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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

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”).
**PLAN PRODUCT AND BENEFIT APPLICATION**

☒ Commercial
☒ Medicaid/OHP*
☒ Medicare**

*Medicaid/OHP 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.

**Medicare Members

This Company policy may be applied to Medicare Plan members only when directed by a separate Medicare policy. Note that investigational services are considered “not medically necessary” for Medicare members.

**COVERAGE CRITERIA**

*Note: Implantation of the StimRouter Neuromodulation System (CPT codes 64555, 64575, or 64585) may be considered medically necessary per the medical policy, [Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (Company)].*

I. The following electrical stimulation therapies are considered investigational for any indication:
   A. Auricular electrostimulation/auricular electroacupuncture
   B. Cefaly supraorbital transcutaneous neurostimulator device
   C. Interferential stimulation (IFS)
   D. Microcurrent electrical stimulation (MENS), including frequency-specific microcurrent (FSM)
   E. Occipital Nerve Stimulation (ONS)
   F. Percutaneous electrical nerve field stimulation
   G. Percutaneous neuromodulation therapy (PNT)
   H. Percutaneous nerve stimulation (PENS)
   I. Percutaneous implanted peripheral nerve stimulation (e.g., StimRouter System; Sprint PNS)
   J. Transcutaneous electrical joint stimulation devices (e.g., BioniCare device)
   K. Transcutaneous electrical modulation pain reprocessing (also known as scrambler therapy)
   L. H-Wave electrical stimulation
   M. Remote electrical neuromodulation (REN) devices (e.g., Nerivio REN device)

II. The following electrical stimulation therapies are considered not medically necessary:
   A. Cranial electrical stimulation for any indication
   B. External trigeminal nerve stimulation (e.g., Monarch eTNS System) for attention deficit
hyberactivity disorder

Link to Evidence Summary

POLICY CROSS REFERENCES

• Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (Company).

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

• All medical records and chart notes pertinent to the request. This includes:
  • History
  • Physical examination
  • Treatment plan

BACKGROUND

Auricular electrostimulation

Auricular electrostimulation, also known as auricular electro-acupuncture or electrical auriculotherapy, is a type of ambulatory electrical stimulation of acupuncture points on the ear and has been developed to provide continuous or intermittent stimulation over a period of several days for a variety of conditions, including pain, depression, anxiety, nausea/vomiting and weight loss. These devices are disposable, preprogrammed units worn behind the ear and connected to acupuncture needles.

Cefaly Supraorbital Transcutaneous Neurostimulator device

Cefaly is a small, portable, battery-powered, supraorbital transcutaneous neurostimulator prescription device that resembles a plastic headband worn across the forehead and atop the ears. The device consists of an adhesive, gel-backed electrode that the patient places directly on the skin in the center of the forehead, connects the electrode to the generator, and then turns on a plastic-framed pulse generator. The pulse generator fits like a pair of glasses. A control button in the center of the device powers the unit and allows the patient to control the level of stimulation.

Cranial Electrical Stimulation
Cranial electrical stimulation works by sending low-level electrical currents to the head via electrodes. The exact mechanism of action remains unclear but has been hypothesized to activate areas of the brain that play important roles in the body’s hormones and emotions. The treatment has been proposed for the treatment of a variety of chronic conditions including, but not limited to stress, alcoholism, drug addiction, anxiety, and depression.

**Interferential stimulation (IFS)**

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.

**Microcurrent electrical nerve stimulation (MENS)**

Microcurrent electrical nerve stimulation (MENS), also referred to as micro-electrical therapy (MET) or micro-electrical neurostimulation, involves applying a very low voltage microamperage current to affected cells or tissue trigger points in order to stimulate the tissues’ response to healing and repair.

MENS differs from TENS in that it uses a significantly reduced level of electrical stimulation. TENS therapy delivers stimulation in the milliamp range, causing muscle contractions, pulsing, and tingling, thereby blocking pain. Conversely, MENS delivers stimulation in the micro amp range, which is undetectable to patients and is thought to act on the body’s naturally occurring electrical impulses to decrease pain by stimulating the healing process.

