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Stationary Ultrasonic Diathermy Devices

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

Ultrasonic diathermy devices **are considered experimental, investigational and/or unproven** for all indications, including but not limited to the treatment of musculoskeletal pain.

Policy Guidelines

None.

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.

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

This medical policy was created with a search of the PubMed database. The most recent literature update was performed through October 24, 2022.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Musculoskeletal Pain

Clinical Context and Therapy Purpose

The purpose of stationary ultrasonic diathermy devices in patients who have musculoskeletal pain is to provide a treatment option that is an alternative to or an improvement on existing therapies. For chronic pain management, a multimodal, multidisciplinary approach that is individualized to the patient is recommended. (4) A multimodal approach to pain management consists of using treatments (i.e., nonpharmacologic and pharmacologic) from 1 or more clinical disciplines incorporated into an overall treatment plan. This allows for different avenues to address the pain condition, often enabling a synergistic approach that impacts various aspects of pain, including functionality. The efficacy of such a coordinated, integrated approach has been documented to reduce pain severity, improve mood and overall quality of life, and increase function.

The following PICO was used to select literature to inform this policy.

Populations
The relevant populations of interest are individuals with musculoskeletal pain.

Interventions
The therapy being considered is stationary ultrasonic diathermy devices. This type of treatment may also be referred to as low-intensity continuous ultrasound or sustained acoustic medicine (SAM).

Comparators
The following therapies are currently being used to treat musculoskeletal pain: pharmacologic and nonpharmacologic therapy.

Outcomes
The general outcomes of interest are reductions in symptoms, functional outcomes, quality of life, medication usage, and health resource utilization.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
Systematic reviews evaluating the clinical effects of stationary ultrasonic diathermy devices on musculoskeletal conditions are summarized in Tables 1 and 2. A crosswalk of studies included in the meta-analyses is provided in Table 3.

Winkler et al. (2022) summarized the clinical effects of the sustained acoustic medicine (SAM®) device versus placebo control in individuals with musculoskeletal injuries. (5) The analysis included 13 studies divided into 3 treatment areas: upper shoulder, neck, and back (3 studies); knee joint (4 studies); and soft tissue injuries of the musculoskeletal system (6 studies). The following clinical outcomes were evaluated: pain, function, and diathermy. Overall, therapy with a SAM device reduced pain, improved overall health quality, and generated deep therapeutic heat. Limitations of this analysis included heterogeneity in treatment area, therapy implementation, and clinical outcomes, small sample sizes, and short follow-up.

Table 1. SR & M-A Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Winkler et al. (2022) (5)	2011 to 2021	13	Participants receiving treatment with a SAM device for upper shoulder, neck, and back pain, chronic knee osteoarthritis symptoms, and soft tissue injuries of the musculoskeletal system	372 (5 to 90)	Upper neck, back, and shoulder: 2 RCTs and 1 observational Knee osteoarthritis symptoms: 2 RCTs, 2 combined pilot studies, 1 observational Soft tissue injuries of the musculoskeletal system: 2 RCTs and 4 observational	1 to 6 weeks

M-A: meta-analysis; RCT: randomized controlled trial; SAM: sustained acoustic medicine; SR: systematic review.

Table 2. SR & M-A Results

Study	Pain	Health quality	Tissue heating
Winkler et al. (2022) (5)			
Total N	Upper neck, back, and shoulder conditions: n=68 Knee osteoarthritis pain: n=188	Upper neck, back, and shoulder conditions: n=68	Soft tissue injuries of the musculoskeletal system: n=114
Pooled effect with SAM (95% CI)	Upper neck, back, and shoulder conditions: SMD, 0.82 (0.25 to 1.40) Knee osteoarthritis pain: SMD, 0.92 (0.55 to 1.29)	SMD, 1.40 (0.79 to 2.02)	SMD, 5.49 (4.59 to 6.39)
I^2 (p)	Upper neck, back, and shoulder conditions: 0% (.005) Knee osteoarthritis pain: 93% (<.001)	25% (<.001)	97% (<.001)

M-A: meta-analysis; SR: systematic; CI: confidence interval; SAM: sustained acoustic medicine; SMD: standard mean difference.

Table 3. Comparison of Trials/Studies Included in SR & M-A

Study	Winkler et al. (2022) (5)
Best et al. (2015)	●
Draper et al. (2018)	●
Draper et al. (2020)	●
Langer et al. (2014)	●
Langer et al. (2015)	●
Langer et al. (2017)	●
Langer et al. (2018)	●
Lewis et al. (2013)	●
Madzia et al. (2020)	●
Petterson et al. (2020)	●
Rigby et al. (2015)	●
Taggart et al. (2014)	●

M-A: meta-analysis; SR: systematic.

Randomized Controlled Trials

There are no RCTs published after the Winkler et al. (2022) systematic review evaluating the clinical effects of stationary ultrasonic diathermy devices on musculoskeletal pain.

Six RCTs were included in the Winkler review (Lewis et al. [2013], Petterson et al. [2020], Langer et al. [2015], Draper et al. [2018], Rigby et al. [2015], and Langer et al. [2017]), of which 3 were rated as "excellent quality" using the Downs and Black checklist for quality evaluation of RCTs and non-RCTs. (6-11) Two of the 3 studies rated as "excellent quality" are summarized in Tables 4 and 5 (Petterson et al. [2020] and Draper et al. [2018]). (7, 9) The third study rated as excellent quality (Langer et al. [2017]) was done in healthy individuals and did not evaluate relevant clinical outcomes. (11)

Table 4. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
Petterson et al. (2020) (7)	US	NR	June 2014 to Sept 2015	Individuals with upper trapezius myofascial pain (NRS ≥3) and restricted mobility Majority women (>63%) enrolled; race/ethnicity not reported	SAM therapy over 4 hours (18,720 Joule treatment) for 4 weeks (n=25)	Sham therapy (n=8)

Draper et al. (2018) (9)	US	NR	March 2014 to Jan 2015	Individuals with mild to moderate knee osteoarthritis (Kellgren-Lawrence grade I/II) in one or both knees, with moderate to severe knee osteoarthritis pain (NRS 3 to 7) Approximately equal proportions of men (47%) and women (53%) enrolled; 88% of participants were non-Hispanic White race	SAM therapy over 4 hours (18,720 Joule treatment) for 6 weeks (n=55)	Sham therapy (n=35)

NR: not reported; NRS: numeric rating scale; RCT: randomized controlled trial; SAM: sustained acoustic medicine.

Table 5. Summary of Key RCT Results

Study	NRS change	GROC change	WOMAC change
Petterson et al. (2020) (7)			
N	33	33	
SAM	Baseline to Week 4: -2.61 (-3.34 to -1.90); <.001	Overall, 2.84	
Control	Baseline to Week 4: -1.58 (-3.40 to 0.24);.087	Overall, 0.46	
Between group difference (95% CI); p-value	Mean difference, -1.03 (-1.71 to -0.358);.003	Mean change, 2.39 (1.99 to 2.77); <.001	
Draper et al. (2018) (9)			
N	82		82
SAM	Baseline to Week 6: -1.96 (-2.92 to 1.0); <.001		Baseline to Week 6: -107.3 (-147.6 to -66.8); <.0001

Control	Baseline to Week 6: -0.85 (-1.93 to 0.26);.13		Baseline to Week 6: −60.8 (-100.3 to -21.2);.003
Between-group difference (95% CI); p-value.	Mean difference, -1.11 (-2.20 to -0.02);.04		Mean difference: -46.5 (-85.6 to -7.4);.020

CI: confidence interval; GROC: Global Rate of Change Score (range, 0 [no change in pain] to 15); NRS: numeric rating scale (range, 0 [no pain] to 10); RCT: randomized controlled trial; SAM: sustained acoustic medicine; WOMAC: Western Ontario McMaster Osteoarthritis Questionnaire.

