Medical Policy

Subject:	Electrical Stimulation as a Treatment for Pain and Other Conditions: Surface and Percutaneous Devices		
Document #:	DME.00011	**Publish Date:**	04/15/2020
Status:	Revised	**Last Review Date:**	02/20/2020

Description/Scope

This document addresses certain types of electrical stimulation devices. These include auricular electrostimulation, H-Wave stimulation, interferential stimulation therapy, microcurrent electrical nerve stimulation, pulsed electrical stimulation, percutaneous neuromodulation therapy, supraorbital transcutaneous neurostimulation, sympathetic therapies, cranial electrical stimulation and remote electrical neuromodulation. The devices differ in various ways including the type and intensity of electrical impulse and technique for delivering electrical stimulation.

Note: For further information on similar technologies, please see the following related documents:

- BEH.00002 Transcranial Magnetic Stimulation
- CG-DME-03 Neuromuscular Stimulation in the Treatment of Muscle Atrophy
- CG-DME-04 Electrical Nerve Stimulation, Transcutaneous, Percutaneous
- DME.00022 Functional Electrical Stimulation (FES); Threshold Electrical Stimulation (TES)

Note: For additional information concerning acupuncture services, please see the following document:

- CG-ANC-03 Acupuncture

Position Statement

Investigational and Not Medically Necessary:

I. Auricular electrostimulation is considered **investigational and not medically necessary** for all indications including, but not limited to, treatment of acute and chronic pain.

II. H-Wave electrical stimulation devices are considered **investigational and not medically necessary** to reduce pain from all causes including, but not limited to, pain associated with diabetic peripheral neuropathy.

III. Interferential therapy (IF) devices are considered **investigational and not medically necessary** for all indications including, but not limited to, providing relief of pain associated with soft tissue injury, musculoskeletal disorders, or to enhance wound or fracture healing.

IV. Microcurrent electrical nerve stimulation (MENS) devices are considered **investigational and not medically necessary** for all indications including, but not limited to, decreasing pain and facilitating healing.

V. Pulsed electrical stimulation is considered **investigational and not medically necessary** for all indications including, but not limited to, the treatment of osteoarthritis.

VI. Percutaneous neuromodulation therapy is considered **investigational and not medically necessary** for all indications.

VII. Supraorbital transcutaneous neurostimulation is considered **investigational and not medically necessary** for all indications, including but not limited to, prophylactic treatment of episodic migraine headaches and treatment of acute migraine headaches, with or without aura.

VIII. Sympathetic therapy is considered **investigational and not medically necessary** for all indications.

IX. Cranial electrical stimulation (CES) is considered **investigational and not medically necessary** for all indications, including but not limited to, treatment of pain, anxiety, insomnia and depression.

X. Remote electrical neuromodulation (REN) is considered **investigational and not medically necessary** for all indications, including but not limited to, treatment of acute migraine headaches, with or without aura.

Rationale

Auricular Electrostimulation Devices

Auricular electrostimulation, also referred to as auricular electroacupuncture, is a type of ambulatory electrical stimulation of acupuncture points intended to provide continuous or intermittent stimulation over a period of several days. It is primarily proposed for the treatment of pain. A number of randomized controlled trials (RCTs) evaluating auricular electrostimulation for pain treatment have been published, and RCTs have been summarized in several systematic reviews. Most recently, Zhao and colleagues (2015) published a systematic review and meta-analysis of RCTs investigating the efficacy and safety of auricular therapy for chronic pain. In meta-analyses of RCTs comparing auricular therapy to sham treatment (4 trials) and comparing auricular therapy to interventions other than sham (7 trials), statistically significant greater benefits were found for auricular therapy. However, the effect was primarily in trials with short-term follow-up (less than 1 month). In a meta-analysis of RCTs with follow-up longer than 3 months (3 trials), there was not a significant difference in effect size between auricular therapy and control interventions.

Previously, Yeh and colleagues (2014) conducted a systematic review and meta-analysis of RCTs published in English or Chinese that compared auricular therapy (including auricular electroacupuncture) to a control intervention and used a validated pain assessment tool. A total of 22 RCTs were included; findings of 13 of these (10 in English and 3 in Chinese) were included in the meta-analysis. The pooled analysis found a statistically significantly greater reduction in pain after auricular therapy versus control (SMD [standard mean difference], -1.59, 95% confidence interval [CI], -2.36 to 0.82). There was heterogeneity among trials and most had short-term follow-up (that is, assessed immediate relief or relief after 24 or 48 hours).

RCTs comparing the P-Stim® device (Octus Spine Laguna Hills, CA) to other therapies have had limitations including a small number of participants (Holzer, 2011; Sator-Katzenschlager, 2004), a high participant withdrawal rate, outcome measures reporting limited clinical improvement in pain intensity during the treatment period

(Bernateck, 2008), and no significant difference between the active treatment and sham treatment groups (Holzer, 2011; Michalek-Sauberer, 2007).

In summary, the available evidence in the peer-reviewed medical literature is insufficient to evaluate the treatment effect of auricular electrostimulation on improving health outcomes, including the treatment of acute and chronic pain and other conditions. To date, no evidence-based clinical practice guidelines recommend the use of auricular electrostimulation devices for any indication. Additional randomized studies with larger number of subjects measuring long-term outcomes are needed to evaluate the efficacy of this treatment approach.

H-Wave Electrical Stimulation Devices

H-Wave electrical stimulation devices have been investigated as a treatment for a variety of conditions including pain from diabetic peripheral neuropathy, muscle spasms, temporomandibular joint (TMJ) dysfunction, reflex sympathetic dystrophy, and healing of wounds such as diabetic peripheral ulcers.

Several RCTs have been published. The early medical literature describes two trials (Kumar and Marshall, 1997; Kumar, 1998) comparing active H-Wave electrical stimulation for the treatment of painful diabetic peripheral neuropathy. Both studies included small numbers of participants (n=31 and 14, respectively). In the first study by Kumar and Marshall (1997), outcomes were assessed using a pain-grading scale ranging from 0 to 5. Both study groups experienced significant declines in pain and the post-treatment mean grade for the active group was significantly lower than the mean grade for the sham group. This study did not state if the participants, investigators, or both were blinded or if any participant withdrew from the study. The second study by Kumar and colleagues (1998) compared H-Wave electrical stimulation with sham stimulation among individuals who did not adequately respond to an initial 4-week trial of a tricyclic antidepressant for pain from diabetic peripheral neuropathy. Stimulation therapy lasted 12 weeks, with outcomes assessed by an investigator blinded to group assignment at 4 weeks after the end of treatment. As in the earlier study, mean pain grade in both groups improved significantly, but the difference between groups after treatment significantly favored active H-Wave stimulation (p=0.03). It is unclear, however, if the participants were blinded to the type of device, and, the report does not include if any participants withdrew from the study.

The effect of H-Wave electrical stimulation on range of motion and strength testing was assessed in a randomized double-blind, placebo-controlled study of 22 individuals who underwent rotator cuff reconstruction (Blum, 2009). Both groups received the same device treatment instructions. Group I was given the H-Wave device to utilize for 1 hour twice a day for 90 days postoperatively. Group II was given the same instructions with a placebo device. Strength testing and range of motion were assessed between the groups preoperatively, 45 days postoperatively, and 90 days postoperatively by using an active/passive scale for five basic ranges of motion. The authors reported that individuals who received H-Wave electrical stimulation compared to placebo demonstrated, on average, significantly improved active range of motion at 45 and 90 days postoperatively (p=0.007 and p=0.007, respectively). Active internal rotation also demonstrated significant improvement compared to placebo at 45 days and 90 days postoperatively (p=0.007 and p=0.006, respectively). There was no significant difference between the two groups for strength testing. Interpretation of study results is preliminary and warrants further confirmation in a larger randomized, double-blind, placebo-controlled study.

