BlueCross BlueShield of Alabama

Name of Policy:
Interferential Stimulator/Stimulation Devices

Policy #: 073
Category: DME

Latest Review Date: January 2014
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Interferential Stimulation (IF) is an anti-inflammatory based treatment modality. Interferential stimulation is characterized by two alternating-current sine waves of differing frequencies that "work" together to produce an interferential current that is also known as a beat pulse or alternating modulation frequency. One of the two currents is usually held at 4,000 Hz, and the other can be held constant or varied over a range of 4,001 to 4,100 Hz. Because of the frequency, the interferential wave meets low impedance when crossing the skin to enter deep into soft tissues. The interferential currents reportedly can stimulate sensory, motor, and pain fibers. These large impulse fibers interfere with the transmission of pain messages at the spinal cord level. This deep tissue penetration stimulates parasympathetic nerve fibers for increased blood flow and edema reduction.

Interferential stimulation is used for symptomatic relief and management of chronic intractable pain and to increase localized blood flow. It is used in the treatment of circulation disorders, range of motion, edema and muscle spasms, a variety of gastrointestinal disorders as well as an adjunctive treatment in the management of post-surgical and post-traumatic pain. Interferential stimulation has also been proposed to increase function of patients with osteoarthritis and to treat other conditions such as dyspepsia, irritable bowel syndrome, and constipation.

An Interferential Stimulator may be used in these settings: pre and post orthopedic surgery; cumulative trauma disorders; back pain; arthritis; athletic and other joint injuries/syndromes; hand/wrist injuries; podiatric conditions/procedures; and pain control of various origins.

Transcutaneous Electrical Nerve Stimulator (TENS) is characterized by biphasic current and selectable parameters such as pulse rate and pulse width. It stimulates sensory nerves to block pain signals. It also stimulates endorphin production to help normalize sympathetic function. The effect of TENS is believed to stimulate A-beta pain-suppressing nerve fibers to overwhelm chronic pain-carrying C fibers. Most TENS units produce current of 1 to 80 microamperes (mA), 9V (average), 2 to 1,000 Hz, with a pulse width of 250 to 400 microseconds (mS).

TENS is used for the relief of chronic pain, particularly back and cervical muscular and disc syndromes, arthritis, neuropathies, shoulder syndromes, and reflex sympathetic dystrophy.

Policy:

Effective for dates of service on or after October 29, 2010:

The **IFS or IFS Sequential Stimulator unit for home use does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's' contract and corporate medical policies. Physicians should always exercise their

best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Interferential current therapy involves the use of a portable, battery operated electrotherapy device. It is characterized by the crossing of two medium, independent frequencies, which work together to effectively stimulate large impulse fibers. These interfere with the transmission of pain messages at the spinal cord level. The deep tissue penetration can be adjusted to stimulate parasympathetic nerve fibers for increased blood flow. It can be used in pre- and post-orthopedic surgery, joint injury syndrome, cumulative trauma disorders, to increase circulation, and pain control of various origins.

It differs from TENS because it has deeper penetration with more comfort (compliance) and increased circulation.

IFS is a treatment which focuses on the subjective measurement of pain relief. Based on this randomized, placebo controlled trials are necessary to determine if the treatment effect exceeds the expected treatment effect.

Taylor et al randomized 40 patients with temporomandular joint syndrome or myofascial pain syndrome to undergo either active or placebo interferential stimulation. The principal outcomes were pain assessed by a questionnaire and range of motion (ROM). There was no statistically significant difference in the outcomes between the two groups.

Van der Heijden et al randomized 180 patients with soft tissue shoulder disorders to undergo therapy in 1 of the following groups in addition to a program of exercise therapy:

1. Interferential therapy plus ultrasound;
2. Active interferential therapy plus dummy ultrasound;
3. Dummy interferential therapy plus active ultrasound;
4. Dummy interferential therapy plus dummy ultrasound (i.e., the placebo group); OR
5. No adjuvant therapy. Principal outcome measures include recovery, functional status, chief complaint, pain, clinical status, and range of motion, at six weeks after the therapy had been completed and at intervals up to one year. The authors reported that neither interferential therapy nor ultrasound proved to be effective as an adjuvant to exercise therapy.

