MEDICAL POLICY	Interferential Stimulation (IFS) (All Lines of Business Except Medicare)
Effective Date: 3/1/2022  3/1/2022 Medical Officer Date	Medical Policy Number: 52 Technology Assessment Committee Approved Date: 10/05; 2/10; 9/14; 9/15; 6/16 Medical Policy Committee Approved Date: 11/07; 11/09; 3/12; 7/13; 8/17; 6/18; 1/19; 12/19; 2/2021; 2/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Interferential stimulation (IFS) therapy is considered **investigational and is not covered** as a treatment for any condition.

Link to Policy Summary

BILLING GUIDELINES

The following codes are not specific to interferential stimulation and may be requested for other stimulation devices: 97014, 97032, and G0283. If these codes are billed or requested for interferential devices, they will be denied as investigational per this medical policy.

CPT/HCPCS CODES

All Lines of Business	
No Prior Authorization Required	
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
Not Covered	
S8130	Interferential current stimulator, 2 channel
S8131	Interferential current stimulator, 4 channel
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as **Not Covered.**	
E1399	Durable medical equipment, miscellaneous

DESCRIPTION

Interferential stimulation (IFS), also known as interferential current (IFC) therapy, is a form of transcutaneous electrical stimulation (TENS) that has been proposed as a potential therapy to relieve pain, inflammation, and other indications. It is a specialized form of electrostimulation or electrotherapy that uses two medium frequency currents simultaneously. The patterns of interference and summation of the two interacting currents generate a more complex waveform than other forms of electrostimulation, which has led to the hypothesis that it may be more effective than other electrotherapies.[1]

IFS differs from TENS in the frequency and manner in which the current is applied. As a result, IFS devices are marketed as able to provide a deeper penetration of the affected tissue to TENS devices.

The exact mechanism by which IFS alleviates symptoms is unclear. One proposed mechanism is that the repeated stimulation causes the nerves carrying the pain signal to become fatigued and stop transmitting pain signals. A second hypothesis is that IFS induces the body to release of pain-relieving and anti-inflammatory substances.[1]

During IFS therapy, electrodes are placed unilaterally or bilaterally over the painful area to be stimulated and current is applied. The amount of current, length of individual sessions, as well as frequency and length of overall treatment has not been optimized for any given condition, and therefore may vary significantly. IFS is typically used as an adjunctive treatment but is also proposed as a stand-alone therapy. Due to variability in published IFS treatment protocols and the fact that IFS is often used in

combination with a variety of other interventions, evaluating the efficacy of IFS for any condition is difficult.

REVIEW OF EVIDENCE

The use of randomized controlled trials (RCTs) is critical in evaluating any intervention in which clinically relevant outcomes consist of subjective, self-reported improvements in pain, function and disability, since these outcomes may be influenced by nonspecific effects like placebo response and the natural history of the disease. As a result, when randomization is used, differences in reported outcomes between treatment groups may be attributed to the treatment in question. In addition, comparative, randomized studies must be sufficiently powered in order to eliminate any spurious results due to chance, and to allow generalizability of results. Ideally, long-term, double-blinded randomized studies are recommended to determine potential sustained benefits. Due to the large body of low-quality evidence regarding IFS, the review below is focused primarily on systematic reviews of double-blinded RCTs, or those comparing IFS to other interventions.

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of interferential simulation (IFS) as a treatment for any condition. Below is a summary of the available RCTs and systematic reviews identified through December of 2021.

Systematic Reviews

Musculoskeletal Pain

In 2010, Fuentes et al. published the results of a systematic review that evaluated the efficacy of IFS in the management of musculoskeletal pain, including 20 randomized controlled trials that assessed the use of IFS on joint pain muscle pain soft tissue shoulder pain, and post-operative pain.[2] The majority of studies (n=14) were of moderate methodological quality, and three were of poor quality. The review noted that it was not known whether the analgesic effect of IFS was superior to that of the concomitant interventions and found that IFS as a stand-alone therapy was not significantly better than placebo or other therapy at discharge or follow-up. Limitations include a lack of studies that evaluate IFS alone, heterogeneity between included studies, and methodological limitations of the individual studies; all of which prevent definitive conclusions regarding the efficacy of IFS on pain outcomes.