Blum and colleagues (2006a; 2006b) reported on the results of a large observational study. The study consisted of a 10-item survey that assessed the therapeutic response to the H-Wave device in 6774 individuals with chronic soft-tissue injury or neuropathic pain. The H-Wave Customer Service Questionnaire measured each individual's subjective assessment of the device's effectiveness regarding decreased or eliminated need for pain medication, increased functioning and activity, and 25% or greater overall improvement. On a 10-unit visual analog scale (VAS) ranging from 0% to 100%, 75% of the study participants reported a reduced or eliminated need for pain medication; 79% reported improved functional capacity or activity; and 78% reported 25% or greater reduction of pain. The study results suggest that the use of H-Wave electrical stimulation may provide an alternative to standard pharmacologic treatment of chronic soft tissue and neuropathic pain. However, limitations of this study include lack of randomization and placebo control and the use of self-reported data. A subsequent meta-analysis by Blum and colleagues (2008) included five studies; two of them were RCTs. The authors concluded that their findings "are encouraging and support the H-Wave device as a potential non-pharmacological alternative in the management of chronic inflammatory and neuropathic pain conditions" and suggest the need for more rigorous controlled studies.

There is insufficient evidence in the peer-reviewed medical literature to support the efficacy of H-Wave electrical stimulation for any other indication.

Interferential Stimulation (IFS) Therapy Devices

IFS for Low Back Pain

A few studies have compared IFS for low back pain to sham or placebo control groups and have not found a significant benefit of IFS. Most recently, Franco and colleagues (2017) conducted an RCT with 6 months of follow-up to determine whether IFS therapy before Pilates exercises was more effective than placebo in individuals with chronic nonspecific low back pain. A total of 148 participants between the ages of 18 and 80 years with chronic nonspecific low back pain were allocated into 2 groups: active IFS plus Pilates or placebo IFS plus Pilates. In the first 2 weeks, participants were treated for 30 minutes with active or placebo IFS. In the following 4 weeks, 40 minutes of Pilates exercises were added after the application of the active or placebo IFS. A total of 18 sessions were offered during 6 weeks. The primary outcome measures were pain intensity, pressure pain threshold, and disability measured at 6 weeks after randomization. No significant differences were found between the groups for pain (0.1 points; 95% CI, -0.9 to 1.0 points), pressure pain threshold (25.3 kPa; 95% CI, -4.4 to 55.0 kPa), and disability (0.4 points; 95% CI, -1.3 to 2.2). The investigators concluded that active IFS before Pilates exercise was not more effective than placebo IFS in individuals with chronic nonspecific low back pain.

A 2007 double-blind RCT by Zambito and colleagues comparing IFS therapy or horizontal therapy (HT) with sham stimulation in 105 women with chronic low back pain due to multiple vertebral fractures did not find a significant difference in outcomes between groups. In addition, several early studies (Taylor, 1987; van Heijden, 1999) failed to show a significant effect of IFS compared with placebo.

Several RCTs (Albornoz-Cabello, 2017; Facci, 2011; Hurley, 2001; Hou, 2002) have found some benefit associated with IFS in individuals with low back pain; however, the lack of a placebo or control group in these studies limits the ability to draw conclusions about the efficacy of IFS. For example, Facci and colleagues (2011) published the results of an RCT comparing IFS (n=50) and TENS (n=50) to a no-treatment control group (n=40) in persons with

chronic low back pain. Participants were assessed by a blinded evaluator before and after completing 10, 30-minute treatment sessions over 2 weeks; participants in the control group were reassessed after 2 weeks. A total of 137 of 150 (91%) participants completed the intervention; analysis was intention-to-treat. The mean pain intensity, as measured by a 10-point VAS, decreased 4.48 cm in the IFS group, 3.91 cm in the TENS group, and 0.85 cm in the control group. There was no statistically significant difference in pain reduction in the active treatment groups. Both groups experienced significantly greater pain reduction than the control group. Since a sham treatment was not used, a placebo effect cannot be ruled out when comparing active to control treatments. In addition, findings from this study do not demonstrate equivalence between IFS and TENS; studies with larger numbers of participants that are designed as equivalence or non-inferiority trials would be needed before drawing this conclusion.

Albornoz-Cabello and colleagues (2017) performed a single-blind RCT which compared IFS to a 'usual care' control group in 64 individuals. Participants were recruited from a private physiotherapy research clinic and had low back pain of more than 3 months, with or without pain radiating to the lower extremities above the knee. Transregional IFS was performed for participants in the experimental group, while the usual care consisted of massage, mobilization and soft-tissue techniques. All participants received up to 10 treatment sessions of 25 minutes over a 2-week period. The primary outcome measure was self-perceived pain assessed with a VAS score; secondary outcomes were measured with the Oswestry Low Back Disability Index. Evaluations were collected at baseline and after the intervention protocol. Significant between-group differences were reported for interferential current therapy on pain perception (p=0.032) and disability level (p=0.002). Limitations of this study include the lack of a sham control, the single-blinded study design, small number of participants, and short-term outcome measurements.

Clinical practice guidelines from the American College of Physicians and the American Pain Society concluded that there was insufficient evidence to recommend IFS therapy for the treatment of low back pain (Chou, 2007).

In 2016, the Agency for Healthcare Research and Quality (AHRQ) (Chou, 2016) published a comparative effectiveness review on noninvasive treatments for acute or subacute low back pain. A total of 156 studies were included with most trials enrolling individuals with pain symptoms of at least moderate intensity (for example, > 5 on a 0- to 10-point numeric rating scale for pain). The review evaluated pharmacotherapy and physical modalities including interferential therapy, PENS, and TENS. Four studies investigated interferential therapy for subacute to chronic low back pain. No study evaluated harms of interferential therapy. The review concluded there was insufficient evidence due to methodological limitations and study imprecision to determine the treatment effects of interferential therapy versus other interventions, or interferential therapy plus another intervention versus the other interventions alone. Additional research was recommended "…to understand optimal selection of treatments, effective combinations and sequencing of treatments, and effectiveness of treatments for radicular low back pain."

IFS for Musculoskeletal Pain

Fuentes and colleagues (2010) published a systematic review and meta-analysis of studies evaluating the efficacy of IFS therapy for the management of musculoskeletal pain. A total of 20 randomized controlled trials met the inclusion criteria; 14 of the trials reported data that could be included in the pooled meta-analysis. IFS therapy as a stand-alone intervention was not found to be more effective than placebo or an alternative intervention. A pooled analysis of 2 studies comparing IFS therapy alone and placebo did not find a statistically significant difference in

pain intensity on completion of the treatment; the pooled mean difference (MD) was 1.17 (95% confidence interval [CI]: 1.70 to 4.05). In addition, a pooled analysis of two studies comparing IFS therapy alone and an alternative intervention (for example, traction or massage) did not find a significant difference in pain intensity at discharge; the pooled MD was -0.16; 95% CI: -0.62 to 0.31. In a pooled analysis of five studies comparing IFS therapy as a co-intervention to a placebo group, there was a non-significant finding (MD=1.60; 95% CI: -0.13 to 3.34). The meta-analysis found IFS therapy plus another intervention to be superior to a control group (that is, no-treatment). A pooled analysis of three studies found an MD of 2.45 (95% CI: 1.69 to 3.22). The latter analysis was limited in that the specific effects of IFS therapy versus the co-intervention could not be determined, and it did not control for potential placebo effects. The authors concluded that the results must be considered with caution due to the low number of studies that used IFS therapy alone. In addition, the heterogeneity across studies and methodological limitations prevent conclusive statements regarding analgesic efficacy.

Acedo and colleagues (2014) compared the muscle relaxation of the upper trapezius induced by the application of TENS and IFS in individuals with chronic nonspecific neck discomfort. A total of 64 individuals randomly assigned to a TENS or IFS received 3 consecutive days of treatment. Efficacy was assessed by electromyography (EMG) in the third week and after the end of treatments. Pain was assessed using a VAS at baseline (before TENS or IFS application) and at the end of the study. EMG assessment data were similar between groups. Those in the IFS group had a significant trapezius relaxation after 3 IFS applications when compared to baseline and intermediate evaluations ($p<0.05$). Both groups showed an improvement at the end of the study when compared to baseline ($p<0.05$). Limitations of this study include the small sample size, short duration of treatment, and lack of long-term measurement of outcomes demonstrating durability of the treatment effect.

Suriya-amarit and colleagues (2014) studied the immediate effects of IFS on shoulder pain and pain-free passive range of motion (PROM) of the shoulder in a double-blind, placebo-controlled clinical trial of individuals (n=30) with hemiplegic shoulder pain. In the IFS group, participants received treatment for 20 minutes with an amplitude-modulated frequency at 100 Hz with an increase in current intensity until the participants felt a strong tingling sensation. The primary outcome measurements were pain intensity and pain-free PROM of the shoulder until the onset of pain, measured at baseline and immediately after treatment. Participants reported a greater reduction in pain during the most painful movement after treatment with IFS than with placebo ($p<0.05$). The IFS group showed a greater improvement in post treatment pain-free PROM than the placebo group in shoulder flexion ($p<0.01$), abduction ($p<0.01$), internal rotation ($p<0.01$), and external rotation ($p<0.01$). Limitations of this study include the small sample size, an inability to generalize the results to the stroke population as a whole, and short-term effects of IFS treatment; therefore, the long-term effects of IFS treatment in individuals with hemiplegic shoulder pain is unknown.

Dissanayaka and colleagues (2016) compared the effectiveness of TENS and IFS both in combination with hot pack, myofascial release, active range of motion exercise, and a home exercise program on subjects with myofascial pain syndrome. A total of 105 subjects with an upper trapezius myofascial trigger point were randomized to one of three therapeutic regimens (n=35 each group): 1) control group: "standard care" with hot pack, active range of motion exercises, myofascial release, and a home exercise program with postural advice; 2) TENS with standard care; or, 3) IFS with standard care. All interventions were administered 8 times during 4 weeks at regular intervals. Pain intensity and cervical range of motion were measured at baseline, immediately after the first treatment, before the eighth treatment, and 1 week after the eighth treatment. The IFS group showed significant

improvement in the outcome measurements when compared to the standard care group ($p<0.05$); however, significant immediate and short-term improvements were reported with TENS and standard care compared to IFS and standard care with respect to pain intensity and cervical range of motion ($p<0.05$).

IFS for OA and other Knee Pain

Several sham-controlled RCTs have been published evaluating IFS for treatment of knee pain (Atamaz, 2012; Defrin, 2015; Gundog, 2011; Jarit, 2003; Kadı, 2019). For example, Atamaz and colleagues (2012) conducted a double-blind RCT comparing the efficacy of IFS, TENS, and shortwave diathermy in 203 individuals with knee OA. Participants were randomized to 1 of 6 groups, 3 with active treatment and 3 with sham treatment. The primary outcome was a 0 to 100 VAS assessing knee pain. Other outcomes included range of motion, time to walk 15 meters, paracetamol intake, the Nottingham Health Profile (NHP) and WOMAC scores. At 1-, 3-, and 6-month follow-up, a statistically significant difference was not reported among the 6 groups in the VAS pain score, the WOMAC pain score, or the NHP pain score. The WOMAC function score, time to walk 15 meters, and the NHP physical mobility score did not differ significantly among groups at any of the follow-up assessments. At the 1-month follow-up, paracetamol intake was significantly lower in the IFS group than the TENS group.

Gundog and colleagues (2011) compared the effectiveness of different amplitude-modulated frequencies of IFS and sham IFS on knee OA. Participants (n=60) were randomly assigned to 1 of 4 groups: 3 IFS groups at frequencies of 40 Hz, 100 Hz, and 180 Hz, or sham IFS. Treatments were performed 5 times a week for 3 weeks on both groups. During the sham treatment, placement of the pads was the same and duration was the same without the application of electrical stimulation. The primary outcome measurement was pain intensity assessed by the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). Mean WOMAC scores 1 month after treatment were 7.2, 6.7, and 7.8 in the 40 Hz, 100 Hz, and 180 Hz groups, respectively, and 16.1 in the sham IFS group ($p<0.05$ compared to the active treatment groups). A secondary outcome reported as pain on movement showed significantly higher benefit in the active treatment groups compared to the sham IFS group. Using a 100-point VAS score 1 month after treatment, the mean VAS score was 16.0, 17.0 and 22.5 in the 40 Hz, 100 Hz, and 180 Hz groups, respectively, and 58.5 in the sham group. There were no significant differences in outcomes among the 3 active treatment groups. Limitations of this study include small study size, the lack of reporting the number of participants assigned to each study group and follow-up rates that were not measured beyond 1 month after treatment.

In 2019, Kadı and colleagues evaluated IFS for treating pain after total knee arthroplasty surgery. A total of 113 individuals were randomized to IFS (n=57) or sham treatment (n=56). There were 98 individuals (87%) who completed the study. After 30 days, there was no significant difference between groups in pain assessed by a VAS, 0.278. Pain medication use (paracetamol) also did not differ significantly between groups after treatment and neither did outcome measures assessing range of motion or edema. In this study, IFS was not beneficial at improving outcomes after total knee arthroplasty.

IFS for Other Conditions

There is insufficient evidence on IFS for other conditions. Several RCTs have been published on IFS in individuals with soft tissue shoulder disorders (van der Heijden, 1999), TMJ syndrome or myofascial pain syndrome (Taylor,

1987), carpal tunnel syndrome (Koca, 2014) and chronic stroke plantar flexor spasticity (Suh, 2014). Studies did not find a significant treatment effect (Taylor, 1987; van der Heijden, 1999) or were limited by small sample sizes (Koca, 2014; Suh, 2014)), high drop-out rates (Koca, 2014) and short term outcome assessment (Suh, 2014).

Summary: Evidence on IFS

A substantial number of RCTs using IFS for musculoskeletal conditions vary in the adjunct treatments that are used, comparison groups, types of controls, and outcome measures. Other methodological limitations in these trials include use of multiple treatment modalities without the ability to isolate the effect of IFS or inadequate placebo control. At this time, there is insufficient or limited evidence in the peer-reviewed medical literature to draw conclusions regarding the efficacy of IFS therapy to decrease pain and facilitate healing for any condition.

Microcurrent Electrical Nerve Stimulation (MENS) Devices

Bertolucci and Grey (1995) compared the efficacy of MENS therapy to mid-laser and laser placebo treatment of 48 individuals with TMJ pain. There was a difference in pain and functional outcomes between laser and MENS therapy with laser being slightly higher; however, the difference was not statistically significant. There was no data to suggest whether the effect was durable and whether the effects continued with repeated use.

