Medical Coverage Policy | Stationary Ultrasonic Diathermy Devices

EFFECTIVE DATE: 07|01|2023
POLICY LAST UPDATED: 09|29|2023

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), 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."

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, 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.

CODING

Medicare Advantage Plans and Commercial Products
The following code is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

K1004 Low frequency ultrasonic diathermy treatment device for home use (Text Revision Effective 10/01/2023)

K1036 Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month (New Code Effective 10/01/2023)

RELATED POLICIES

None

PUBLISHED

Provider Update, May 2023

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