MEDICAL POLICY	Electrical Stimulation: Non-Covered Therapies (All Lines of Business Except Medicare)
Effective Date: 1/1/2023  1/1/2023 Medical Officer Date	Medical Policy Number: 331 Medical Policy Committee Approved Date: 6/2022; 10/2022; 11/2022; 12/2022

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 (*unless otherwise directed by a Medicare medical policy. Note that investigational services are considered "**not medically necessary**" for Medicare members.)*

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.

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

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POLICY CRITERIA

I. The following electrical stimulation therapies are considered **investigational and not covered** 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 and not covered**:
   A. Cranial electrical stimulation for any indication
   B. External trigeminal nerve stimulation (e.g., Monarch eTNS System) for attention deficit hyperactivity disorder

Link to Policy Summary

BILLING GUIDELINES

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.

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array

64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
Prior Authorization Required per EviCore	
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
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
No Prior Authorization Required	
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)
Not Covered	
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
0767T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)

0768T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
0769T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
0783T	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
K1002	Cranial electrotherapy stimulation (CES) system, any type
K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
S8130	Interferential current stimulator, 2 channel
S8131	Interferential current stimulator, 4 channel
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
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.**	
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
A9999	Miscellaneous dme supply or accessory, not otherwise specified
E1399	Durable medical equipment, miscellaneous
64999	Unlisted procedure, nervous system

DESCRIPTION

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.

REVIEW OF EVIDENCE

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[2-6]
- Cefaly supraorbital transcutaneous neurostimulator for headaches/migraines[7]
- Cranial electrical stimulation for
    - Chronic pain[8,9]
    - Depression and anxiety disorders[10-12]
- H-Wave Device[13]
- Interferential stimulation for
    - Osteoarthritis[14-17]
    - Low back pain[18,19]
    - Gastrointestinal disorders[20]
    - fibromyalgia[21]
    - neck pain[22-25]
    - total knee arthroplasty[26]
    - recurrent jaw pain[27]
    - idiopathic carpal tunnel syndrome[28]
    - chronic stroke plantarflexor spasticity[29]
    - urinary incontinence[30-32]
    - elbow pain[27-33]
    - post-traumatic complex regional pain syndrome, type 1[34]
    - hemiplegic shoulder pain[35]
- Microcurrent electrical nerve stimulation
    - Pain management[36-41]
    - Wound healing[42-44]
    - Symptoms of advanced diabetes[45,46]
- Occipital Nerve Stimulation[47-50]
- Percutaneous electrical nerve stimulation (PENS)[51-53]
- Percutaneous neuromodulation therapy (PNT)[51]
- Peripheral Nerve Stimulation[54,55]
- Remote electrical neuromodulation (REN) devices[56]
- Scrambler Therapy[57,58]

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.[59]

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.[60]

Cranial Electrical Stimulation

- The International Federation of Clinical Neurophysiologists (IFCN) published 2017 evidence-based guidelines addressing the therapeutic use of transcranial direct current stimulation.[61] 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.[62] 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.[63]

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)."[64] 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."[65]

Percutaneous Electrical Nerve Stimulation

- American Academy of Neurology (AAN), American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), American Academy of Physical Medicine and Rehabilitation (AAPMR) published evidence-based guidelines for the treatment of diabetic neuropathy in 2011. The guidelines recommend that percutaneous electrical nerve stimulation be considered for the treatment of peripheral diabetic neuropathy, based on one study.[66]
- American College of Occupational and Environmental Medicine (ACOEM) published 2020 guidelines for non-invasive and minimally-invasive management of low back disorders and recommended against PENS.[67]

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.[68]

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)

Most electrical stimulation devices are approved as 510(k) Class II devices by the FDA.[69] 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 SBl202-B and SBl201-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 (Rehabilicare, Inc.)

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.

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