BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.174 Stationary Ultrasonic Diathermy Devices

Annual Effective Policy Date: April 1, 2024

Original Policy Date: March 2022

Related Policies:

2.01.105 - Dry Hydrotherapy for Chronic Pain Conditions

Stationary Ultrasonic Diathermy Devices

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of stationary ultrasonic diathermy devices improves the net health outcome in individuals with musculoskeletal pain.

POLICY STATEMENT

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

POLICY GUIDELINES

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

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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

FDA REGULATORY STATUS

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), and PainShield™ MD (NanoVibronix Inc., Elmsford, NY). 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

RATIONALE

Summary of Evidence

For individuals with musculoskeletal pain treated with stationary ultrasonic diathermy devices, the evidence includes a meta-analysis and 2 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. Limitations of the available data include heterogeneity in treatment areas, treatment implementation, and clinical outcomes, 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2023	New policy - Add to Pain Management section	Policy created with literature review through October 24, 2022. Ultrasonic Diathermy Devices for the treatment of musculoskeletal pain are considered investigational.
March 2024	Replace policy	Policy updated with literature review through December 29, 2023; no references added. Policy statements unchanged. New policy date corrected from 12/08/2022 to 1/12/2023 in policy history.