

<b>7.01.174 Stationary Ultrasonic Diathermy Devices</b>	
<b>Original Policy Date:</b> April 1, 2023	<b>Effective Date:</b> March 1, 2024
<b>Section:</b> 7.0 Surgery	<b>Page:</b> Page 1 of 11

**Policy Statement**

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

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

**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

**Coding**

The following HCPCS code is specific for Stationary Ultrasonic Diathermy Devices:

- **K1004:** Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories

**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.

**Related Policies**

- Biofeedback as a Treatment of Chronic Pain
- Dry Hydrotherapy for Chronic Pain Conditions

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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

### Background

#### Therapeutic Ultrasound

Therapeutic ultrasound is a noninvasive method used to treat a variety of musculoskeletal conditions.<sup>1</sup> Therapeutic ultrasound produces acoustic vibrations of high frequency ( $\geq 20$  kilohertz) that are outside the range of human hearing.<sup>2</sup> 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.<sup>1,2</sup> 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.<sup>1</sup> 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.<sup>3</sup> 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.

### Literature Review

Evidence reviews 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## **Musculoskeletal Pain**

### **Clinical Context and Therapy Purpose**

The purpose of stationary ultrasonic diathermy devices in individuals 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 individual is recommended.<sup>4</sup> 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 review.

### ***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 the appendix (Table A1).

Winkler et al (2022) summarized the clinical effects of the sustained acoustic medicine (sam<sup>®</sup>) device versus placebo control in individuals with musculoskeletal injuries.<sup>5</sup> 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) <sup>5</sup>	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) <sup>5</sup>			
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)

Study	Pain	Health quality	Tissue heating
<i>P</i> (p)	Upper neck, back, and shoulder conditions: 0% (.005)  Knee osteoarthritis pain: 93% (<.001)	25% (<.001)	97% (<.001)

CI: confidence interval; SAM: sustained acoustic medicine; SMD: standard mean difference.

### 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.<sup>6,7,8,9,10,11</sup> Two of the 3 studies rated as "excellent quality" are summarized in Tables 3 and 4 (Petterson et al [2020] and Draper et al [2018]).<sup>7,9</sup> The third study rated as excellent quality (Langer et al [2017]) was done in healthy individuals and did not evaluate relevant clinical outcomes.<sup>11</sup>

**Table 3. Summary of Key RCT Characteristics**

Study; Trial	Countries	Sites	Dates	Participants	Interventions
<b>Petterson et al (2020)<sup>7</sup></b>	US	NR	June 2014 to Sept 2015	Individuals with upper trapezius myofascial pain (NRS $\geq 3$ ) 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)
<b>Draper et al (2018)<sup>9</sup></b>	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 4. Summary of Key RCT Results**

Study	NRS change	GROC change	WOMAC change
<b>Petterson et al (2020)<sup>7</sup></b>			
<b>N</b>	33	33	
<b>SAM</b>	Baseline to Week 4: -2.61 (-3.34 to -1.90); <.001	Overall, 2.84	
<b>Control</b>	Baseline to Week 4: -1.58 (-3.40 to 0.24);.087	Overall, 0.46	
<b>Between group difference (95% CI); p-value</b>	Mean difference, -1.03 (-1.71 to -0.358);.003	Mean change, 2.39 (1.99 to 2.77); <.001	
<b>Draper et al (2018)<sup>9</sup></b>			
<b>N</b>	82		82
<b>SAM</b>	Baseline to Week 6: -1.96 (-2.92 to 1.0); <.001		Baseline to Week 6: -107.3 (-147.6 to -66.8); <.0001
<b>Control</b>	Baseline to Week 6: -0.85 (-1.93 to 0.26);.13		Baseline to Week 6: -60.8 (-100.3 to -21.2);.003
<b>Between-group difference (95% CI); p-value</b>	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 5 and 6) 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 5. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
<b>Petterson et al (2020)<sup>7</sup></b>	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)
<b>Draper et al (2018)<sup>9</sup></b>	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.

<sup>a</sup> 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.

<sup>b</sup> 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.

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

<sup>d</sup> 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.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

**Table 6. Study Design and Conduct Limitations**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Petterson et al (2020) <sup>7</sup>						
Draper et al (2018) <sup>9</sup>					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.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

<sup>b</sup> Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

<sup>d</sup> 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.

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

<sup>f</sup> 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.

### Section Summary: Musculoskeletal Pain

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.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 7.

**Table 7. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05050448 <sup>a</sup>	Comparative Usability Evaluation of Sustained Acoustic Medicine (SAM) Devices and Topical Gel for Knee Pain Related to Osteoarthritis	60	Sep 2022
NCT05882812 <sup>a</sup>	Sustained Acoustic Medicine (SAM) for Symptomatic Treatment of Knee Pain Related to Osteoarthritis	120	Dec 2024
NCT05883241 <sup>a</sup>	Sustained Acoustic Medicine (SAM) for Symptomatic Treatment of Pain Related to Bone Fracture	90	Dec 2024
<i>Unpublished</i>			
NCT05254574 <sup>a</sup>	Sustained Acoustic Medicine for Knee Osteoarthritis Pain	90 (30 actual)	Jan 2023

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## Appendix 1

**Table A1. Comparison of Trials/Studies Included in SR & M-A**

Study	Winkler et al (2022) <sup>5</sup>
Best et al (2015)	



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): 1158-64. 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.

### Documentation for Clinical Review

- No records required

### Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	None	
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 <b>(Code effective 10/1/2023)</b>

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/01/2023	New policy.
11/01/2023	Coding update.
03/01/2024	Annual review. No change to policy statement. Literature review updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Stationary Ultrasonic Diathermy Devices 7.01.174</p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Ultrasonic diathermy devices for the treatment of musculoskeletal pain are considered <b>investigational</b>.</li> </ul>	<p>Stationary Ultrasonic Diathermy Devices 7.01.174</p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Ultrasonic diathermy devices for the treatment of musculoskeletal pain are considered <b>investigational</b>.</li> </ul>