



**ULTRASOUND THERAPY FOR
WOUND HEALING (MIST THERAPY™)
HS-153**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

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**Ultrasound Therapy for
Wound Healing
(MistTherapy™)**

Policy Number: HS-153

Original Effective Date: 2/4/2010

Revised Date(s): 2/4/2011; 2/2/2012

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Chronic wounds, including venous ulcers, diabetic foot ulcers, and pressure sores, are a significant health problem in the United States, affecting approximately 1% of adults. Difficult-to-heal wounds lead to high rates of morbidity and mortality, negative effects on quality of life, and lengthy periods of medical care. Although leg and foot ulcers have numerous causes, such as malfunctioning veins, diseased arteries, mixed venous-arterial disease, nerve damage due to diabetes, trauma, or immobility, over 90% of the lesions are related to venous disease, arterial disease, and nerve damage. Another common type of chronic wound is pressure sores, which develop due to soft tissue breakdown at sites of repeated or prolonged contact between underlying bone and external surfaces. Regardless of the cause, chronic wound treatment usually begins with conservative therapies such as pressure relief, sterile dressings, and topical antibiotics. Debridement to remove dead or severely damaged tissue may also be necessary. If conservative treatments fail to promote wound healing, surgical treatments such as closure of a malfunctioning vein, transplantation of a flap of tissue from another site to cover the wound, or amputation of a digit or foot may be necessary.

The Mist Therapy™ System has been developed to provide simultaneous cleansing and debridement of wounds. Treatment with this device involves holding an ultrasonic handset 1 cm away from the wound and applying a saline solution to the handset, generating a saline mist that is designed to carry low levels of ultrasonic energy into the wound. According to the device manufacturer, this treatment promotes healing of acute, traumatic, and chronic wounds by stimulating cellular activities that contribute to healing and by cleaning the wound surface. Under normal circumstances, patients undergo Mist Therapy on an outpatient basis in 3 sessions per week and 3 to 12 minutes of treatment per session, depending on wound size.

Results of the available studies provide preliminary evidence that, as a supplement to standard wound care, Mist Therapy improves healing of chronic diabetic foot ulcers and of chronic ulcers due to insufficient lower limb blood flow.

In an RCT that examined wound healing in 55 patients who underwent up to 12 weeks of Mist Therapy for diabetic foot ulcers, this therapy was associated with a statistically significant improvement in wound healing. Complete healing was achieved by 41% of patients who underwent true Mist Therapy versus 14% of patients who underwent placebo therapy. For patients who had wounds due to insufficient lower limb blood flow, another RCT found that Mist Therapy was associated with a statistically significant improvement in partial wound healing. After 12 weeks of treatment, > 50% wound healing occurred for 63% of patients who underwent Mist Therapy versus 29% of patients who underwent standard wound care alone. Although these results are promising, these RCTs were relatively small (n=55 to 70 evaluable patients) and no other controlled trials of Mist Therapy were identified to confirm the efficacy of this treatment for diabetic foot ulcers and ulcers due to insufficient lower limb blood flow. Furthermore, the latter RCT used 50% rather than 100% wound healing as the measure of success and did not report whether any patients achieved complete wound healing. There is currently insufficient evidence to support the effectiveness of ultrasound therapy in the management of members with chronic wounds (Hayes, 2007).

POSITION STATEMENT

Low-frequency, non-contact ultrasound therapy (Mist Therapy™) for wound healing and reduction of chronic wound pain **are considered experimental and investigational and are NOT a covered benefit.**

CODING

CPT®* Codes No applicable codes

Non Covered CPT Category III®* Codes

0183T Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment and instruction(s) for ongoing care, per day.

ICD-9-CM Procedure Code - No applicable codes

HCPCS Codes - No applicable codes

Non Covered ICD-9-CM Diagnosis Code - All diagnosis are non-covered.

*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Ennis, W.J., Valdes, W., Gainer, M., & Meneses, P. (2006). Evaluation of clinical effectiveness of MIST ultrasound therapy for the healing of chronic wounds. *Advances in Skin and Wound Care*, 19(8), 437-446.
2. Ennis, W.J., Foremann, P., Mozen, N., & et al. (2005). Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study. *Ostomy Wound Management*, 51(8), 24-39. Hayes Directory. (2007, May 15). Low-energy ultrasound using the Mist Therapy™ system (Celleration Inc.) for treatment of wounds. Retrieved from <http://www.hayesinc.com>
3. Kavros, S.J., Miller, J.L., & Hanna, S.W. (2007). Treatment of ischemic wounds with noncontact, low-frequency ultrasound: the Mayo Clinic experience, 2004-2006. *Advances in Skin and Wound Care*, 20(4), 221-226.

Government Agencies, Professional and Medical Organizations

N/A

Other

1. Celleration Inc. (2007). MIST therapy system: scientific overview. Retrieved from <http://www.celleration.com>

HISTORY AND REVISIONS

| Date | Action |
|-------------|--|
| 2/2/2012 | • Approved by MPC. No changes. |
| 12/1/2011 | • New template design approved by MPC. |
| 2/4/2011 | • Approved by MPC. |