During MENS therapy, the physical therapist or physician administers the microamperage current to various parts of the patient’s body by using vinyl graphite gloves or electrodes. 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. MENS has been proposed as both an adjunctive and a stand-alone therapy for a wide variety of indications that require either pain reduction or stimulation of the healing process. Due to variability in published MENS treatment protocols and the fact that MENS is often used in combination with a variety of other interventions, evaluating the efficacy of MENS for any condition is difficult.

**Occipital Nerve Stimulation (ONS)**

ONS involves the implantation of subcutaneous electrodes at the base of the skull over the greater, lesser, or third occipital nerves. The electrodes are connected to leads which are tunneled together in a
caudal direction to an impulse generator implanted in the chest wall, low back, buttocks, or abdomen. The generators can be controlled by the physician or patient and can provide continuous or intermittent stimulation. Additionally, the generators can be non-rechargeable with a 2-to-5-year lifespan or rechargeable.

**Percutaneous Electrical Nerve Stimulation (PENS)**

Percutaneous electrical nerve stimulation (PENS) uses acupuncture-like needles as electrodes. These needles are placed in the soft tissues or muscles at dermatomal levels corresponding to local pathology (needles are usually inserted above and below and into the central area of pain). A 5-Hz frequency with a pulse width of 0.5 mS is usually used. If relief is not attained within 15 minutes, the frequency may be lowered to 1 Hz. According to PENS proponents, the main advantage of PENS over TENS is that it bypasses the local skin resistance and delivers electrical stimuli at the precisely desired level near the nerve endings located in soft tissue, muscle, or periosteum of the involved dermatomes.

**Percutaneous Neuromodulation Therapy (PNT)**

Percutaneous neuromodulation therapy (PNT) is a variation of PENS but utilizes different electrical impulses; it utilizes an alternating low and high frequency current at varying pulse. The electrical stimulation is delivered via needle-like electrodes which is purported to allow the stimulation to reach the deep tissue. Some use the terms PENS and PNT interchangeably. It is proposed that PNT inhibits pain transmission by creating an electrical field that hyperpolarizes C-fibers, thus preventing action potential propagation along the pain pathway.

**Peripheral Nerve Stimulation (PNS)**

PNS is a minimally invasive pain management modality intended to manage acute and chronic pain. Unlike spinal cord stimulation, where leads are placed in the epidural space, PNS leads are placed just adjacent or parallel to a nerve. A similar technology, peripheral nerve field stimulation, involves placement of the leads subcutaneously in the region of the pain where they stimulate smaller peripheral nerves and nerve.

**REGULATORY STATUS**

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

**U.S. Food & Drug Administration (FDA)**

Most electrical stimulation devices are approved as 510(k) Class II devices by the FDA. Examples of FDA-approved devices include, but are not limited to:
**Auricular Electrostimulation devices:**
- AcuStim (S.H.P. International), approved 2002
- P-Stim™ System (NeuroScience Therapy), approved 2006
- E-pulse® (AMM Marketing), approved 2009
- Electro Auricular Device (EAD) (Key Electronics), approved 2014
- P-Stim (Biegler Gmbh)
- ANSIstim® (DyAnsys), approved 2015
- Stivax System (Biegler Gmbh), approved 2016

**Cefaly supraorbital transcutaneous nerve stimulator device** (Cefaly Technology), approved in 2016

**Cranial Electrical Stimulation devices:**
- Alpha-Stim® Cs (Electromedical Products, Inc)
- BR-2 Biorest (Biorest, Inc)
- Biotron18 (Biotronics Corp)
- CES Ultra™ (Neuro-Fitness, LLC)
- Elexoma Medic (Redplane AG)
- FM 10/C (Johari Digital Healthcare, Ltd)
- HP-1 Healthpax or Nurtipax (Health Directions, Inc)
- LB-2000 (Life Balance Intl., Inc)
- LISS SBI202-B and SBI201-M (Medical Consultants Intl., Ltd)
- NET-2000 Microcurrent Stimulator (Auri-Stim Medical, Inc)
- NF-1 Mindpeace (NeuroFitness)
- NH 2002 (Life Balance Intl., Inc)
- NTI-1000 (Neurotek, Inc)
- TESA-1 (Kalaco Scientific, Inc)