In 2014, Page et al. published the results of a systematic review that evaluated the efficacy of different electrotherapies for adhesive capsulitis (frozen shoulder), including three RCTs comparing IFS to sham or other interventions.[3] Two of the RCTs used IFS in combination with other treatments, and one RCT used IFS in isolation. The included trials were small in sample size (n=20 to 50), and heterogeneous in terms of comparator groups. Two studies were unblinded, had a high risk of performance bias and detection bias for the self-reported outcomes, and had incomplete outcome data. The review concluded that, based on very low quality evidence, they were uncertain whether interferential current was more or less effective than any given comparator evaluated.

Osteoarthritis

In 2015, Zeng et al. published the results of a systematic review that evaluated the efficacy of different electrical stimulation therapies in pain relief of patients with knee osteoarthritis (OA), including six RCTs comparing IFS to sham or other interventions.[4] Of the six types of electrical stimulation therapies evaluated, IFS showed the most promise in terms of pain reduction. However, the included studies were limited by between study heterogeneity in patient populations and IFS treatment protocols, small sample size (n= 12 to 123), and short-term post-treatment follow-up (0 weeks to 6 months), making the validity of the reported results difficult to interpret.

In 2019, Ferreira published a systematic review with meta-analysis of randomized controlled trials that evaluated non-surgical and non-pharmacological interventions commonly used for knee OA.[5] Amongst 52 RCT's, the authors identified only 5 meeting meta-analysis criteria. IFS was noted to require more research to draw conclusions, and exercise was identified as the most efficacious intervention for knee OA.

Low Back Pain

In 2017, Chou et al. published a systematic review of nonpharmacologic therapies for low back pain, which was used as the basis for the 2017 American College of Physicians Clinical Practice Guideline discussed below.[6,7] This review evaluated studies published through November 2016, and it included four randomized controlled trials (RCTs) (n=62 to 240) comparing IFS to other interventions or IFS in combination with another therapy versus other interventions for nonradicular low back pain. No trial compared interferential therapy versus sham therapy.[8-11] Trials varied in the number and duration of IFS sessions and in technical parameters. Follow-up was between 3 to 12 months (1 week to 10 months following the end of therapy). Two of the trials found no difference between IFS and either traction or spinal manipulation for any of the outcomes reported.[8,10] One trial found the IFS significantly improved some short-term pain outcomes, but not all, when compared to superficial massage.[11] One trial compared a combination of interferential therapy plus spinal manipulation versus manipulation alone but reported no differences in outcomes between the two treatments.

Three trials were rated poor quality and one trial was of moderate quality. Methodological limitations included failure to blind patients or care providers, high attrition, and failure to perform intention-to-treat analysis. In addition, one trial also reported potentially important baseline differences, and one trial failed to report use of co-interventions and compliance to assigned therapies. The review concluded that there was insufficient evidence to determine effects of IFT as a stand-alone or an adjunctive therapy.

Gastrointestinal (GI) Disorders

In 2018, Moore et al. published the results of a review the evaluated effects of IFS for gastrointestinal motility disorders, including 17 studies (11 of which were RCTs).[12] Three RCTs evaluated adults and eight evaluated children with various GI indications including constipation, irritable bowel disease, dyspepsia, neurogenic bowel dysfunction, post-operative Hirschsprung's disease, and others.[13-18] The reviewed stated that although IFS appears to be promising in children, the studies are preliminary and suffered

from methodological limitations, including small sample size, heterogeneous patient populations and stimulation parameters and lack of appropriate control groups.

Other Conditions

IFS has been evaluated in systematic reviews for indications not addressed above. These reviews drew similar conclusions about the efficacy of IFS as the reviews above, citing lack of generalizable results, low quality evidence, too few trials, and the inability to draw definitive conclusions about the efficacy of IFS.