Werners et al reported on the results of a study that randomized 152 patients with low back pain to either treatment with interferential therapy or traction. Therefore, this study was not placebo controlled. Outcomes were based on the results of the Oswestry Disability Index and a pain visual analog scale. The authors reported that both groups recorded improvements in both groups over a three-month period; there was no statistically significant difference in outcomes between the two groups. Without a placebo group, it is unknown whether the improvement is related to the natural history of the disease or any intervention.

Hurley et al randomly assigned 60 patients with back pain to one of three groups:

1. Interferential therapy of the painful area;
2. Interferential therapy of the spinal nerve; and
3. A control group, who received no interferential therapy.

Therefore, this study was not placebo controlled. All patients received educational materials. Those assigned to active treatment groups received two to three treatments per week for variable periods of time. The principal outcome measures were based on results of pain-rating index and the Roland-Morris Disability Questionnaire. Placement of the interferential therapy electrodes over the spinal nerve, compared to the painful area, resulted in a significantly larger reduction in disability scores. However, the lack of a placebo group limits interpretation of these data.

In a randomized trial, Hou et al studied a various combination of therapies in a group of 119 patients with myofascial disease and active trigger points, including hot packs, "stretch and spray," ischemic compression, myofascial release, and interferential therapy. There was no control or placebo group, and thus interpretation of data is limited.

In conclusion, the results of the placebo-controlled trials have reported negative finds of the interferential therapy and have not shown a positive treatment effect from this therapy.

In a recent literature search one randomized controlled trial by Defrin, Ariel, and Peretz published the results of sixty-two patients with osteoarthritic knee pain that were randomized to one of four active treatment groups or two control groups (sham or non-treated). Acute pre- versus post-treatment reductions in pain were found in all active groups but not in either control group. Stimulation resulted in a modest pre-treatment elevation of pain threshold over the four weeks of the study. This study is limited due to the small number of subjects and detection bias. Additional evidence is needed to establish the acute and long-term effects of interferential stimulation. This evidence does not alter the policy statement of non-coverage.

November 2008 Update
A literature search was performed for the period of October 2006 through February 2008. Poitras and Brosseau conducted a Cochrane-structured systematic review of management of back pain with therapeutic modalities including transcutaneous electrical nerve stimulation and interferential current. The authors found no eligible studies on which to base recommendations for IFS.

A randomized double-blinded trial compared IFS or horizontal therapy (HT) with sham stimulation in 105 older women with chronic low back pain due to multiple vertebral fractures. All participants received a full therapeutic exercise program, and blinded evaluation revealed no differences between the groups following two weeks of active or sham stimulation. However, the active stimulation groups showed post-treatment improvements of about 30% in visual analogue scores (VAS) for pain and in the Backill score at the six- and 14-week follow-up evaluations. Analgesic consumption decreased by 47%, 57%, and 31%, in the IFS, HT, and control groups, respectively. The proportion of patients who improved in the HT group was greater than in the sham HT group (odds ratio, OR = 0.34, 95% CI 0.13-0.91), but did not

achieve statistical significance for the IFS group (odds ratio, OR = 0.49, 95% CI 0.18-1.29). Additional study is needed.

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

2010 Update
In 2010, Fuentes et al published a systematic review and meta-analysis of studies evaluating the effectiveness of IFS for treating pain. A total of 20 studies met the following inclusion criteria: randomized controlled trial (RCT); included adults diagnosed with a painful musculoskeletal condition; compared IFS (alone or as a co-intervention) to placebo; no treatment or an alternative intervention; and assessed pain on a numeric scale. Fourteen of the trials reported data that could be included in a pooled analysis. Interferential stimulation as a stand-alone intervention was not found to be more effective than placebo or an alternative intervention. For example, a pooled analysis of two studies comparing IFC alone and 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 two studies comparing IFC alone and 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 five studies comparing IFC 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 IFC plus another intervention to be superior to a control group (e.g., no-treatment). A pooled analysis of three studies found an MD of 2.45 (95% CI:1.69 to 3.22). The latter analysis is limited in that the specific effects of IFC versus the co-intervention cannot be determined, and it does not control for potential placebo effects.

An earlier systematic review, published in 2008, addressed management of back pain with therapeutic modalities including TENS and interferential current published in 2008. The authors found no eligible studies on which to base recommendations for IFS. The two trials identified that compared IFC alone to placebo had relatively small sample sizes in each treatment group. Defrin et al included a total of 62 patients with osteoarthritic knee pain, randomly assigned to one of six groups (there were four active treatment groups and two control groups, sham and non-treated). Acute pre- versus post-treatment reductions in pain were found in all active groups but not in either control group. Stimulation resulted in a modest pre-treatment elevation of pain threshold over the four weeks of the study. Taylor et al randomly assigned 40 patients with temporomandibular joint syndrome or myofascial pain syndrome to undergo either active or placebo interferential therapy. The principal outcomes were pain assessed by a questionnaire and range of motion (ROM). There were no statistically significant differences in the outcomes between the two groups.

As with any treatment focused on pain relief, randomized placebo-controlled trials are particularly important to determine if any treatment effect exceeds the expected treatment effect.

2011 Update

In 2011, Facci et al in Brazil published an RCT that compared IFS (n=50) or transcutaneous electrical stimulation (TENS) (n=50) to a no-treatment control group (n=40) in patients with chronic low-back pain. Patients were assessed by a blinded evaluator before and after completing ten 30-minute treatment sessions over two weeks. Patients in the control group were reassessed after two weeks. A total of 137 of 150 (91%) patients 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 IFC group, 3.91 cm in the TENS group, and 0.85 cm in the control group. There was not a 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. Moreover, findings from this trial do not demonstrate equivalence between IFS and TENS; studies with larger numbers of patients that are designed as equivalence or non-inferiority trials would be needed before drawing this conclusion.

In a 2011 study, Gundog et al in Turkey randomly assigned 60 patients with knee osteoarthritis to one of four groups; three IFS groups at frequencies of 40 Hz, 100 Hz, and 180 Hz, or sham IFC. IFC or sham IFC treatments were performed five times a week for three weeks. During the sham treatment, placement of the pads was the same and duration was the same, but no electrical stimulation was applied. The primary outcome was pain intensity assessed by the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). Mean WOMAC scores one 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 IFC group ($p<0.05$ compared to the active treatment groups) . Secondary outcomes also showed significantly higher benefit in the active treatment groups compared to the sham IFC group. For example, one outcome was pain on movement according to a 100-point VAS score. One month after treatment, the mean VAS score was 16.0 in the 40 Hz group, 17.0 in the 100 Hz group, 22.5 in the 180 Hz group, and 58.5 in the sham group. There were no significant differences in outcomes among the three active treatment groups. The number of patients assigned to each group and patient follow-up rates were not reported.

2012 Update

Musculoskeletal pain, range of motion, and function

In 2012, Atamaz and colleagues conducted a double-blind RCT comparing the efficacy of IFS, transcutaneous electrical stimulation (TENS), and shortwave diathermy in 203 patients with knee osteoarthritis. Patients were randomized to one of six groups, three with active treatment and three with sham treatment. The primary outcome was a zero to 100 visual analog scale (VAS) assessing knee pain. Other outcomes included range of motion, time to walk 15 meters, paracetamol intake, the Nottingham Health Profile (NHP) and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). At the 1-, 3-, and 6-month follow-ups, there was not a statistically significant difference among the six groups in the VAS pain score, the WOMAC pain score or the NHP pain score. Moreover, 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 one-month follow-up, paracetamol intake was significantly lower in the IFS group than the TENS group.

In summary, a large number of RCTs have been performed using IFS for musculoskeletal conditions. These have varied in the adjunct treatments that are used, comparison groups, types

of controls, and outcome measures. Many of these trials have methodologic limitations such as an inadequate placebo control and/or the use of multiple treatment modalities. While some of these studies have reported benefit, the majority do not. A meta-analysis of RCTs did not find a significant benefit of IFS over control for treating pain. The body of evidence suggests, although is not definitive, that IFS is not efficacious for improving pain, function and/or range of motion for patients with musculoskeletal conditions.

