Aetna considers the use of phonophoresis experimental and investigational for all indications, including any of the following (not an all-inclusive list):

- Adhesive capsulitis
- Carpal tunnel syndrome
- Epicondylalgia
- Iliotibial band syndrome
- Knee osteoarthritis / knee pain
- Medial tibial stress syndrome
- Myositis ossificans
- Patellofemoral pain syndrome
- Rotator cuff tendinopathy
- Shoulder impingement syndrome
- Sinusitis
- Trapeziometacarpal joint arthritis
- Tuberculous lymphadenitis

Phonophoresis has been used to enhance the absorption of analgesics and anti-inflammatory agents. Controlled clinical trials, however, have failed to demonstrate that phonophoresis
increases the rate or extent of absorption of these agents.

**Background**

Phonophoresis, also known as sonophoresis, has been claimed to enhance the percutaneous absorption of certain pharmacological agents such as anti-inflammatory steroids and local anesthetics from intact skin into the underlying subcutaneous structures by ultrasound, therefore improving their effectiveness. This procedure is commonly used in physical therapy practices. The procedure generally utilizes an ultrasound apparatus that generates frequencies of 0.7 to 1.1 MHz. The ultrasound intensities employed usually range from 1.1 to 3.0 Watts per cm². Both continuous-mode as well as pulse-mode applications were utilized, and most treatments lasted from 5 to 8 mins, with the exception of treatments of larger areas (greater than 36 cm²) requiring more than 8 mins. The exact mechanism enabling drugs to be propelled into the subcutaneous structures is still unclear.

Phonophoresis has been suggested by early studies to enhance the absorption of analgesics and anti-inflammatory agents. More recent, better-controlled studies have consistently failed to demonstrate that phonophoresis increases the rate of absorption or the extent of absorption over placebo. Several reviews stated that more research is needed to ascertain optimal techniques and conditions for safe and efficacious utilization of physical modalities including phonophoresis; and there is a need for additional research to establish clinical effectiveness and determine optimal treatment parameters for the physical agents (e.g., phonophoresis) used most frequently to alleviate pain in hand therapy.

In a randomized study (n = 60) comparing the effectiveness of ibuprofen phonophoresis with conventional ultrasound therapy in patients with knee osteoarthritis, Kozanoglu et al (2003) found that ibuprofen phonophoresis was not superior to conventional ultrasound.

Ellis et al (2007) stated that Iliotibial band friction syndrome
(ITBFS) is a common injury of the lateral aspect of the knee particularly in runners, cyclists and endurance sports. A number of investigators suggested that ITBFS responds well to conservative treatment, however, much of this notion appears anecdotal and is not supported by available evidence. These researchers performed a systematic review of the literature on the conservative treatment of ITBFS. With respect to the management of ITBFS, 4 randomized controlled trials were identified. The interventions examined included the use of non-steroidal anti-inflammatory drugs, deep friction massage, phonophoresis versus immobilization and corticosteroid injection. This review highlighted both the paucity in quality and quantity of research regarding the conservative treatment of ITBFS. There seems limited evidence to suggest that the conservative treatments that have been studied offer any significant benefit in the management of ITBFS. The authors noted that future research will need to re-examine those conservative therapies, which have already been examined, along with others, and will need to be of sufficient quality to enable accurate clinical judgements to be made regarding their use.

In a review on factors that influence the quality and effectiveness of ultrasound and phonophoresis treatment, Goraj-Szczypiorowska and colleagues (2007) noted that although phonophoresis is commonly used among physical therapists, doubts persist as to the relevance and effectiveness of this method. Despite its popularity, the issue of conditions underlying the effectiveness of phonophoresis treatment has still not been adequately addressed. Particular areas of interest include: (i) treatment parameters to be followed in physical therapy, (ii) appropriate dosage forms of drugs to ensure propagation of ultrasound waves, (iii) principles of homoeostasis and other physiological processes that play a decisive role in achieving the biological and therapeutic effects of ultrasound therapy, and (iv) indications and contraindications to this kind of treatment. The dearth of objective research methods and reliable scientific verification does not allow unambiguous determination of the effectiveness of
phonophoresis.

