DEEP BRAIN STIMULATION

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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DEEP BRAIN STIMULATION (cont.)

Description:

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into the brain to improve the symptoms of selected brain disorders i.e., essential tremor and Parkinson disease. A "test" electrode is placed to determine if electrical stimulation will suppress the symptoms. If suppressed, a permanent electrode is placed. DBS has been investigated for the treatment of a variety of other neurologic and psychiatric disorders including alcohol addiction, Alzheimer disease, anorexia nervosa, chronic pain, cluster headaches, depression, dystonia, epilepsy, multiple sclerosis, dyskinesias, obsessive-compulsive disorder (OCD) and Tourette syndrome.

Deep brain stimulation devices, include but are not limited to:

- Activa® Tremor Control System
- Brio™ Neurostimulation System (now called Infinity™)
- Reclaim®
- Vercise Deep Brain Stimulation System (Boston Scientific)

Definitions:

Disabling, Medically Unresponsive:
Causes significant limitation in activities of daily living and is not controlled by maximal dosage of medication for at least 3 months before implant.

Essential Tremor:
A brain disorder involving rhythmic tremors of the voluntary muscles when an individual is moving or trying to move. There is no identifiable cause.

Medication-refractory:
Inadequate control by maximum dosage of medication for at least 3 months before implantation; drug resistant.

Microelectrode Mapping:
Intraoperative microelectrode mapping (neurophysiologic mapping or testing) required for precise placement of electrodes during deep brain stimulation.

Parkinson Disease (PD):
A brain disorder involving tremors and movement difficulty, i.e., rigidity, akinesia, bradykinesia, dyskinesias, and lack of coordination. PD may affect one or both sides of the body.

Primary Dystonia:
Dystonia is a brain disorder involving involuntary muscle contractions that force certain parts of the body into contorted, sometimes painful movements or postures. Dystonia can affect certain portions of the body (focal dystonia and multifocal dystonia) or the entire body (generalized dystonia). Primary dystonia is defined when dystonia is the only symptom unassociated with other pathology.
DEEP BRAIN STIMULATION (cont.)

Criteria:

For neurostimulation for refractory epilepsy, see BCBSAZ Medical Coverage Guideline #O942, “Responsive Neurostimulation for Refractory Partial Epilepsy”.

Parkinson Disease:

- Unilateral deep brain stimulation of the thalamus for treatment of Parkinson disease is considered medically necessary with documentation of ALL of the following:
  1. Disabling, medically unresponsive tremor (see Definitions section)
  2. No unstable medical problems or cardiac pacemaker
  3. No medical condition that requires repeated MRIs
  4. No dementia that may interfere with the ability to cooperate
  5. No botulinum toxin injections within the last 6 months

- Bilateral deep brain stimulation of the thalamus for treatment of Parkinson disease is considered medically necessary with documentation of ALL of the following:
  1. Disabling, medically unresponsive tremor in both upper limbs (see Definitions section)
  2. No unstable medical problems or cardiac pacemaker
  3. No medical condition that requires repeated MRIs
  4. No dementia that may interfere with the ability to cooperate
  5. No botulinum toxin injections within the last 6 months

- Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus for treatment of Parkinson disease is considered medically necessary with documentation of ALL of the following:
  1. Good response to levodopa
  2. ONE of the following:
     • Minimal score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when individual has been without medication for about 12 hours
     • Parkinson disease for at least 4 years
  3. Motor complications not controlled by pharmacologic therapy
  4. No unstable medical problems or cardiac pacemaker
  5. No medical condition that requires repeated MRIs
  6. No dementia that may interfere with the ability to cooperate
  7. No botulinum toxin injections within the last 6 months
DEEP BRAIN STIMULATION (cont.)

Criteria: (cont.)

Essential Tremor:

- Unilateral deep brain stimulation for treatment of essential tremor is considered **medically necessary** with documentation of **ALL** of the following:
  1. Disabling, medically unresponsive tremor (see Definitions section)
  2. Symptoms have been present for 3 months or greater
  3. No dementia that may interfere with the ability to cooperate
  4. Brain MRI is normal or shows no evidence of structural abnormalities
  5. No prior intracranial surgery at targeted area
  6. Stimulation is to the thalamus, globus pallidus or subthalamic nucleus area of the brain

- Bilateral deep brain stimulation of the thalamus for treatment of essential tremor is considered **medically necessary** with documentation of **ALL** of the following:
  - Disabling, medically unresponsive tremor in both upper limbs (see Definitions section)
  - No unstable medical problems or cardiac pacemaker
  - No medical condition that requires repeated MRIs
  - No dementia that may interfere with the ability to cooperate
  - No botulinum toxin injections within the last 6 months

Primary Dystonia:

Unilateral or bilateral deep brain stimulation for treatment of primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), is considered **medically necessary** with documentation of the following:

  1. Individual is 7 years of age or older
  2. Symptoms are chronic and medication-refractory (see Definitions section)
  3. Stimulation is to the globus pallidus or subthalamic nucleus area of the brain

Microelectrode Mapping:

- Intraoperative microelectrode mapping is **required** and considered **medically necessary** for precise placement of electrodes during deep brain stimulation.
DEEP BRAIN STIMULATION (cont.)

Criteria: (cont.)

Other:

Unilateral or bilateral deep brain stimulation 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.

These indications include, but are not limited to:

- Cluster headaches
- Multiple sclerosis
- Post-traumatic dyskinesia
- Tardive dyskinesia
- Treatment of other psychiatric or neurologic disorders, e.g., Tourette syndrome, depression, obsessive compulsive disorder, epilepsy, anorexia nervosa, alcohol addiction, chronic pain

Resources:

Literature reviewed 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.

DEEP BRAIN STIMULATION (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’ atah nilingíí Blue Cross Blue Shield of Arizona haadą́ yiʼéégo binaʼdilikdgo éi doodge Háída bígí aniyeedíííí t’áadoo le’e yína’dilikdgo beehaz’ aánii hóló díí tí’áá hazaadke’ehí háká a’dooowolgo bee ház’a doo bááqh ilínggó. Ata’ halné’íííí kojí’ bích’j’ hodííihíihíirm 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 لدى شخص تسامع أسلحة بخصوص Blue Cross Blue Shield of Arizona السورورية بلغتك من دون آية تكلفة. للتحدث مع مترجم الأصل يرجى 877-475-4799.
DEEP BRAIN STIMULATION (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay maga 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 makeasap 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 그런 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 매개하기 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。通訳とお話しされる場合、877-475-4799 までお電話ください。

Farsi: اگر شما یا کسی که شما به آن کمک می‌کنید، سوالی در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian: Blue Cross Blue Shield of Arizona تاکنون، به‌طور رایگان، اطلاعات به زبان خود را دریافت نمایید 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 prevodilcem, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่คิดค่าใช้จ่าย ที่ 877-475-4799.