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 interferential stimulation. For example, in 2012, Kajbafzadeh and colleagues in Iran randomized 30 children with intractable constipation to receive IFS or sham stimulation. Children ranged in age from three to twelve years-old, and all had failed six months of conventional therapy e.g., dietary changes and laxatives. Patients received fifteen 20-minute sessions, three times a week over five weeks. Over six months, the mean frequency of defecation increased from 2.5 times per week to 4.7 times per week in the treatment group and from 2.8 times per week to 2.9 times per 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 that there was a statistically significant difference between groups in constipation symptoms.

The evidence is insufficient to permit conclusions concerning the effect of the technology on health outcomes. Therefore, IFS is considered investigational.

Another RCT was published by Clarke and colleagues in 2009; the study was conducted in Australia. Thirty-three children with slow transit constipation (mean age, 12 years) were randomized to receive IFS or sham treatment. They received twelve 20-minute sessions over four weeks. The primary outcome was health-related quality of life and the main instrument used was the Pediatric Quality of Life Inventory (PedsQL). The authors only reported within-group changes; they did not compare the treatment and control groups. There was not a statistically significant change in QOL, as perceived by the parent in either the active or sham treatment group. The mean parentally perceived 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 score on the PedQL group as perceived by the child, did increase significantly in the active treatment group (mean of 72.9 pre-treatment and 81.1 post-treatment, p=0.005).

Irritable bowel disease

An RCT with adults was published in 2012 by Coban and colleagues in Turkey. The authors randomized 67 individuals with irritable bowel syndrome to active or placebo interferential current simulation (IFS). Patients with functional dyspepsia were excluded. Patients received a total of four 15- minute sessions over four weeks. Fifty-eight of 67 (87%) patients completed the study. One month after treatment, primary outcomes measures did not differ significantly between the treatment and control groups. Treatment response was defined as more than a 50% improvement in symptoms. For the symptom of abdominal discomfort, for example, the response rate 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 visual analogue scale (VAS) measure, 72% of the treatment group and 69% of the control group reported improvement in abdominal discomfort.

Dyspepsia
One RCT, by Koklu and colleagues in Turkey, was identified that evaluated interferential current stimulation for treating dyspepsia. The study randomized patients to active IFS (n=25) or sham treatment (n=25); patients were unaware of treatment allocation. There were 12 treatment sessions over four weeks; each session lasted 15 minutes. A total of 44 of 50 (88%) randomized patients completed the therapy session and follow-up questionnaires at two and four weeks. The authors did not specify primary outcome variables; they measured the frequency of ten gastrointestinal symptoms. In an intention-to-treat (ITT) 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 of 25 (64%) patients in each group reported experiencing heartburn. At four weeks, nine patients (36%) in the treatment group and 13 patients (52%) in the sham group reported heartburn; p=0.02. Among symptoms that did not differ at follow-up between groups, 24 of 25 patients (96%) in each group reported epigastric discomfort before treatment. In the ITT analysis at four weeks, five of 25 patients (20%) in the treatment group and six of 25 (24%) patients in the placebo group reported epigastric discomfort.

Conclusions
IFS has been tested for a variety of gastrointestinal (GI) conditions, with a small number of trials completed for each condition. The results of these trials are mixed, with some reporting benefit and others reporting no benefit. This body of evidence is inconclusive to determine whether IFS is an efficacious treatment for GI conditions.

