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

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. American Association of Neurological Surgeons (AANS). Spinal cord stimulation. AANS. Retrieved from http://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spinal-Cord-Stimulation. Accessed 12-26-23.
4. Canlas B, Drake T, Gabriel E. A severe case of complex regional pain syndrome I (reflex sympathetic dystrophy) managed with spinal cord stimulation. *Pain Pract*. 2010;10(1):78-83.
5. Clavo B, Robaina F, Montz R, et al. Effect of cervical spinal cord stimulation on cerebral glucose metabolism. *Neurol Res*. 2008;30(6):652-654.
6. Clavo B, Robaina F, Montz R, et al. Modification of glucose metabolism in radiation-induced brain injury areas using cervical spinal cord stimulation. *Acta Neurochir* (Wien). 2009;151(11):1419-1425.
7. De Andres J, Tatay J, Revert A, et al. The beneficial effect of spinal cord stimulation in a patient with severe cerebral ischemia and upper extremity ischemic pain. *Pain Pract*. 2007;7(2):135-142.
8. Forouzanfar T, Kemler MA, Weber WE, et al. Spinal cord stimulation in complex regional pain syndrome: Cervical and lumbar devices are comparably effective. *Br J Anaesth*. 2004;92(3):348-353.
9. Garcia-March G, Sanchez-Ledesma MJ, Diaz P, et al. Dorsal root entry zone lesion versus spinal cord stimulation in the management of pain from brachial plexus avulsion. *Acta Neurochir Suppl* (Wien). 1987;39:155-158.
10. Martelletti P, van Suijlekom H. Cervicogenic headache: Practical approaches to therapy. *CNS Drugs*. 2004;18(12):793-805.
11. National Institute of Neurological Disorders and Stroke (NINDS). Complex regional pain syndrome information page. Last Reviewed: 11-28-23. NINDS. Retrieved from https://www.ninds.nih.gov/Disorders/All-Disorders/Complex-Regional-Pain-Syndrome-Information-Page. Accessed 12-26-23.
12. Robaina FJ, Dominguez M, Diaz M, et al. Spinal cord stimulation for relief of chronic pain in vasospastic disorders of the upper limbs. *Neurosurgery*. 1989;24(1):63-67.
13. Simpson BA, Bassett G, Davies K, et al. Cervical spinal cord stimulation for pain: A report of 41 patients. *Neuromodulation*. 2003;6(1):20-26.

