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Medical Policy Manual Durable Medical Equipment, Policy No. 83.07

Interferential Current Stimulation

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DESCRIPTION

Interferential current stimulation (IFS) is a type of electrical stimulation. It is believed that IFS permeates the tissues more effectively and with less unwanted stimulation of cutaneous nerves, making it more comfortable than transcutaneous electrical stimulation (TENS). IFS has been investigated primarily as a technique to reduce pain but has also been proposed to increase function of patients with osteoarthritis and to treat other conditions such as dyspepsia, irritable bowel syndrome, and constipation.

MEDICAL POLICY CRITERIA

I. Interferential current stimulation is considered **not medically necessary** for the treatment of pain.

II. Interferential current stimulation is considered **investigational** for the treatment of all other indications.

III. Devices capable of combination therapies (e.g., NexWave™) that provide several modalities (e.g., interferential current stimulation, and neuromuscular electrical stimulation, and transcutaneous electrical stimulation) are considered **investigational** for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Functional Neuromuscular Stimulation, DME, Policy No. 83.04
2. Threshold Electrical Stimulation as a Treatment of Motor Disorders, DME, Policy No. 83.05
3. Electrical Stimulation for the Treatment of Wounds, DME, Policy No. 83.09
4. Electrical Stimulation for the Treatment of Arthritis, DME, Policy No. 83.10
5. Electromagnetic Therapy, Durable Medical Equipment, Policy No. 83.13
6. Transcutaneous Electrical Modulation Pain Reprocessing, Medicine, Policy No. 143
7. Percutaneous Neuromodulation Therapy (PNT), Surgery, Policy No. 44
8. Occipital Nerve Stimulation, Surgery, Policy No. 174

BACKGROUND

Interferential current stimulation (IFS) uses paired electrodes of two independent circuits carrying high-frequency (4,000 Hz) and medium-frequency (150 Hz) alternating currents. These superficial electrodes are aligned on the skin around the affected area. There are no standardized protocols for the use of interferential therapy; the therapy may vary according to the frequency of stimulation, pulse duration, treatment time, and electrode-placement technique.

REGULATORY STATUS

A number of interferential stimulator devices have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA), including, but not limited to the Medstar™ 100 (MedNet Services, the RS-4i® (RS Medical), the IF-4000 (Apex Medical Corporation), and the neoGEN-Series® (RST-Sanexas). IFS may be included in multimodal electrotherapy devices such as transcutaneous electrical nerve stimulation and functional electrostimulation, such as the NexWave™ (Zynex Medical).

EVIDENCE SUMMARY

The principal outcomes associated with treatment of a condition due to any cause may include: relief of pain, improved functional level, return to work, and improved overall health. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for the placebo effect and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo. The focus of this review is on evidence from systematic reviews and RCTs.

Treatment with an electrical stimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an electrical stimulation device should be compared to one or more forms of conservative therapy.

MUSCULOSKELETAL PAIN, RANGE OF MOTION, AND FUNCTION

Systematic Reviews

Rampazo (2023) conducted a systematic review (SR) and meta-analysis to assess the efficacy of IFS in patients with chronic, nonspecific low back pain.[1] Thirteen RCTs that reported pain intensity and disability after IFS treatment were included (n=1,367 participants). IFS reduced pain intensity and disability immediately after treatment, compared to placebo (pain mean difference=-1.57 points; 95% confidence interval [CI] -2.17 to -0.98); (disability mean

difference=-1.51 points; 95% CI -2.57 to -0.46). The authors rated this evidence as moderate quality with a moderate effect size. There was no significant difference in pain intensity or disability at intermediate follow-up. Low quality evidence suggested that IFS combined with other interventions (e.g., massage or exercise) did not further reduce pain intensity or disability compared to these interventions in isolation.

Hussein (2021) published aSR which included 19 trials in a meta-analysis of patients (n=1167) with musculoskeletal pain.[2] Two trials compared interferential current stimulation (IFS) with placebo and the pooled mean difference in pain was significantly reduced with IFS versus placebo (-0.98; 95% CI, -1.42 to -0.54; p<0.0001), but not in the 6 trials comparing IFS to other interventions (-0.04; 95% CI, -0.20 to 0.12; p<0.65). When used as an adjunct to other pain interventions, IFS did not significantly improve pain compared with placebo in four studies (-0.06; 95% CI, -0.6 to 0.48; p=0.82) or compared with active treatment in eight studies (0.02; 95% CI, -0.88 to 0.92; p=not reported). The authors concluded that IFS reduced musculoskeletal pain when used as a single agent compared with placebo, but this is limited by the small number of trials (n=2) and patients enrolled (n=91) in these trials.