These reviews addressed:

- fibromyalgia[19]
- neck pain[20]

Randomized Controlled Trials

IFS has been evaluated in RCTs as a therapy for a number of indications including:

- total knee arthroplasty[21]
- recurrent jaw pain[22]
- idiopathic carpal tunnel syndrome[23]
- chronic stroke plantarflexor spasticity[24]
- urinary incontinence[25-27]
- elbow pain[22-28]
- post-traumatic complex regional pain syndrome, type 1[29]
- chronic neck pain[30-32]
- hemiplegic shoulder pain[33]

Similar to the RCTs included in the systematic reviews above for other indications, these RCTs are limited by small sample sizes, short-term follow-up, and high numbers of patients lost to follow-up. Despite these design flaws, in recent studies, numerous RCTs have reported no differences between IFC and alternative therapies or sham control groups. Before definitive assessments can be made, higher-quality studies with longer follow-up are needed.

CLINICAL PRACTICE GUIDELINES

Low Back Pain

American College of Physicians (ACP)

In 2017, the ACP published clinical practice guidelines on noninvasive treatments for acute, subacute, and chronic low back pain.[34] These guidelines provided recommendations based on a systematic review of RCTs and systematic reviews published through April of 2015, with an extended review through November 2016 (see evidence section above for the published results of this systematic review).

The guidelines determined that there was insufficient evidence of the benefits and harms of IFS as a therapy for chronic low back and radicular low back pain. IFS was not addressed for acute or subacute low back pain.

National Institute for Health and Care Excellence (NICE)

In 2016 (updated in 2020), NICE published clinical guidelines on the assessment and management of low back pain and sciatica in adults over the age of 16 years, which stated the following:[35]

> "Do not offer interferential therapy for managing low back pain with or without sciatica."

The guideline "concluded that there was a lack of evidence of clinical benefit to support a recommendation for the use of Interferential therapy as a treatment for low back pain or sciatica", stating, "no difference between interventions was observed when comparing interferential therapy with" any of the other treatments.

Knee Osteoarthritis

American Association of Orthopedic Surgeons (AAOS)

In 2021, the AAOS published evidence-based clinical practice guidelines for management of osteoarthritis of the knee.[36] Interferential stimulation was not mentioned in the guideline, but transcutaneous electrical nerve stimulation was reviewed and found to have limited evidence to support its use for symptomatic osteoarthritis of the knee.

"The Transcutaneous Electrical Nerve Stimulation recommendation has been downgraded two levels because of inconsistent evidence and a lack of internal consistency with recommendations of equal supporting evidence."

POLICY SUMMARY

There is insufficient evidence that the use of interferential stimulation (IFS) as a stand-alone or adjunctive therapy is effective for any indication, compared to other treatment modalities. The body of evidence includes randomized controlled trials for a wide variety of indications, including pain and gastrointestinal conditions, which are limited by small sample sizes, heterogeneous patient populations and IFS procedure protocol, and little to no post-treatment follow-up. Therefore, based on the lack of larger well-designed randomized trials with long-term follow-up, conclusions cannot be reached about the effectiveness of IFS therapy on pain reduction for any condition. In addition, the mechanism by which IFS alleviates symptoms, including pain outcomes, is currently unclear. Lastly, recent high quality clinical practice guidelines either recommend against the use of IFS or cannot recommend either for or against the use of IFS due to insufficient evidence for indications for which it is commonly proposed.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.
The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food & Drug Administration (FDA) Device Approval

Most interferential stimulators are approved as 510(k) Class II devices by the FDA, with more than 30 devices receiving 510(k) clearance.[37] Examples of FDA-approved devices include, but are not limited to:

- BMLS02-6 and BMLS03-6 (Biomedical Life Systems, Inc.)
- IF-4000 (Apex Medical Corporation)
- IF-100507 (Everlife Medical Equipment Co., Ltd.)
- Medstar™ 100 (MedNet Services. Inc.)
- Netwave and RTM1000 (Ryan Telemedicine)

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Clinical Trials (All Lines of Business Except Medicare)
- Clinical Trials and IDE Studies (Medicare Only)
- Microcurrent Electrical Nerve Stimulation (MENS)
- Peripheral Nerve Stimulation for Chronic Pain (Medicare Only)

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