There has been interest in using MENS therapy in the treatment of migraine headaches. However, there are no double-blind, randomized controlled clinical trials of MENS therapy in the treatment of migraine. MENS therapy has been addressed in a few small randomized controlled trials and case series for conditions such as age-dependent muscle weakness (Kwon, 2017), chronic nonspecific back pain (Koopman, 2009), delayed onset muscle soreness (Curtis, 2010), diabetes mellitus (Gossrau, 2011; Lee, 2009), fibromyalgia (Moretti, 2012), generalized pain, hypertension (Lee, 2009), multiple sclerosis, and unhealed wounds (Lee, 2009). None of these studies are large controlled clinical trials designed to test the effectiveness of MENS therapy against a placebo device. Therefore, based on the lack of available evidence, conclusions cannot be reached about the effectiveness of MENS therapy on pain management.

Pulsed Electrical Stimulation (PES) Devices

PES, including pulsed electromagnetic stimulation, devices (also referred to as pulsed short-wave electromagnetic field stimulation [PEMF]) have been used to decrease pain and joint damage and improve function in individuals with OA or RA. The proponents of the BioniCare® PES device (BioniCare Medical Technologies, Inc., Sparks, MD) theorize that PES devices can facilitate bone formation and cartilage repair and alter inflammatory cell function.

A number of RCTs have been published evaluating PES and/or PEMF and these have been summarized in systematic reviews. Several Cochrane reviews have addressed PES and/or PEMF stimulation for treatment of pain and related conditions: Kroeling (2013) on neck pain, Li (2013) on osteoarthritis and Page (2016) on rotator cuff disease. The Cochrane reviews by Page and colleagues and by Kroeling and colleagues (which identified four relevant trials each on PEMF) did not pool study findings due to heterogeneity among trials.

A systematic review by Negm and colleagues (2013) included seven small sham controlled RCTs examining PES or PEMF for the treatment of knee OA. The total sample size was 459 individuals. Five of the trials were conducted outside of the United States, and only one trial was considered to be at low risk of bias. There was no significant difference between the active and sham groups for the outcome of pain. Physical function was significantly higher with PES or PEMF stimulation, with a standardized mean difference of 0.22. The internal validity of the included studies is limited due to a number of factors, including a high risk of bias and inconsistency in the reported results. All of the studies had small sample sizes with wide confidence intervals around outcomes, leading to imprecise estimates of the treatment effect.

Li and colleagues (2013) performed a meta-analysis of nine studies (n=636 participants) evaluating the use of PES and PEMF stimulation for treating OA. The meta-analysis found that participants who were randomized to PES or PEMF stimulation rated their pain relief as greater than sham-treated participants by 15.10 more on a scale of 0 to 100; however, no statistically significant effect was found on function or quality of life. In three studies, a high risk of bias was identified for incomplete outcome data. For all nine studies, the authors noted there were inadequacies in reporting of study design and conduct, making it unclear whether there was bias due to selective outcome reporting.

Additional RCTs or quasi-randomized trials were published after the systematic reviews. Wuschech and colleagues (2015) evaluated 10-minute daily treatment with the MAGCELL® ARTHRO (Physiomed® Elektromedizin, Germany) in a semi-randomized, double-blind, sham-controlled study of 57 subjects with OA. Due to efficacy at the interim analysis, only the first 26 subjects underwent randomization; the remainder were assigned to the active treatment group, although subjects and assessors remained blinded to treatment. Treatment was performed for 5 minutes, twice daily over 18 days. In the sham group, WOMAC total score was 56.9 at baseline and 56.2 at follow-up. In the active PEMF group, WOMAC total score decreased from 65.4 to 42.9. Intention-to-treat analysis showed that the active PEMF group had a clinically and statistically significant reduction in pain ($p<0.001$) on the WOMAC score compared to the sham group. Stiffness ($p=0.032$) and disability in daily activities ($p=0.005$) on the WOMAC score were also significantly reduced in the active PEMF group. Limitations of this study include the small sample size and whether it was sufficiently powered to draw meaningful conclusions, as the power analysis indicated that 28 participants would be needed per group. To date, the MAGCELL ARTHRO device has not received FDA 510(k) clearance for use in the treatment of any condition.

Bagnato and colleagues (2016) evaluated the effectiveness of a wearable PEMF device in the management of pain in knee OA. In this randomized, double-blind, sham-controlled trial, 60 subjects were treated with 12 hours of nightly ActiPatch® therapy (BioElectronics Corporation, Frederick, MD). After 1 month of treatment, there was a clinically significant decrease (25.5%) in VAS pain scores in the PEMF group compared with a 3.6% reduction in the sham group (effect size, -0.73; 95% CI, -1.24 to -0.19). WOMAC total score was reduced by 18.4% in the active treatment group compared to 2.3% for controls (effect size, -0.34; 95% CI, -0.85 to 0.17). SF-36 Physical Component Summary scores also improved significantly with nightly PEMF. Limitations of this study include the small number of subjects and lack of long-term efficacy outcomes.

Dundar and colleagues (2016) performed a sham-controlled double-blind RCT of 40 subjects who received either conventional physical therapy or physical therapy and PEMF therapy for knee OA pain. The investigators reported

there was no additional treatment benefit after 20 minutes of adjuvant PEMF therapy on pain reduction as measured by either the VAS or WOMAC pain scales.

Multanen and colleagues (2018) conducted a double-blind cross-over RCT in which 108 women with fibromyalgia received 12 weeks of PEMF therapy and 12 weeks of sham (inactive) treatment, in random order. There was a 3-week washout period between treatments. The primary outcomes were pain on a 100-point VAS and a validated symptom and function questionnaire, the Fibromyalgia Impact Questionnaire (FIQ). No significant differences were found between groups in the primary outcome measures at any time. Study findings suggest that PEMF is not effective for reducing pain or improving symptoms in individuals with fibromyalgia.

In 2013, the American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the treatment of OA of the knee. Due to the overall inconsistent finding for electrotherapeutic modalities, the AAOS was unable to make a recommendation for or against the use in individuals with symptomatic OA of the knee. The strength of the recommendation was inconclusive.

In summary, there is insufficient evidence in the peer-reviewed published literature to support the efficacy of PES and PEMF devices for decreasing pain and improving function in individuals with OA and RA. The conclusions drawn from the available studies are limited by methodological limitations and inconsistency of the study results. No published studies for RA were identified. Methodologically sound, well-designed randomized, double-blind, controlled trials with larger populations are required before any clinical benefits can be suggested from the use of PES when compared to other established treatment modalities.

Percutaneous Neuromodulation Therapy (PNT) Devices

PNT is described as a variation of PENS developed as a treatment for chronic or intractable pain. Four cross-over RCTs were conducted by one group of investigators (two studies by Ghoname, 1999; Hamza, 1999; White, 2001). Results of these studies suggest that PNT reduces low back pain and disability due to this pain; however, the randomized crossover studies also provided evidence that these benefits were temporary since pain reoccurred between treatment sessions and during 1-week periods in which treatment was stopped before a change in treatment conditions.