Ferreira (2019) published a SR with meta-analysis of 39 studies evaluating non-surgical and non-pharmacological interventions for knee osteoarthritis, which included studies on iIFS.[3] The authors concluded that IFS was not considered among the most promising interventions and that additional studies are needed before IFS could be recommended. These conclusions are consistent with a previous SR in which, although IFS was found to be more effective for pain in knee osteoarthritis compared to other stimulation techniques, the authors noted that, "heterogeneity and the limitation in sample size of some studies could be a potential threat to the validity of results."[4]

Huisstede (2017) published a SR evaluating the effectiveness of physical therapy and electrophysical modalities, one of which was IFS, for carpal tunnel syndrome.[5] A total of 22 RCTs and two reviews met inclusion criteria. Although short-term evidence may support interferential current, there was no long-term outcomes evaluated. The authors stated additional studies are needed to evaluate long-term effects of electrophysical therapy for carpal tunnel syndrome.

Fuentes (2010) published a SR with meta-analysis of studies evaluating the effectiveness of IFS for treating pain.[6] A total of 20 studies met the following inclusion criteria: 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 RCTs 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. For example, a pooled analysis of two studies comparing IFS alone and placebo did not find a statistically significant difference in pain intensity at discharge. In addition, a pooled analysis of two studies comparing IFS alone and an alternative intervention (e.g., traction or massage) did not find a significant difference in pain intensity at discharge. Moreover, a pooled analysis of five studies comparing IFS as a co-intervention to a placebo group did not find any between group differences. These results do not support the use of interferential stimulation for the treatment of pain.

Randomized Controlled Trials

Menezes (2023) published results from a placebo-controlled RCT that investigated whether adjustment of IFS intensity influences pain. Pain measurements included cutaneous sensory

threshold (von Frey filaments), pressure pain threshold (algometry), and pain intensity (11-point numerical scale) in healthy subjects under mechanically induced pain.[7] 102 health university students were blindly randomized to receive sensory IFS (n=24), fixed motor IFS (n=26), adjusted motor IFS (n=27), or placebo IFS (n=25). After a 40 minute stimulation session, participants were assessed by a blinded investigator. Pain was assessed immediately after treatment. Adjusted motor IFS caused a significant reduction in cutaneous sensory threshold in the hand (mean difference=2.39, CI 1.39 to 3.38) and forearm (mean difference=3.01, CI 2.87 to 3.14) compared to placebo. Adjusted motor IFS significantly increased pressure pain thresholds in the hand (mean difference=27.59, CI 26.80 to 28.37) and forearm (mean difference=34, CI 25.74 to 42.25) compared to placebo. Adjusted motor IFS reduced pain intensity by 4.01 points (CI 3.64 to 4.55) compared to placebo. No adverse events were reported. This study is limited by lack of intermediate and long-term follow-up.

Alqualo-Costa (2021) conducted a randomized controlled trial (RCT) of IFS and photobiomodulation in 168 adults with knee osteoarthritis.[8] Participants were randomized to one of four groups: active IFS plus placebo photobiomodulation, placebo IFS plus active photobiomodulation, active IFS plus active photobiomodulation, and placebo IFS plus placebo photobiomodulation. Patients received treatments three times a week for four weeks, totaling 12 sessions. Both patients and outcome assessors were blinded to treatment allocation. The combination of active IFS plus active photobiomodulation significantly reduced pain intensity at rest and during movement compared to the IFS alone and placebo groups. Similar improvements were not shown in the group that received IFS alone. This study was limited by its small sample size and multiple statistical comparisons.

Albornoz-Cabello (2019) published the results of a single-blinded RCT evaluating the effect of adding IFS to exercise on pain, disability, psychological status and range of motion in patients with neck pain.[9] Patients were randomly divided into a supervised exercise program (n=42) or supervised exercise program plus IFS (n=42) in 10 sessions across two weeks. Significantly more improvement was found in the IFS group compared to control at posttreatment for: pain rated on a visual analogue scale (2.73 ± 1.24 vs 4.99 ± 1.56); degree of disability assessed by the Neck Disability Index (10.60 ± 4.77 vs 18.45 ± 9.04) and CORE Outcome Measure scores (19.18 ± 9.99 vs 35.12 ± 13.36); anxiety and depression scales (6.17 ± 4.27 vs 7.90 ± 4.87); apprehension scores (28.17 ± 9.61 vs 26.29 ± 11.14); and active and passive right rotation. No long-term follow-up data were reported.

