OVERVIEW
Low-frequency ultrasound (US) in the kilohertz (KHz) range may improve wound healing.

MEDICAL CRITERIA
BlueCHiP for Medicare
Low frequency, non-contact, non-thermal ultrasound (MIST Therapy) is covered when one of the following criteria is met:

- Acute or chronic painful venous stasis ulcers, which are too painful for sharp or excisional debridement;
- Acute or chronic arterial/ischemic ulcers, which are too painful for sharp or excisional debridement;
- Diabetic or neuropathic ulcers;
- Radiation injuries or ulcers;
- Patients with wounds or ulcers with documented contraindications to sharp or excisional debridement;
- Burns which are painful and/or have significant necrotic tissue;
- Wounds that have not demonstrated signs of improvement after 30 days of documented standard wound care;
- Preparation of wound bed sites for application of bioengineered skin products or skin grafting.

Frequency/Duration
Per Medicare, low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided 2-3 times per week to be considered “reasonable and necessary.” The length of individual treatments will vary per wound size according to manufacturer recommendations.

Observable, documented improvements in the wound(s) should be evident after two (2) weeks or six (6) treatments. Improvements would include documented reduction in pain, necrotic tissue, wound size, or improved granulation tissue.

Per Medicare guidelines, the initial authorization will be for up to six (6) weeks or eighteen (18) treatments with documented improvements of pain reduction, reduction in wound size, improved and increased granulation tissue, or reduction in necrotic tissue. Continued treatments beyond eighteen (18) sessions per episode of treatment requires re-review.

PRIOR AUTHORIZATION
BlueCHiP for Medicare
Prior authorization is required for BlueCHiP for Medicare only and is obtained via the online tool for participating providers. See the Related Policies section.

Commercial Products
POLICY STATEMENT
BlueCHiP for Medicare

Non-contact ultrasound treatment for wounds is covered for BlueCHiP for Medicare members who meet the medical criteria as outlined below and is considered not medically necessary for all other indications as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

NOTE: Medicare policy is developed separately from Blue Cross & Blue Shield of Rhode Island (BCBSRI) policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

Commercial Products
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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. 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.

For BlueCHiP for Medicare members, non-contact ultrasound treatment for wounds is considered medically necessary when used for the indications listed in the medical criteria. There is no scientific literature to
support the use of non-contact ultrasound treatment for other indications, therefore all other indications are considered not medically necessary.

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

97610

**RELATED POLICIES**
Preauthorization via Web-Based Tool for Procedures

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

**REFERENCES**


*This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.*