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 covered for BlueCHiP for Medicare members.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial Products
Non-contact ultrasound treatment for wounds is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

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 applicable surgery or when services are not medically necessary.

BACKGROUND
Several devices are available, including the MIST Therapy® system, which delivers ultrasonic energy to wounds via a saline mist without direct skin contact.

Ultrasound (US) is defined as a 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, 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 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.

Non-contact low-frequency ultrasound (US) in the kilohertz range is proposed to promote wound healing. The available published evidence does not permit conclusions concerning the effect of non-contact US on health outcomes compared to standard wound treatment. Well-designed, blinded studies that have adequate numbers of patients and that include all relevant outcomes are needed to further evaluate the efficacy of this treatment. Therefore, non-contact ultrasound treatment for wounds is considered not medically necessary.

**CODING**
The following code is covered for BlueCHiP for Medicare members only. It is considered not medically necessary for Commercial products.

97610

**RELATED POLICIES**
Not applicable

**PUBLISHED**
Provider Update, February 2017
Provider Update, February 2016
Provider Update, January 2015
Provider Update, July 2013
Provider Update, May 2012
Provider Update, May 2011
Provider Update, July 2010

**REFERENCES**


