

ORIGINAL EFFECTIVE DATE:08/09/11LAST REVIEW DATE:04/17/18LAST CRITERIA REVISION DATE:09/27/16ARCHIVE DATE:09/27/16

NEUROMUSCULAR ELECTRICAL 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 "<u>Description</u>" 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 "<u>Criteria</u>" 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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NEUROMUSCULAR ELECTRICAL STIMULATION (cont.)

Description:

Neuromuscular Electrical Stimulation (NMES):

NMES is a form of electrical stimulation that attempts to strengthen muscles weakened by disuse or relax muscle spasms secondary to central nervous system injuries or cerebral palsy. NMES is used at night during sleep to increase blood flow to the muscles in which fibers are atrophied. NMES can also be used in the outpatient setting as an adjunct therapy to treat muscle atrophy.

NMES has been investigated for the treatment of dysphagia (e.g., VitalStim[™]), in conjunction with speech pathology services. Calibrated current is delivered by electrodes to motor nerves in the throat to re-educate muscles and improve swallowing function.

Combination NMES/TENS Unit:

A single device which provides both neuromuscular electrical stimulation to strengthen muscles and transcutaneous electrical nerve stimulation (TENS) to manage pain. Devices include, but are not limited to: AvivaStim XP[™], Flex-MT[™] and InTENSity[™] Twin Stim® III.

Functional Neuromuscular Electrical Stimulation:

Functional NMES involves the use of an orthotic device with microprocessor-controlled electrical muscular stimulation. Devices have been developed to restore function to individuals with damaged or destroyed nerve pathways (e.g., spinal cord injury, stroke, multiple sclerosis, cerebral palsy). Electrodes are placed transcutaneously or percutaneously and deliver stimulation by way of a control unit.

Devices include, but are not limited to:

 <u>NESS H200® formerly known as the Handmaster NMS I System</u>: A noninvasive, custom-fit orthosis that attaches to the forearm and wrist and connects to a control unit. Electrodes inside the orthosis deliver stimulation to help move the hand.

NESS L300® Foot Drop System:

A noninvasive leg cuff with electrodes that is worn below the knee. A gait sensor attaches to the shoe and lets the leg cuff know if the individual's heel is on the ground or in the air. A handheld remote control allows for stimulation adjustment.

<u>NESS L300® Plus System</u>:

A noninvasive system that builds on the L300 Foot Drop System by adding a thigh cuff to give the individual greater control over bending and straightening their knee.



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NEUROMUSCULAR ELECTRICAL STIMULATION (cont.)

Description: (cont.)

Functional Neuromuscular Electrical Stimulation: (cont.)

Devices include, *but are not limited to:* (cont.)

Parastep® Ambulation System:

Uses percutaneous stimulation to deliver electrical pulses to trigger action potentials at selected nerves at the quadriceps, common peroneal nerve, paraspinals and gluteals. Individual uses a walker or elbow-support crutches, wears the control unit in a belt and activates stepping through use of a finger-controlled switch.

- <u>Reciprocating Gait Orthosis (RGO) With Electrical Stimulation</u>: Uses a hip-knee-ankle-foot device linked together with a cable at the hip joint.
- WalkAide®:

A noninvasive, self-contained unit worn below the knee. Uses sensor technology to analyze the movement of the leg and foot and stimulates the common peroneal nerve as it passes near the head of the fibula below the knee.

- <u>Functional NMES Exercise Bicycle</u>: Uses computerized Functional Electrical Stimulation (FES) to enable an individual with a spinal cord injury to actively pedal a stationary bicycle for exercise and conditioning. Functional NMES exercise equipment systems include, *but are not limited to*:
 - ERGYS®, ERGYS 2®, ERGYS 3®, REGYS® Rehabilitation Systems from Therapeutic Alliances, Inc.
 - RT300-S, RT300-SP FES Motorized Cycle Ergometers from Restorative Therapies, Inc.



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NEUROMUSCULAR ELECTRICAL STIMULATION (cont.)