14. Simons M, & Laham RJ. New therapies for angina pectoris. (Topic 1524, Version 44.0; last updated: 10-11-22.) In: Parikh N, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2018. www.uptodate.com. Accessed 12-26-23.
15. Abdi S. Complex regional pain syndrome in adults: Treatment, prognosis, and prevention. (Topic 5630, Version 47.0; last updated: 01/19/23). In: Saperia GM, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2019. www.uptodate.com. Accessed 12-26-23.
16. Thomson S. Spinal cord stimulation for neuropathic pain. San Francisco, CA: International Neuromodulation Society (INS); April 24, 2016. Available at: http://www.neuromodulation.com/spinal-cord-stimulation-for-neuropathic-pain.
17. Eldabe S, Burger K, Moser H, et al. Dorsal root ganglion (DRG) stimulation in the treatment of phantom limb pain (PLP). *Neuromodulation*. 2015;18(7):610-616; discussion 616-617.
18. Van Buyten JP, Smet I, Liem L, et al. Stimulation of dorsal root ganglia for the management of complex regional pain syndrome: A prospective case series. *Pain Pract*. 2015;15(3):208-216.
19. Rowland DC, Wright D, Moir L, et al. Successful treatment of pelvic girdle pain with dorsal root ganglion stimulation. *Br J Neurosurg*. 2016 Jul 17:1-2.
20. Weiner RL, Yeung A, Montes Garcia C, et al. Treatment of FBSS low back pain with a novel percutaneous DRG wireless stimulator: Pilot and feasibility study. *Pain Med*. 2016;17(10):1911-1916.
21. Deer TR, Grigsby E, Weiner RL, et al. A prospective study of dorsal root ganglion stimulation for the relief of chronic pain. *Neuromodulation*. 2013;16(1):67-71; discussion 71-72.
22. Liem L, Russo M, Huygen FJ, et al. One-year outcomes of spinal cord stimulation of the dorsal root ganglion in the treatment of chronic neuropathic pain. *Neuromodulation*. 2015;18(1):41-48; discussion 48-49.
23. Schu S, Gulve A, ElDabe S, et al. Spinal cord stimulation of the dorsal root ganglion for groin pain-a retrospective review. Pain Pract. 2015;15(4):293-299.
24. van Bussel CM, Stronks DL, Huygen FJ. Successful treatment of intractable complex regional pain syndrome type I of the knee with dorsal root ganglion stimulation: A case report. *Neuromodulation*. 2015;18(1):58-60; discussion 60-61.
25. Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for CRPS and causalgia at 3 and 12 months: Randomized comparative trial. *Pain*. 2017;158(4):669-681.
26. Maino P, Koetsier E, Kaelin-Lang A, et al. Efficacious dorsal root ganglion stimulation for painful small fiber neuropathy: A case report. *Pain Physician*. 2017;20(3):E459-E463.
27. Chang Chien GC, Mekhail N. Alternate intraspinal targets for spinal cord stimulation: A systematic review. *Neuromodulation*. 2017;20(7):629-641.
28. Huygen F, Liem L, Cusack W, Kramer J. Stimulation of the L2-L3 dorsal root ganglia induces effective pain relief in the low back. *Pain Pract*. 2018;18(2):205-213.
29. Vuka I, Vucic K, Repic T, et al. Electrical stimulation of dorsal root ganglion in the context of pain: A systematic review of in vitro and in vivo animal model studies. *Neuromodulation*. 2018;21(3):213-224.
30. Yang A, Hunter CW. Dorsal root ganglion stimulation as a salvage treatment for complex regional pain syndrome refractory to dorsal column spinal cord stimulation: A case series. *Neuromodulation*. 2017;20(7):703-707.
31. Goebel A, Lewis S, Phillip R, Sharma M. Dorsal root ganglion stimulation for complex regional pain syndrome (CRPS) recurrence after amputation for CRPS, and failure of conventional spinal cord stimulation. *Pain Pract*. 2018;18(1):104-108.
30. US Food and Drug Admin. Code of Federal Regulations Title 21, Volume 8, Subpart A, Sec 803.3, (k) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803&showFR=1 Accessed 12-26-23.

