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PHARMACY / MEDICAL POLICY – 7.01.174

Stationary Ultrasonic Diathermy Devices

BCBSA Ref. Policy:	7.01.174	
Effective Date:	Apr. 1, 2026	RELATED MEDICAL POLICIES:
Last Revised:	Mar. 9, 2026	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Musculoskeletal conditions affect the bones, the muscles, and tissues that hold bones together. These include tendons, ligaments, joints, and cartilage. Types of musculoskeletal problems can include pain, muscle spasms, and problems with movement caused by tissue damage near a joint. The goal of treatment for these conditions is to relieve pain and repair tissues. One way this can be done is with therapeutic ultrasound in a medical office. A wand is moved over the skin to apply sound waves to the body that can't be heard by the human ear. Another treatment method is ultrasonic diathermy. It uses vibrations and heat that move more deeply into tissues in specific areas of the body. Portable or wearable ultrasonic diathermy devices allow this type of treatment at home. The use of ultrasonic diathermy devices to treat musculoskeletal pain is unproven (investigational). More studies are needed to see if this type of treatment improves health outcomes.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Investigational
Ultrasonic diathermy devices	**Ultrasonic diathermy devices for the treatment of musculoskeletal pain are considered investigational.**

Coding

Code	Description
HCPCS	
K1004	Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories
K1036	Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Individuals with certain medical conditions may not be appropriate candidates for diathermy, including but not limited to those:

- With an implanted medical device (pacemaker, deep brain stimulation device, etc.)
- With a healing fracture in the area to be treated
- With a malignancy in the area to be treated
- Who are pregnant

Benefit Application

Ultrasonic diathermy may be offered as part of a comprehensive program in pain management as offered by pain management centers.

Evidence Review

Description

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.

Background

Therapeutic Ultrasound

Therapeutic ultrasound is a noninvasive method used to treat a variety of musculoskeletal conditions.[1] Therapeutic ultrasound produces acoustic vibrations of high frequency (≥20 kilohertz) that are outside the range of human hearing.[2] 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.[1,2] 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.[1] Furthermore, individuals 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.[3] 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.

Summary of Evidence

For individuals with musculoskeletal pain treated with stationary ultrasonic diathermy devices, the evidence includes a meta-analysis and three 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 three 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 two RCTs that are also included in the meta-analysis, treatment with a SAM device for four 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, small sample sizes, and length of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06257537	Sustained Acoustic Medicine for Symptomatic Treatment of Knee Pain Related to Osteoarthritis	300	Feb 2026
NCT05883241[a]	Sustained Acoustic Medicine (SAM) for Symptomatic Treatment of Pain Related to Bone Fracture	90	Feb 2026
Unpublished			
NCT05882812[a]	Sustained Acoustic Medicine (SAM) for Symptomatic Treatment of Knee Pain Related to Osteoarthritis	200	Feb 2024
NCT05050448[a]	Comparative Usability Evaluation of Sustained Acoustic Medicine (SAM) Devices and Topical Gel for Knee Pain Related to Osteoarthritis	60	Dec 2022
NCT05254574[a]	Sustained Acoustic Medicine for Knee Osteoarthritis Pain	90 (30 actual)	Jan 2023

NCT: National Clinical Trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines that discuss the role of stationary ultrasonic diathermy devices in individuals with musculoskeletal pain were identified.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Several stationary ultrasonic diathermy devices have been granted 510(k) clearance by the US Food and Drug Administration (FDA) including Manasport (ManaMed, Inc., Las Vegas, NV), Sustained Acoustic Medicine (SAM) (ZetrOZ, Inc., Trumbull, CT), and 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."

FDA product code: PFW

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 February 11, 2026.
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/pmtf-final-report-2019-05-23.pdf**. Accessed February 11, 2026.
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. PMID 30078928

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

History

Date	Comments
04/01/22	New policy, approved March 14, 2023. Policy created with literature review through October 24, 2022. Ultrasonic Diathermy Devices for the treatment of musculoskeletal pain are considered investigational.
10/01/23	Coding update. Added new HCPCS code K1036.
04/01/24	Annual Review, approved March 11, 2024. Policy updated with literature review through December 29, 2023; no references added. Policy statements unchanged.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through November 19, 2023; reference added. Policy statements unchanged.
04/01/26	Annual Review, approved March 9, 2026. Policy updated with literature review through December 1, 2025; no references added. Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member

benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.