Policy Statement

Interferential current stimulation is considered investigational.

Policy Guidelines

There are no specific CPT codes describing interferential current stimulation. The following CPT code might be used:
- **97014**: Application of a modality to 1 or more areas; electrical stimulation (unattended)

The following HCPCS code might also be used:
- **G0283**: Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

The following HCPCS codes are available for these stimulation devices:
- **S8130**: Interferential current stimulator, 2 channel
- **S8131**: Interferential current stimulator, 4 channel

Description

Interferential current stimulation (IFS) is a type of electrical stimulation used to reduce pain. The technique has been proposed to decrease pain and increase function in patients with osteoarthritis and to treat other conditions such as constipation, irritable bowel syndrome, dyspepsia, and spasticity.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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

Regulatory Status

A number of IFS devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, including the Medstar™ 100 (MedNet Services) and the RS-4i® (RS Medical). IFS may be included in multimodal electrotherapy devices such as transcutaneous electrical nerve stimulation and functional electrostimulation.
Rationale

Background
Interferential current stimulation (IFS) is a type of electrical stimulation that has been investigated as a technique to reduce pain, improve function and range of motion, and treat gastrointestinal disorders.

IFS uses paired electrodes of two independent circuits carrying high-frequency and medium-frequency alternating currents. The superficial electrodes are aligned on the skin around the affected area. It is believed that IFS permeates the tissues more effectively and with less unwanted stimulation of cutaneous nerves, is more comfortable than transcutaneous electrical nerve stimulation. There are no standardized protocols for the use of IFS; IFS may vary by frequency of stimulation, the pulse duration, treatment time, and electrode-placement technique.

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

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

Musculoskeletal Conditions
RCTs with placebo control are extremely important to assess treatments of painful conditions, due to the expected placebo effect, the subjective nature of pain assessment in general, and the variable natural history of pain that often responds to conservative care. Therefore, to establish whether an intervention for pain is effective, a placebo comparison is needed.

Clinical Context and Therapy Purpose
The purpose of using interferential current stimulation (IFS) in patients who have musculoskeletal conditions is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of IFS improve health outcomes for those with musculoskeletal conditions?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with musculoskeletal conditions.
Interventions
The therapy being considered is IFS.

Comparators
The following therapies are currently being used: physical therapy, medication, and other types of electrical stimulation.

Outcomes
The specific outcomes of interest are pain control, increased functional capacity, and improved QOL. IFS would be used as adjunctive treatment with observed effects to be expected within six months.

Systematic Reviews
A network meta-analysis by Zeng et al (2015) identified 27 RCTs on 5 types of electrical stimulation therapies used to treat pain in patients with knee osteoarthritis (OA).1 Reviewers found that IFS was significantly more effective than control interventions for pain relief (standardized mean difference, 2.06; 95% credible interval, 1.10 to 3.19) and pain intensity (standard mean difference, -0.92; 95% credible interval, -1.72 to -0.05). The validity of these conclusions is uncertain due to the limitations of the network meta-analysis, which used indirect comparisons to make conclusions. A further limitation is that the findings of placebo-controlled studies were not reported separately; rather, they were pooled in the analysis of usual care comparators.

Fuentes et al (2010) published a systematic review and meta-analysis of RCTs evaluating the effectiveness of IFS for treating musculoskeletal pain.2 Twenty RCTs met the following inclusion criteria: adults diagnosed with a painful musculoskeletal condition (e.g., knee, back, joint, shoulder, or OA pain); compared IFS alone or as a cointervention with placebo, no treatment, or an alternative intervention; and assessed pain using a numeric rating scale. Fourteen of the trials reported data that could be pooled. IFS as a stand-alone intervention was not found to be more effective than placebo or an alternative intervention at reducing pain. For example, a pooled analysis of 2 studies comparing IFS alone with placebo did not find a statistically significant difference in pain intensity at discharge; the pooled mean difference (MD) was 1.17 (95% confidence interval [CI], -1.70 to 4.05). Also, a pooled analysis of 2 studies comparing IFS alone with an alternative intervention (e.g., 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). Moreover, in a pooled analysis of 5 studies comparing IFS as a cointervention with a placebo, there was a nonsignificant finding in pain intensity at discharge (MD=1.60; 95% CI, -0.13 to 3.34; p=0.07). The meta-analysis found IFS plus another intervention to be superior to a control group (e.g., no treatment) for pain intensity at day 1 and 4 weeks; a pooled analysis of 3 studies found an MD of 2.45 (95% CI, 1.69 to 3.22; p<0.001). However, that analysis did not distinguish the specific effects of IFS from the cointervention nor did it control for potential placebo effects.

