SACRAL NERVE NEUROMODULATION AND 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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SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

Description:

Sacral Nerve Modulation/Stimulation (SNM):
SNM has been investigated as a treatment for urinary and fecal incontinence. The SNM device consists of an implantable pulse generator that delivers controlled electrical impulses. The pulse generator is attached to wire leads that connect to the sacral sensory nerves. Two external components of the system help control the electrical stimulation. A control magnet is kept by the individual and can be used to turn the device on or off. Prior to implantation, a peripheral nerve stimulation test is conducted to determine if the individual is an appropriate candidate for the device.

Definitions:

Urgency-Frequency:
Uncontrollable urge to urinate that results in very frequent, small volumes.

Urinary Retention:
Inability to completely empty the bladder of urine.

Urinary Stress Incontinence:
Involuntary loss of urine from the urethra due to increased intra-abdominal pressure.

Urinary Urge Incontinence:
 Leakage of urine when there is a strong urge to void.
SACRAL NERVE NEUROMODULATION AND STIMULATION  (cont.)

Criteria:

**Urinary Incontinence:**

- A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead is considered **medically necessary** with documentation of **ALL** of the following:
  1. ONE of the following diagnoses:
     - Non-obstructive urinary retention
     - Overactive bladder
     - Urgency-frequency syndrome
     - Urinary urge incontinence
  2. Documented failure or intolerance to at least two conventional conservative treatments (e.g., behavioral training such as bladder training, prompted voiding, pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy and/or surgical corrective therapy)
  3. Incontinence is not related to a neurologic condition
  4. Individual is an appropriate surgical candidate

- Permanent implantation of a sacral nerve neuromodulation device is considered **medically necessary** with documentation of **ALL** of the following:
  1. Trial period criteria above are met
  2. Trial stimulation demonstrates at least 50% improvement in symptoms over a period of at least 48 hours

- Sacral nerve neuromodulation for all other urinary 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.

These urinary disorders include, **but are not limited to**:

- Stress or urge urinary incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury or other types of chronic voiding dysfunction)
SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

Criteria: (cont.)

Fecal Incontinence:

- A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead is considered medically necessary with documentation of ALL of the following:
  
  1. Chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth
  2. Failure or intolerance to conservative therapy (e.g., dietary modification, the addition of oral bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy
  3. Individual is an appropriate surgical candidate
  4. Condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease
  5. Incontinence is not related to another neurologic condition
  6. Individual has not had rectal surgery in the previous 12 months, or in the case of cancer, the individual has not had rectal surgery in the past 24 months

- Permanent implantation of a sacral nerve neuromodulation device is considered medically necessary with documentation of ALL of the following:
  
  1. Trial period criteria above are met
  2. Trial stimulation demonstrates at least 50% improvement in symptoms over a period of at least 48 hours

- Sacral nerve neuromodulation/stimulation for all other fecal 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.

These indications include, but are not limited to:

- Treatment of chronic constipation
- Chronic pelvic pain
SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

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.

Resources prior to 05/22/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

SACRAL NERVE NEUROMODULATION AND 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 kwe’é atah níilígíí Blue Cross Blue Shield of Arizona haada yit’éego bíná’íidíkído éi doodago Háída bijá anilyeeedíííí t’aado le’é yíina’ííídíkído beehaz’áanii hólo díí t’áá hazaadk’ehii háká a’doowolgo bee haz’a doo báah ilínígóó. Atá’ halné’ígíí kójí bíchí’í hodííííinh 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 thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعده أسلحة بخصوص توصيفات من الضرورية بلغتك من دون أية تكلفة، للتحدث مع مترجم الأصل يمكن الاتصال ب 877-475-4799.
SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinitulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang na makakuha ng tulon at impormasyon sa iyong wika ng walang gastos. Upara 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 귀하의 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 풍부시기 위해서는 877-475-4799 로 전화해주시오.

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:

Tagalog: Kung ikaw, o ang iyong tinitulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang na makakuha ng tulon at impormasyon sa iyong wika ng walang gastos. Upara makausap ang isang tagasalin, tumawag sa 877-475-4799.

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Farsi: