Department of Origin: Integrated Healthcare Services	**Effective Date:** 03/05/24
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 03/05/24
Clinical Policy Document: Neurostimulation, Spinal Cord/Dorsal Column and Dorsal Root Ganglion	**Replaces Effective Clinical Policy Dated:** 05/25/23
Reference #: MC/I010	**Page:** 1 of 8

PURPOSE:
The intent of this clinical policy document is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria – Requests for spinal cord/dorsal column (SCS/DCS) or dorsal root ganglion stimulation - Must satisfy any of the following: I - III

I. Percutaneous (temporary) trial to predict whether the device will induce significant pain relief of chronic pain - must satisfy both of the following: A and B

   A. Indications for trial - must satisfy one of the following: 1 or 2
      1. Spinal cord/dorsal column stimulation (SCS/DCS) for any of the following: a - d
         a. Failed back surgery syndrome with low back pain and significant radicular pain; or
         b. Cervical/ low back *complex regional pain syndrome* (CRPS); or
         c. Inoperable chronic ischemic limb pain, secondary to peripheral vascular disease; or
         d. Last resort treatment of c*hronic*, intractable neuropathic pain of certain origin (ie, lumbosacral arachnoiditis and radiculopathies, phantom limb/stump pain, peripheral neuropathy [including diabetic peripheral neuropathy], post-herpetic neuralgia, intercostal neuralgia, cauda equina injury, incomplete spinal cord injury, or plexopathy) - must satisfy both of the following: 1) and 2)
            1) Pain is characterized as moderate to severe (5 or more on a 10-point VAS scale); and
            2) Pain is refractory to 12 or more months of pharmacologic treatment including all of the following: i - iii
               i. Non-steroidal anti-inflammatory drugs; and
               ii. Tricyclic antidepressants; and
               iii. Anticonvulsants.

      2. Dorsal root ganglion stimulation (eg, Axium Neurostimulator System) trial for the treatment of moderate to severe (5 or more on a 10-point VAS scale) chronic intractable pain of the lower limb(s) in members with *complex regional pain syndrome* (CRPS) types I or II.

   B. Member meets all of the following: 1 - 3
      1. Documentation of thorough diagnostic testing completed, indicating an objective basis for the pain complaint including a pre-trial assessment of function, using a tools such as, but not limited to, the Oswestry Disability Questionnaire, the Roland-Morris Disability Questionnaire, and the physical health scales of the Medical Outcomes Study 36-Item Short-Form Health Survey [SF-36]); and

2. Failure of 6 months of conservative treatment (such as, but not limited to, pharmacotherapy, psychotherapy, and physical therapy), as defined by unsatisfactory pain control; and

3. Documentation of a mental health evaluation (such as, but not limited to, face-to-face assessment with or without psychological questionnaires and/or psychological testing) by a mental health provider revealing no evidence of existing behavioral health problems (such as, but not limited to, alcohol or drug dependence, depression, and psychosis) that are inadequately controlled.

II. Permanent implanted spinal cord/dorsal column or dorsal root ganglion stimulator for a positive response to a percutaneous trial as demonstrated by the following: A and B

A. Greater than or equal to 50% reduction in pain during the period of the trial; and

B. Improvement in function (must submit documentation of pre-and post-trial assessment scores from assessment tools such as, but not limited to, the Oswestry Disability Questionnaire, the Roland-Morris Disability Questionnaire, and the physical health scales of the Medical Outcomes Study 36-Item Short-Form Health Survey [SF-36]).

[Note: If the device implantation is approved, electronic analysis is also covered (CPTs 95970-95973).]

III. Replacement or revision of stimulator generator/battery, lead or electrode, or patient programmer – must satisfy the following: A, and B or C, as applicable

A. The initial placement indication was for one of the following: 1 or 2
   1. Spinal cord/dorsal column stimulation (SCS/DCS) for any of the following: a - d
      a. Failed back surgery syndrome with low back pain and significant radicular pain; or
      b. Cervical, low back or lower limb *complex regional pain syndrome* (CRPS)
      c. Inoperable chronic ischemic limb pain, secondary to peripheral vascular disease; or
      d. Last resort treatment of chronic, intractable neuropathic pain of certain origin (ie, lumbosacral arachnoiditis and radiculopathies, phantom limb/stump pain, peripheral neuropathy [including diabetic peripheral neuropathy], post-herpetic neuralgia, intercostal neuralgia, cauda equina injury, incomplete spinal cord injury, or plexopathy)

   2. Dorsal root ganglion stimulation - c*hronic* intractable pain of the lower limb(s) in members with *complex regional pain syndrome* (CRPS) types I or II.

B. Request is for replacement of the existing generator/battery or patient programmer - must satisfy any of the following: 1 - 2
   1. The battery life is less than 1 year; or

   2. The device is *malfunctioning* and no longer under warranty.

C. Request is for replacement and/or revision of lead/electrode due to migration and/or no longer functioning properly is considered medically necessary.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

The following is considered investigative (see Investigative List)

- Implantable subcutaneous target stimulator devices

DEFINITIONS:
Chronic:
Greater than or equal to 6 months in duration

Complex Regional Pain Syndrome (also known as reflex sympathetic dystrophy [RSD]):
A chronic (lasting greater than six months) pain condition that most often affects one limb (arm, leg, hand, or foot) usually after an injury. CRPS is believed to be caused by damage to, or malfunction of, the peripheral and central nervous systems. The central nervous system is composed of the brain and spinal cord; the peripheral nervous system involves nerve signaling from the brain and spinal cord to the rest of the body. CRPS is characterized by prolonged or excessive pain and changes in skin color, temperature, and/or swelling in the affected area.

