Anthem

Medical Policy

Subject: Ultrasonic Diathermy Devices
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Description/Scope

This document addresses the use of ultrasonic diathermy devices. This involves sound waves produced by ultrasound that travel deep into tissue to create therapeutic heat.

Position Statement

Investigational and Not Medically Necessary:

Ultrasonic diathermy devices are considered **investigational and not medically necessary** for all indications.

Rationale

Therapeutic ultrasound is a physical medicine modality used to treat a variety of musculoskeletal conditions. By using an ultrasound device, sound waves are produced that heat deep tissue below the surface of the skin. Ultrasound machines can be large and require individuals to be immobile while being used in an office or facility setting. Newer technology now has enabled the miniaturization of ultrasound, providing a portable, wearable bioelectronic device that can be used at home. These new devices can deliver diathermy via low intensity therapeutic ultrasound using electrodes attached to adhesive bandages applied to the skin over the desired treatment area. The low intensity ultrasound unit can provide treatment for several hours. This new paradigm in therapeutic ultrasound is such that duration is considered to be as important as frequency and intensity. The concept provides sustained mechanical stimulation of tissue.

A 2015 study by Rigby and colleagues reported on the measurement of intramuscular heating produced by a low intensity therapeutic ultrasound device. There were 20 participants randomly assigned to receive active treatment and 6 participants to receive placebo treatment. The intramuscular temperature was measured using thermocouples inserted at 1.5 and 3 cm depths into muscle. Temperatures were recorded during treatment and 30 minutes after treatment. An intramuscular temperature increase of 1° Celsius was found 10 ± 5 minutes into the treatment. There was an increased temperature of 48° Celsius 80 ± 10 minutes into the treatment. The heating from the low intensity therapeutic ultrasound device was similar to that of traditional therapeutic ultrasound, however further research is needed to understand the clinical and physiologic effects of the low intensity device.

A 2013 randomized, double-blinded, placebo-controlled study by Lewis and colleagues evaluated the effect of low intensity therapeutic ultrasound on chronic trapezius myalgia in 30 participants. The enrolled participants did not discontinue their opioid medication; the authors sought to look at the add-on effect of the low intensity ultrasound in the management of pain. Participants were randomized to active treatment (n=20) and placebo (n=10). The subjects participated in at least 10 1-hour daily ultrasound treatment sessions at the onset of pain caused by trapezius spasm. There was 100% compliance in the 10 treatment sessions. Using a visual analogue scale to measure pain, the majority of participants reported the greatest reduction in pain during the first 3 to 4 days of usage. The average pain reduction in the placebo group was 8%. In the active group, the average pain reduction was 12% in females and 19% in males. Short duration of treatment and lack of follow-up limit this study to ascertain effectiveness and improved net health outcomes.

A randomized, double-blind, placebo-controlled study by Petterson and colleagues (2020) reported on 33 subjects with upper trapezius myofascial pain who were treated with either a low intensity continuous ultrasound device (n=25) or a placebo device (n=8). This study was meant to build off the results of the Lewis 2013 study noted above. Petterson and colleagues sought to determine if 4 hours of low intensity continuous ultrasound for 4 weeks increased pain reduction (compared to the 1-hour treatment in the Lewis study). Outcome measures were the change in pain on the numeric rating scale 0-10 following low intensity continuous ultrasound treatment and subject's overall feeling using the 15-point global rate of change scale. Baseline measurements were taken. Individuals were given a diary and advised to fill out the diaries daily after treatment. Devices were only to be applied if the daily pain rating was greater than or equal to 3/10. The average device use was 2.77 times per week in the ultrasound group and 3.2 times per week in the placebo group. In the ultrasound group, baseline numeric rating scale score was 5.60 points and 2.98 at week 4. In the placebo group, baseline numeric rating scale score was 5.44 and 3.86 at week 4. In the ultrasound treatment group, the global rate of change points were 2.84 compared to 0.46 in the placebo group. All participants completed the 4-week study. No adverse events were reported. This study is limited by the short duration of evaluation. Furthermore, while the study is described as blinded, it is unknown whether participants were able to predict their treatment allocation given that the device's purported mechanism of action is related to heating increases in body tissue, a sensation that would be expected to be detectable by users. Evaluation of improved net health outcomes and lasting efficacy of low intensity continuous ultrasound are still unknown. The authors note that "many myofascial pain conditions are chronic" and "future studies should examine the effectiveness and safety over a longer period of use."

