Policy Statement

Interferential current stimulation is considered investigational.

Policy Guidelines

There are no specific CPT codes describing interferential current stimulation. The following CPT codes might be used:

- 64550: Application of surface (transcutaneous) neurostimulator (e.g., TENS unit)
- 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 devices:

- S8130: Interferential current stimulator, 2 channel
- S8131: Interferential current stimulator, 4 channel

Description

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

Related Policies

- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
- Transcutaneous Electrical Nerve Stimulation

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 interferential stimulator devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, including the Medstar™ 100 (MedNet Services) and the RS-4i® (RS Medical).
Rationale

Background
Interferential current stimulation (IFS) is a type of electrical stimulation that uses paired electrodes of 2 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. IFS has been investigated as a technique to reduce pain, improve range of motion, and treat gastrointestinal disorders. 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
Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

Musculoskeletal Conditions
Randomized controlled trials (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.

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

In 2010, Fuentes et al published a systematic review and meta-analysis of RCTs evaluating the effectiveness of IFS for treating musculoskeletal pain. Twenty RCTs met the following inclusion criteria: adults diagnosed with a painful musculoskeletal condition (e.g., knee, back, joint, shoulder, or osteoarthritic 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 included in a pooled analysis. 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). In addition, 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.

Two placebo-controlled randomized trials were included in the Fuentes meta-analysis, one of which (Defrin et al, 2005) was also included in the Zeng meta-analysis. The trial by Defrin included 62 patients with osteoarthritic knee pain. Patients were randomized to 1 of 6 groups (4 active treatment groups and 2 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 4-week trial. In 1987, Taylor et al randomized 40 patients with temporomandibular joint syndrome or myofascial pain syndrome to active or placebo IFS. Principal outcomes were pain assessed by a questionnaire and range of motion. There were no statistically significant differences in the outcomes between groups.

Two more recent RCTs, both published in 2012, were included in the Zeng 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 compared IFS, transcutaneous electrical nerve stimulation, shortwave diathermy, and sham interventions for treating knee osteoarthritis. 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 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 (NHP) score, and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) score. At the 1-, 3-, and 6-month follow-ups, there was no statistically significant difference across the 6 groups in the VAS pain score, NHP pain score, or WOMAC pain score. Moreover, WOMAC function score, time to walk 15 meters, and 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 in the TENS group.

Gundog et al randomized 60 patients with knee osteoarthritis to 1 of 4 groups: 3 IFS groups at frequencies of 40 Hz, 100 Hz, and 180 Hz, and sham IFS. The primary outcome was pain intensity assessed by the WOMAC. Mean WOMAC scores 1 month after treatment were 7.2 in the 40-Hz group, 6.7 in the 100-Hz group, 7.8 in the 180-Hz group, and 16.1 in the sham IFS group (p<0.05 vs active treatment groups). Secondary outcomes (e.g., VAS score) also showed significantly higher benefit in the active treatment groups compared with the sham IFS group. The number of patients assigned to each group and patient follow-up rates were not reported.

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 it 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**

**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, in 2012, Kajbafzadeh et al in Iran randomized 30 children with intractable constipation to receive 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 6 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 in 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 a dozen 20-minute sessions over 4 weeks; the primary outcome was health-related quality of life (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**

A 2012 RCT by Coban et al randomized 67 adults with irritable bowel syndrome to active or placebo IFS. Patients with functional dyspepsia were excluded. Patients received four 15-minute IFS sessions over 4 weeks. Fifty-eight (87%) of 67 patients completed the study. One month after treatment, primary outcomes 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**

We identified 1 RCT, by Koklu et al (2010) in Turkey, that evaluated IFS for treating dyspepsia. The trial randomized patients to active IFS (n=25) or sham treatment (n=25); patients were unaware of 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 authors did not specify primary outcome variables; they measured the frequency of 10 gastrointestinal symptoms. In an intention-to-treat analysis at 4 weeks, IFS was superior to placebo for the symptoms of early satiation and heartburn, but not for the other 8 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 at follow-up between groups, 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 for a variety of gastrointestinal conditions, with a small number of trials completed for each condition. Trial results 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.

**Poststroke Spasticity**

A single-blind RCT evaluating IFS as a treatment of chronic stroke was published by Suh et al in 2014. Forty-two inpatient stroke patients with plantarflexor 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 1 hour after the intervention. The primary outcomes were gastrocnemius spasticity (measured on a 0 to 5 Modified Ashworth Scale) and 2 balance-related measures: the Functional Reach Test and the Berg Balance Scale. In addition, 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 the Modified Ashworth Scale was 1.55 (0.76) in the IFS group and 0.40 (0.50) in the placebo group. A major limitation of the study was that outcomes were only measured 1 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 chronic stroke.

**Summary of Evidence**
For individuals who have musculoskeletal conditions who receive IFS, the evidence includes RCTs and meta-analyses. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Placebo-controlled randomized trials 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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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, published in 2007, concluded that there was insufficient evidence to recommend interferential current stimulation (IFS) for the treatment of low back pain.¹⁷

**American College of Occupational and Environmental Medicine**
The American College of Occupational and Environmental Medicine published several relevant guidelines in 2011:

Shoulder disorders: The guideline stated that the evidence on IFS is insufficient and, depending on the specific disorder, either did not recommend IFS or were neutral on whether to recommend it.¹⁸
Low back disorders: The guideline stated that the evidence on IFS is insufficient and the intervention is not recommended. The exception is that IFS may be considered as an option on a limited basis for acute low back pain with or without radicular pain.19

Knee disorders: The guideline stated that IFS is recommended for postoperative anterior cruciate ligament reconstruction, meniscectomy, and knee chondroplasty immediately postoperatively in the elderly. This was a level C recommendation.20

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT02381665</td>
<td>Efficacy of Interferential Therapy in Chronic Constipation (CON-COUR) (CON-COUR)</td>
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<td>Mar 2019</td>
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NCT: national clinical trial.

References


**Documentation for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.
The following services may be considered investigational.

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<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
<td>64550</td>
<td>Application of surface (transcutaneous) neurostimulator (e.g., TENS unit)</td>
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<td><em>(Code revision effective 1/1/2018)</em></td>
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<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation</td>
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<td></td>
<td></td>
<td>(unattended)</td>
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<tr>
<td></td>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation</td>
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<tr>
<td></td>
<td></td>
<td>(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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<td></td>
<td>G0283</td>
<td>Electrical stimulation (unattended), to 1 or more areas for indication(s)</td>
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<td>other than wound care, as part of a therapy plan of care</td>
</tr>
<tr>
<td></td>
<td>S8130</td>
<td>Interferential current stimulator, 2 channel</td>
</tr>
<tr>
<td></td>
<td>S8131</td>
<td>Interferential current stimulator, 4 channel</td>
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**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>
<th>Action</th>
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<tr>
<td>07/31/2015</td>
<td>Policy title change from Electrical Stimulation for Pain and Other Conditions</td>
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<td></td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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<td></td>
<td>BCBSA Medical Policy adoption</td>
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<td>08/01/2016</td>
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<tr>
<td>02/01/2018</td>
<td>Coding update</td>
<td>Administrative Review</td>
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</tbody>
</table>

**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.