The purpose of the study limitations tables (see Tables 6 and 7) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Petterson et al. (2020) (7)	5. Participants racial/ethnic background was not described			1,7. Only short-term pain outcomes measured; participants self-reported pain	1,2. Short follow-up (4 weeks)
Draper et al. (2018) (9)	4. Enrolled populations do not reflect relevant diversity (88% White participants)	5. Participants were permitted to continue use of pain medications	5. Participants were permitted to continue use of pain medications	1,7. Only short-term pain outcomes measured; participants self-reported pain	1,2. Short follow-up (6 weeks)

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated

surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Petterson et al. (2020) (7)						
Draper et al. (2018) (9)					1. Power calculations not reported	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

<u>Section Summary: Musculoskeletal Pain</u>

A meta-analysis evaluated the clinical effects of a SAM device versus control for patients with musculoskeletal injuries. The analysis included 13 studies divided into 3 treatment areas: upper shoulder, neck, and back (3 studies, including 2 RCTs); knee joint (4 studies, including 2 RCTs); and soft tissue injuries of the musculoskeletal system (6 studies, including 2 RCTs). The following clinical outcomes were evaluated: pain, function, and diathermy. Overall, therapy with a SAM device reduced pain, improved overall health quality, and generated deep therapeutic heat. In 2 RCTs included in the meta-analysis, treatment with a SAM device for 4 hours daily for 4 to 6 weeks demonstrated improvements in 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.

Practice Guidelines and Position Statements

No guidelines that discuss the role of stationary ultrasonic diathermy devices in individuals with musculoskeletal pain were identified.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 8.

Table 8. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05050448[a]	Comparative Usability Evaluation of Sustained Acoustic Medicine (SAM) Devices and Topical Gel for Knee Pain Related to Osteoarthritis	60	Sep 2022
NCT05254574[a]	Sustained Acoustic Medicine for Knee Osteoarthritis Pain	90	Jan 2023
Unpublished			
NCT04177537	Efficacy of SAM Sport as an Addon to Traditional Therapy in Treating Sports-related Injuries	15	Oct 2015
NCT05254470	Customer Survey of Athletic Trainers Who Utilize SAM Ultrasound Device in Routine Care	135	Feb 2022

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	K1004, K1036

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

References

1. U. S. Food and Drug Administration. Ultrasonic Therapy Product or Ultrasonic Diathermy. Updated September 28, 2020. Available at <https://www.accessdata.fda.gov> (accessed October 26, 2022).
2. Matthews MJ, Stretanski MF. Ultrasound Therapy. In: StatPearls [Internet]. StatPearls Publishing; 2022.
3. Uddin SMZ, Komatsu DE, Motyka T, et al. Low-intensity continuous ultrasound therapies- A systematic review of current state-of-the-art and future perspectives. J Clin Med. Jun 18 2021; 10(12). PMID 34207333
4. U.S. Department of Health and Human Services. Pain management best practices. May 2019. Available at <https://www.hhs.gov> (accessed October 26, 2022).
5. Winkler SL, Urbisci AE, Best TM. Sustained acoustic medicine for the treatment of musculoskeletal injuries: a systematic review and meta-analysis. BMC Sports Sci Med Rehabil. Dec 18 2021; 13(1):159. PMID 34922606
6. Lewis GK, Langer MD, Henderson CR, et al. Design and evaluation of a wearable self-applied therapeutic ultrasound device for chronic myofascial pain. Ultrasound Med Biol. Aug 2013; 39(8):1429-1439. PMID 23743101
7. 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. PMID 32606899
8. Langer MD, Lewis GK. Sustained acoustic medicine: a novel long duration approach to biomodulation utilizing low intensity therapeutic ultrasound. Proc SPIE Int Soc Opt Eng. May 2015; 9467. PMID 30078928
9. Draper DO, Klyve D, Ortiz R, et al. 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. Oct 16 2018; 13(1):257. PMID 30326947
10. Rigby JH, Taggart RM, Stratton KL, et al. Intramuscular heating characteristics of multihour low-intensity therapeutic ultrasound. J Athl Train. Nov 2015; 50(11):1158-1164. PMID 26509683
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.

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
11/15/2024	Reviewed. No changes.
09/15/2023	New medical document. Ultrasonic diathermy devices are considered experimental, investigational and/or unproven for all indications, including but not limited to the treatment of musculoskeletal pain.