Description: (cont.)

Therapeutic Neuromuscular Electrical Stimulation:

Therapeutic NMES uses electrical pulses by way of skin contact adhesive electrodes housed in a garment. It uses continuous current pulses to stimulate the nerves in the quadriceps area of the body. The pulses are intended to cause muscular contraction through the application of electrical stimulation to the peripheral nervous system.

Therapeutic NMES has been investigated as a post-surgical means of re-educating and strengthening the quadriceps muscle, improving knee stability, treating quadriceps atrophy and assisting with pain management. It has been investigated for use in helping avoid or delay surgery as well.

Devices include, but are not limited to:

• <u>NeuroTech® Kneehab™:</u>

A battery operated, portable neuromuscular electrical stimulator two-piece garment that is wrapped around the individual's quadriceps above the knee. It is a one-program unit.

- <u>Kneehab XP Conductive Garment</u>: A portable, two-channel transcutaneous electrical muscle stimulator garment that uses multipath®, a technology that enables the garment to deliver quadriceps contractions. The garment is fastened around the thigh and above the kneecap.
- Kneehab XP Controller:

Designed to work in conjunction with the Kneehab XP Conductive Garment to deliver highly focused quadriceps contractions, the Kneehab XP Controller (Type 411) is a portable, two-channel transcutaneous electrical muscle stimulator incorporating multipath.

Kneehab XP®:

Uses multipath for quadriceps strengthening and improved knee stability and transcutaneous electrical neuromuscular stimulation (TENS) for pain management. Works by re-educating and strengthening the quadriceps muscle through cycles of contraction and relaxation. This device also uses a garment wrapped around the thigh.



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NEUROMUSCULAR ELECTRICAL STIMULATION (cont.)

Criteria:

Neuromuscular Electrical Stimulation:

Requests for NMES/TENS combination units must meet both the criteria for NMES and the criteria for TENS. For TENS, see BCBSAZ Medical Coverage Guideline #0851, *"Transcutaneous Electrical Nerve Stimulation (TENS)"*.

- > Neuromuscular electrical stimulation is considered *medically necessary* for ANY of the following:
 - 1. Prevent or retard disuse atrophy after > 4 weeks immobility (e.g., bed rest, casting of a body part) when nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves
 - 2. Muscle atrophy contracture due to scarring of soft tissue as in burn lesions and hip replacement surgery
 - 3. Relax muscle spasms that are secondary to central nervous system injuries or cerebral palsy
- Neuromuscular electrical stimulation for treatment of the following conditions 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 conditions include, but are not limited to:

- Dysphagia
- Scoliosis



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NEUROMUSCULAR ELECTRICAL STIMULATION (cont.)

Criteria: (cont.)

Functional Neuromuscular Electrical Stimulation:

- Functional neuromuscular electrical stimulation as a technique to restore function following nerve damage or nerve injury for the following 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.

These indications include, but are not limited to:

- A technique to provide ambulation
- Treatment of upper limb paralysis
- Activation of muscle groups in the forearm to produce functional movement patterns in the hand
- Foot drop
- Functional neuromuscular electrical stimulation as a technique for exercise and/or conditioning is considered exercise equipment and, therefore, a *benefit plan exclusion* and *not eligible for coverage*.



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NEUROMUSCULAR ELECTRICAL STIMULATION (cont.)

Criteria: (cont.)

Therapeutic Neuromuscular Electrical Stimulation:

- Therapeutic neuromuscular electrical stimulation for all indications, before or after surgery, 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:

- Adjunctive treatment in the management of acute, post-surgical or post-traumatic pain
- Adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee
- For early post-surgical quadriceps strengthening and improved post-surgical knee stability secondary to quadriceps strengthening
- For increasing local blood circulation
- For symptomatic relief and management of chronic, intractable pain
- For management of intractable pain and relief of pain associated with arthritis
- To re-educate the guadriceps muscle
- To maintain or increase range of motion of the knee joint
- To prevent or retard disuse atrophy in the quadriceps

Resources:

Literature reviewed 04/17/18. 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 09/27/16 may be requested from the BCBSAZ Medical Policy and Technology Research Department.



