VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY

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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VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY (cont.)

Description:

Vagus Nerve Stimulation:
Vagus nerve stimulation (VNS) is the delivery of intermittent electrical impulses to the brain via the vagus nerve.

Implantable VNS:
An implantable, programmable electronic pulse generator delivers stimulation to the left vagus nerve. The generator is implanted within the carotid artery sheath. VNS requires not only the surgical implantation of the device, but also subsequent neurostimulator programming, which occurs intraoperatively and typically during additional outpatient visits. The stimulator can be programmed to deliver electrical impulses at regular intervals or on demand by passing a magnet over the generator. Implantable VNS is a treatment alternative for individuals with medically refractory seizures. It has also been investigated as a treatment for depression, essential tremor, headaches, obesity, heart failure and fibromyalgia.

The NeuroCybernetic Prosthesis (NCP®) system was approved through the premarket approval (PMA) process for use in conjunction with drugs or surgery "as an adjunctive treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures." There have been subsequent expanded approvals including adjunctive therapy for seizures in individuals 4 years of age or older with partial-onset seizures that are refractory to antiepileptic medications.

The gammaCore-S® (ElectroCore LLC), a noninvasive VNS device was approved through the 510K process for acute treatment of adults with episodic cluster headaches. The device is applied to the side of the neck to deliver a mild electrical stimulation of the vagus nerve that is carried to the central nervous system.

The VNS Therapy™ System was approved through the premarket approval (PMA) process "for the adjunctive long-term treatment of chronic or recurrent depression for individuals 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments."

Vagus Nerve Blocking Therapy:
Vagus (vagal) nerve blocking therapy has been investigated in the treatment of obesity. It consists of an intra-abdominal implantable device that delivers electrical stimulation to branches of the vagus nerve on the anterior abdominal wall. The intent is to cause intermittent blocking of signals to the intra-abdominal vagus nerve to disrupt hunger sensations and induce feelings of satiety.

The Maestro® Rechargeable System is FDA approved to provide vagal nerve blocking therapy for weight regulation in obese individuals. The system includes a pulse generator that is implanted subcutaneously on the thoracic sidewall and flexible leads are placed on the abdominal anterior and posterior vagal nerve trunks. The system delivers high-frequency pulses of current to vagal nerve trunks. Therapy parameters and the treatment schedule can be customized by a clinician.
VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY (cont.)

Description: (cont.)

Non-Implantable VNS:
VNS may also be delivered transcutaneously. This procedure uses a combined stimulation unit and ear electrode to stimulate the auricular branch of the vagus nerve which supplies the skin over the concha of the ear. Individuals self-administer electric stimulation for several hours a day; no surgical procedure is required. The gammaCore® has been investigated for treatment of headaches. No non-implantable device has received FDA approval.

Criteria:

- Implantable vagus nerve stimulation via a device implanted within the carotid artery sheath for the treatment of medically refractory seizures is considered medically necessary.

- Implantable vagus nerve stimulation via a device implanted within the carotid artery sheath 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
  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.

Examples include, but are not limited to:

- Depression
- Essential tremor
- Fibromyalgia
- Headaches
- Heart failure
- Obesity
- Tinnitus
- Traumatic brain injury
- Upper limb impairment due to stroke
VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY (cont.)

Criteria: (cont.)

- Intra-abdominal vagus nerve blocking therapy for all indications 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:
- Obesity

- Transcutaneous (non-implantable) vagus nerve stimulation devices for all indications are 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, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 11/20/18. 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.

Resources prior to 03/20/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY (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/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield de 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: Déé kwe’é atah nílínígíí Blue Cross Blue Shield de Arizona haada yit’éego bina’díldíkgo éí doodago Háída bįį aniyeedííííígį́ t’áadoo le’e yina’díldíkgo beehaz’áanii hóół díí t’áa haazadk’ehįį háká a’doowolgo bee haz’ą doo bąąl ilínígóó. Āta’ halné’įį kįįjį bichį’ hodiilnih 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 viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو ألمى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona الضرورية بلغتنا من دون أي تكلفة . للتحدث مع مترجم الاستجابة ب. 877-475-4799.
VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY (cont.)

Multi-Language Interpreter Services: (cont.)

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

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 문제가 있어서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 매기기 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 на 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。通訳をお話しされる場合、877-475-4799までお電話ください。

Farsi:

آگر شما یا کسی که شما به آن کمک می‌کنید، سوالی در مورد اطلاعات به زبان خود را به تلفن ارائه دهید و سپس با 877-475-4799 تماس حاصل نمایید.

Assyrian:

بگویید انگار کسانی که به شما کمک می‌کنند، سوال دارند و سپس با 877-475-4799 تماس حاصل نمایید.

Serbo-Croatian: Ukoiko 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 หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้ความช่วยเหลือและข้อมูลภาษาของคุณได้โดยไม่เสียชาร์จ ติดต่อที่ 877-475-4799.