



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 11/07/23
LAST REVIEW DATE: 11/19/24
CURRENT EFFECTIVE DATE: 11/19/24
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ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 4TH QTR 2024

IMPLANTABLE PERIPHERAL NERVE STIMULATION DEVICES

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Peripheral nerve stimulation (PNS) is targeted to treat the origin of pain from the peripheral nerve, electrical impulses are delivered to the nerve. Unlike other modalities PNS offers greater selectivity and accuracy by targeted well-defined neuronal targets. PNS involves the use of an implanted device, generator and remote control that is used to adjust stimulation. The device can be implanted temporarily or permanently implanted. PNS has been used for the treatment of chronic pain, post-surgical pain, post-traumatic pain of the back and/or extremities, facial/head pain, peripheral mononeuropathy, complex regional pain syndrome (CRPS) and phantom limb pain.

Implantable peripheral nerve stimulation devices cleared by the U.S. Food and Drug Administration include, *but are not limited to*:

- Moventis PNS
- Nalu™ Neurostimulation System
- Neuspera Nuity™ System
- StimQ Peripheral Nerve Stimulator System
- StimRouter® Neuromodulation System

Criteria:

- Implantable peripheral nerve stimulation devices are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

These devices include, *but are not limited to*:

- Moventis PNS
- Nalu™ Neurostimulation System
- Neuspera Nuity™ System
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Resources:

Literature reviewed 11/07/23. We do not include marketing materials, poster boards and non-published literature in our review

1. Abd-Elsayed A, D'Souza RS. Peripheral Nerve Stimulation: The Evolution in Pain Medicine. *Biomedicines*. Dec 23 2021;10(1)doi:10.3390/biomedicines10010018
2. Abdi S. Complex regional pain syndrome in adults: Treatment, prognosis, and prevention. In: Goddeau RP, ed. *UpToDate*. UpToDate; 2023. Accessed September 5, 2023. <https://www.uptodate.com/contents/complex-regional-pain-syndrome-in-adults-treatment-prognosis-and-prevention>
3. Al-Danakh A, Safi M, Alradhi M, et al. Posterior Tibial Nerve Stimulation for Overactive Bladder: Mechanism, Classification, and Management Outlines. *Parkinsons Dis*. 2022;2022:2700227. doi:10.1155/2022/2700227
4. Albright-Trainer B, Phan T, Trainer RJ, et al. Peripheral nerve stimulation for the management of acute and subacute post-amputation pain: a randomized, controlled feasibility trial. *Pain Manag*. Apr 2022;12(3):357-369. doi:10.2217/pmt-2021-0087
5. Amorizzo E, Colini-Baldeschi G. Peripheral Nerve Stimulation: Two Cases of Intractable Neuropathic Pain. *Anesth Pain Med*. Apr 2021;11(2):e113162. doi:10.5812/aapm.113162
6. Buchfuhrer MJ, Baker FC, Singh H, et al. Noninvasive neuromodulation reduces symptoms of restless legs syndrome. *J Clin Sleep Med*. Aug 1 2021;17(8):1685-1694. doi:10.5664/jcsm.9404
7. Centers for Medicare & Medicaid Services. LCD-Peripheral Nerve Stimulation (L37360). Accessed August 18, 2023, <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=37360>
8. Char S, Jin MY, Francio VT, et al. Implantable Peripheral Nerve Stimulation for Peripheral Neuropathic Pain: A Systematic Review of Prospective Studies. *Biomedicines*. Oct 17 2022;10(10)doi:10.3390/biomedicines10102606
9. Dana E, Gupta H, Pathak R, Khan JS. Genitofemoral peripheral nerve stimulator implantation for refractory groin pain: a case report. *Can J Anaesth*. Jan 2023;70(1):163-168. Implantation d'un stimulateur du nerf périphérique génito-crural pour une douleur réfractaire à l'aîne : une présentation de cas. doi:10.1007/s12630-022-02348-4
10. Ferreira-Dos-Santos G, Hurdle MFB, Gupta S, Clendenen SR. Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation for the Treatment of Lower Extremity Pain: A Rare Case Report. *Pain Pract*. Nov 2019;19(8):861-865. doi:10.1111/papr.12810

