NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN

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 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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NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN (cont.)

Description:

Neuroablation is a procedure designed to destroy neural tissue for the treatment of chronic pain. A lesion is created on the nerve to interrupt the nerve impulse/pathway thus preventing the pain signal from traveling to the brain. Neuroablation may also be referred to as neurotomy, rhizotomy or denervation.

Direct visual rhizotomy (DVR) is an endoscopic, ultra-minimally invasive procedure that has been investigated for the treatment of low back pain. In DVR, the nerve root branches that transmit pain are cut under direct vision to permanently eliminate pain. In neuroablation, the nerve pathway is interrupted but not permanently severed.

The iOvera® system (Myoscience, Inc.) is a portable, handheld device that has been investigated for cryoanalgesia of peripheral nerves for pain relief. Freezing cold is applied via small-gauge closed-end needles to the selected site for the blocking of pain. Following treatment, the axon regenerates and nerve signaling restored.

Neuroablation methods addressed in this guideline include:

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
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<tbody>
<tr>
<td>Chemodenervation (chemical)</td>
<td>Administration of alcohol, phenol or high-concentration local anesthetics around the nerve</td>
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<tr>
<td>Cryodenervation (cryoneurolysis, cryoablation)</td>
<td>Involves the use of extreme cold to destroy abnormal tissue</td>
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<tr>
<td>Laser denervation</td>
<td>Involves the removal of material from a solid (or occasionally liquid) surface by irradiating it with a laser beam</td>
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<tr>
<td>Non-pulsed radiofrequency denervation (radiofrequency rhizotomy)</td>
<td>Application of heat to the nerve</td>
</tr>
<tr>
<td>Pulsed radiofrequency denervation (radiofrequency rhizotomy)</td>
<td>Application of short bursts of electrical current of high voltage in the radiofrequency range but without heating the tissue enough to cause coagulation</td>
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NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN (cont.)

Criteria:

For cryosurgery, cryoablation, cryotherapy and cryoneurolysis for foot disorders, see BCBSAZ Medical Coverage Guideline #O589, “Foot Disorder Treatments”.

Chemodenervation, Cryodenervation and Non-Pulsed Radiofrequency Neuroablation:

- Initial neuroablation by chemodenervation, cryodenervation, or non-pulsed radiofrequency is considered medically necessary for ANY of the following indications:

  1. Chronic pain of the spine with documentation of ALL of the following:
     - Severe segmental pain of the spine (zygapophyseal/facet joint pain origin); radicular pain may or may not be present
     - Pain has limited activities of daily living for three (3) months or greater
     - Pain has not responded to 3 months of comprehensive pain management and other conservative treatments, such as medication and/or physical therapy, or trigger point injection
     - The source of pain is not attributed solely to: disc herniation, spinal stenosis, spinal instability at the level of intended ablation, nerve root compression due to disc herniation, bone spur or tumor at the level of intended ablation
     - Pain was successfully relieved (reduced by at least 75 - 100%) as documented in record which may include percent change in analog pain scale with one or two trial diagnostic nerve block/facet joint injections at the proposed targeted site

  2. Severe cancer pain that has not responded to pharmacological pain management
  3. Trigeminal neuralgia (tic douloureux) that has not responded to pharmacological pain management

- Repeat neuroablation by chemodenervation, cryodenervation or non-pulsed radiofrequency for chronic pain of the spine, severe cancer pain and trigeminal neuralgia is considered medically necessary when a minimum of six months has elapsed since the previous successful treatment.
NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN (cont.)

Criteria: (cont.)

Chemodenervation, Cryodenervation and Non-Pulsed Radiofrequency Neuroablation: (cont.)

- Neuroablation by chemodenervation, cryodenervation, or non-pulsed radiofrequency for all other indications not previously listed or if above criteria not met 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, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, but are not limited to:

  - Radiofrequency denervation of the sacroiliac joint
  - Radiofrequency ablation of the sacral nerves S1-S4
  - Cryodenervation of peripheral nerves

Other Neuroablation Methods:

- Neuroablation by all other methods not previously listed for treatment of chronic pain 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, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These methods include, but are not limited to:

  - Laser denervation
  - Pulsed radiofrequency denervation
NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN (cont.)

Criteria: (cont.)

Direct Visual Rhizotomy (DVR):

- Direct visual rhizotomy (DVR) for treatment of pain 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, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Resources:

Literature reviewed 01/31/17. 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.


NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN (cont.)

Resources: (cont.)


13. InterQual® Care Planning Procedures. Neuroablation, Percutaneous.


NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN (cont.)

Resources: (cont.)


NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC 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’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 kweé éi halilii Blue Cross Blue Shield of Arizona haada yiit’éego bina’ilii’iido éi doodago Háida bjá aniyeedi’ii t’aadoo le’é vina’ilikido bheha’ááníi hólo díí t’áá hazaad’ehí háká a’doowolgo bée haza’ doo báalh iliní’ítii. Atá’ halné’ilí’ii kojí’ bích’éí’ hodilihii 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. Đề nghị chuyển với một thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدته أسئلة بخصوص الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.
NEUROABLATION AND OTHER PROCEDURES FOR TREATMENT OF CHRONIC PAIN (cont.)

Multi-Language Interpreter Services: (cont.)

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

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해 궁금한 점이 있다면 귀하의 언어로 비용 부담없이 치료를 받을 수 있는 권리가 있습니다. 그렇게 동역사와 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: آگاه شما، یا کسی که شما باید کمک میکنید، سوالان در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 تا کمک حاصل نمایید.

Assyrian: Ne lekhani, le bekkiri la yaz bani, Blue Cross Blue Shield of Arizona la la gany bani, gana le bani la la abyatar 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: สำหรับคนที่เกี่ยวข้องและผู้ที่ต้องการขอคำแนะนำเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถติดต่อขอคำแนะนำที่สะอาด และขอให้มีการแจ้งการติดต่อตามเวลา โทร 877-475-4799