



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/27/24
LAST REVIEW DATE: 09/27/24
CURRENT EFFECTIVE DATE: 09/27/24
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

TRIAL SPINAL CORD STIMULATOR PLACEMENT

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:

Spinal Cord Stimulation is a neuromodulation treatment for chronic neuropathic or ischemic pain after conservative treatments have failed. A spinal cord stimulator is a device that is surgically or percutaneously implanted in the spine that sends electrical impulses to specific regions of the spinal cord to relieve pain.

A spinal cord stimulator contains electrodes and a generator. The electrodes are surgically or percutaneously implanted into the epidural space of the spine. For the trial, a temporary external generator may be connected to the electrodes. For permanent implantation, the generator is surgically placed under the skin usually near the buttocks or abdomen. Once a spinal cord stimulator is placed, individuals can regulate the electrical stimulation level using a remote control. The remote control and its antenna are outside the body.

Spinal cord stimulator placement involves two procedures: one procedure to trial the spinal cord stimulator, and one procedure for permanent implantation. The trial is done to test the effectiveness of pain control and the individual's ability to tolerate it prior to permanent implantation. The trials typically last between a few days to a week. It is considered a successful trial if there is at least a 50% reduction in pain. If the trial procedure is successful, most individuals undergo permanent spinal cord stimulator implantation surgery about a week or two after the trial.

This policy addresses the trial procedure.

Criteria:

- Placement of a trial spinal cord stimulator is considered **medically necessary** with documentation of **ALL** of the following:
 1. Chronic neuropathic or ischemic pain as indicated by **ONE** of the following:
 - Complex regional pain syndrome (CRPS)
 - Lower extremity pain at rest due to critical limb ischemia
 - Failed back surgery syndrome (FBSS)
 2. Conservative treatment modalities (pharmacological, surgical, psychological, physical) have failed or are unsuitable or are contraindicated.
 3. Psychological evaluation complete and no untreated psychiatric disorders
 4. Absence of **ALL** of the following contraindications:
 - Uncontrolled coagulopathy
 - Severe thrombocytopenia
 - Active infection

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- Placement of a trial spinal cord stimulator for all other indications not previously listed or if above criteria not met is 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 indications include, *but are not limited to*:

- Cancer-related pain
- Chronic visceral abdominal pain
- Diabetic neuropathy-related pain
- Heart failure
- Postherpetic neuralgia
- Refractory angina pectoris

Resources:

Literature reviewed 09/27/24. We do not include marketing materials, poster boards and non-published literature in our review

1. American Association of Neurological Surgeons (AANS). Spinal Cord Stimulation. AANS. Updated April 15, 2024. Accessed August 20, 2024. <https://www.aans.org/patients/conditions-treatments/spinal-cord-stimulation/>
2. Bordeleau M, Léonard G, Gauthier L, et al. Classification of Qualitative Fieldnotes Collected During Quantitative Sensory Testing: A Step Towards the Development of a New Mixed Methods Approach in Pain Research. *J Pain Res.* 2021;14:2501-2511. doi:10.2147/jpr.S301655
3. Bulat E, Chakravarthy V, Crowther J, Rakesh N, Barzilai O, Gulati A. Exceptional Cases of Spinal Cord Stimulation for the Treatment of Refractory Cancer-Related Pain. *Neuromodulation.* Jul 2023;26(5):1051-1058. doi:10.1016/j.neurom.2022.06.002
4. Duarte R, Copley S, Nevitt S, et al. Effectiveness and Safety of Intrathecal Drug Delivery Systems for the Management of Cancer Pain: A Systematic Review and Meta-Analysis. *Neuromodulation.* Aug 2023;26(6):1126-1141. doi:10.1016/j.neurom.2022.03.003
5. Duarte RV, McNicol E, Colloca L, Taylor RS, North RB, Eldabe S. Randomized Placebo-/Sham-Controlled Trials of Spinal Cord Stimulation: A Systematic Review and Methodological Appraisal. *Neuromodulation.* Jan 2020;23(1):10-18. doi:10.1111/ner.13018

