Clinical Practice Guideline: **Non-invasive Interactive Neurostimulation (InterX®)**

Date of Implementation: **September 15, 2016**

Product: **Specialty**

GUIDELINES

American Specialty Health (ASH) considers Non-invasive Interactive Neurostimulation (e.g., InterX®) unproven given the lack of evidence to support this form of modality.

For more information, see the ASH *Techniques and Procedures Not Widely Supported as Evidence Based (CPG 133 – S*) policy.

Patients must be informed verbally and in writing of the nature of any procedure or treatment technique that is considered experimental/investigational or unproven, poses a significant health and safety risk, and/or is scientifically implausible. If the patient decides to receive such services, they must sign a *Member Billing Acknowledgment Form (*for Medicare use *Advance Beneficiary Notice of Non-Coverage form*) indicating they understand they are assuming financial responsibility for any service-related fees. Further, the patient must sign an attestation indicating that they understand what is known and unknown about, and the possible risks associated with such techniques prior to receiving these services. All procedures, including those considered here, must be documented in the medical record. Finally, prior to using experimental/investigational or unproven procedures, those that pose a significant health and safety risk, and/or those considered scientifically implausible, it is incumbent on the practitioner to confirm that their professional liability insurance covers the use of these techniques or procedures in the event of an adverse outcome.

DESCRIPTION/BACKGROUND

Non-invasive, Interactive Neurostimulation (NIN) (e.g., InterX®) is used for the treatment of acute and chronic pain with a proposed benefit of returning patients to active rehabilitation faster. It is used for post-surgical rehabilitation, sports injury rehabilitation, chronic neuropathic pain, and chronic musculoskeletal conditions. NIN/InterX uses high amplitude, high density stimulation to the cutaneous nerves, activating the natural pain-relieving mechanisms of the body (segmental and descending inhibition). The device displays a number on the front that when contacted with the skin, shows the therapist where the body has the greatest ability to receive the stimulation (least amount of resistance to current). Users of the device state that this tells them where to focus the treatment for greater healing. Treatment can be applied locally, to the dermatomes, over orthopedic metal implants and directly to the affected area, however often the first treatment is not over the

area of pain. It is hypothesized that by applying NIN to the nerves across the skin, the body will release its own natural pain-relieving chemicals. The InterX has multiple attachments that permit treatment to the scalp, face, spine and nerve points which, according to the manufacturer, will create the greatest pain-relieving results. InterX® therapy is to be delivered by a trained practitioner, often in a clinical or sports setting. Typical treatments last from 15 - 30 minutes and the procedure involves applying the hand-held device or its remote probes directly to the skin. Treatment is on the skin of the involved area, and often non-involved areas on the opposite side of the body or the back. According to the manufacturer's website for InterX®, the device may be held stationary or moved along the skin in sweeping motions, depending on the chosen mode of treatment. The patient may feel a tickling or vibrating sensation, or a prickling or fine "needling" sensation. Some people may be more sensitive than others to neurostimulation. People who are very sensitive to neurostimulation may potentially experience temporary discomfort or light-headedness. The number of treatments will depend upon the severity of the condition and the duration of the problem. According to those that use the device, often patients feel relief after 1–3 treatments but complex long-standing conditions may require more effort. The manufacturer states that the InterX® products can be applied independently as a full treatment or concurrently with existing therapy (physical or occupational) activities to meet and enhance therapy goals. The number of visits and duration of treatment is highly dependent upon the complexity of the patient's medical history and condition, and whether the InterX® product is used independently or as a concurrent treatment. The manufacturer states that once therapy has begun, it is important to complete the full, recommended treatment course in order to experience optimum relief from symptoms. Neurostimulation activates a physical response, which may increase the sensation of pain for a few hours. Adherence to the full course of treatment will minimize symptoms that a patient may experience during the natural healing process. The treatment plan consists of the following:

- **Scan** - the treatment area is scanned using the InterX device to identify specific areas of low impedance. These are considered optimal treatment points for InterX stimulation. The scanning can be done either by sliding the device over the skin or by placing the device and taking numerical measurements.
- **Target** - the areas of low impedance are then targeted with very specific stimulation. The interactive stimulation adjusts constantly in response to changes in the electrophysiology of the tissue. This specific, dynamic stimulation is unique to this technology.
- **Dynamic** - if appropriate, the patient is moved through a series of positions, stretches or exercises while stimulation is applied to points of pain. It is hypothesized that given the size of the device, it can be combined with neuromuscular and proprioceptive re-education for enhanced results.

EVIDENCE REVIEW

Gorodetskyi et al. (2007) evaluated 60 patients with hip fracture and stabilization surgery; one group received post-op treatment using NIN and the other received a sham NIN