In a single-blinded study, Kang and colleagues (2007) randomized 70 individuals with knee OA to PNT stimulation (at the highest tolerable intensity) or placement of electrodes without stimulation (sham intervention). Individuals in the sham group were informed that they would not perceive the normal "pins and needles" with this new device. Individuals received a single treatment and were followed up for 1 week. The neuromodulation group had 100% follow-up; 7 of 35 (20%) individuals from the sham group dropped out. VAS pain scores improved immediately after active (from 5.4 to 3.2) but not sham (5.6 to 4.9) treatments. VAS scores (4.6 vs. 5.2) were not significantly different for the 2 groups at 48 hours after treatment. Changes in the WOMAC scale were significantly better for the category of stiffness (1 point change vs. 0 point change) but not for pain or function at 48 hours. Measures of satisfaction in the study participants were significantly higher in the neuromodulation group (77% vs. 11% good to excellent) at up to 1-week follow-up. Interpretation is limited by the discrepancy between participant satisfaction ratings and 48-hour VAS pain scores, and the differential loss to follow-up in the 2 groups. These results raise questions about the effectiveness of the blinding and the contribution of short-term pain relief and placebo effects to

these results. Questions also remain about the duration of the treatment effects since the study reported only short-term follow-up.

An RCT was published by Gilmore and colleagues in 2019 on percutaneous peripheral nerve stimulation for treatment of chronic neuropathic post-amputation pain. The study included 28 lower-extremities amputees who were randomized to 4 weeks of percutaneous stimulation or sham treatment. After this 4-week period, the sham group could cross over to receive active treatment for 4 weeks and the active treatment group received an additional 4 weeks of treatment. The proportion of participants with at least a 50% pain reduction at 4 weeks, the primary outcome measure, was significantly higher in the active treatment group (7/12, 58%) than the sham group (2/14, 14%), p=0.037. At week 8, 8 of 12 (67%) individuals assigned to active treatment reported at least a 50% reduction in pain. After crossing over to active treatment after 4 weeks, the proportion of individuals assigned to the sham group that reported at least a 50% reduction in pain remained the same at 14%. The study had a small sample size and a short duration of comparative follow-up.

Supraorbital Transcutaneous Neurostimulation

Prophylactic Treatment of Migraine Headache

Schoenen and colleagues (2013) evaluated the safety and effectiveness of trigeminal neurostimulation in migraine headache prevention using the supraorbital transcutaneous stimulator, the Cefaly device (STX-Med., Herstal, Belgium). The multicenter double-blind, sham-controlled RCT (PREMICE study) included 67 adults (18-65 years) who experienced two or more migraine headache attacks (with or without aura) per month and had not taken any preventive antimigraine medications in the previous 3 months. After a 1-month run-in, participants were randomized 1:1 to active or sham stimulation applied 20 minutes daily for 3 months. Primary outcomes measures included a change in migraine days and at least 50% reduction in migraine days. A total of 59 of the 67 randomized participants were included in the intent-to-treat analysis. The primary outcome measure was reported as a non-significant greater decrease in migraine days per month (active: 6.94 vs. 4.88 [-2.06]; sham: 6.54 vs. 6.22 [-0.32]; p=0.054); however, the 50% responder rate was significantly greater in the active treatment group than in the sham group (38% vs. 12.1%; p=0.023). Monthly migraine attacks (p=0.044), monthly headache days (p=0.041), and monthly acute antimigraine drug intake (p=0.007) were also significantly reduced in the treatment group but not in the sham group. The investigators reported no adverse events (AEs) in either group. A greater proportion of participants in the active treatment group were moderately or very satisfied with the Cefaly device (71% vs. 39%). Limitations of this study include the small number of participants and the likelihood of bias as potential unblinding to treatment may have occurred during the trial. The investigators noted that the stimulation electrodes of the active device could be painful to finger touch while the sham device electrodes would not be painful. In addition, there were apparent differences between the two groups at baseline, as participants randomized to the treatment group were of younger (average) age and had a shorter duration of migraine attacks.

Treatment of Acute Migraine Headache

Data collected from a satisfaction survey described the observational experience of 2313 individuals with migraine headaches from France, Belgium, and Switzerland who used the Cefaly device for 40 days (Magis, 2013). The rate of reported AEs was 4.3%, and 2% (n=46) of users stopped treatment with the device due to AEs. The most

common AE reported was intolerance to the paresthesias felt during electrical stimulation (1.3% of users). Other common AEs included sleepiness (0.5%), headache following treatment (0.5%), and forehead skin irritation (0.2%). A total of 53% of users elected to purchase the device after the trial period; the remainder returned the device. For those individuals who returned the device, 59% used it for the recommended length of time during the rental period, similar to the utilization duration observed in the randomized trial.

Chou and colleagues (2017) performed a prospective, open-label pilot study of 30 individuals who experienced acute migraine attacks with or without aura. Participants at a single clinic site were treated with a 1 hour session of trigeminal nerve stimulation with the Cefaly device. Pain intensity was scored using a VAS before the treatment, after the treatment session, and at 2 hours after treatment initiation. Participants were allowed to take rescue migraine medication with treatment recorded at 2 and 24 hours. The primary outcome was the mean change in pain intensity after the 1-hour treatment compared to baseline, which was reported as significantly reduced by 57.1% after the 1-hour Cefaly treatment (-3.22 ± 2.40; $p<0.001$) and by 52.8% at 2 hours (-2.98 ± 2.31; $p<0.001$). No participants took rescue medication within the 2-hour observation phase; however, 34.6% of participants used a rescue mediation within the 24-hour follow-up. No adverse events were reported. A limitation of drawing conclusions from this pilot study was the small sample size, open-label design, lack of blinding to treatment, and no control group.

In September 2017, the FDA cleared the Cefaly Acute device, a substantially equivalent device to the predicate Cefaly device, as an external trigeminal nerve stimulator for use in the treatment of adults ≥ 18 years of age with migraine attacks, with or without aura. The FDA 510(k) clearance was based on results from a multicenter, randomized, double-blind, placebo-controlled Acute Treatment of Migraine With e-TNS trial (ACME; NCT02590939), completed in March 2017. According the clinicaltrial.gov website, eligible participants were 18 to 65 years (mean age, approximately 40 years), had a history of episodic or chronic migraine with or without aura meeting the diagnostic criteria the International Classification of Headache Disorders (ICHD-3-beta) with the exception of "complicated migraine", experienced a migraine attack lasting for at least 3 hours with migraine pain intensity stabilized for at least 1 hour, and not have taken an acute migraine medication within the past 3 hours. Study participants were randomly assigned 1:1 to a single treatment with active or sham stimulation. The primary endpoint was the mean change in VAS pain score at 1 hour compared to baseline. Secondary endpoints included change in VAS pain scores at 2 and 24 hours from baseline, and the proportion of participants who did not use pain medications at these time points. To date, the ACME trial results have not been published in the peer-reviewed medical literature.

The Quality Standards Subcommittee of the American Academy of Neurology (AAN) and American Headache Society (AHS) updated their evidence-based recommendations for use of pharmacologic treatment for episodic migraine prevention in adults. The guidelines do not address the use of any type of Cefaly device for prevention of episodic migraines or the treatment of acute migraine headache (Silberstein, 2012).

In summary, there is insufficient evidence in the peer-reviewed published medical literature demonstrating a significant net health benefit on the use of any type of Cefaly device for the prevention of migraine headaches or the treatment of acute migraine headaches, with or without aura. Outcomes from peer-reviewed published randomized controlled trials of large sample populations with blinding of participants are needed to determine if supraorbital transcutaneous neurostimulation with any Cefaly device improves health outcomes when compared to

existing therapies for prevention of episodic migraine headaches or the treatment of acute migraine headaches, and to assess longer-term safety and adverse effects.

Sympathetic Therapy

Sympathetic therapy is a patented method of delivering electrostimulation via peripheral nerves to create a unique form of stimulation of the sympathetic nervous system. It incorporates dual interfering waveforms with specific electrode placement on the upper and lower extremities (eight electrodes per treatment). Electrodes are placed bilaterally over dermatomes, thus accessing the autonomic nervous system via the peripheral nervous system.

A literature search identified only one small, non-randomized study by Guido and colleagues (2002). A total of 20 individuals with chronic pain and peripheral neuropathies were treated daily with the Dynatron STS™ (Dynatron Corporation, Salt Lake City, UT) for 28 days. Pain was reported as moderate to severe by 11 of 15 individuals prior to treatment, with a decrease in pain reported by 6 of the individuals at conclusion of the treatment. For these 15 individuals who remained in the study (5 dropped out), the authors reported the mean cumulative VAS scores for multiple locations of pain decreased from 107.8 to 45.3. However, drawing conclusions concerning the efficacy of Dynatron STS for the management of chronic, intractable pain is limited due to the small participant population, lack of a randomized control group, placebo effects and lack of data on pain severity in a quarter of the subjects in this study. There is a lack of additional peer-reviewed literature concerning the efficacy of sympathetic therapy in terms of pain relief or for any other indication. Consequently, no conclusions can be drawn regarding the usefulness of this modality in terms of improving health outcomes or quality of life in individuals with moderate to severe pain.

Cranial Electrical Stimulation (CES) Devices

In 2018, Shekelle and colleagues published a systematic review of RCTs on the benefits and harms of CES for treatment of pain, depression, anxiety and insomnia. To be eligible for inclusion in the review, studies needed to evaluate adults in the outpatient setting, compare CES to a sham control or an alternative intervention, and report outcome measures using standardized instruments. A total of 26 studies (28 articles) met the eligibility criteria. These included 14 studies evaluating CES for painful conditions, 3 on depression, 5 on depression and anxiety, 2 on insomnia, 1 on anxiety and 1 on anxiety and insomnia. Trial results were not considered to be suitable for pooling in meta-analyses. Studies on each of the indications were found to have methodological limitations. For example, most trials were small with fewer than 30 participants. The quality of evidence was judged to be insufficient for all conditions except one, anxiety and depression, for which the quality of evidence was judged to be low. Four of the 5 trials on anxiety and depression were published in the 1970s and used devices that are no longer available. The fifth trial (Barclay, 2014) enrolled 115 individuals with anxiety disorder, 23 of whom had co-morbid depression. The study used an Alpha-Stim device and compared active to sham treatment. Compared with sham CES, the active CES group had statistically significantly lower scores on the Hamilton Rating Scale for Anxiety (HAM-A) and the Hamilton Depression Scale (HAM-D) from baseline to the study endpoint at 5 weeks, p=0.001. A limitation of the study was a relatively short follow-up.

A 2014 Cochrane review by Kavirajan and colleagues focused on CES for treatment of depression. No studies met the review's eligibility criteria which were RCTs comparing CES to sham CES in the acute treatment of depression

in adults aged 18 to 75 years. The authors concluded that there is insufficient evidence supporting CES for treating depression.

No studies were identified that evaluated the Cervella device for treatment of anxiety, insomnia and/or depression.

The American Psychiatric Society guideline on treatment of major depressive disorder (2010) did not address CES.

Remote electrical neuromodulation (REN) Devices

A double-blind RCT by Yarnitsky and colleagues (2019) evaluated the Nerivio Migra REN device. The trial included 252 adults who met ICHD-3-beta criteria for migraine, had 2-8 migraines per month and less than 12 headache days per year. Participants needed to either be on no preventive migraine medication or be stable on medication. Individuals were randomized to receive either active or sham stimulation devices. A total of 202 participants (99 in the active group and 103 in the sham group) who completed a test treatment session within 1 hour of symptom onset and reported pain at 2 hours formed the modified intention-to-treat population. The treatment session lasted 45 minutes and outcomes were reported at 2 hours. Significantly more individuals in the active treatment group (66 of 99, 66.7%) than the sham group (40/103, 38.8%) ($p<0.001$) reported pain relief at 2 hours. Rescue medication use at 2 hours was reported by 1% of the active treatment group and 3.8% of the sham group; the difference was not statistically significant, $p=0.190$. Additional RCTs are needed that seek to replicate positive findings in other groups of individuals and that evaluate REN use over longer periods of time.

Background/Overview

Auricular Electrostimulation Devices

Auricular electrostimulation, or electroacupuncture, is a type of ambulatory electrical stimulation of acupuncture points on the ear over several days. Point stimulation by P-Stim is proposed for use in the treatment of: 1) preoperative, intraoperative and postoperative acute pain therapy (including dental procedures); 2) chronic pain syndromes associated with back pain, cervical syndrome, fibromyalgia, migraine headaches, sciatic-related pain; and, 3) pain associated with OA and RA. Other proposed uses include treatment of anxiety, depression, and special fields of anesthesia. P-Stim is generally well tolerated and can be combined with other forms of therapy.

According to the manufacturer and the U.S. Food and Drug Administration (FDA) 510(k) clearance summary (March 30, 2006), P-Stim is a single-use miniaturized, battery-powered, low frequency transcutaneous electrical nerve stimulator with a pre-programmed frequency, pulse, and duration for the stimulation of auricular acupuncture points. The device is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify three auricular acupuncture points. The P-Stim device connects to the three acupuncture needles with caps and stainless steel wires. The device is powered by three zinc air batteries, each with a voltage of 1.4 V, and is preprogrammed to be on for 180 minutes, then off for 180 minutes, with a maximum battery life of up to 96 hours. The indications for use of P-Stim (and the FDA 510(k) cleared, substantially equivalent devices) are in the practice of acupuncture by qualified practitioners of acupuncture. All three devices have similar operating principles as electrical nerve stimulators including a single output channel and mode with similar pulse width and frequencies.

Supraorbital Transcutaneous Neurostimulation

The Cefaly device was cleared by the FDA in March 2014 as a Class II "transcutaneous electrical nerve stimulator (TENS)" *de novo* device for prophylactic (preventive) treatment of episodic migraine headaches (that is, migraine headaches occurring less than 15 times a month) in adults 18 years of age or older. On September 15, 2017, the FDA cleared the Cefaly Acute device as substantially equivalent to the predicate device (Cefaly) for use during an acute migraine attack with or without aura.

The externally worn nerve stimulator is applied to the forehead using a self-adhesive electrode positioned bilaterally over the upper branches of the trigeminal nerve. The battery-powered headband device is intended to stimulate the upper branches of the trigeminal nerve in order to reduce the frequency of migraine attacks. The device consists of two distinct components: an electrical pulse generator (EPG) and a self-adhesive electrode. The Cefaly EPG is made of ABS plastic and consists of electrical circuits controlled by firmware and powered by two 1.5V batteries. The front of the Cefaly EPG has a single button that is used to turn the device on/off and adjust the intensity of the electrical stimulus during a treatment session. Visual and auditory indicators inform the user when the device is on or off and assists in troubleshooting if the device it is not working properly (for example, the device indicates if batteries need replacement and if electrical connection between device and skin is unacceptable). The back side of the Cefaly EPG has two metal blades that serve to electrically connect it to the Cefaly electrode.

A treatment session begins by attaching the Cefaly electrode to the middle of the forehead and fastening the Cefaly EPG to the electrode. When the on/off button is depressed, a pulsatile electrical stimulus is applied for 20 minutes. During the first 14 minutes, the intensity of the stimulus gradually increases until it reaches a maximum. At any time while the stimulus intensity is increasing, the user can press the button on the front of the device to select an intensity that is lower than the maximum, and it will remain constant at this lower value for the remainder of the treatment session. The device turns the stimulus off automatically after 20 minutes, or alternatively, the user can stop a treatment session by pressing the button twice or simply removing the device from their forehead.

According to the manufacturer, the following are limitations of use of the device:

- The Cefaly device cannot be used by an individual who has a cardiac pacemaker or an implanted or wearable defibrillator.
- The Cefaly device cannot be used by an individual who has an implanted metallic or electronic device in their head.
- The Cefaly device should not be used by an individual with chronic migraine, refractory migraine, medication overuse headache, or chronic tension-type headaches. The safety and effectiveness of the device has not been demonstrated for individuals with these conditions.
- The Cefaly device should not be applied on the neck or chest, and it should not be used in the presence of electronic monitoring equipment (for example, cardiac monitors), in the bath or shower, while sleeping, while driving, or while operating machinery.
- The long-term effects of using the Cefaly device are unknown.

H-Wave Electrical Stimulation Devices

H-Wave devices are classified by the FDA as a powered muscle stimulator "intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area." H-Wave is used in both low frequency and high frequency settings. The H-Wave Muscle Stimulator device (Electronic Waveform Lab, Inc., Huntington Beach, CA) received FDA 510(k) clearance as a Class II device in 1997.

IFS Therapy Devices

IFS therapy, also referred to as interferential therapy (IF/IFT), is a type of electrical stimulation that uses paired electrodes of two independent circuits carrying high-frequency (4,000 Hz) and medium-frequency (150 Hz) alternating currents. The superficial electrodes are aligned on the skin. It is believed that IFS permeates the tissues more effectively, with less unwanted stimulation of cutaneous nerves, and is more comfortable than TENS. IFS therapy devices are regulated by the FDA as Class II devices, with more than 50 instruments receiving 510(k) clearance.

MENS Devices

MENS therapy involves the application of a very precise, low, tightly controlled electrical current to specific points on the body. These points of low electrical resistance correspond with classical acupuncture points. Proposed uses include chronic and acute pain, swelling, TMJ dysfunctions, post-operative care, sports injuries and arthritis. The MICROCURRENT (Precision MICROCURRENT, Inc., Newberg, OR) has received FDA 510(k) clearance as a Class II device.

PES and PEMF Devices

In 2003, the FDA cleared the BioniCare Stimulator BIO-1000™ (now called the BioniCare Knee System with the OActive Knee Brace), indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with OA of the knee that has not adequately responded to NSAID therapy. The BioniCare BIO-1000 device is applied to the knee and can be worn under clothing and during sleep. The device should be used at least 6 hours per day. A low-amplitude pulsed electric field is delivered to the area surrounding the knee, which is purported to provide improvement in knee pain and function.

The OrthoCor™ Active Knee System™ (OrthoCor Medical, Arden Hills, MN) uses PEMF energy at a radiofrequency of 27.12 MHz to treat pain. The OrthoCor Knee System received 510(k) marketing clearance (K091996, K092044) from FDA in 2009 and is classified as a shortwave diathermy device for use other than applying therapeutic deep heat. It is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue and for the treatment of muscle and joint aches and pain associated with overexertion, strains, sprains, and arthritis. The system includes single-use packs (pods) that deliver hot or cold and are supplied in packets of 15. The predicate devices are the OrthoCor (K091640) and Ivivi Torino II™ (K070541).

The SofPulse® (Models: 912-M10, and Roma3™, Torino II™; Ivivi Health Sciences, LLC, Montvale, NJ) received 510(k) marketing clearance (K070541) in 2008 as short-wave diathermy devices that apply electromagnetic energy

at a radiofrequency of 27.12 MHz. The devices are indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

PNT Devices

An electrical stimulation device identified as Percutaneous Neuromodulation Therapy™ Nerve Stimulation System (Vertis Neuroscience, Inc, Vancouver, WA) received FDA 510(k) clearance in 2002. The clearance order stated that the therapy is "indicated for symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment for the management of post-surgical pain and post-trauma pain." Its primary indication is for low back pain and spinal pain. The procedure involves the insertion of pairs of electrodes into the skin of the lower back area with the intent of stimulating nerve fibers that lie in the deep tissues. Treatments may be given several times a week, typically for about 30 minutes at a time.

The SPRINT peripheral nerve stimulation system (SPR Therapeutics, Cleveland, OH) was cleared by the FDA in 2018. FDA documents state that the system consists of a percutaneous electrode placed using an introducer needle near a target peripheral nerve and an external pulse generator that delivers stimulation to the percutaneous electrode. The FDA further states the device is indicated for treatment of post-traumatic pain, post-operative pain and chronic, intractable pain.

Sympathetic Therapy

Sympathetic therapy describes a type of electrical stimulation of the peripheral nerves that is designed to stimulate the sympathetic nervous system in an effort to normalize the autonomic nervous system and alleviate chronic pain. Unlike TENS or IFS therapy, sympathetic therapy is not designed to treat local pain, but is designed to induce a systemic effect on sympathetically induced pain. Sympathetic therapy uses four intersecting channels of various frequencies with bilateral electrode placement on the feet, legs, arms, and hands. Electrical current is then induced with beat frequencies between 0-1000Hz. Treatment may include 1 hour of daily treatments in the physician's office followed by home treatments if the initial treatment was effective. The Dynatron STS device (Dynatronics Corporation, Salt Lake City, UT) and companion home device, Dynatron STS Rx, are devices that deliver sympathetic therapy and have received FDA 510(k) clearance.

CES Devices

Cranial Electrotherapy Stimulation (CES), also known as electrosleep, cranial electrotherapy, and transcranial electrotherapy, involves transcutaneous delivery of low-level electrical stimulation (<1000 *u*A) to the head via electrodes. CES devices vary in terms of the location of electrode placement varies which can include the earlobes, mastoid processes and the zygomatic arches. maxilla-occipital junction. The mechanism of action of CES remains unclear and has been hypothesized to include deactivating cortical brain activity and altering brain connectivity to the default mode network (DMN) (Feusner, 2012).

The first CES device was approved by the FDA in the late 1970s for treatment of anxiety, insomnia and depression and a number of devices have subsequently been cleared by the FDA through the 510(k) process as substantially equivalent. Most recently, Cervella (Innovative Neurological Devices, LLC, Carmel, IN) was cleared by the FDA

in March 2019 for treatment of anxiety, depression and insomnia. The device, which provides a very low level of electric current to the individual's brain, includes electrodes integrated into the ear pads of noise-cancelling Bluetooth-enabled headphones. The device is controlled by an app on the individual's smart device. Using the app, the person can control the intensity level and duration of the treatment. The manufacturer recommends 30 minute treatment sessions.

The Alpha-Stim®AID device (Electromedical Products International, Mineral Wells, TX) was cleared by the FDA in 1992 as a treatment of anxiety, insomnia and depression. Electrical stimulation is delivered via electrodes attached to earclips. The Alpha-Stim®M pain treatment device, listed below under MENS devices, can also be used to deliver CES to treat anxiety, insomnia and/or depression associated with pain.

REN Devices

The FDA approved a de novo application for a REN device (Nerivio Migra®, Theranica Bio-Electronics Ltd., Israel) in May, 2019. The Nerivio Migra system delivers low energy electrical pulses to the individual's upper arm via an armband. The device is battery-powered and controlled by software installed on a user's personal mobile device. The FDA stated that the device is indicated for acute treatment of migraine with or without aura in adults who do not have chronic migraine.

