

# Medical Coverage Policy



**Blue Cross  
Blue Shield**  
of Rhode Island

## Non-Contact Ultrasound Treatment for Wounds- PREAUTH

Device/Equipment    Drug    Medical    Surgery    Test    Other

|                 |          |                      |          |
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| Effective Date: | 6/1/2010 | Policy Last Updated: | 4/5/2011 |
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**Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

**Prospective review is not required.**

### Description:

This policy addresses the use of low-frequency, non-contact, non-thermal, ultrasound therapy for wound management.

The mechanical energy from ultrasound therapy is typically transmitted to tissue through a coupling gel. Several high-intensity ultrasound devices with contact probes are currently available for wound debridement. A non-contact low-intensity ultrasound device has been developed that does not require use of a coupling gel or other direct contact. The MIST Therapy™ System (Celleration) delivers a saline mist to the wound with low-frequency ultrasound (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.

### Medical Criteria:

Low frequency, non-contact, non-thermal ultrasound (MIST Therapy) is covered for **BlueCHIP for Medicare members only** who meet one of the following criteria:

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

### **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.

### **Policy:**

**Prior medical review 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 members as** there is inadequate peer-reviewed data to support its use.

### **Coverage:**

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, Benefit Booklet for applicable physical therapy 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:**

Not applicable.

### **Published:**

Provider Update, May 2009  
Provider Update, May 2010

Provider Update, July 2010  
Provider Update, May 2011

**References:**

<http://celleration.com/reimbursement.html>. Accessed on 1/31/09.

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.

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