

**EFFECTIVE DATE:** 09|01|2019

**POLICY LAST UPDATED:** 05|21|2019

## OVERVIEW

Low-frequency ultrasound (US) in the kilohertz (KHz) 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

**BlueCHiP for Medicare and Commercial Products**

Not applicable

## POLICY STATEMENT

**BlueCHiP for Medicare**

Non-contact ultrasound treatment for wounds is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

### Commercial Products

Non-contact ultrasound treatment for wounds is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

## 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 (greater than 20 KHz). US in the megahertz (MHz) range (1–3 MHz) has been used for the treatment of 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 and collagen production, and increases in macrophage responsiveness, fibrinolysis, and nitric oxide levels. The therapeutic effects of US energy in the KHz range have also been examined. Although the precise effects are not known, 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 US is typically transmitted to tissue through a coupling gel. Several high-intensity US devices with contact probes are currently available for wound debridement. Recently, low-intensity US devices have been developed that do not require use of a coupling gel or other direct contact. The MIST Therapy™ System (Celleration, Eden Prairie, MN) delivers a saline mist to the wound with low-frequency US (40 KHz). A second device, the Qoustic Wound Therapy System™ (Arobella Medical, Minnetonka, MN), also uses sterile saline to deliver ultrasound energy (35 KHz) for wound debridement and irrigation.

For individuals who have any wound type (acute or nonhealing) who receive noncontact ultrasound therapy, the evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, the service is considered not medically necessary.

## CODING

### BlueCHiP for Medicare and Commercial Products

The following code is not covered/not medically necessary

**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

Not applicable

## PUBLISHED

Provider Update, July 2019

Provider Update, November 2018

Provider Update, January 2018

Provider Update, February 2017

Provider Update, February 2016

Provider Update, January 2015

## REFERENCES

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