



Medical Policy

Stationary Ultrasonic Diathermy Devices

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Policy Number: 199

BCBSA Reference Number: 7.01.174 (For Plan internal use only)

NCD/LCD: N/A

Related Policies

Dry Hydrotherapy for chronic pain conditions, [#164](#)

Biofeedback as a Treatment of Chronic Pain, [#210](#)

Policy

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members**

Ultrasonic diathermy devices for the treatment of musculoskeletal pain are considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO BlueSM	This is not a covered service.
Medicare PPO BlueSM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
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

Description

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, 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.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

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.

Summary of Evidence

For individuals with musculoskeletal pain treated with stationary ultrasonic diathermy devices, the evidence includes a meta-analysis and 3 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 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, small sample sizes, and short follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
3/2025	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2023	Clarified coding information.
3/2023	New medical policy describing ongoing investigational indications. Policy was transferred from MP #400 Medical Technology Assessment Noncovered Services.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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 18, 2024.
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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.
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