**Interferential Stimulation devices:**
- 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)

**Microcurrent Electrical Nerve Stimulation devices:**
- Alpha-Stim PPM (personal pain manager)
- Inspirstar IS02 Microcurrent Stimulator (Inspirstar Inc.)
- Promax-MC, Microcurrent Device, Model MC-4440 (Rehabolicare, Inc.)
EVIDENCE REVIEW
Due to the volume of electrical stimulation devices for a wide variety of conditions, the evidence table below lists the most recent peer-reviewed literature and is focused on randomized trials and systematic reviews. A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of various electrical stimulation devices for any indication. Below is a summary of the available evidence identified through April 2022.

- **Auricular stimulation for pain management**\(^3\)\(^-\)\(^7\)
- **Cefaly supraorbital transcutaneous neurostimulator for headaches/migraines**\(^8\)
- **Cranial electrical stimulation for**
  - Chronic pain\(^9\)\(^,\)\(^10\)
  - Depression and anxiety disorders\(^11\)\(^-\)\(^13\)
- **H-Wave Device**\(^14\)
- **Interferential stimulation for**
  - Osteoarthritis\(^15\)\(^-\)\(^18\)
  - Low back pain\(^19\)\(^,\)\(^20\)
  - Gastrointestinal disorders\(^21\)
  - Fibromyalgia\(^22\)
  - Neck pain\(^23\)\(^-\)\(^26\)
  - Total knee arthroplasty\(^27\)
  - Recurrent jaw pain\(^28\)
  - Idiopathic carpal tunnel syndrome\(^29\)
  - Chronic stroke plantarflexor spasticity\(^30\)
  - Urinary incontinence\(^31\)\(^-\)\(^33\)
  - Elbow pain\(^28\)\(^-\)\(^34\)
  - Post-traumatic complex regional pain syndrome, type 1\(^35\)
  - Hemiplegic shoulder pain\(^36\)
- **Microcurrent electrical nerve stimulation**
  - Pain management\(^37\)\(^-\)\(^42\)
  - Wound healing\(^43\)\(^-\)\(^45\)
  - Symptoms of advanced diabetes\(^46\)\(^,\)\(^47\)
- **Occipital Nerve Stimulation**\(^48\)\(^-\)\(^51\)
- **Percutaneous electrical nerve stimulation (PENS)**\(^52\)\(^-\)\(^54\)
- **Percutaneous neuromodulation therapy (PNT)**\(^52\)
- **Peripheral Nerve Stimulation**\(^55\)\(^,\)\(^56\)
- **Remote electrical neuromodulation (REN) devices**\(^57\)
- **Scrambler Therapy**\(^58\)\(^,\)\(^59\)

**CLINICAL PRACTICE GUIDELINES**

*Auricular stimulation*
• The American College of Chest Physicians (ACCP) published clinical practice guidelines in 2003 that addressed lung management. The guideline offers a ‘weak recommendation’ for electroacupuncture for chemotherapy-induced acute vomiting.\(^{60}\)

_Cefaly supraorbital transcutaneous neurostimulator_

• National Institute for Health and Care Excellence published guidelines in 2016 on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraines. The guidelines state that evidence is limited in quantity and quality, but the stimulation devices may be an option for patients.\(^{61}\)

_Cranial Electrical Stimulation_

• The International Federation of Clinical Neurophysiologists (IFCN) published 2017 evidence-based guidelines addressing the therapeutic use of transcranial direct current stimulation.\(^{62}\) Authors stated that tDCS has probable but not definite efficacy for treatment of nondrug-resistant major depression when administered with the anode over the left dorsolateral prefrontal complex (DLPFC) and cathode over the right orbitofrontal area. However, authors also concluded that tDCS is probably ineffective for drug-resistant major depression and there is insufficient evidence to develop a recommendation for treatment of depression with tDCS using an anode over the left DLPFC and a cathode over the right DLPFC.