Jewell et al (2009) examined if physical therapy interventions predicted meaningful short-term improvement in 4 measures of physical health, pain, and function for patients diagnosed with adhesive capsulitis. Data were examined from 2,370 patients (mean age of 55.3 years, SD = 12.4; 65 % females, 35 % males) classified into ICD-9 code 726.0 who had completed an episode of outpatient physical therapy. Principal components factor analysis was used to define intervention categories from specific treatments applied during the episode of care. A nested logistic regression model was used to identify intervention categories that predicted a 50 % or greater change in Physical Component Summary-12 (PCS-12), physical function (PF), bodily pain (BP), and hybrid function (HF) scores. None of the patients achieved a 50 % or greater improvement in PCS-12 scores. Improvement in BP scores was more likely in patients who received joint mobility interventions (odds ratio [OR] = 1.35, 95 % confidence interval [CI]: 1.10 to 1.65). Improvement in HF scores was more likely in patients who received exercise interventions (OR = 1.50, 95 % CI: 1.03 to 2.17). Use of iontophoresis, phonophoresis, ultrasound, or massage reduced the likelihood of improvement in these 3 outcome measures by 19 % to 32 %. The authors concluded that these results are consistent with findings from randomized clinical trials that demonstrated the effectiveness of joint mobilization and exercise for patients with adhesive capsulitis. However, ultrasound, massage, iontophoresis, and phonophoresis reduced the likelihood of a favorable outcome, which suggests that use of these modalities should be discouraged.

An UpToDate review on “Rotator cuff tendinopathy” (Simons and Kruse, 2014) lists electrical stimulation, iontophoresis, laser, phonophoresis, and therapeutic ultrasound as adjunct therapies. Moreover, it states that “No clear evidence exists to support the use of the modalities listed here and we do not routinely use them in the care of our patients”.

Jain et al (2010) hypothesized that transdermal steroid delivery
would yield short-term improvements for trapezio-metacarpal (TM) joint arthritis, although these improvements would not persist at later follow-up (3 or 6 months). A total of 84 consecutive TM joints in 62 patients presenting to an orthopedic hand surgeon were randomized to receive either steroid delivery by iontophoresis or phonophoresis or placebo delivery via iontophoresis or phonophoresis. The researchers and patients were blinded as to the treatment assignment. Patients were evaluated before treatment and at 3 follow-up appointments. Subjects were assessed via the Michigan Hand Outcomes Questionnaire, Short Form 12, analog pain score, and provocative and strength testing. The subjects' study group, gender, and arthritic grade were statistically analyzed versus patient-reported and physician-assessed data over the different time points. Following subject recruitment, 17 joints discontinued the study due to joint discomfort, electing for other treatments. Approximately 50 % of the 67 subject joints opted for alternative treatment after the first or second follow-up; 34 subject joints completed all follow-up time points. There was no significant predictive relationship between the independent variables and their ability to predict the 9 dependent measures of pain, strength, and well-being. There were trends for the pain to decrease over time, although the trends were not uniform between the different pain metrics and groups. The strength for both iontophoresis groups tended to increase over time, whereas the phonophoresis groups tended to decline. The authors concluded that although there were some trends in the follow-up data, the overall lack of significant differences in the data suggested that transdermal steroid delivery might not be helpful in providing short- or long-term relief of arthritic symptoms.