Randomized Controlled Trials
Two placebo-controlled randomized trials were included in the Fuentes et al (2010) meta-analysis, one of which (Defrin et al [2005]2) was also included in the Zeng et al (2015) meta-analysis. The Defrin et al (2005) trial included 62 patients with OA knee pain.2 Patients were randomized to one of six groups (four active treatment groups and two control groups, sham and nontreated). Acute pre- vs posttreatment reductions in pain were found for all active groups but neither control group. Stimulation resulted in a modest pretreatment elevation of pain threshold over this four-week trial. Taylor et al (1987) randomized 40 patients with a temporomandibular joint syndrome or myofascial pain syndrome to active or placebo IFS.3 Principal outcomes were pain assessed by a questionnaire and range of motion. There were no statistically significant differences in the outcomes between groups.

Two other RCTs, both published in 2012, were included in the Zeng et al (2015) meta-analysis. One found significantly better outcomes with IFS vs placebo while the other did not find
significant differences between active and sham interventions. Atamaz et al (2012) compared IFS, transcutaneous electrical nerve stimulation, shortwave diathermy, and sham interventions for treating knee OA. A total of 203 patients were randomized to 1 of 6 groups, 3 with active treatment and 3 with sham treatment. The primary outcome was knee pain as assessed on a visual analog scale (VAS; range, 0-100). Other outcomes included range of motion, time to walk 15 meters, paracetamol intake, the Nottingham Health Profile score, and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) score. At the 1-, 3-, and 6-month follow-ups, there were no statistically significant differences across the six groups in VAS pain scores, Nottingham Health Profile pain scores, or WOMAC pain scores. Moreover, WOMAC function scores, time to walk 15 meters, and Nottingham Health Profile physical mobility scores did not differ significantly among groups at any follow-up assessments. At the one-month follow-up, paracetamol intake was significantly lower in the IFS group than in the transcutaneous electrical nerve stimulation group.

Gundog et al (2012) randomized 60 patients with knee OA to 1 of 4 groups: 3 IFS groups at frequencies of 40 Hz, 100 Hz, and 180 Hz, and sham IFS. In addition to the placebo-controlled trials, several RCTs have compared IFS with another active intervention or with usual care. However, studies with active comparators, as well as those with usual care control groups, may be subject to the placebo effect. Receiving an older or known, rather than a novel, intervention, may elicit a placebo response.

Section Summary: Musculoskeletal Conditions
Placebo-controlled randomized trials of IFS for treating musculoskeletal pain and impaired function have mostly found that IFS does not significantly improve outcomes. A meta-analysis limited to placebo-controlled trials also did not find a significant benefit of IFS for treating pain and function. RCTs with usual care or active treatment comparisons may be subject to the placebo effect.

Gastrointestinal Disorders
Clinical Context and Therapy Purpose
The purpose of using IFS in patients who have gastrointestinal disorders (e.g., constipation, irritable bowel syndrome, and dyspepsia) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of IFS improve health outcomes for those with gastrointestinal disorders?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with a gastrointestinal disorder such as constipation, irritable bowel syndrome, or dyspepsia.

Interventions
The therapy being considered is IFS.

Comparators
The following therapies are currently being used: dietary changes, medication, and other types of electrical stimulation.