In a 2015 case series, Best and colleagues sought to determine whether long-duration low intensity therapeutic ultrasound using a wearable device could reduce pain and increase function in individuals with elbow or Achilles tendinopathy. The study participants were shown how to apply the low intensity therapeutic ultrasound device in the office and then instructed to apply it to their affected tendon for 4-hour treatment sessions at least 5 times a week for 6 weeks. Pain was assessed using a standardized 11-point numeric rating scale. A dynamometer was used to measure strength. There were 5 participants enrolled with Achilles tendinopathy and all 5 completed the 6-week study. There were 20 participants with elbow tendinopathy, with 11 participants completing the 6-week study. Of the 9 participants who did not complete the study, 2 withdrew due to inconvenience, 2 withdrew due to difficulty operating the device and skin sensitivity, 3 withdrew because they were no longer in pain, 1 was lost to follow-up, and 1 was noncompliant with the visit schedules. The reported baseline average pain rating was 5.29 ± 2.49. For those with elbow tendinopathy who completed the full 6-week study, 62.5% reported at least a 50% decrease in pain and had an average 3.94 ± 2.15 point decrease from baseline. The baseline grip strength in the injured arm was 26.88 ± 9.89 kilogram force (kgf). There was a 2.83 ± 5.52 kg improvement in grip strength over the first 2 weeks. Those with Achilles tendinopathy reported a baseline "worst" pain in the preceding week to be moderate to severe (range: 6–10 on 11-point numeric rating scale). From week 2 to week 6, the self-reported "worst" level of pain decreased from 8.2 at baseline to 2.4. Dynamometer showed an improvement in exerted force of the affected leg with treatment, particularly from baseline to week 4, however statistical analysis on the pain and strength data were not performed due to the limited

sample size. This study has limitations including the high drop-out rate and lack of sham control. The findings would not be generalizable to all types of tendinopathy since only the elbow and Achilles were included in this study. Larger, randomized studies are necessary to effectively evaluate the efficacy of the device.

Langer and colleagues (2014) describe two pilot studies for individuals with osteoarthritis of the knee. In the first study, 12 participants used the low intensity therapeutic ultrasound for a period of 12 to 60 days. The device was used daily for 4 hours. Pain scores were reported on a 0-10 visual analogue scale. Participants reported a decrease in pain between 2 and 4 points. The second study was a placebo-controlled, double-blind clinical trial. Subjects were enrolled if they had mild to moderate knee osteoarthritis, were between 35-80 years of age, and reported a frequent pain score of 3 to 7 on the visual analogue scale during the week preceding enrollment. There were 7 participants enrolled in the pilot phase, with 3 participants receiving placebo and 4 participants receiving low intensity therapeutic ultrasound. Study duration was 6 weeks in which 6 participants wore the device. The ultrasound device was applied for 4 hours each morning. The average pain score decrease seen in the active group was 1.3 ± 1.5, while the placebo group observed an average decrease of 1.5 ± 1.9. The authors note difficulty in the data analysis in that pain scores were not constantly reported by some of the subjects. One participant reported minor skin irritation due to the bandage adhesive, and discontinued treatment after 4 weeks. No adverse effects due to the ultrasound therapy were noted. While pain reduction was observed, lack of placebo control in the first study makes differences difficult to substantiate. In the second study, it should be noted that pain reduction was also seen in the placebo group as well as the treatment group. A lack of follow-up for duration of pain relief makes it difficult to ascertain effectiveness of treatment.

A 2018 prospective, randomized, double-blind, placebo-controlled study by Draper and colleagues examined whether low intensity therapeutic ultrasound was effective in treating pain and improving function in subjects with osteoarthritis of the knee. There were 90 subjects enrolled; 55 received active treatment and 35 received placebo. Low intensity therapeutic ultrasound was used for 4 hours per day daily for 6 weeks. Using a numeric rating scale, primary outcome was change in pain intensity from baseline and after 6 weeks. Using the Western Ontario and McMaster Universities scale (WOMAC) questionnaire to assess pain, stiffness, and function, secondary outcome of functional change was measured from baseline and after 6 weeks. There were 51 participants in the active group and 33 participants in the placebo group that completed the 6-week study. Of the 6 subjects who did not complete the study, 3 dropped out due to damage to the device, 2 had skin irritation, and 1 was lost to follow-up. After 6 weeks of treatment, pain was reduced by 1.96 points in the active group and 0.85 points in the placebo group. The WOMAC score was improved by 505 points in the active group and 311 points in the placebo group after 6 weeks of treatment. While the study showed reduced pain and improved joint function in those with moderate to severe osteoarthritis knee pain, longer follow-up times are necessary to determine efficacy and duration of symptom relief.