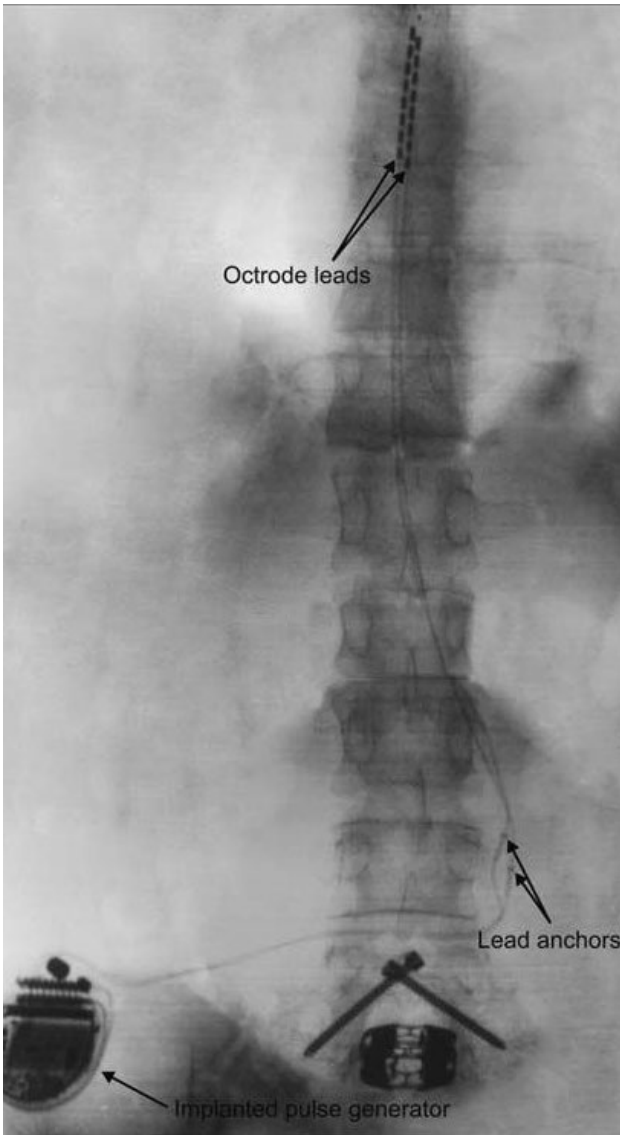
31. Al-Kaisy A, Van Buyten JP, Smet I, et al. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med*. 2014;15(3):347-354.
32. De Andres J, Monsalve-Dolz V, Fabregat-Cid G, et al. Prospective, randomized blind effect-on-outcome study of conventional vs high-frequency spinal cord stimulation in patients with pain and disability due to failed back surgery syndrome. *Pain Med*. 2017;18(12):2401-2421.
33. Kapural L, Yu C, Doust MW, et al. Novel 10-kHz high-frequency therapy (HF10 Therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: The SENZA-RCT Randomized Controlled Trial. *Anesthesiology*. 2015;123(4):851-860.
34. Perruchoud C, Eldabe S, Batterham AM, et al. Analgesic efficacy of high-frequency spinal cord stimulation: A randomized double-blind placebo-controlled study. *Neuromodulation.* 2013;16(4):363-369; discussion 369.
35. Russo M, Van Buyten JP. 10-kHz high-frequency SCS therapy: A clinical summary. *Pain Med.* 2015;16(5):934-942.
36. Tiede J, Brown L, Gekht G, et al. Novel spinal cord stimulation parameters in patients with predominant back pain. *Neuromodulation*. 2013;16(4):370-375.
37. Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation with BURST (SUNBURST) Study: Results from a prospective, randomized controlled trial using a novel burst waveform. *Neuromodulation.* 2018;21(1):56-66.
38. D'Souza RS, Barman R, Joseph A, Abd-Elsayed A. Evidence-based treatment of painful diabetic neuropathy: A systematic review. *Curr Pain Headache Rep*. 2022;26:583–594.
39. Feldman EL. Management of diabetic neuropathy. (Topic 5280, Version 49.0; Last Reviewed: 08/30/23) In: Goddeau, Jr, DO, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2022. www.uptodate.com. Accessed 12/26/23.
40. Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of high-frequency (10-kHz) spinal cord stimulation in patients with painful diabetic neuropathy: A randomized clinical trial. *JAMA Neurol.* 2021;78(6):687-698.
41. Strand NH, Burkey AR. Neuromodulation in the treatment of painful diabetic neuropathy: A review of evidence for spinal cord stimulation. *J Diabetes Sci Technol*. 2022 Mar;16(2):332-340.

DOCUMENT HISTORY:

Created Date: 01/18/12
Reviewed Date: 01/15/13, 12/30/13, 12/24/14, 12/24/15, 12/05/16, 12/05/17, 12/05/18, 12/05/19, 12/04/20, 11/29/21, 11/29/22, 11/22/23
Revised Date: 01/08/14**,** 01/06/16, 01/18/21, 03/04/21, 09/27/21, 12/10/21, 01/06/22, 05/25/23

Attachment A

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



Nondiscrimination & Language Access Policy

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, sex, sexual orientation, or gender identity. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:
Provide free aids and services to people with disabilities to communicate effectively with us, such as:
- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:
- Qualified interpreters
- Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *contract*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
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.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً . اتصل بن اعلى رقم الهاتف 1.866.631.5404(رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_: य_द आप ि◌हंदी बोलते ह_ तो आपके ि◌लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັ້ງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY:711).