



Geisinger Health Plan Policies and Procedure Manual

Policy: MP212

Section: Medical Benefit Policy

Subject: Non-contact Low-frequency Ultrasound for Wound Management (MIST Therapy)

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

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

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- 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 of 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.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

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

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

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:

Ennis WJ, Formann 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.

Ennis WJ, Valdes W, Gainer M, Meneses P. Evaluation of clinical effectiveness of MIST ultrasound therapy for the healing of chronic wounds. *Advances in Skin & Wound Care* 2006;19(8):437-446.

Kavros SJ, Schenck EC. Use of Non-contact low-frequency ultrasound in the treatment of chronic foot and leg ulcerations. A 51 patient analysis. *J. Am Podiatric Med Assn.* Mar/Apr 2007;97(2):95-101.

Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with non-contact, low-frequency ultrasound: the Mayo Clinic experience, 2004-2006. *Advances in Skin & Wound Care.* April 2007;20(4):221-226.

Tan, J, Abisi, S, Smith, A, and Burnand, KG. A painless method of ultrasonically assisted debridement of chronic leg ulcers: a pilot study. *Eur J Vasc Endovasc Surg.* 2007;33(2):234-238.

Breuing, KH, Bayer, L, Neuwalder, J, and Orgill, DP. Early experience using low-frequency ultrasound in chronic wounds. *Ann Plast Surg.* 2005;55(2):183-187.

Uhlemann C, Heinig B, Wollina U. Therapeutic ultrasound in lower extremity wound management. *Int J Low Extrem Wounds.* 2003 Sep;2(3):152-7.

Unger PG. Sound evidence: Low-frequency, non-contact, nonthermal ultrasound therapy: A review of the literature. *Ostomy/Wound Management.* Jan. 2008;54(1):57-60.

Gehling, Samies JH. The effect of non-contact, low intensity, low frequency therapeutic ultrasound on lower extremity chronic wound pain: A retrospective chart review. *Ostomy/Wound Management.* Mar. 2007;53(3):44-50.

ECRI Institute. HTAIS Hotline Service. Non-contact, Low-frequency Ultrasound for Healing of Chronic Wounds. Updated 11/21/07.

U.S. Food and Drug Administration 510(k) Premarket Notification Database. Celleration MIST Therapy System Summary of Safety and Effectiveness. No. K032378. Rockville, MD: FDA. June 25, 2004. No. K050129. May 2005. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf.

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

Beheshti A, Shafigh Y, Parsa H, Zangivand AA. Comparison of high-frequency and MIST ultrasound therapy for the healing of venous leg ulcers. *Adv Clin Exp Med.* 2014; 23(6):969-975

Prather JL, Tummel EK, Patel AB, et al. Prospective randomized controlled trial comparing the effects of noncontact low-frequency ultrasound with standard care in healing split-thickness donor sites. *J Am Coll Surg*. 2015;221(2):309-318.

Gibbons GW, Orgill DP, Serena TE, et al. A prospective, randomized, controlled trial comparing the effects of noncontact, low-frequency ultrasound to standard care in healing venous leg ulcers. *Ostomy Wound Manage*. 2015;61(1):16-29.

Chang YR, Perry J, Cross K. Low-frequency ultrasound debridement in chronic wound healing: a systematic review of current evidence. *Plast Surg* 2017; 25(1):21-26.

Cullum N, Liu Z. Cullum N, Liu Z. Therapeutic ultrasound for venous leg ulcers. *Cochrane Database of Systematic Reviews* 2017, Issue 5. Art. No.: CD001180

Centers for Medicare & Medicaid services. Novitas L35125 Wound Care A53001 Billing and Coding: Wound Care

Mei L, Zhang Z. Advances in biological application of and research on low-frequency ultrasound. *Ultrasound Med Biol*. 2021 Oct;47(10):2839-2852

Chen H, Yu Z, Liu N, et al. The efficacy of low-frequency ultrasound as an added treatment for chronic wounds: A meta-analysis. *Int Wound J*. 2023; 20(2):448-457.

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, 3/20, 3/21, 3/22, 3/23, 3/24

CMS UM Oversight Committee Approval: 12/23, 5/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.