Donovan et al (2011) examined the anesthetic effect of 1-MHz phonophoresis using lidocaine on the anterior forearm following 5- and 10-min interventions. This was a cross-over study in a laboratory involving 22 healthy participants (13 women, 9 men; age, 23.0 +/- 3.2 yrs; height, 169.1 +/- 7.2 cm; weight, 70.9 +/- 13.9 kg). All subjects received 4 interventions on 4 different days: (i) 1.5 W/cm, 100 % duty cycle with
lidocaine for 5 mins (short); (ii) 1.5 W/cm, 50 % duty cycle with
ilocaine for 10 mins (long); (iii) no ultrasound for 10 mins with
ilocaine gel (lidocaine sham); and (iv) no ultrasound for 10
mins with ultrasound gel (true sham). Skin sensation was
measured for analysis. The main outcome measures were
Semmes-Weinstein Monofilament (SWM) scores, with higher
scores indicating less sensitivity. There was a significant time
main effect for SWM scores (p < 0.001). Baseline SWM scores
were the lowest (3.00 +/- 0.53; p ≤ 0.006) and post-SWM scores
(0 mins) were the highest (3.63 +/- .44; p < 0.001), indicating an
anesthetic effect at this time. The authors concluded that
neither the long nor the short treatment decreased skin
sensation compared with sham conditions. All interventions
resulted in decreased skin sensation when comparing baseline
SWM scores to all post-treatment scores. Phonophoresis with
lidocaine did not result in an enhanced anaesthetic effect on
human subjects.

Gurney et al (2011) noted that phonophoresis has been a
mainstay in physical therapy. The most common drug used in
phonophoresis is hydrocortisone acetate (HA). A number of
studies have been done examining phonophoresis in the
delivery of HA through the skin to underlying tissues; however,
a study has never been done examining the absorption of HA
using phonophoresis on human connective tissue. In a
randomized controlled study, these researchers examined if
phonophoresis will facilitate the transmission of HA in human
connective tissue. A total of 21 patients undergoing anterior
cruciate ligament reconstruction surgery were randomly
assigned to either a sham or true phonophoresis treatment
group. The latter group received 6 minutes of 10 % HA
ultrasound at a point consistent with the gastrocnemius slip of
the semitendinosis tendon (treatment site). The sham group
received 6 minutes of 10 % HA ultrasound to the same area, but
the ultrasound was not turned on. The slip and a sample of the
distal attachment of the tendon (control) were removed.
Samples were analyzed for HA levels. Although the mean and
median levels of HA found at the treatment site were greater
than those of the control site (means, 34.1 versus 22.9 parts
per billion; medians, 7 versus 0 parts per billion), the levels of HA found at the treatment site were not significantly greater than those at the control site (p = 0.15). There were no statistically significant differences between the true and sham phonophoresis groups in HA levels (p = 0.80) nor in age, sex, or skin thickness. The authors concluded that phonophoresis does not appear to facilitate the absorption of HA in connective tissue when compared with simple absorption (sham). Thus, the use of phonophoresis should be re-considered in inflammatory conditions.

Lake and Wofford (2011) determined the effectiveness of therapeutic modalities for the treatment of patients with patella-femoral pain syndrome (PFPS). In May and August 2010, Medline was searched using the following databases: PubMed, CINAHL, Web of Science Citation Index, Science Direct, ProQuest Nursing & Allied Health, and Your Journals@OVID. Selected studies were randomized controlled trials that used a therapeutic modality to treat patients with PFPS. The review included articles with all outcome measures relevant for the PFPS patient: knee extension and flexion strength (isokinetic and isometric), patella-femoral pain assessment during activities of daily life, functional tests (e.g., squats), Kujala patella-femoral score, and electromyographic (EMG) recording from knee flexors and extensors and quadriceps femoris cross-sectional areas. Authors conducted independent quality appraisals of studies using the PEDro Scale and a system designed for analysis of studies on interventions for patella-femoral pain. A total of 12 studies met criteria: 1 on the effects of cold and ultrasound together, ice alone, iontophoresis, and phonophoresis; 3, neuromuscular electrical stimulation; 4, EMG biofeedback; 3, electrical stimulation for control of pain; and 1, laser. Most studies were of low-to-moderate quality. Some reported that therapeutic modalities, when combined with other treatments, may be of some benefit for pain management or other symptoms. There was no consistent evidence of any beneficial effect when a therapeutic modality was used alone. Studies did not consistently provide added benefit to conventional physical therapy in the treatment
of PFPS. The authors concluded that none of the therapeutic modalities reviewed has sound scientific justification for the treatment of PFPS when used alone.

An UpToDate review on “Patellofemoral pain syndrome” (O’Connor and Mulvaney, 2014) states that “There is no empiric evidence to support the use of ultrasound, iontophoresis, phonophoresis, or electrical stimulation in the treatment of PFPS“.

The American College of Occupational and Environmental Medicine’s occupational medicine practice guidelines on “Elbow disorder” (ACOEM, 2012) phonophoresis is not recommended for acute, subacute, or chronic lateral epicondylalgia. Furthermore, the ACOEM guidelines offer no recommendation regarding the use of phonophoresis for acute, subacute, or chronic ulnar neuropathies at the elbow.

Bakhtiary et al (2013) compared the effectiveness of iontophoresis and phonophoresis of dexamethasone sodium phosphate (Dex-P) treatment for mild-to-moderate carpal tunnel syndrome (CTS). A total of 52 hands in 34 consecutive patients with mild-to-moderate CTS confirmed by EMG were allocated randomly into 2 groups. One group received iontophoresis of 0.4 % Dex-P and the other group received phonophoresis of 0.4 % Dex-P. Phonophoresis (using ultrasound 1 MHz, 5-cm probe, 1.0 W/cm, pulse 1:4, 5 mins/session) and iontophoresis (using galvanic current, negative electrode, 2 mA/min, total dose 40 mA for 20 mins) was applied over the wrist chin for 10 daily treatment sessions (5 sessions/week). Measurements were performed before and after treatment and at follow-up 4 weeks later, and included pain assessment by visual analog scale, electroneurographic measurement (motor and sensory latency, motor and sensory action potential amplitude), and pinch and grip strength. Improvement was significantly more pronounced in the phonophoresis group than in the iontophoresis group for motor latency [mean difference 0.8 m/s; 95 % CI: 0.5 to 1.1], motor action potential amplitude (4.1 mV; 95 % CI: 3.0 to 5.2), finger
pinch strength (31.6 N; 95 % CI: 15.9 to 47.3), hand grip strength (27.1 N; 95 % CI: 13.5 to 40.5), and pain relief (2.1 points on a 10-point scale; 95 % CI: 1.3 to 2.9). Effects were sustained in the follow-up period. The authors concluded that phonophoresis of Dex-P treatment was more effective than iontophoresis of Dex-P for treatment of CTS. Moreover, they stated that further investigation is needed to examine the combination therapy effects of these treatments with other conservative treatments in CTS patients.

In a case report, Ansari et al (2013) described the results of a novel treatment, erythromycin phonophoresis, in a woman with chronic rhino-sinusitis (CRS). A 31-year old woman with a 7-month history of CRS refractory to conventional medical management was treated with erythromycin phonophoresis to both maxillary sinuses. Individual sinus symptom severity was assessed and sinus CT scans were obtained both pre-treatment and post-treatment. After treatment, the total sinusitis symptom score improved from 12 to 0 and the CT scan showed almost complete disease resolution. At 5-month follow-up, the patient reported sustained improvement. The authors concluded that erythromycin phonophoresis has potential as an effective treatment for CRS.

Packer et al (2013) stated that the dental anesthesia sonophoresis device (DASD) is a novel device that is intended to reduce the discomfort associated with intra-oral mucosa needle puncture. The DASD produces ultrasonic energy that provides a sonophoretic effect on the oral mucosa, generating micro-channels through the lipids between the keratinized cells that make up the stratum corneum. Once the topical anesthetic has permeated the stratum corneum, it quickly diffuses through the soft tissue, desensitizing the nerve endings and reducing the perception of pain caused by needle penetration. In a pilot study, these researchers evaluated whether topical anesthesia applied using the DASD will reduce the discomfort of the needle puncture when compared to the control device. A split-mouth model, using 50 healthy subjects with puncture site at the maxillary canine vestibule, was used for this study. Subjects
received a needle puncture on both sides of the mouth. Prior to the needle puncture, there was randomized application of 5% lidocaine with the DASD and a control device. Subjects rated their discomfort after needle punctures utilizing the visual analog scale pain scoring system. There was no statistically significant difference in the pain perception using the DASD versus the control device.