A 2020 prospective study by Madzia and colleagues described the efficacy of low intensity therapeutic ultrasound combined with 1% topical diclofenac coupling patch for treatment of symptomatic knee pain from osteoarthritis. Results were from 32 participants enrolled. All participants reported moderate to severe knee pain, had mild to moderate osteoarthritis (Kellgren-Lawrence grade II-III score) confirmed by x-ray, had baseline day numerical rate score between 3 and 7, had no history of intraarticular injections to the knee in the previous 6 months, no trauma to the knee, and no implants or surgery to the treated knee. Duration of treatment was 7 days, using the device 4 hours per day. Pain measurements before and after daily treatment were recorded by the participants. Functional measurements were taken during office visits. For the entire participant cohort, pretreatment numeric rating scale for baseline pain was 4.06 ± 2.39. At 7 days following treatment, pain decreased to 2.00 ± 2.41. The participants who had a greater than 1-point reduction in pain following the first treatment were considered rapid responders. For the rapid responders, baseline numeric rating scale score was 4.26 ± 2.41 and 1.30 ± 1.5 after 7 days of treatment. A secondary outcome of WOMAC was recorded at baseline and 7 days after treatment. For the entire participant cohort, WOMAC pain score improved by 66 points, stiffness score improved by 41 points, and functionality score improved by 244 points. In the rapid responder group, pain score improved by 92 points, stiffness score improved by 55 points, and functionality score improved by 364 points. There were no reported adverse events or study-related complications reported. While the participants in this study showed improvement in pain and function from osteoarthritic knee pain, the short duration of treatment (7 days) and lack of control group makes it difficult to generalize the findings and ascertain extended duration of symptom relief.

In a 2018 literature review by Daniels and colleagues, the authors sought to determine the effect low intensity therapeutic ultrasound has on measurable outcomes. Included were the Best, 2015 study; Lewis 2013 study; and Rigby 2015 study (all discussed above). While all three of the studies showed a positive effect for the measured outcomes, based on inconsistency in the measured outcomes amongst the studies the authors conclude there is insufficient evidence to support the use of low intensity therapeutic ultrasound for increasing temperature, decreasing pain, and increasing function. One of the studies had a lack of a control group, there were different measured outcomes among the studies, and there were variations of treatment implementation which does not allow for generalization of the results. Further research is necessary to determine long-term effects of the use of low intensity therapeutic ultrasound for the treatment of pain.

A 2021 systematic review and meta-analysis by Winkler and colleagues summarized the clinical effects of low intensity, continuous ultrasound on musculoskeletal injuries. Included were 13 studies which looked at diathermy (tissue heating), functional outcomes, quality of life, reduction in pain, and safety of the intervention. The included studies were divided into three treatment areas: 1) upper shoulder, neck and back (3 studies); 2) knee joint (4 studies), 3) soft tissue injuries of the musculoskeletal system (6 studies). The upper neck, back and shoulder studies included 2 randomized controlled trials and 1 prospective non-randomized study. Two of the studies compared the intervention (low intensity, continuous ultrasound) to a placebo control. One study reported on intervention in a case cohort. Study characteristics and evaluations varied among the 3 studies. Two studies used intervention during heightened or breakthrough pain, but only daily during the third study. Two of the studies used intervention for 2 weeks, whereas 1 study used it for 4 weeks. Outcomes were measured by visual analog scale, numeric rating scale, or global rate of change scale. All 3 studies for upper neck, back and shoulder pain reported improvement in pain and overall health improvement. There were 4 studies pertaining to the knee joint, including 2 randomized controlled trials, 1 prospective non-randomized trial, and 2 combined pilot studies. Comparison of intervention (low intensity, continuous ultrasound) to placebo occurred in 3 of the 4 studies for knee joints. All participants had chronic knee osteoarthritis. In all of the studies, intervention was applied for 4 hours per day. One study applied intervention for 1 week and 3 studies applied intervention for 6 weeks. Outcomes were measured by visual analog scale, numeric rating scale, and WOMAC. The participants on average reported improvement in pain. However, WOMAC scores were not sufficiently available to conduct an analysis. There were 6 studies analyzed for self-treatment and soft tissue injuries (2 randomized controlled trials, 3 clinical case series, and 1 safety and usability study). Two of the studies compared intervention (low intensity, continuous ultrasound) to a placebo control group. Two studies reported on deep tissue heating on various locations on the body and 2 studies focused on healing soft-tissue injuries to musculoskeletal tissue. The 2 randomized trials reported clear objectives and described the outcomes and findings. Three of the studies did not have specific controls due to study design or purpose. Numeric scale rating was used in 2 of these studies. Measures of functional improvement were applied in 3 studies. One study looked at measurement of lactic acid clearance. One study included usability and treatment satisfaction. The authors reported the majority of participants successfully applied the device and found it easy to use. Overall, the participants described reduction in pain following intervention. Follow-up was short-term and there was no information about functional outcomes or improvement in net health outcomes. The included studies had different outcomes along with variations of treatment implementation. Lack of information that low intensity ultrasound is as beneficial as any