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NEUROMUSCULAR ELECTRICAL STIMULATION (cont.)

Resources: (cont.)

- 1. 8.03.01 BCBS Association Medical Policy Reference Manual. Functional Neuromuscular Electrical Stimulation. Re-issue date 03/08/2018, issue date 03/31/1996.
- Bremner CB, Holcomb WR, Brown CD, Perreault ME. The Effectiveness of Neuromuscular Electrical Stimulation in Improving Voluntary Activation of the Quadriceps: A Critically Appraised Topic. J Sport Rehabil. Nov 11 2016:1-21.
- 3. Choi JB. Effect of neuromuscular electrical stimulation on facial muscle strength and oral function in stroke patients with facial palsy. *Journal of physical therapy science*. Sep 2016;28(9):2541-2543.
- 4. Frost J, Robinson F, Hibberd J. A comparison of neuromuscular electrical stimulation and traditional therapy, versus traditional therapy in patients with longstanding dysphagia. *Current opinion in otolaryngology & amp; head and neck surgery.* Mar 16 2018.
- 5. Hauger AV, Reiman MP, Bjordal JM, Sheets C, Ledbetter L, Goode AP. Neuromuscular electrical stimulation is effective in strengthening the quadriceps muscle after anterior cruciate ligament surgery. *Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA.* Aug 17 2017.
- 6. Jungheim M, Schubert C, Miller S, Ptok M. Swallowing Function After Continuous Neuromuscular Electrical Stimulation of the Submandibular Region Evaluated by High-Resolution Manometry. *Dysphagia.* Aug 2017;32(4):501-508.
- 7. Law T, Lee KY, Wong RW, et al. Effects of electrical stimulation on vocal functions in patients with nasopharyngeal carcinoma. *The Laryngoscope*. May 2017;127(5):1119-1124.
- 8. Meng P, Zhang S, Wang Q, et al. The effect of surface neuromuscular electrical stimulation on patients with post-stroke dysphagia. *Journal of back and musculoskeletal rehabilitation*. Dec 15 2017.
- 9. Sproson L, Pownall S, Enderby P, Freeman J. Combined electrical stimulation and exercise for swallow rehabilitation post-stroke: a pilot randomized control trial. *International journal of language & amp; communication disorders.* Mar 2018;53(2):405-417.
- 10. UpToDate.com. Adolescent idiopathic scoliosis: Management and prognosis. 03/14/2018, 03/02/2016, 01/08/2014.
- 11. UpToDate.com. Oropharyngeal dysphagia: Clinical features, diagnosis, and management. 09/06/2017, 06/02/2015, 12/12/2013.



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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, <u>crc@azblue.com</u>. 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 <u>https://ocrportal.hhs.gov/ocr/portal/lobby.jsf</u>, 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 <u>https://www.hhs.gov/ocr/office/file/index.html</u>

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 nílínigií Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éi doodago Háida bíjá anilyeedígií t'áadoo le'é yína'ídíłkidgo beehaz'áanii hólo díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígií kojj' bich'j' hodíilnih 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. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعده أسنلة بخصوص Blue Cross Blue Shield of Arizona، قلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة .للتحدث مع مترجم اتصل ب .877-475-4798



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Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga 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 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 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 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:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 4799-475-877 .[تماس حاصل نمایید.

Assyrian:

٤, ٤سههر، بر سو فدّيهها ومندذمه، عنهار، ٤نهكمدهر، عمقة حمة Alue Cross Blue Shield of Arizona ٤ اسمهر، ٤نهكمدهر، معممة ومحكندهر. امتلامة محموطتمة حكمدمه ميكنانه. كامجرمعة خطر سو ممة إنفتاء مذة نعمر، خك هكنفور مدينة 1979-475-877.

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: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใช่จาย พดคยกบลาม โทร 877-475-4799