Outcomes
The specific outcomes of interest are pain control, increased functional capacity, and improved QOL. Safety and efficacy of IFS would be evaluated at one month following a four week treatment.
**Constipation**

Several RCTs evaluating IFS for treating children with constipation and/or other lower gastrointestinal symptoms were identified. The RCTs had small sample sizes and did not consistently find a benefit of IFS. For example, Kajbafzadeh et al (2012) in Iran randomized 30 children with intractable constipation to IFS or sham stimulation. Children ranged in age from 3 to 12 years old and had failed 6 months of conventional therapy (e.g., dietary changes, laxatives). Patients received 15, IFS sessions (20 minutes long), 3 times a week for 5 weeks. Over six months, the mean frequency of defecation increased from 2.5 times a week to 4.7 times a week in the treatment group and from 2.8 times a week to 2.9 times a week in the control group. The mean pain during defecation score decreased from 0.35 to 0.20 in the treatment group and from 0.29 to 0.22 in the control group. The authors reported a statistically significant between-group difference in constipation symptoms.

Another RCT, published by Clarke et al (2009), was conducted in Australia. Thirty-three children with slow transit time constipation (mean age, 12 years) were randomized to IFS or sham treatment. They received 12, 20-minute sessions over 4 weeks; the primary outcome was health-related QOL, and the main assessment instrument used was the Pediatric Quality of Life Inventory. The authors only reported within-group changes; they did not compare the treatment and control groups. There was no statistically significant change in QOL, as perceived by the parent group. The mean parent-reported QOL scores changed from 70.3 to 70.1 in the active treatment group and from 69.8 to 70.2 in the control group. There was also no significant difference in QOL, as perceived by the child after sham treatment. The Pediatric Quality of Life Inventory score, as perceived by the child, did increase significantly in the active treatment group (mean, 72.9 pretreatment vs 81.1 posttreatment, p=0.005).

**Irritable Bowel Disease**

An RCT by Coban et al (2012) randomized 67 adults with irritable bowel syndrome to active or placebo IFS. Patients with functional dyspepsia were excluded. Patients received 4, 15-minute IFS sessions over 4 weeks. Fifty-eight (87%) of 67 patients completed the trial. One month after treatment, primary outcome measures did not differ significantly between treatment and control groups. For example, for abdominal discomfort, the response rate (i.e., >50% improvement) was 68% in the treatment group and 44% in the control group. For bloating and discomfort, the response rate was 48% in the treatment group and 46% in the placebo group. Using a VAS, 72% of the treatment group and 69% of the control group reported improvement in abdominal discomfort.

**Dyspepsia**

One RCT, by Koklu et al (2010) in Turkey, has evaluated IFS for treating dyspepsia. The trial randomized adults to active IFS (n=25) or sham treatment (n=25); patients were unaware of their treatment allocation. Patients received 12 treatment sessions over 4 weeks; each session lasted 15 minutes. Forty-four (88%) of 50 randomized patients completed the therapy session and follow-up questionnaires at 2 and 4 weeks. The trialists did not specify primary outcome variables; rather, they measured the frequency of ten gastrointestinal symptoms. In an intention-to-treat analysis at four weeks, IFS was superior to placebo for the symptoms of early satiation and heartburn, but not for the other eight symptoms. For example, before treatment, 16 (64%) of 25 patients in each group reported experiencing heartburn. At 4 weeks, 9 (36%) patients in the treatment group and 13 (52%) patients in the sham group reported heartburn (p=0.02). Among symptoms that did not differ between groups at follow-up, 24 (96%) of 25 patients in each group reported epigastric discomfort before treatment. In the intention-to-treat analysis, 5 (20%) of 25 patients in the treatment group and 6 (24%) of 25 patients in the placebo group reported epigastric discomfort.

**Section Summary: Gastrointestinal Disorders**

IFS has been tested as a treatment option for a variety of gastrointestinal conditions, with a small number of trials completed for each condition. Trial results were mixed, with some reporting...
benefit and others not. This body of evidence is inconclusive on whether IFS is an efficacious treatment for gastrointestinal conditions.

Poststroke Spasticity
Clinical Context and Therapy Purpose
The purpose of using IFS in patients who have poststroke spasticity is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of IFS improve health outcomes for those with poststroke spasticity?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with poststroke spasticity.

Interventions
The therapy being considered is IFS.

Comparators
The following therapy is currently being used: standard stroke rehabilitation.

Outcomes
The specific outcomes of interest are improved function and QOL. Effect of IFS would be assessed one hour after a single treatment.