established alternative makes it difficult to generalize these findings.

Background/Overview

Several ultrasonic diathermy devices have been granted 510(k) clearance by the United States Food and Drug Administration (FDA) including the ZTX Ultrasonic Diathermy device (ZetrOZ™, Inc., Trumbull, CT) and the 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, 2013).

Definitions

Ultrasound: A screening or diagnostic technique in which very high frequency sound waves are passed into the body, and the reflected echoes are detected and analyzed to build a picture of the internal organs.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS

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
E1399	Durable medical equipment, miscellaneous [when specified as an ultrasonic diathermy treatment device for home use]

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Best TM, Moore B, Jarit P, et al. Sustained acoustic medicine: wearable, long duration ultrasonic therapy for the treatment of tendinopathy. Phys Sportsmed. 2015; 43(4):366-374.
2. Daniels S, Santiago G, Cuchna J, Van Lunen B. The effects of low-intensity therapeutic ultrasound on measurable outcomes: a critically appraised topic. J Sport Rehabil. 2018; 27(4):390-395.
3. Draper DO, Klyve D, Ortiz R, Best TM. 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. 2018; 13(1):257.
4. Langer MD, Lewis GK Jr. Sustained acoustic medicine: a novel long duration approach to biomodulation utilizing low intensity therapeutic ultrasound. Proc SPIE Int Soc Opt Eng. 2015; 9467. pii: 94670I.
5. Langer MD, Levine V, Taggart R, et al. Pilot clinical studies of long duration, low intensity therapeutic ultrasound for osteoarthritis. Proc IEEE Annu Northeast Bioeng Conf. 2014. pii: 14789673.
6. Lewis GK Jr, Langer MD, Henderson CR Jr, Ortiz R. Design and evaluation of a wearable self-applied therapeutic ultrasound device for chronic myofascial pain. Ultrasound Med Biol. 2013; 39(8):1429-1439.
7. Madzia A, Agrawal C, Jarit P, et al. Sustained acoustic medicine combined with a diclofenac ultrasound coupling patch for the rapid symptomatic relief of knee osteoarthritis: multi-site clinical efficacy study. Open Orthop J. 2020; 14:176-185.
8. 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.
9. Rigby JH, Taggart RM, Stratton KL, et al. Intramuscular heating characteristics of multihour low-intensity therapeutic ultrasound. J Athl Train. 2015; 50(11):1158-1164.
10. Winkler SL, Urbisci AE, Best TM, et al. Sustained acoustic medicine for the treatment of musculoskeletal injuries: a systematic review and meta-analysis. BMC Sports Sci Med Rehabil. 2021; 13(1):159.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. PainShield MD Summary of Safety and Effectiveness. No. K081075. Rockville, MD: FDA. April 22, 2008. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf8/K081075.pdf. Accessed on June 22, 20232.
2. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. ZTX Ultrasonic Diathermy Summary of Safety and Effectiveness. No. K130978. Rockville, MD: FDA. December 6, 2013. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf13/K130978.pdf, Accessed on June 22, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action

Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section. Updated Coding section with 10/01/2023 HCPCS changes, added K1036 and revised descriptor for K1004.
Revised	08/11/2022	MPTAC review. Title change to Ultrasonic Diathermy Devices. Position statement revised to reflect title change. Updated Description/Scope, Rationale, Background/Overview, References, and Index sections. Updated Coding section; added E1399 NOC code.
Reviewed	02/17/2022	MPTAC review. Updated Description/Scope, Rationale, Background/Overview, References, and Index sections.
Revised	02/11/2021	MPTAC review. Title change to Low Intensity Therapeutic Ultrasound. Updated Description/Scope, Rationale and References sections.
New	02/20/2020	MPTAC review. Initial document development.

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Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.