CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN

- Dorsal Root Ganglion Stimulation
- Spinal Cord Stimulation
- Motor Cortex Stimulation

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

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

Description:

Spinal Cord Stimulation:
Spinal cord stimulation delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain. Spinal cord stimulation has been used in a wide variety of chronic refractory pain conditions, including pain associated with cancer, failed back pain syndromes, arachnoiditis, and chronic reflex sympathetic dystrophy.

Spinal cord stimulation devices consist of several components: 1) the lead that delivers the electrical stimulation to the spinal cord; 2) an extension wire that conducts the electrical stimulation from the power source to the lead; and 3) a power source that generates the electrical stimulation. The lead may incorporate from 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk. There are two basic types of power source. In one type, the power source (battery) can be surgically implanted. In the other, a radiofrequency receiver is implanted, and the power source is worn externally with an antenna over the receiver. Totally implantable systems are most commonly used. The individual’s pain distribution pattern dictates at what level in the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used; for example, a lead with 8 electrodes may be selected for those with complex pain patterns or bilateral pain.

Implantation of a spinal cord stimulator is typically a two-step process:

▪ Temporary Spinal Cord Stimulation: An electrode is temporarily implanted in the epidural space allowing a trial period of stimulation to determine if stimulator will be effective.
▪ Permanent Spinal Cord Stimulation: After stimulator effectiveness is confirmed, the electrodes and power source or radiofrequency receiver are permanently implanted

Successful spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Motor Cortex Stimulation:
Motor cortex stimulation, which utilizes the same electrodes as spinal cord stimulation but delivers the electrical stimulation to the motor cortex, has been investigated for the management of chronic, intractable pain of various origins, such as facial, phantom limb and central (post-stroke) pain.
CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

Description: (cont.)

Dorsal Root Ganglion Stimulation:
The Axium™ Neurostimulator System is an implanted device that stimulates the dorsal root ganglion. It is
directed as an aid in the management of moderate-to-severe intractable pain of the lower limbs in adults
with complex regional pain syndrome types 1 and II.

Wireless Injectable Neurostimulators:
A variation of the Spinal Cord Stimulator is the wireless injectable stimulator. These miniaturized
neurostimulators are transfaraminally placed at the dorsal root ganglion (DRG) and are used to treat pain.
The Freedom Spinal Cord Stimulator is used for treating chronic, intractable pain of the trunk and/or lower
limbs. Both have been approved or cleared by the FDA.

Burst Stimulation:
The burst stimulation device works in conjunction with standard spinal cord stimulators to provide
stimulation in “bursts” rather than at a constant rate for chronic pain. The BurstDR stimulation device
approved by the FDA is programmed to work with certain St Jude Spinal Cord Stimulators.

Criteria:

For peripheral subcutaneous field stimulation, see BCBSAZ Medical Coverage Guideline #O752,
“Peripheral Subcutaneous Field Stimulation”.

Temporary Spinal Cord Stimulation:

- Temporary spinal cord stimulation with standard or high frequency stimulation for the treatment of
  severe and/or chronic neurologically-based intractable pain of the trunk or limbs is considered
  medically necessary with documentation that other treatment modalities (pharmacologic, surgical,
  psychological, physical, if applicable) have failed or are judged to be unsuitable or contraindicated.

- Permanent spinal cord stimulation with standard or high frequency stimulation for the treatment of
  severe and/or chronic neurologically-based intractable pain of the trunk or limbs is considered
  medically necessary with documentation of ALL of the following:

  - Permanent Spinal Cord Stimulation:
    1. The treatment is used only as a last resort; other treatment modalities (pharmacologic, surgical,
       psychological, physical, if applicable) have failed or are judged to be unsuitable or contraindicated
    2. Temporarily implanted electrode demonstrates at least 50% pain relief prior to permanent
       implantation
CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

Criteria: (cont.)

**Permanent Spinal Cord Stimulation:** (cont.)

- Dorsal root ganglion neurostimulation for the treatment of severe and/or chronic neurologically-based intractable pain of the trunk or limbs is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

- Spinal cord stimulation for all other indications not previously listed or if above criteria not met is considered *experimental or investigational* based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

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

- Cancer-related pain
- Critical limb ischemia to forestall amputation
- Heart failure
- Refractory angina pectoris

**Motor Cortex Stimulation:**

- Motor cortex stimulation for all indications is considered *experimental or investigational* based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

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

- Trigeminal neuralgia
CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

Resources:

Literature reviewed through 05/15/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

Resources: (cont.)


CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

**Resources:** (cont.)


CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

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’ 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 kweʼé atah nilinígíí Blue Cross Blue Shield of Arizona haada yitʼéego binaʼidžídko éí doocdago Háída biýa aniyleedííí tʼáadoo leʼé vinaʼidžídko beezaʼáanii hóóló díí tʼáá hazaadkeį́hí háhá aʼdoowolgo bee hažʼa doob baąl ilinígóó. Ataʼ halneʼíiígíí kojí bizhíʼí hodilíínih 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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viễn, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تساعدة أسئلة بخصوص Blue Cross Blue Shield of Arizona الضرورية بلغتك من دون إعانة كلمة، للتحدث مع مترجمًاصل ب 877-475-4799.
CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

Multi-Language Interpreter Services: (cont.)

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

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

که شما یا کسی که شما به او کمک می‌کنید، سوالی در مورد اطلاعاتی به زبان خود را به تلفن رایگان دریافت نمایید 877-475-4799.

Assyrian:

Blue Cross Blue Shield of Arizona

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

Thai: หากคุณต้องการความช่วยเหลือจาก Blue Cross Blue Shield of Arizona คุณสามารถขอความช่วยเหลือโดยโทรศัพท์ 877-475-4799