Types of Devices Used for Treatment

Auricular Electrical Stimulation Devices

- AcuStim™ (S.H.P. International PTY., LTD., Fullarton, S.A., Australia)
- E-pulse (AMM Marketing LLC, Coral Springs, FL)
- P-Stim device (Octus Spine Laguna Hills, CA)

H-Wave Electrical Stimulation Devices

- H-Wave Muscle Simulator (Electronic Waveform Lab, Inc., Huntington Beach, CA)

IFS Therapy Devices

- BioStim® INF, INF Plus™ (BioMedical Life Systems, Inc., Vista, CA)
- Endomed Interferential Stimulators (Enraf Nonius B.V., Rotterdam, The Netherlands)
- Flex-IT™ (EMSI, Alexander, VA)
- Soleo Galva Electrotherapy System (Zimmer MedizinSysteme GmbH, Neu-Ulm, Germany)
- IF 4000 (ProMed Specialties, Huntingdon Valley, PA)
- IF 8000 (Biomotion, Madison, AL)
- FastStart® IF, OrthoStim4™, SurgiStim4™, VQ™ Vector (VQ OrthoCareSM, Irvine, CA)
- RSJ, RS JC, RS-4i® Sequential Stimulator; RS-2i® Interferential Stimulator (RS Medical, Vancouver, WA)
- Stereodynator® (Gbo Medizintechnik AG, Rimbach, Germany)
- PRO ElecDT® 2000 (Hako-Med, Las Vegas, NV)
- Vectorsurge 5 Model 470 (Metron Medical-Australia PL, Victoria, Australia)

MENS Devices

- Algonix® (Medilab GmbH & Co., Germany)
- Alpha-Stim®M (Electromedical Products International, Inc., Mineral Wells, TX,)
- Electro-Myopulse 75 L, Electro-Myoscope 85P, Myopulse 75C (Biomedical Design Instruments, U.S.A.)
- Micro Plus™ Microcurrent Electrical Nerve Stimulator (BioMedical Life Systems, Inc. Vista, CA)

PNT Devices

- BioWave PRO® Neuromodulation Pain Therapy Relief, Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave Corporation, Norwalk, CT)
- SPRINT® PNS system (SPR Theraeutics, Cleveland, OH)
- Vertis PNT System (Vertis Neuroscience, Inc., Vancouver, WA)

PES and PEMF Stimulation Devices

- BioniCare Knee System (includes the OActive Knee Brace), formerly known as the BIO-1000™ System (BioniCare Medical Technologies, Inc., Sparks, MD)
- Diatermed II (Carci, São Paulo, Brazil)
- OrthoCor™ Active Knee System™ (OrthoCor Medical, Arden Hills, MN)
- SofPulse®, SofPulse® (Models: 912-M10, and Roma3™, Torino II™; Ivivi Health Sciences, LLC, Montvale, NJ)

Supraorbital Transcutaneous Neurostimulation

- Cefaly (STX-MED SPRL, Belgium)
- Cefaly Acute (STX-MED SPRL, Belgium)

Sympathetic Therapy

- Dynatron STS and Dynatron STS Rx (Companion Home Device) (Dynatronics Corporation, Salt Lake City, UT)

CES Devices

- Cervella (Innovative Neurological Devices, LLC, Carmel, IN)
- Alpha-Stim AID (Electromedical Products International, Mineral Wells, TX)

REN Devices

- Nerivio Migra®, Theranica Bio-Electronics Ltd., Israel)

Definitions

Visual analog scale (VAS): A pain assessment tool that helps an individual describe the intensity of their pain by marking on a line their level of discomfort; a VAS is a straight line with the left end of the line representing no pain and the right end of the line representing the worst pain.

Coding

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

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

CPT

64999	Unlisted procedure, nervous system [when specified as percutaneous neuromodulation therapy]

HCPCS

E0762	Transcutaneous electrical joint stimulation device system, includes all accessories (PES)
E1399	Durable medical equipment, miscellaneous [when specified as auricular electrostimulation, H-Wave, microcurrent stimulation, PNT, REN or sympathetic therapy devices, or headband device for trigeminal nerve stimulation for migraines]
K1002	Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type
S8130	Interferential current stimulator, 2 channel
S8131	Interferential current stimulator, 4 channel
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient

ICD-10 Diagnosis

All diagnoses

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Sympathetic Therapy

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
Revised	02/20/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. In title, changed "related" to "other". Added statement that cranial electrical stimulation (CES) is considered investigational and not medically necessary for all indications, including but not limited to, treatment of pain, anxiety, insomnia and depression. Added statement that remote electrical neuromodulation (REN) is considered investigational and not medically necessary for all indications, including but not limited to, treatment of acute migraine headaches, with or without aura. Updated Rationale, Background, References and Index sections. Updated Coding section; added K1002.
Reviewed	08/22/2019	MPTAC review. Updated Rationale, Background and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Rationale and References sections.
Revised	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Revised INV & NMN statement for

		supraorbital transcutaneous neurostimulation. Updated Rationale, Background, References, and Websites for Additional Information sections.
Reviewed	11/03/2016	MPTAC review. Updated formatting in Position Statement section. Updated Description, Rationale, Background, References, Websites for Additional Information and Index sections.
Reviewed	11/05/2015	MPTAC review. Updated Description, Rationale, Discussion, Device tables, References, Websites for Additional Information, and Index sections. Removed ICD-9 codes from Coding section.
Revised	11/13/2014	MPTAC review. Added investigational and not medically necessary statement for supraorbital transcutaneous neurostimulation for all indications. Updated Rationale, Background, Coding, References, Index and Websites for Additional Information sections.
Revised	08/14/2014	MPTAC review. Added investigational and not medically necessary statement for auricular electrostimulation for all indications. Minor format changes throughout document. Updated Rationale, Background, Coding, References, Index and Websites for Additional Information sections.
Reviewed	05/15/2014	MPTAC review. Updated Rationale, References and Websites for Additional Information sections.
Reviewed	05/09/2013	MPTAC review. Updated Rationale, Background, References, and Websites for Additional Information.
Reviewed	05/10/2012	MPTAC review. Updated Description, Rationale, Background tables, References, Websites for Additional Information, and Index.
Reviewed	05/19/2011	MPTAC review. Updated Description, Rationale, Background, References, Websites for Additional Information, and Index.
Reviewed	05/13/2010	MPTAC review. Updated Discussion, Rationale, Coding, References, and Index.
Reviewed	05/21/2009	MPTAC review. Updated and clarified Description/scope of document. Updated Rationale, Background/Overview, product tables, Definitions, and References.
Reviewed	05/15/2008	MPTAC review. Updated Rationale, Background, Definitions, and References.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. Position Statements clarified. Rationale, Background, Index, and References updated. Product tables added.
Reviewed	06/08/2006	MPTAC annual review. Updated References.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes.
	11/22/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	Medical review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	10/28/2004	DME.00011	Electrical Stimulation as a Treatment for Pain and Related Conditions: Surface and Percutaneous Devices
WellPoint Health Networks, Inc.	09/25/2004	2.07.12	Pulsed Electrical Stimulation in the Treatment of Osteoarthritis
	12/2/2004	2.10.14	Sympathetic Therapy as a Treatment of Chronic Pain
	04/28/2005	5.01.01	Inferential Current Stimulation