Non-Contact Ultrasound Treatment for Wounds

Description of Procedure or Service

Ultrasound (US) produces vibrations of the same physical nature as sound but with frequencies above the range of human hearing (>20 KHz). US in the megahertz (MHz) range (1-3 MHz) has been used for the treatment of musculoskeletal disorders, primarily 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 and collagen production, and increases in macrophage responsiveness, fibrinolysis and nitric oxide levels. The therapeutic effects of US energy in the kilohertz (low frequency) range have been examined. It has been proposed that 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 is typically transmitted to 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 use of a coupling gel or other direct contact. The MIST Therapy System delivers US energy (40 KHz) to the wound through saline mist particles; it includes a generator, a transducer, and a disposable applicator for discharge of prepackaged saline. A second device, the Qoustic Wound Therapy System™, also uses sterile saline to deliver ultrasound energy (35 KHz) for wound debridement and irrigation.

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

1. Incidence of complete wound closure.
2. Time to complete wound closure (reflecting accelerated wound closure).
3. Incidence of complete wound closure following surgical wound closure.
4. Pain control.

In 2005, the Celleration MIST Therapy® device received marketing clearance (K050129) through the United States Food and Drug Administration’s (FDA) 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 2007, the AR1000 Ultrasonic Wound Therapy System (Arobella Medical) received marketing clearance, listing the Celleration 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, burns) for the removal of nonviable tissue including but not limited to...
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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™. Several other devices have been
approved as being substantially equivalent to the earlier devices.

Related Policies
Electrostimulation and Electromagnetic Therapy for Wounds
Topical Negative Pressure Therapy for Wounds

***Note: This Medical Policy is complex and technical. For questions concerning the technical
language and/or specific clinical indications for its use, please consult your physician.

Policy

The use of non-contact ultrasound is considered investigational for the treatment of wounds.
BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the
Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit
design; therefore member benefit language should be reviewed before applying the terms of this
medical policy.

When Non-Contact Ultrasound Treatment for Wounds is covered

Not applicable.

When Non-Contact Ultrasound Treatment for Wounds is not covered

Non-contact ultrasound treatment for wounds is considered investigational.

Policy 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.

For individuals who have any wound type (acute or nonhealing) who receive noncontact ultrasound
therapy, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant
outcomes are symptoms, change in disease status, morbidity events, quality of life, and treatment-related
morbidity. The single double-blinded, sham-controlled RCT, which included patients with nonhealing
diabetic foot ulcers, had substantial methodologic flaws that limit the validity of the findings (eg, high
dropout rate, baseline differences between groups). In the remaining studies comprising the evidence
base, all but 1 RCT comparing NLFU to standard wound care had improved (statistically significant)
results on the primary outcome with NLFU. However, these studies also had several methodologic
limitations. 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 acceptable outcomes. A majority of trials included patients with venous leg ulcers. None of
the RCTs evaluating venous leg ulcers reported complete healing or another acceptable outcome as the
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.
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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 97610

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


Policy Implementation/Update Information

3/16/09 Original policy issued.
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6/22/10  Policy Number(s) removed (amw)
12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/10. Policy accepted as written. The use of non-contact ultrasound is considered investigational for the treatment of wounds. (adn)
12/20/11 Description section and Policy Guidelines section updated. No change in policy statement, the use of non-contact ultrasound is considered investigational for wound treatment. Specialty Matched Consultant Advisory Panel review 11/30/11. (adn)
1/1/13 Reference added. Specialty Matched Consultant Advisory Panel review 12/4/12. No change to policy statement. (sk)
2/25/14 References added. No change to Policy statement. (sk)
12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)
4/1/16 Reference added. Policy Guidelines updated. (sk)
3/31/17 Reference added. Wound Closure Endpoints information added to Description section. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.