Kadi (2019) published a double blind, placebo controlled RCT on IFS after arthroscopic knee surgery.[10] Patients received IFS treatment (n=49) or sham (n=49, pads applied with no current) for 30 minutes, twice a day for five days postoperatively. No significant difference was found between the groups with respect to pain, range of motion, or edema at days 0, 5, or 30. At the end of the 5th day, the amount of paracetamol used was significantly lower in the IFS group (p < 0.05).

Albornoz-Cabello (2017) published a RCT evaluating the effects of IFS on low back pain lasting greater than three months.[11] Patients received interferential current (n=44) or usual care (n=20). All treatments consisted of 10 sessions, 25 minutes each for two weeks. Assessments (self-pain and Oswestry Low Back Disability Index) were completed at baseline and at the end of study. Although the authors stated transregional IFS improved low back pain, no long-term follow-up was noted on the study. In addition, this study was limited in size.

Koca (2014) published a single-blind RCT that evaluated IFS for treating symptoms associated with idiopathic carpal tunnel syndrome.[12] Patients were randomized to one of three groups and received either splint therapy, transcutaneous electrical nerve stimulation (TENS) or IFS (n=25 per group). Patients in the TENS and IFS groups had a total of 15 therapy sessions (five per week) lasting 20 minutes each. All patients were permitted to use paracetamol as needed during the study, except on assessment days. Sixty-three of 75 patients (84%) completed the study. The authors assessed a number of outcomes and did not specify primary endpoints. There were no statistically significant differences in outcomes between TENS and splint therapy. Patients in the IFS group had significantly greater improvement than those in the TENS and splint groups on most reported clinical outcomes including pain measured on a 10-point VAS, symptom severity and functional capacity. For example, six week VAS scores were a mean of 4.80 (SD: 1.18) in the IFS group, 6.37 (SD: 1.18) in the splint group, and 6.68 (SD: 1.42) in the TENS group (p<0.01 for the comparison between IFS and each of the other groups). The study was limited by the small sample size and high drop-out rate.

Lara-Paloma (2013) 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).[13] 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 10 weeks; outcomes were assessed by blinded personnel at baseline and immediately after the final session. 60 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. Authors reported a statistically significant improvement in the reduction of RMDQ scores in the treatment group; however, this difference did not meet the pre-defined minimal difference of 2.5 points. A number of secondary outcomes were also assessed and findings were mixed. 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, 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.

Atamaz (2012) conducted a double-blind RCT comparing the efficacy of IFS, TENS, and shortwave diathermy in 203 patients with knee osteoarthritis.[14] Patients were randomized to one of six groups, three with active treatment and three with sham treatment. The primary outcome was knee pain as measured by a 0 to 100 visual analog scale (VAS). 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 one, three, and six-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.

Gundog (2011) published a study that 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 IFS.[15] IFS or sham IFS 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 IFS group. However, interpretation of these findings is restricted by the small sample size, which limits the ability to rule out the role of chance as an explanation of study findings. In addition, the number of patients assigned to each group and patient follow-up rates were not reported. Because high loss to follow-up can be associated with treatment type (and thus bias results toward a specific treatment group), the lack of this information restricts overall interpretation of results.

Facci (2011) published an RCT that compared IFS (n=50) and TENS (n=50) to a no-treatment control group (n=40) in patients with chronic low-back pain.[16] 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 IFS 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.

A number of additional RCTs have not provided evidence that IFS provides treatment benefits over sham treatment in conditions including back pain,[17-19] osteoarthritic knee pain,[20] myofascial disease,[21] soft tissue shoulder disorders,[22] chronic nonspecific neck pain,[23] and temporomandibular joint syndrome.[24]

Section Summary

Studies that have reported some benefit of IFS treatment for pain were limited by small sample sizes, short-term follow-up, and lack of a placebo comparator group. Overall, the current body of evidence suggests that IFS is not efficacious for improving pain, function and/or range of motion for patients with musculoskeletal conditions.