Winters et al (2013) stated that medial tibial stress syndrome (MTSS) is a common exercise-induced leg injury among athletes and military personnel. Several treatment options have been described in the literature, but it remains unclear which treatment is most effective. The objective of this systematic review was to evaluate the effectiveness of any intervention in the treatment of MTSS. Published or non-published studies, reporting randomized clinical trials (RCTs) or non-RCTs of any treatment in subjects with MTSS were eligible for inclusion. Treatments were assessed for effects on pain, time to recovery or global perceived effect. Computerized bibliographic databases (MEDLINE, CENTRAL, EMBASE, CINAHL, PEDro and SPORTDiscus) and trial registries were searched for relevant reports, from their inception to June 1, 2012. Grey literature was searched for additional relevant reports. The Cochrane Risk of Bias Tool was used to appraise study quality of RCTs whereas the Newcastle Ottawa Scale was used to appraise non-RCTs. The “levels of evidence”, according to the Oxford Centre for Evidence-Based Medicine, addressed the impact of the assessed trials. Two reviewers independently performed the search for articles, study selection, data extraction and appraised methodological quality. A total of 11 trials were included in this systematic review. All RCTs revealed a high-risk of bias (Level 3 of evidence). Both non-RCTs were found to be of poor quality (Level 4 of evidence). Randomized clinical trials, studying the effect of a lower leg brace versus no lower leg brace, and iontophoresis versus phonophoresis, were pooled using a fixed-effects model. No significant differences were found for lower leg braces (standardized mean difference [SMD] -0.06; 95% CI: -0.44 to 0.32, p = 0.76), or iontophoresis (SMD 0.09; 95% CI: -0.50 to 0.68, p = 0.76). Iontophoresis,
phonophoresis, ice massage, ultrasound therapy, periosteal pecking and extracorporeal shockwave therapy (ESWT) could be effective in treating MTSS when compared with control (Level 3 to 4 of evidence). Low-energy laser treatment, stretching and strengthening exercises, sports compression stockings, lower leg braces and pulsed electromagnetic fields have not been proven to be effective in treating MTSS (level 3 of evidence). The authors concluded that none of the studies was sufficiently free from methodological bias to recommend any of the treatments investigated. Of those examined, ESWT appeared to have the most promise.

An UpToDate review on “Shoulder impingement syndrome” (Simons et al, 2014) lists acupuncture, electrical stimulation, iontophoresis, laser, phonophoresis, and therapeutic ultrasound as adjunct therapies. Moreover, it states that “No clear evidence exists to support the use of the modalities listed here in the treatment of SIS, and we do not routinely use them in the care of our patients”.

An UpToDate review on “Overview of geriatric rehabilitation: Program components and settings for rehabilitation” (Hoenig and Kortebein, 2014) states that “Iontophoresis/Phonophoresis -- These modalities utilize electric current (iontophoresis) or ultrasound energy (phonophoresis) to force a therapeutic medication (e.g., glucocorticoid) into tissues. Both are used to treat soft tissue musculoskeletal injuries. Although evidence is limited, the few randomized controlled trials indicate that these modalities are generally no more effective than placebo”.

**Myositis Ossificans:**

Bagnulo et al (2014) noted that myositis ossificans (MO) is a potential complication of muscle contusion. In a case-series study, these researchers presented the findings of patients who developed traumatic MO (confirmed on diagnostic ultrasound) who participated in a treatment regimen consisting of phonophoresis of acetic acid with ultrasound. In all cases, a trial of phonophoresis therapy significantly decreased patient
signs, symptoms and the size of the calcification on diagnostic ultrasound in most at a 4-week post-diagnosis mark. The authors concluded that due to the potential damage to the muscle and its function that surgical excision carries, safe and effective conservative treatments for MO are crucial. They also stated that “Research on conservative care is necessary for chiropractors and other manual therapists to appropriately manage patients with MO. Proving to be effective in this case and the paucity of literature on conservative treatment, this area needs to be investigated … Acetic acid phonophoresis deserves more attention in the literature. For conclusive information about conservative care, studies must investigate long-term effects of conservative care in a randomized trial with a clinically significant number of participants”. These findings need to be validated by well-designed studies.

