I. Policy: Non-contact Low-frequency Ultrasound for Wound Management (MIST Therapy)

II. Purpose/Objective: To provide a policy of coverage regarding Non-contact Low-frequency Ultrasound for Wound Management (MIST Therapy)

III. Responsibility:
   A. Medical Directors
   B. Medical Management

IV. Required Definitions

   1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
   2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
   3. Devised – the date the policy was implemented.
   4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
   5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

   a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
   c. in accordance with current standards of good medical treatment practiced by the general medical community.
   d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
   e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

   (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
   (iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
The MIST Therapy® System utilizes non-contact, low frequency ultrasound driven atomized mist to produce a non-thermal, mechanical cleansing action thought to create surface tension at the cellular level. Although the mechanism of action of MIST Therapy has not been established in clinical trials, this process, known as “microstreaming”, is thought to alter cell membrane structure, function and permeability, which has been suggested to stimulate tissue repair.

For the Medicare and Medicaid Business Segment Only: Low-frequency, non-contact ultrasound (MIST Therapy) will be considered medically necessary when provided as wound therapy for the following clinical conditions:

- 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 of 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 or improvement after 30 days of documented standard wound care
- Preparation of wound bed sites for application of bioengineered skin products or skin grafting

LIMITATIONS FOR MEDICARE BUSINESS SEGMENT ONLY:
Per CMS, low frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided 2-3 times per week to be considered “reasonable and necessary.”

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

Medicare will cover up to 6 weeks or 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 18 sessions per episode of treatment will be considered only upon individual consideration.

EXCLUSIONS: The Plan does NOT provide coverage for Non-contact, Low frequency Ultrasound (MIST Therapy) as a “stand-alone” treatment for any indication because it is considered unproven. Although the currently available literature regarding the use of non-contact, low-frequency ultrasound is encouraging, the studies have been conducted under varying conditions and protocols, making it impossible to establish superiority in effectiveness of this technology on health outcomes when compared to established technologies or treatments.

CODING ASSOCIATED WITH:
Non-contact Low-frequency Ultrasound for Wound Management (MIST Therapy)
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

97610   Low frequency, non-contact, non-thermal ultrasound including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per-day
A4639  Replacement pad for infrared heating pad system, each
A6000  Non-contact wound warming wound cover for use with the non-contact wound warming device and warming card
E0221  Infrared heating pad system
E0231  Non-contact wound warming device (temperature control unit, ac adapter and power cord) for use with warming card and wound cover
E0232  Warming card for use with the non contact wound warming device and non contact wound warming wound cover


Associated Key Words:
Celleration MIST System®, AR1000 Ultrasonic Wound Therapy
LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Novitas Solutions, Inc. Local Coverage Determination (LCD):  Wound Care (L35139)


ECRI, HTAIS Emerging Technology Reports (online), Noncontact, low-frequency ultrasound for chronic wounds. Published: 10/22/2010

ECRI, HTAIS. Hotline (online) Noncontact, Low-frequency Ultrasound for Healing Chronic Wounds. Published: 03/26/2012


This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 02/2008

**Revised:** 3/10 (CMS Criteria); 3/17 (add CMS limitations)

**Reviewed:** 2/09, 3/11, 4/12, 4/13, 4/14; 4/15, 4/16, 3/18, 3/19