2013 Update
Musculoskeletal pain, range of motion, and function
In 2013, Lara-Paloma and colleagues in Spain published data from a single-blind RCT in patients with chronic low back pain that compared massage with IFS (n=31) to superficial massage (n=30). The superficial massage intervention involved gentle techniques using light pressure in the lumbar area. In contrast, in the treatment group, providers could use deeper massage, and dorsal-lumbar, as well as lumbar areas were massaged. Patients received 20 sessions over ten weeks; outcomes were assessed by blinded personnel at baseline and immediately after the final session. Sixty of 61 participants completed the study. The primary outcome was change in the score on the Roland-Morris Disability Questionnaire (RMDQ, range 0: no disability to 24: severe disability). Baseline scores on the RMDQ were 10.33 (standard deviation [SD]: 3) in the massage with IFS group and 11.13 (SD: 2.9) in the control group. Post-treatment, scores were 7.96 (SD: 3.3) and 10.97 (SD: 3.1), respectively. The difference between groups was statistically significant, favoring the intervention group. However, the reduction in RMDQ in the intervention group, 2.37points, did not meet the pre-defined minimal clinically important difference of 2.5 points. A number of secondary outcomes were also assessed and findings were mixed; the intervention group improved significantly more than the control group on some measures but not others. As with the primary outcome, the absolute change in scores in the intervention group on secondary outcomes tended to be small. For example, on a 10-point visual analogue scale (VAS), the mean score in the intervention group was 6.67 (SD: 1.67) at baseline and 5.01 (SD: 1.89) at follow-up. This change in the VAS score

did not reach the pre-defined threshold for clinical significance of 2.0 points. A limitation in the study design was that the potential impact of IFS could not be isolated because a combination intervention was used. Beneficial effects in the treatment group may have been due to use of deeper or more extensive massage rather than the addition of IFS.

Summary
There is insufficient evidence from well-designed trials that interferential current stimulation (IFS), a type of electrical stimulation, improves health outcomes (e.g., pain, range of motion) for patients diagnosed with painful musculoskeletal conditions. The limited amount of evidence from a few small trials comparing IFS alone to a placebo or sham intervention for treating does not consistently show benefit. Some trials do not control for potential placebo effects, others do not adequately evaluate the incremental effects of IFS beyond that of a co-intervention and/or do not adequately evaluate the equivalence of IFS and an alternative intervention. There is also insufficient evidence that IFS improves health outcomes for patients with other conditions, such as dyspepsia, irritable bowel syndrome, and constipation. Therefore, interferential stimulation is considered investigational.

Practice Guidelines, and Position Statements
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 stimulation for the treatment of low back pain.

In 2008, the American College of Occupational and Environmental Medicine (ACOEM) issued a guideline on management of chronic pain. The guideline concluded that the evidence on the effectiveness of interferential stimulation for the treatment of complex regional pain syndrome (CRPS) is insufficient and the intervention is not recommended.

No clinical guidelines were identified that discussed interferential current stimulation for the treatment of dyspepsia, constipation, or irritable bowel disease.

Key Words:
Interferential current therapy (IF), interferential stimulation (IF), interferential stimulator, transcutaneous electrical nerve stimulation (TENS), sequential stimulator, RS-4i Sequential stimulator

Approved by Governing Bodies:
A number of interferential stimulator devices have received FDA approval including:
Medstar 100®, HMP 4000+® (Mednet Services) FDA listed 9/11/1997
RS-4V®, RS JM® (RS Medical) FDA listed 11/27/2002
PMD2000® (Phoenix Medical Devices) FDA listed 5/29/2004
RTM1000 NTS2® (Ryan Telemedicine) FDA listed 6/6/2003

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

Effective for dates of service on or after January 1, 2012:

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

Previous Codes

Effective for dates of service prior to January 1, 2012:

There is not a specific CPT code to describe the interferential current stimulation unit.

HCPCS	**E1399**	Durable medical equipment, miscellaneous (No current CPT code—must be filed with E1399 and accompanied by a narrative describing device)

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Policy History:

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Medical Policy Group, March 2012 **(3)**: 2011 Literature Update, updated Key Points and References
Medical Policy Panel, December 2012
Medical Policy Group, December 2012 **(3)**: 2012 Literature Update, updated Key Points and References. Policy statement remains unchanged
Medical Policy Panel, December 2013
Medical Policy Group, January 2014 **(3)**: 2013 Updates to Key Points and References; no change in policy statement; removed policy statements greater than 3 years old