GASTROINTESTINAL DISORDERS

Systematic Reviews

Iacona (2019) published a SR of neuromodulation approaches for constipation and fecal incontinence in children which included five IFS studies consisting of two RCTs, one prospective study, and two pilot studies (n=126).[25] Follow-up times ranged from 1 to 6 months across the studies. All of the studies reported an improvement in symptoms reported including defecation frequency, soiling episodes, and abdominal pain. This SR included the 2012 RCT by Kajbafzadeh that randomized 30 children with intractable constipation to receive IFS or sham stimulation.[26] Children ranged in age from 3 to12 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. Three of the other five studies were conducted by the same group, although the patient groups were different.[27-29] Overall, the authors concluded additional evidence including longer length of follow-up is needed to consider neuromodulation as an established therapy for the management of constipation and fecal incontinence.

Moore (2018) published a SR evaluating the effects of IFS for gastrointestinal motility disorders.[30] In all, 17 studies met inclusion criteria. Eleven were RCTs, of which three evaluated adults and the others evaluated children. The authors stated that although there was a significant decrease in symptoms, there were methodological limitations, including, but not limited to lack of an adequate placebo. Therefore, more studies are needed, especially for adults.

Randomized Controlled Trials

Vitton (2023) conducted a double-blind, multi-center RCT to assess the efficacy of transabdominal IFS for the treatment of chronic constipation in adults.[31] The primary endpoint was eight-week efficacy, defined by the number of complete, spontaneous bowel movements in the last four weeks of the eight-week stimulation period. The primary endpoint was not met; there was no significant difference between the IFS and sham group responders (73.2% in the IFS group vs. 67.1% in the sham group). The IFS group had a significantly higher mean score on the Patient Assessment of Constipation Symptoms questionnaire (PAC-SYM). No significant differences were observed in other secondary endpoints.

The results of a single-blind, sham-controlled RCT conducted in Australia was published by Moore (2020).[32] Thirty-three women (mean age, 45 years) with functional constipation were randomized to IFS (n=17) or sham treatment (n=16). The IFS was self-delivered by the participants in their homes for one hour per day for six weeks. The participants were trained by an unblinded study coordinator in the placement of the 4 electrodes as either crossed for active IFS or uncrossed for sham IFS. The primary outcome was the number of patients with greater than or equal to 3 spontaneous bowel movements per week. Although active IFS significantly increased the primary outcome (53% versus 12%; p=0.02), there were no between-group differences on numerous other secondary outcomes, such as quality of life and the more clinically meaningful and guideline-recommended outcome of spontaneous complete bowel movement.

In addition to the RCTs discussed by Iacona, above, a RCT was published by Clarke (2009) which included 33 children with slow transit constipation (mean age, 12 years) who were randomized to receive IFS or sham treatment.[33] 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). This RCT is limited by small sample size.

Coban (2012) published an RCT which randomized 67 adults with irritable bowel syndrome to active or placebo interferential current simulation (IFS).[34] 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.

Koklu (2010) published a RCT that evaluated IFS for treating dyspepsia.[35] 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 10 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.

Section Summary

IFS has been tested for a variety of gastrointestinal (GI) conditions. The results of the RCTs are mixed, with some reporting benefit and others reporting no benefit. The current evidence is insufficient and inconclusive to determine whether IFS is an effective treatment for GI conditions.

CHRONIC STROKE

Systematic Reviews

No SRs were identified.

Randomized Controlled Trials

Suh (2014) published a single-blind RCT evaluating IFS as a treatment of chronic stroke.[36] Forty-two inpatient stroke patients with plantar flexor spasticity were randomized to a single 60-minute session of IFS or placebo IFS following 30 minutes of standard rehabilitation. In the placebo group, electrodes were attached but 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. In addition, gait speed was measured using a 10 meter walk test and gait function was assessed with the Timed Up and Go Test. The IFS group performed significantly better than the placebo group on all the aforementioned outcomes ($p < 0.05$ for each comparison). For example, the mean 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 one hour after the intervention and no data were available on long-term impacts of the intervention.

