Wounds: Non-Contact Ultrasound Treatment

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

POLICY CRITERIA

Non-contact low frequency ultrasound treatment (e.g., Mist Therapy™) of wounds is considered experimental/investigational and is not covered.

CPT/HCPCS CODES

<table>
<thead>
<tr>
<th>All Lines of Business</th>
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<tbody>
<tr>
<td>Not covered</td>
<td>97610</td>
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<td>Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day</td>
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DESCRIPTION

The Mist Therapy™ System has been marketed to provide 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.

**REVIEW OF EVIDENCE**

A review of the available evidence shows that there is insufficient evidence to characterize how much benefit MIST Therapy adds to wound healing over standard care for specific wound types. The evidence is also insufficient to make a determination on how well it works when compared with alternative therapies as there is only one study available on the high-frequency ultrasound comparison and no studies are available on other comparisons.(1)

Overall, a moderate to low-quality body of evidence suggests that MIST Therapy, as an adjunct to standard wound care (SWC), has the potential to enhance wound healing when compared with standard wound care alone. However, limitations of the evidence were: small sample sizes, limited follow-up, retrospective designs one study, limited reporting on safety issues and substantial attrition.(2,3)

There is some evidence that low-frequency non-contact ultrasound may have benefit as an adjunct to standard treatment in the treatment of wounds that are hard to heal. More studies are needed with larger samples and longer follow-up to clarify this.(4,5,7,9)

**CLINICAL PRACTICE GUIDELINES**

National Institute for Health and Care Excellence

The 2011 National Institute for Health and Care Excellence (NICE) guidelines has indicated that, although there is some evidence that the MIST Therapy system promotes wound healing, the quality of that evidence is not adequate to recommend its routine use. NICE has recommended more research comparing the healing of wounds treated with the MIST Therapy system and those treated with standard care.(10)

**INSTRUCTIONS FOR USE**

Providence Health Plan (PHP) and Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHP and PHA Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. PHP and PHA reserve the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.
The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

**REGULATORY STATUS**

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

**REFERENCES**

1. ECRI: Custom Product Briefs – Guidance. MIST Therapy System (Celleration, Inc.), Noncontact, Low-frequency Ultrasound for Healing Chronic Wounds. Published 7/16/2014