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6. Hong SW, Kim MJ, Park CH, Park S, Kim JH. Dorsal root ganglion stimulation combined with spinal cord stimulation for effective treatment of postherpetic neuralgia - A case report. *Anesth Pain Med (Seoul)*. Oct 2021;16(4):387-390. doi:10.17085/apm.21032
7. Lee T, Omosor E, Hussain N. A Case Series of Permanent Dorsal Root Ganglion Stimulation. *Cureus*. Jan 2022;14(1):e21193. doi:10.7759/cureus.21193
8. Li X, Chen P, He J, et al. Comparison of the Efficacy and Safety of Temporary Spinal Cord Stimulation versus Pulsed Radiofrequency for Postherpetic Neuralgia: A Prospective Randomized Controlled Trial. *Pain Res Manag*. 2022;2022:3880424. doi:10.1155/2022/3880424
9. Liu B, Yang Y, Zhang Z, Wang H, Fan B, Sima L. Clinical Study of Spinal Cord Stimulation and Pulsed Radiofrequency for Management of Herpes Zoster-Related Pain Persisting Beyond Acute Phase in Elderly Patients. *Pain Physician*. Jun 2020;23(3):263-270.
10. McKenzie-Brown AMPSG. Spinal cord stimulation: Placement and management. In: Fishman S, ed. *UpToDate*. UpToDate; (2024). Accessed August 5, 2024.
11. Mekhail NA, Argoff CE, Taylor RS, et al. High-frequency spinal cord stimulation at 10 kHz for the treatment of painful diabetic neuropathy: design of a multicenter, randomized controlled trial (SENZA-PDN). *Trials*. Jan 15 2020;21(1):87. doi:10.1186/s13063-019-4007-y
12. Paolini F, Ferini G, Bonosi L, et al. Spinal Cord Stimulation to Treat Unresponsive Cancer Pain: A Possible Solution in Palliative Oncological Therapy. *Life (Basel)*. Apr 7 2022;12(4)doi:10.3390/life12040554
13. 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*. Jun 1 2021;78(6):687-698. doi:10.1001/jamaneurol.2021.0538
14. Petersen EA, Stauss TG, Scowcroft JA, et al. Long-term efficacy of high-frequency (10 kHz) spinal cord stimulation for the treatment of painful diabetic neuropathy: 24-Month results of a randomized controlled trial. *Diabetes Res Clin Pract*. Sep 2023;203:110865. doi:10.1016/j.diabres.2023.110865
15. Schnapp WD, Delcroix GJ. Improved Sensation Resulting From Spinal Cord Stimulation for the Treatment of Painful Diabetic Neuropathy: The Possible Role of Stochastic Resonance. *Pain Physician*. Dec 2022;25(9):E1399-e1403.
16. Shanthanna H, Eldabe S, Provenzano DA, et al. Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. *Reg Anesth Pain Med*. Jun 2023;48(6):273-287. doi:10.1136/rapm-2022-104097
17. Sheng L, Liu Z, Zhou W, Li X, Wang X, Gong Q. Short-Term Spinal Cord Stimulation or Pulsed Radiofrequency for Elderly Patients with Postherpetic Neuralgia: A Prospective Randomized Controlled Trial. *Neural Plast*. 2022;2022:7055697. doi:10.1155/2022/7055697



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21. Vervaat FE, van der Gaag A, Smetsers C, et al. Design and rationale of the efficacy of spinal cord stimulation in patients with refractory angina pectoris (SCRAP) trial. *Clin Cardiol*. Jun 2023;46(6):689-697. doi:10.1002/clc.24016
22. Wan CF, Song T. Efficacy of Pulsed Radiofrequency or Short-Term Spinal Cord Stimulation for Acute/Subacute Zoster-Related Pain: A Randomized, Double-Blinded, Controlled Trial. *Pain Physician*. May 2021;24(3):215-222.
23. Wang EJ, Berninger LE, Komargodski O, Smith TJ. Painful Diabetic Neuropathy - Spinal Cord Stimulation, Peripheral Nerve Stimulation, Transcutaneous Electrical Nerve Stimulation, and Scrambler Therapy: A Narrative Review. *Pain Physician*. Nov 2022;25(8):E1163-e1173.
24. Xue S, Yang WJ, Cao ZX, Sun T. Comparing the efficacy and safety of short-term spinal cord stimulation and pulsed radiofrequency for zoster-related pain: A systematic review and meta-analysis. *Medicine (Baltimore)*. Mar 18 2022;101(11)doi:10.1097/md.0000000000029073
25. Yong RJ, Tran OV, McGovern AM, Patil PG, Gilligan CJ. Long-Term Reductions in Opioid Medication Use After Spinal Stimulation: A Claims Analysis Among Commercially-Insured Population. *J Pain Res*. 2024;17:1773-1784. doi:10.2147/jpr.S441195
26. Zuidema X, van Daal E, van Geel I, et al. Long-Term Evaluation of Spinal Cord Stimulation in Patients With Painful Diabetic Polyneuropathy: An Eight-to-Ten-Year Prospective Cohort Study. *Neuromodulation*. Jul 2023;26(5):1074-1080. doi:10.1016/j.neurom.2022.12.003

Coding:

CPT: 62321, 62323, 62325, 63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688
HCPCS: C1767, C1778, C1816, C1820, C1822, C1823, C1826, C1827, C1883, C1897, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, L8695

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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel (ad hoc)	09/27/24	Approved guideline
Medical Directors (Dr. Raja, Dr. Sutanto)	09/19/24	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 nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 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 tinutulungan, 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 ... 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: หากคน หรือคนที่คุณกำลังช่วยเหลือถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสมารถที่จะได้รับความช่วยเหลือและขอมูลในภาษา ของคุณได้โดยไมม่ค่าใช้จ่าย โปรดขอมูลาม โทร 877-475-4799