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11. Gilmore C, Iffeld B, Rosenow J, et al. Percutaneous peripheral nerve stimulation for the treatment of chronic neuropathic postamputation pain: a multicenter, randomized, placebo-controlled trial. *Reg Anesth Pain Med*. Jun 2019;44(6):637-645. doi:10.1136/rapm-2018-100109
12. Gilmore CA, Kapural L, McGee MJ, Boggs JW. Percutaneous Peripheral Nerve Stimulation (PNS) for the Treatment of Chronic Low Back Pain Provides Sustained Relief. *Neuromodulation*. Jul 2019;22(5):615-620. doi:10.1111/ner.12854
13. Gupta S, Clendenen S, Ferreira-Dos-Santos G, Hurdle MF. Ultrasound-Guided Intercostal Peripheral Nerve Stimulator Implantation: Technique Report and Feasibility Study in a Cadaver. *Pain Med*. Aug 1 2020;21(Suppl 1):S32-s37. doi:10.1093/pm/pnaa012
14. Iffeld BM, Plunkett A, Vijjeswarapu AM, et al. Percutaneous Neuromodulation of the Brachial Plexus and Sciatic Nerve for the Treatment of Acute Pain Following Surgery: Secondary Outcomes From a Multicenter, Randomized, Controlled Pilot Study. *Neuromodulation*. Apr 2023;26(3):638-649. doi:10.1111/ner.13492
15. Iffeld BM, Plunkett A, Vijjeswarapu AM, et al. Percutaneous Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study. *Anesthesiology*. Jul 1 2021;135(1):95-110. doi:10.1097/aln.0000000000003776
16. Iffeld BM, Said ET, Finneran JJ, et al. Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: Neuromodulation of the Femoral Nerve for Postoperative Analgesia Following Ambulatory Anterior Cruciate Ligament Reconstruction: A Proof of Concept Study. *Neuromodulation*. Jul 2019;22(5):621-629. doi:10.1111/ner.12851
17. Johnson S, Marshall A, Hughes D, et al. Mechanistically informed non-invasive peripheral nerve stimulation for peripheral neuropathic pain: a randomised double-blind sham-controlled trial. *J Transl Med*. Nov 6 2021;19(1):458. doi:10.1186/s12967-021-03128-2
18. Kalia H, Pritzlaff S, Li AH, et al. Application of the novel Nalu™ Neurostimulation System for peripheral nerve stimulation. *Pain Manag*. Oct 2022;12(7):795-804. doi:10.2217/pmt-2021-0050
19. Ni Y, Yang L, Han R, et al. Implantable Peripheral Nerve Stimulation for Trigeminal Neuropathic Pain: A Systematic Review and Meta-Analysis. *Neuromodulation*. Aug 2021;24(6):983-991. doi:10.1111/ner.13421
20. Oswald J, Shahi V, Chakravarthy KV. Prospective case series on the use of peripheral nerve stimulation for focal mononeuropathy treatment. *Pain Manag*. Nov 2019;9(6):551-558. doi:10.2217/pmt-2019-0028
21. Overstreet CK, Cheng J, Keefer EW. Fascicle specific targeting for selective peripheral nerve stimulation. *J Neural Eng*. Nov 11 2019;16(6):066040. doi:10.1088/1741-2552/ab4370

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22. Pahwa R, Dhall R, Ostrem J, et al. An Acute Randomized Controlled Trial of Noninvasive Peripheral Nerve Stimulation in Essential Tremor. *Neuromodulation*. Jul 2019;22(5):537-545. doi:10.1111/ner.12930
23. Parekattil SJ, Ergun O, Gudeloglu A. Management of Chronic Orchialgia: Challenges and Solutions - The Current Standard of Care. *Res Rep Urol*. 2020;12:199-210. doi:10.2147/rru.S198785
24. Regnier SM, Chen J, Gabriel RA, Chakravarthy KV. A review of the StimRouter(®) peripheral neuromodulation system for chronic pain management. *Pain Manag*. May 2021;11(3):227-236. doi:10.2217/pmt-2020-0042
25. Schnack LL, Oexeman S, Rodriguez-Collazo ER. Implantable Neuromodulation Device in the Lower Limb: An Adjunctive Procedure in Patients with Continued Chronic Pain After Failed Revisional Microneurosurgical Procedure in a Nonreconstructable Zone of Injury. *Clin Podiatr Med Surg*. Jan 2021;38(1s):e31-e43. doi:10.1016/j.cpm.2021.09.002
26. Strauss I, Valle G, Artoni F, et al. Characterization of multi-channel intraneural stimulation in transradial amputees. *Sci Rep*. Dec 17 2019;9(1):19258. doi:10.1038/s41598-019-55591-z
27. U.S. Food and Drug Administration. 510(k) Premarket Notification Database. Accessed September 5, 2023, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>
28. van Heteren EPZ, van Roosendaal BWP, van Gorp E, et al. Spinal Cord Stimulation With Additional Peripheral Nerve/Field Stimulation Versus Spinal Cord Stimulation Alone on Back Pain and Quality of Life in Patients With Persistent Spinal Pain Syndrome. *Neuromodulation*. Apr 2023;26(3):658-665. doi:10.1016/j.neurom.2021.11.010
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30. Yagüe S, Veciana M, Martínez-Yélamos A, et al. Effects of Bihemispheric Transcranial Direct Current Stimulation Combined With Repetitive Peripheral Nerve Stimulation in Acute Stroke Patients. *J Clin Neurophysiol*. Jan 1 2023;40(1):63-70. doi:10.1097/wnp.0000000000000840

Coding:

CPT: 64555, 64575, 64585, 64590, 64595
HCPCS: C1778, C1787, L8680, L8681, L8682, L8683, L8685, L8687, L8688, L8689



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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	11/19/24	Review with no revisions
Medical Policy Panel	11/07/23	Approve guideline
Medical Director (Dr. Raja)	08/30/23	Development

Policy Revisions:



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ 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: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights 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, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idilkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowotgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi: اگر شما، یا کسی که شما به او کمک میکنید، سوال در مورد Blue Cross Blue Shield of Arizona، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید.]

Assyrian: Blue Cross Blue Shield of Arizona, imate prawo da... 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณกำลังช่วยเหลือมีอาการเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถขอความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไม่มีค่าใช้จ่าย โปรดขอยกหมายเลข โทร 877-475-4799