

Medical Coverage Policy



Non-Contact, Non-thermal Ultrasound Treatment for Wounds - PREAUTH

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	6/1/2010	Policy Last Updated:	5/7/2013
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

Low-frequency ultrasound (US) in the kilohertz (KHz) range may improve wound healing. 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. More recently, the therapeutic effects of US energy in the KHz range have been examined. It has been proposed that 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. A non-contact low-intensity US device has been developed that does 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); it includes a generator, a transducer, and a disposable applicator for discharge of prepackaged saline.

Although the Mist Therapy System™ system has been cleared by the FDA, at this time there is insufficient clinical evidence to support its clinical effectiveness. Current available scientific evidence does not permit conclusions concerning the effect of this technology on health outcomes. Well-designed and blinded studies with additional subjects, that include all relevant outcomes, are needed to evaluate this treatment. Therefore, non-contact ultrasound treatment for wounds is considered not medically necessary for Commercial members as there is no proven efficacy.

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

Medical Criteria:

BlueCHiP for Medicare:

Low frequency, non-contact, non-thermal ultrasound (MIST Therapy) is **covered** when one of the following criteria is met:

- I. Acute or chronic painful venous stasis ulcers, which are too painful for sharp or excisional debridement;
- II. Acute or chronic arterial/ischemic ulcers, which are too painful for sharp or excisional debridement;
- III. Diabetic or neuropathic ulcers;
- IV. Radiation injuries or ulcers;
- V. Patients with wounds or ulcers with documented contraindications to sharp or excisional debridement;
- VI. Burns which are painful and/or have significant necrotic tissue;
- VII. Wounds that have not demonstrated signs of improvement after 30 days of documented standard wound care;
- VIII. 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.

Policy:

Blue CHiP for Medicare:

Preauthorization is required for BlueCHiP for Medicare members only.

Non-contact ultrasound treatment for wounds is covered for BlueCHiP for Medicare members who meet the medical criteria as outlined above 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 BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), 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 as Medicare offers.

Commercial

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 Evidence of Coverage, Subscriber Agreement, Benefit Booklet, for applicable surgery or not medically necessary benefits/coverage.

Coding:

The following code is covered for **BlueCHIP for Medicare members only:**
0183T

Also Known As:

Mist Therapy System™
Non-Contact Ultrasound

Related Topics:

None

Published:

Provider Update, July 2013
Provider Update, May 2012
Provider Update, May 2011
Provider Update, July 2010
Provider Update, May 2010
Provider Update, May 2009

References:

<http://celleration.com/>

Ennis WJ, Foremann P, Mozen N et al. Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study. *Ostomy Wound Management*;2005;51(8):24-39.

Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with noncontact, low-frequency ultrasound: the Mayo clinic experience, 2004-2006. *Advanced Skin Wound Care*;2007;20(4):221-6.

Kavros SJ, Liedl DA, Boon AJ et al. Expedited wound healing with noncontact, low-frequency ultrasound therapy in chronic wounds: a retrospective analysis. *Advanced Skin Wound Care*;2008;21(9):416-23.

Samies J, Gehling M. Acoustic pressure wound therapy for management of mixed partial- and full-thickness burns in a rural wound center. *Ostomy Wound Management*;2008;54(3):56-9.

Association for the Advancement of Wound Care (AAWC). Pressure Ulcer Guideline. Available online at: www.guideline.gov

Association for the Advancement of Wound Care (AAWC). Venous Ulcer Guideline. Available online at: www.guideline.gov

History:

Annual Update - March 2013

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