.01.79 Noncontact Ultrasound Treatment for Wounds

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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FEP 2.01.79 Noncontact Ultrasound Treatment for Wounds

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POLICY HISTORY

Date	Action	Description
September 2012	New Policy	
March 2014	Update Policy	Policy updated with literature review, references added other renumbered or removed; policy statement unchanged.
March 2015	Update	Policy updated with literature review, reference 7; policy statement unchanged.
June 2016	Update	Policy updated with literature review, references 1-2, 4-7 and 10 added; policy statement unchanged.
March 2017	Update	Policy updated with literature review through November 11, 2017; references 8 and 18-19 added; notes 16-17 updated. Policy statement unchanged except "not medically necessary" corrected to "investigational" due to FDA 510k approval of devices.

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