An UpToDate review on “Quadriceps muscle and tendon injuries” (Von Fange, 2016) does not mention phonophoresis as a management tool for MO.

**Tuberculous Lymphadenitis:**

Chen et al (2016) stated that electro-phonophoresis (EP) has been used in various clinical fields. These researchers evaluated the skin permeability of isoniazid (INH) and rifampicin (RIF) in patients with tuberculous lymphadenitis with the aid of EP to validate the clinical applications of this transdermal delivery system for the treatment of superficial extra-pulmonary tuberculosis. Isoniazid and RIF solutions were delivered transdermally, with or without EP, in the surrounding tissue of the lesion for 30 minutes. Local pyogenic fluids or necrotic tissue samples from the infection sites in patients were collected at 1 hour after dosing. Drug concentrations in samples were evaluated by high performance liquid chromatography. The median INH and RIF intra-lesional concentrations were 0.365 (interquartile range [IQR] 0.185 to 1.775) μg/ml and 1.231 (IQR 0.304 to 1.836) μg/ml in oral group; 2.964 (IQR 0.193 to 7.325) μg/ml and 2.646 (IQR 1.211 to 3.753) μg/ml in INH- and RIF-transdermal plus EP group.
Drug concentrations in the local sites of patients receiving INH or RIF through EP transdermal delivery were statistically higher than those observed in patients only taking INH and RIF orally. However, this enhancement was not observed in the transdermal delivery of INH or RIF without EP in contrast to the oral administrations of drugs. The authors concluded that EP can effectively enhance the skin permeability of INH and RIF in patients with tuberculous lymphadenitis. The increase in drug concentrations in the lesions could help eradication of the germs; shorten the treatment course and increase the cure rate of patients with tuberculous lymphadenitis. These finding need to be validated by well-designed studies to show that EP would improve health outcomes in patients with tuberculous lymphadenitis.

An UpToDate review on “Tuberculous lymphadenitis” (Spelman, 2016) does not mention phonophoresis as a management tool.

**Knee Pain:**

In a double blinded, randomized clinical trial, Nakhostin-Roohi et al (2016) evaluated the effects of virgin olive oil phonophoresis on female athletes' anterior knee pain (AKP). A total of 93 female athletes suffering from AKP voluntarily participated in this study. Patients were randomly assigned into olive oil (n = 31), piroxicam (n = 31) or base gel phonophoresis (n = 31) groups. At the baseline visit, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire was filled by subjects who were then treated with olive oil, piroxicam or pure phonophoresis for 12 sessions. After 6 and 12 sessions of physiotherapy, subjects filled the questionnaire again. Main outcomes were significant improvement in pain, stiffness, physical function, and total WOMAC scores. Although, there was a significant reduction in symptoms of AKP at the end of the therapy in all groups (p < 0.05), but in olive oil group, this improvement was seen after 6 sessions of treatment (p < 0.001). A significant difference between olive oil group and piroxicam and/or phonophoresis group was observed after 6 sessions of therapy (p < 0.05). The
authors concluded that it could be proposed that phonophoresis with virgin olive oil is as effective as piroxicam gel on lowering WOMAC scores of AKP in female athletes and also has several beneficial properties including faster effect and shorter duration of therapy. The exact mechanism of beneficial action of virgin olive oil on AKP is unclear and requires further studies.

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**The above policy is based on the following references:**

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Aetna Clinical Policy Bulletin Number: CPB 0210 –
Phonophoresis

There are no amendments for Medicaid.