• National Institute for Health and Care Excellence (NICE) published 2015 guidelines addressing transcranial direct current stimulation (tDCS) for depression.\(^{63}\) On the basis of published evidence, NICE concluded that treatment of depression with tDCS did not raise any major safety concerns but there is uncertainty about mode of administration, number of treatment sessions needed, and duration of treatment effects.

_Interferential stimulation_

• The American College of Physicians published clinical practice guidelines in 2017 on noninvasive treatments for acute, subacute, and chronic low back pain, and determined there was insufficient evidence to support IFS as a therapy for low back pain.

• National Institute for Health and Care Excellence published 2020 guidelines for the assessment and management of low back pain and sciatica and recommended against offering IFS for managing low back pain.

_Microcurrent electrical nerve stimulation_

• The American Physical Therapy Association (APTA) published 2013 guidelines on physical therapy management for congenital muscular torticollis. The guidelines offer a weak recommendation for MENS as one of several possible supplemental interventions, but should only be applied by clinicians skilled in that modality.\(^{64}\)

_Occipital Nerve Stimulation_

• Congress of Neurological Surgeons published 2015 evidence-based guidelines for occipital nerve stimulation in patients with medically refractory occipital neuralgia stated, “data from a recent
systematic review of the literature supports the use of occipital nerve stimulation (ONS) as a treatment option for patients with medically refractory occipital neuralgia (ON) (Level III recommendation).” However, the validity of this recommendation is questionable as it is a level 3 recommendation based on poor quality case series and expert opinion.

- National Institute for Health and Care Excellence (NICE) published 2013 guidelines for occipital nerve stimulation for intractable chronic migraine, stating, “(t)he evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.”

**Percutaneous Electrical Nerve Stimulation**


**Peripheral Electrical Nerve Stimulation**

- National Institute for Health and Care Excellence (NICE) published guidance in 2013 regarding peripheral nerve field stimulation for chronic low back pain (ranging from just below the rib cage to the creases of the buttocks). NICE recommendations note that evidence on efficacy is very limited, in both quality and quantity. Likewise, evidence on safety is also limited and there is a risk of complications from any implanted device. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

**BILLING GUIDELINES AND CODING**

**Auricular stimulation**

- The HCPCS S8930 code is the only code that may be used to bill auricular electrostimulation.

- CPT codes 97813 or 97814 are not specific to auricular electrostimulation, therefore, if they are billed for this service, they will be denied.

**Cefaly Supraorbital Transcutaneous Neurostimulator device**

The following codes are not appropriate for the Cefaly device as they describe stimulation using more than one lead:
• A4595
• E0720
• E0730

Interferential Stimulation

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.

Microcurrent electrical stimulation (MENS)

When billed through eviCore for physical therapy/occupational therapy services, 97032 requires prior authorization.

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<td>Cranial electrotherapy stimulation (CES) system supplies and accessories, per month</td>
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<td>K1002</td>
<td>Cranial electrotherapy stimulation (CES) system, any type</td>
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<td>K1023</td>
<td>Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm</td>
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<td>S8130</td>
<td>Interferential current stimulator, 2 channel</td>
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<td>S8131</td>
<td>Interferential current stimulator, 4 channel</td>
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<td>S8930</td>
<td>Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient</td>
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<td>Miscellaneous DME supply, accessory, and/or service component of another HCPCS code</td>
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<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<td>C1820</td>
<td>Generator, neurostimulator (implantable), with rechargeable battery and charging system</td>
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<td>C1823</td>
<td>Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads</td>
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<td>Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller</td>
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<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
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<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
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<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
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<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
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<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
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<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
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<td>G0283</td>
<td>Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
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*Coding Notes:*

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered.** If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended.**
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website** for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

**REFERENCES**


**POLICY REVISION HISTORY**

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