Eslamian (2020) published a RCT comparing IFS to electrical acupuncture (EAC) in patients with hemiplegic shoulder pain after stroke. This study randomized patients to receive either IFS (n=20) or EAC (n=20) twice a week for a total of 10 sessions in addition to standard of care. The primary outcome was reduction in pain intensity at 5-weeks compared to baseline as measured using a 10 cm Visual Analogue Scale (VASs). Secondary outcomes included th e Shoulder Pain and Disability Index (SPADI), a self-reported assessment of pain and disability, as well as objective range of motion (ROM) assessment before and 5 weeks after treatment. The authors found that 75% of IFS and 65% of EAC patients reached a clinically significant improvement of at least 13 on the SPADI questionnaire. Clinically significant improvement in pain intensity (defined as 1.4 points on the VAS at 5-weeks) was found in 35.0% of the IFS group and 70.0% of the EAC group. There was a significant improvement in all active and passive ROM measurements within each group ($p < 0.05$) except passive ROM in internal ($p = 0.09$) and external rotation ($p = 0.15$) in the IFS group and active ROM in abduction in EAC group ($p = 0.08$). This study has several limitations, including lack of sham control group, very small sample size, short follow-up interval.

Section Summary

There is insufficient evidence to show an improvement on health outcomes for IFS in patients with chronic stroke.

OTHER INDICATIONS

Korkut (2023) published the results of a prospective randomized sham-controlled study investigating the effects of IFS on pelvic floor symptoms, prolapse stages, pelvic floor muscle (PFM) strength/endurance, quality of life (QoL), sexual function, perception of subjective improvement (PSI), and satisfaction in women with pelvic organ prolapse (POP).[37] Patients (n=25) were randomly assigned to IFS or sham IFS (n=12). a greater increase in PFM strength/endurance, P-QoL-role limitations, P-QoL-sleep/energy scores, PSI, and satisfaction level, and a decrease in cystocele stages were observed in the IF group than in the sham group ($p < 0.05$). Further, there was a greater increase in PFM endurance in the IFS group in MT ($p < 0.05$). Limitations to this study include small sample size and lack of long-term follow-up.

Daia (2019) published a RCT evaluating IFS for improving bladder management following spinal cord injury.[38] The study included 332 patients randomized to either IFS plus standard of care (n=162) or standard care alone (n=170). Patients were classified by the American spinal cord injury association impairment scale (AIS). Micturition data were recorded daily for 30 days. The study found IFS to be effective in patients with AIS levels B and C, significantly decreasing post voidance residuum (PVR) quantity and short-term quantity of urine lost compared with patients receiving standard care. No significant improvements in urinary

management were observed following IFS treatment of patients with AIS level A. A global evaluation of the means of square root values for PVR was 14.95±11.95 and 21.79±12.70 for IFS and control groups, respectively (p<0.001). No urodynamic evaluation was performed, which is a limitation of the study. In addition, the design of the study did not allow for discrimination between contributions of spontaneous recovery and those attributed to IFS in this study population of acute and sub-acute spinal cord injury. The authors concluded that these preliminary findings require additional studies.

PRACTICE GUIDELINE SUMMARY

THE AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

The American College of Occupational and Environmental Medicine published guidelines on non-invasive and minimally invasive management of low back disorders which found the evidence on IFS to be insufficient and did not recommend it.[39]

AMERICAN COLLEGE OF PHYSICIANS AND THE AMERICAN PAIN SOCIETY

Clinical practice guidelines from the American College of Physicians and the American Pain Society updated in 2017 addressed the benefits of certain nonpharmacological treatments for low back pain, one of which was interferential therapy. Interferential therapy was not amongst the treatment recommendations.[40]

SUMMARY

The current higher quality research on interferential current stimulation (IFS) treatment of pain reported no differences in health outcomes between the IFS treatment groups compared to other treatment groups. Overall, the current research suggests that IFS is not better than other treatment options. No clinical guidelines based on research recommend IFS. Therefore, IFS is considered not medically necessary for the treatment of pain.

There is not enough research to know if or how well interferential current stimulation (IFS) works to treat people with gastrointestinal disorders. This does not mean that it does not work, but more research is needed to know for sure. In addition, there is not enough research to show that IFS improves health outcomes for any other condition. No clinical guidelines based on research recommend IFS. Therefore, IFS is considered investigational as a treatment for all other conditions, including but not limited to gastrointestinal disorders or when combined with other stimulation modalities.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
	E1399	Durable medical equipment, miscellaneous
	S8130	Interferential current stimulator, 2 channel
	S8131	Interferential current stimulator, 4 channel

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