CRPS is divided into two types: CRPS-I and CRPS-II. Individuals without a confirmed nerve injury are classified as having CRPS-I (previously known as reflex sympathetic dystrophy syndrome). CRPS-II (previously known as causalgia) is when there is an associated, confirmed nerve injury. As some research has identified evidence of nerve injury in CRPS-I, it is unclear if these disorders will always be divided into two types. Nonetheless, the treatment is similar.

Malfunctioning:
The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

BACKGROUND:
Spinal cord stimulation (SCS) relieves pain by delivering low-voltage electrical current to the spinal cord to block pain sensation. SCS has two phases: temporary and permanent implantations. The temporary phase involves temporarily implanting a lead/s that is/are connected to a temporary SCS. Programming of the temporary stimulator is specific to the patient's pain origin. This temporary phase has the following benefits:

- Assists both the patient and physician in determining if SCS is an effective method to relieve the patient's pain.
- Assists both the patient and physician in determining which type of SCS system is the most effective.
- Enables both the patient and physician in assessing which stimulation programs or settings are the most effective.

If the temporary phase shows evidence that SCS is an effective method to relieve the patient's pain (greater than or equal to 50% relief of symptoms) and improve the patient's function (comparison of pre- and post-trial disability assessment scores using tools such as the Oswestry Disability Questionnaire, the Roland-Morris Disability Questionnaire, and the physical health scales of the Medical Outcomes Study 36-Item Short-Form Health Survey [SF-36] must show improvement), the next step is to implant a permanent SCS. It is important to be aware that although it is called "permanent," SCS therapy is

reversible. Before implanting the permanent SCS device, the temporary lead/s is/are first removed. The location/s of the lead/s depend/s on the patient's pain origin, and the generator is usually implanted in the abdominal or buttock region, although other more comfortable areas may be determined by the physician. SCS implantation is usually a same-day-surgery procedure although some physicians may require that the patient stay overnight for observation.

A technique with a different neural target than dorsal column stimulation is dorsal root ganglion stimulation. Electrodes are placed through the intraspinal epidural space in contact with the sensory dorsal root ganglia. Electrical fields are generated that can selectively stimulate different parts of the dorsal root ganglia. This is intended to allow focusing of stimulation onto specific nerve roots or parts of nerve roots.

Examples of DCS include, but are not limited to, Eon, EonC, Eon Mini, Genesis IPG System, Intellis, Itrel4, Precision Plus SCS System, Precision Spectra, PrimeAdvanced Neurostimulator, Protégé, Restore, RestoreAdvanced, RestorePrime, Restore Sensor, RestoreUltra, Specify, Synergy, Vanta, Vectris, or WaveWriter Alpha). High-frequency devices include, but are not limited to Senza or burst (Burstdr).

Prior Authorization: Yes, per network provider agreement.

CODING:
CPT®
63650 Percutaneous implantation of neurostimulator electrode array, epidural
63655 Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63663 Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63664 Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddles placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685 Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688 Revision or removal of implanted spinal neurostimulator pulse generator or receiver

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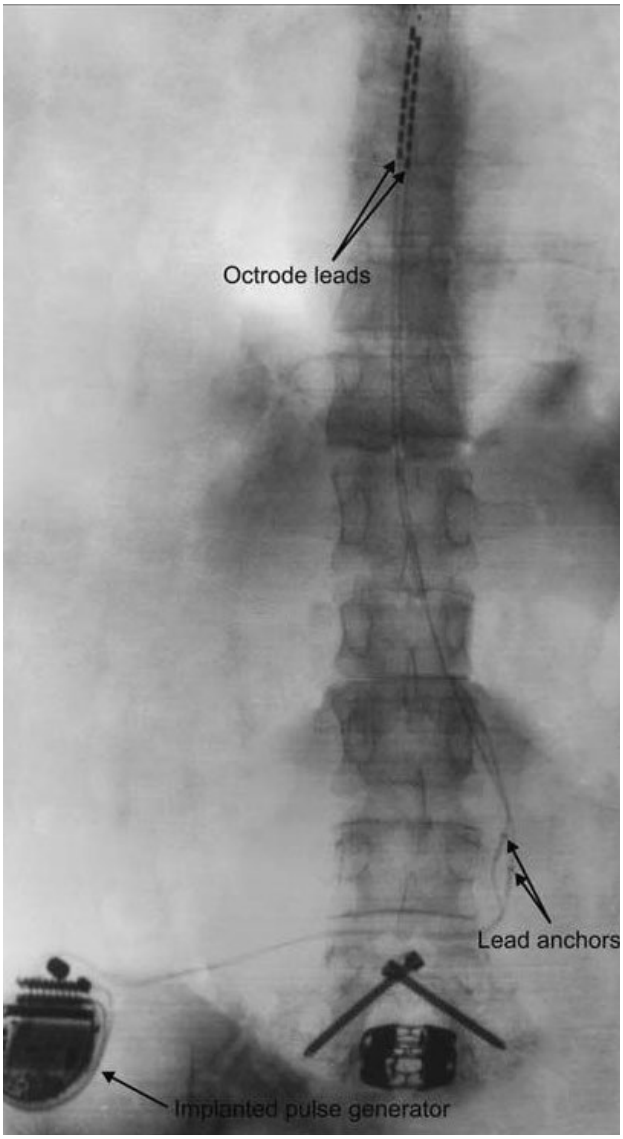
Attachment A

X-Ray Image of an Implanted Spinal Cord Stimulator
Retrieved from Medscape



Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).