Randomized Controlled Trials
A single-blind RCT evaluating IFS as a treatment of chronic stroke was published by Suh et al (2014).15 Forty-two inpatient stroke patients with plantar flexor spasticity were randomized to a single 60-minute session with IFS or placebo IFS treatment following 30 minutes of standard rehabilitation. In the placebo treatment, electrodes were attached; however, the current was not applied. Outcomes were measured immediately before and one hour after the intervention. The primary outcomes were gastrocnemius spasticity (measured on a 0 to 5 Modified Ashworth Scale) and two balance-related measures: the Functional Reach Test and the Berg Balance Scale. Also, gait speed was measured using a 10-meter walk test, and gait function was assessed with the Timed Up & Go Test. The IFS group performed significantly better than the placebo group on all outcomes (p<0.05 for each comparison). For example, the mean (standard deviation) difference in Modified Ashworth Scale score was 1.55 (0.76) in the IFS group and 0.40 (0.50) in the placebo group. A major limitation of the trial was that outcomes were only measured one hour after the intervention and no data were available on longer-term impacts of the intervention.

Section Summary: Poststroke Spasticity
Data from a small RCT with very short follow-up provides insufficient evidence on the impact of IFS on health outcomes in patients with post-stroke spasticity.

Summary of Evidence
For individuals who have musculoskeletal conditions who receive IFS, the evidence includes RCTs and meta-analyses. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Placebo-controlled randomized trial(s) have found that IFS when used to treat musculoskeletal pain and impaired function(s) does not significantly improve outcomes; additionally, a meta-analysis of placebo-controlled trials did not find a significant benefit of IFS for decreasing pain or improving function. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have gastrointestinal disorders who receive IFS, the evidence includes RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. IFS has been tested for a variety of gastrointestinal conditions, with a small number of trials completed for each condition. The results of the trials are mixed, with some reporting benefit and others not. This body of evidence is inconclusive on whether IFS is an efficacious treatment for gastrointestinal conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have poststroke spasticity who receive IFS, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The RCT had a small sample size and very short follow-up (immediately posttreatment). The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements

American College of Physicians and the American Pain Society
Clinical practice guidelines from the American College of Physicians and the American Pain Society (2009) concluded that there was insufficient evidence to recommend interferential current stimulation (IFS) for the treatment of low back pain.16,

American College of Occupational and Environmental Medicine
The American College of Occupational and Environmental Medicine published several relevant guidelines. For shoulder disorders, guidelines found the evidence on IFS to be insufficient and, depending on the specific disorder, either did not recommend IFS or were neutral on whether to recommend it.17, For low back disorders, guidelines found the evidence on IFS to be insufficient and did not recommend. The sole exception was that IFS could be considered as an option on a limited basis for acute low back pain with or without radicular pain.18, For knee disorders, guidelines recommended IFS for postoperative anterior cruciate ligament reconstruction, meniscectomy, and knee chondroplasty immediately postoperatively in the elderly.19, This was a level C recommendation.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>Ongoing</td>
<td>NCT02381665</td>
<td>Efficacy of Interferential Therapy in Chronic Constipation (CON-COUR) (CON-COUR)</td>
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</table>

NCT: national clinical trial.

References

17..dump

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT®</td>
<td>64550</td>
<td>Application of surface (transcutaneous) neurostimulator (e.g., TENS unit)</td>
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<td>(Deleted code effective 1/1/2019)</td>
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<tr>
<td></td>
<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (unattended)</td>
</tr>
<tr>
<td></td>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes</td>
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<tr>
<td>HCPCS</td>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<tr>
<td></td>
<td>G0283</td>
<td>Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
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<td></td>
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<td>Interferential current stimulator, 4 channel</td>
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ICD-10 Procedure

None

Policy History

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

<table>
<thead>
<tr>
<th>Effective Date</th>
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<td>07/31/2015</td>
<td>Policy title change from Electrical Stimulation for Pain and Other Conditions</td>
<td>Medical Policy Committee</td>
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<td>Policy revision without position change</td>
<td>BCBSA Medical Policy adoption</td>
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<td>08/01/2016</td>
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<td>11/01/2017</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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

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

**Prior Authorization Requirements (as applicable to your plan)**

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

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.