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Medical Policy

Subject:	**Low Intensity Therapeutic Ultrasound for the Treatment of Pain**		
Document#:	**DME.00041**	**Publish Date:**	**04/15/2020**
Status:	**New**	**Last Review Date:**	**02/20/2020**

Description/Scope

This document addresses the use of a low intensity therapeutic ultrasound device for the treatment of pain.

Position Statement

Investigational and Not Medically Necessary:

The use of a low intensity therapeutic ultrasound device is 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. The ultrasound used is typically high intensity and is applied over a short period of time. Ultrasound machines are frequently 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 deliver 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 and is called sustained acoustic medicine (SAM).

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

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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, lack of follow-up and small group sizes limit this study to ascertain safety and effectiveness.

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

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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 small sample size, 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) describes two pilot studies for individuals with osteoarthritis (OA) 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 OA, 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, the small sample size and lack of placebo control in the first study make 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. Small group sizes and a lack of follow-up for duration of pain relief make 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 McMaster Osteoarthritis 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

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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, larger sample sizes are necessary to ascertain safety and efficacy. Longer follow-up should be completed to determine duration of relief of symptoms.

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. The studies had small group sizes, one 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.

Background/Overview

In 2013 the United States Food and Drug Administration granted 510(k) clearance regarding the ZTX Ultrasonic Diathermy device (ZetrOZ, Inc, Trumbull, CT). The intended use 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

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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 code, 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, includes all components and accessories**
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. **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.**

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Government Agency, Medical Society, and Other Authoritative Publications:

1. **U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. ZTX Ultrasonic Diathermy Summary of Safety and Effectiveness. No. K K130978. Rockville, MD: FDA. December 6, 2013. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf13/K130978.pdf, Accessed on January 14, 2020.**

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
New	02/20/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

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