treatment. All other aspects of rehabilitation were the same over ten days. There were significantly better results for the patients receiving treatment by NIN in addition to standard rehabilitation for pain and function. The authors suggest that the findings of the pilot study justify a larger trial. Nigam et al. (2011) evaluated the potential clinical benefit of the InterX neurostimulation device on pain reduction and rehabilitative outcome. NIN therapy using the InterX device was performed in patients undergoing total knee replacement (TKR). Sixty-one patients were randomized to two groups: the control group received the standard hospital course of pain medication and rehabilitation twice daily for 3 post-op days while the experimental group received 8 sessions of NIN therapy over 3 post-op days in addition to the standard course received by the Control group. Pain and range of motion were collected as the primary study measures. The authors concluded their study demonstrated the clinical benefit of NIN therapy as an addition to the standard rehabilitation protocol. The subjects receiving InterX fared significantly better clinically, given they had reduced pain and increased ROM within the post-op 3 day period relative to the control group. Biggs et al. (2012) compared the hypoalgesic effects of transcutaneous electrical nerve stimulation (TENS) and non-invasive interactive neurostimulation (InterX[®]) on experimentally induced blunt pressure pain using healthy human volunteers. A repeated measures parallel group study on healthy human volunteers randomized to receive strong non-painful TENS or non-invasive interactive neurostimulation for 21 min on the forearm (*N*= 10/group). Pressure algometry was used to determine blunt pressure pain threshold at baseline, 10-, and 20-min during stimulation, and 5 min post stimulation. ANOVA found no effects for Intervention, time × intervention interaction, or time. The authors concluded that there were no significant differences in hypoalgesia between NIN and TENS. Power was limited due to study design. Schabrun et al. (2012) assessed the effectiveness of interactive neurostimulation (INS) therapy on the treatment of pain associated with myofascial trigger points (MTPs) in adults with mechanical neck pain in a preliminary, randomized, sham-controlled trial. 23 adults with pain and MTPs in the neck or shoulder lasting>2 weeks received INS (active or sham) was delivered for 10 minutes in a single session over the MTP area in each patient. Pain was assessed immediately and on day 5. On day 5, functional outcome measures were also assessed. Authors concluded that this study demonstrated improvements in function in individuals with MTPs following INS therapy, which may be of clinical significance in certain patients with neck or shoulder pain. Further large-scale clinical trials are required to confirm this effect and to determine if INS also reduces pain and neck disability.

Teodorczyk-Injeyan et al. (2015) evaluated the effect of treatment with NIN (InterX5000) on the production of inflammatory biomarkers in chronic and recurrent mechanical neck pain (NP) syndrome through a pilot study. Twenty-five NP patients and 14 asymptomatic subjects included for baseline comparison only completed the study. The patients received 6 InterX5000 or placebo treatments within 2 weeks, and pretreatment and post-treatment blood samples were collected for in vitro determination of biomarker production. Compared with asymptomatic subjects, baseline production levels of all proinflammatory

mediators (TNFα, IL-1β, IL-6, and CCL2/MCP-1) were significantly improved or trended higher in patients with NP. The increase in IL-10 and tumor necrosis factor receptor II levels did not reach statistical significance. Neither InterX5000 nor placebo therapy had any significant effect on the production of the inflammatory mediators over the study period. Authors concluded that inflammatory cytokine pathways are activated in NP patients yet not normalized by InterX5000 treatment. Zeng et al. (2015) investigated the efficacy of different electrical stimulation (ES) therapies in pain relief of patients with knee osteoarthritis (OA). 27 trials and six kinds of ES therapies, including high-frequency transcutaneous electrical nerve stimulation (h-TENS), low-frequency transcutaneous electrical nerve stimulation (l-TENS), neuromuscular electrical stimulation (NMES), interferential current (IFC), pulsed electrical stimulation (PES), and noninvasive interactive neurostimulation (NIN), were included. Authors concluded that IFC seems to be the most promising pain relief treatment for the management of knee OA. However, evidence was limited due to the heterogeneity and small number of included trials. Although the recommendation level of the other ES therapies is either uncertain (h-TENS) or not appropriate (l-TENS, NMES, PES and NIN) for pain relief, it is likely that none of the interventions is dangerous. Razzano et al. (2017) evaluated whether the use of NIN for chronic plantar fasciitis could result in greater improvement in a foot functional score, lower levels of reported pain, reduced patient consumption of NSAIDs, and greater patient satisfaction compared with electric shockwave therapy in patients without a response to standard conservative treatment in a prospective randomized trial. The study group was evaluated at baseline (time 0), week 4 (time 1), and week 12 (final follow-up point). Group 1 (55 patients) experienced significantly better results compared with group 2 (49 patients) in term of the outcomes, visual analog scale score, and daily intake of etoricoxib 60 mg. Authors concluded that NIN was an effective treatment of chronic resistant plantar fasciitis, with full patient satisfaction in >90% of cases. The present prospective randomized controlled study showed superior results for noninvasive neurostimulation compared with electric shockwave therapy, in terms of the functional score, pain improvement, and use of NSAIDs. Razzano et al. (2019) compared the results in terms of improvement of a foot functional score, lower level of reported pain, and return to sports in 2 groups of contact sport athlete affected by a grade I or II lateral ankle sprain. Patients were randomized using random blocks to the NIN program (group I) or a sham device (group II). The outcome measurements were the use of a self-reported Inability Walking Scale, patient-reported subjective assessment of the level of pain using a standard visual analogue scale, and daily intake of nonsteroidal anti-inflammatory drugs (etoricoxib 60 mg). Patients were also reached by telephone at 2 and 4 months of follow-up to register their return to sport activity. Beyond baseline evaluation, follow-ups were done after 5 (1 week) and 10 sessions (2 weeks) of treatment, and then at 30 days after the end of therapy. Of the 70 athletes admitted to the study, 61 eligible patients were randomized using random blocks to group I (n = 32) and group II (n = 29). Group I patients showed better improvement in terms of functional impairment (Inability Walking Scale), reported pain (visual analogue scale), and daily intake of etoricoxib 60 mg. Athletes of group I registered a faster resuming of sport

activities. According to authors, this prospective, randomized trial showed NIN can improve short-term outcomes in athletes with acute grade I or II ankle sprain and that it can hasten resuming of sport activities.

Given the heterogeneity and limitations of available literature, no conclusions can be drawn on the effectiveness of NIN.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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