Medical Coverage Policy | Stationary Ultrasonic Diathermy Devices

EFFECTIVE DATE: 07|01|2023
POLICY LAST REVIEWED: 03|18|2026

OVERVIEW

An ultrasonic diathermy device applies ultrasonic energy to specific body parts at a frequency higher than 20 kilohertz in order to generate deep heat within body tissues for the treatment of certain medical conditions, such as the alleviation of pain, muscle spasms, and joint contractures. Newer portable stationary devices can be self-applied and used at home to deliver diathermy via continuous low-intensity therapeutic ultrasound. Electrodes attached to adhesive bandages are applied to the skin over the desired treatment area. The continuous low-intensity ultrasound unit can provide treatment for several hours.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable.

POLICY STATEMENT

Medicare Advantage Plans

Ultrasonic diathermy devices for the treatment of musculoskeletal pain is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Ultrasonic diathermy devices for the treatment of musculoskeletal pain is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Medicare Advantage Plans and Commercial Products

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage

BACKGROUND

Therapeutic ultrasound is a noninvasive method used to treat a variety of musculoskeletal conditions. Therapeutic ultrasound produces acoustic vibrations of high frequency (≥20 kilohertz) that are outside the range of human hearing. The vibrations generated during therapeutic ultrasound allow the body to generate heat in targeted tissues that are high in collagen (muscles, tendons, ligaments, etc); this is referred to as ultrasound/ultrasonic diathermy. The increased vibrations and heat to the affected areas simulate soft tissue injury repair and pain relief.

Conventionally, high-frequency/high-intensity therapeutic ultrasound is provided in a clinic setting with an average length of treatment ranging from 5 to 10 minutes per session. In this setting, the ultrasound is transmitted through a wand that is applied to the skin with gentle, circular movements. A hypo-allergenic gel aids in the transmission of ultrasonic energy and prevents overheating at the surface of the applicator.

It is important to note that individuals with implanted metal devices, including pacemakers, prostheses, and intrauterine devices, are at risk of serious injury if they undergo diathermy. Furthermore, patients with certain medical conditions, including cancer and others, may not be appropriate candidates for diathermy.

Ultrasonic Diathermy Devices

Newer portable/wearable, stationary devices can be used at home to deliver diathermy via continuous low-intensity therapeutic ultrasound. Electrodes attached to adhesive bandages are self-applied to the skin over the desired treatment area. This type of treatment may also be referred to as sustained acoustic medicine. Similar to conventional high-frequency/high-intensity therapeutic ultrasound, a high-frequency/low-intensity ultrasonic diathermy device applies ultrasonic energy to specific body parts in order to generate deep heat within body tissues for the treatment of certain medical conditions, such as the alleviation of pain, muscle spasms, and joint contractures. The continuous low-intensity ultrasound device provides treatment for several hours.

Several stationary ultrasonic diathermy devices have been granted 510(k) clearance by the United States Food and Drug Administration (FDA) including Manasport™ (ManaMed, Inc., Las Vegas, NV), Sustained Acoustic Medicine (sam®) (ZetrOZ™, Inc., Trumbull, CT), PainShield™ MD (NanoVibronix Inc., Elmsford, NY) and Ultrasound Stimulator (Jkh USA, Irvine, CA). The intended use of these devices is to supply ultrasound "to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, muscle spasms, joint contractures, and increase local circulation."

For individuals with musculoskeletal pain treated with stationary ultrasonic diathermy devices, the evidence includes a meta-analysis and 3 randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The meta-analysis included 13 studies of participants with musculoskeletal injuries divided into 3 treatment areas: upper shoulder, neck, and back; knee joint; and soft tissue injuries of the musculoskeletal system. The following clinical outcomes were evaluated: pain, function, and diathermy. The meta-analysis demonstrated that therapy with a Sustained Acoustic Medicine (SAM) device reduced pain, improved overall health quality, and generated deep therapeutic heat. In 2 RCTs that are also included in the meta-analysis, treatment with a SAM device for 4 hours daily for 4 to 6 weeks improved pain scores in individuals with upper trapezius myofascial pain and mild to moderate knee osteoarthritis with moderate to severe associated pain. An additional RCT reported that treatment with a SAM device for 4 hours daily for 8 weeks demonstrated improvements in pain scores in individuals with chronic lower back pain. Limitations of the available data include heterogeneity in treatment areas, treatment implementation, and clinical outcomes, as well as sample sizes and short follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

K1004 Low frequency ultrasonic diathermy treatment device for home use

K1036 Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month

RELATED POLICIES

None

PUBLISHED

Provider Update, May 2026
Provider Update, May 2025
Provider Update, March 2024
Provider Update, May 2023

REFERENCES

1. U.S. Food and Drug Administration. Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-and-premarket-notification-510k-submissions-ultrasonic-diathermy-devices. Updated February 21, 2023. Accessed November 25, 2025.
2. Matthews MJ, Stretanski MF. Ultrasound Therapy. In: StatPearls [Internet]. StatPearls Publishing; 2023.

3. Uddin SMZ, Komatsu DE, Motyka T, et al. Low-Intensity Continuous Ultrasound Therapies—A Systematic Review of Current State-of-the-Art and Future Perspectives. J Clin Med. Jun 18 2021;10(12). PMID 34207333
4. U.S. Department of Health and Human Services. Pain management best practices. May 2019. https://www.hhs.gov/sites/default/files/pain-mgmt-best-practices-draft-final-report-05062019.pdf. Accessed December 1, 2025.
5. Winkler SL, Urbisci AE, Best TM. Sustained acoustic medicine for the treatment of musculoskeletal injuries: a systematic review and meta-analysis. BMC Sports Sci Med Rehabil. Dec 18 2021; 13(1): 159.PMID 34922606
6. Lewis GK, Langer MD, Henderson CR, et al. Design and evaluation of a wearable self-applied therapeutic ultrasound device for chronic myofascial pain. Ultrasound Med Biol. Aug 2013; 39(8): 1429-39. PMID 23743101
7. Petterson S, Plancher K, Klyve D, et al. Low-Intensity Continuous Ultrasound for the Symptomatic Treatment of Upper Shoulder and Neck Pain: A Randomized, Double-Blind Placebo-Controlled Clinical Trial. J Pain Res. 2020; 13: 1277-1287. PMID 32606899
8. Langer MD, Lewis GK. Sustained Acoustic Medicine: A Novel Long Duration Approach to Biomodulation Utilizing Low Intensity Therapeutic Ultrasound. Proc SPIE Int Soc Opt Eng. May 2015; 9467. PMID30078928
9. Draper DO, Klyve D, Ortiz R, et al. Effect of low-intensity long-duration ultrasound on the symptomatic relief of knee osteoarthritis: a randomized, placebo-controlled double-blind study. J Orthop Surg Res. Oct 16 2018; 13(1): 257. PMID 30326947
10. Rigby JH, Taggart RM, Stratton KL, et al. Intramuscular Heating Characteristics of Multihour Low-Intensity Therapeutic Ultrasound. J Athl Train. Nov 2015; 50(11): 1158-64. PMID 26509683
11. Langer MD, Byrne HK, Henry T, et al. The effect of low intensity wear-able ultrasound on blood lactate and muscle performance after high intensity resistance exercise. J Exerc Physiol. 2017;20(4):132-146.
12. Ortiz R, Motyka T, Petterson S, et al. Sustained acoustic medicine treatment of discogenic chronic low back pain: A randomized, multisite, double-blind, placebo-controlled trial. J Back Musculoskelet Rehabil. 2024; 37(5): 1321-1332. PMID 38905030

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.