HYPERHIDROSIS TREATMENT

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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HYPERHIDROSIS TREATMENT (cont.)

Description:

Hyperhidrosis: Hyperhidrosis can be defined as excessive sweating beyond a level required to maintain normal body temperature. There are two categories of hyperhidrosis, primary and secondary. The sweating can be focal (in a localized area of the body such as the axillae, palms, perineal-inguinal area and/or soles although any area on the body can be affected) or generalized (over the entire body).

Primary Hyperhidrosis: Hyperhidrosis is known as primary hyperhidrosis when it is the only condition. Primary hyperhidrosis is also known as essential or idiopathic hyperhidrosis.

Secondary Hyperhidrosis: Hyperhidrosis is known as secondary hyperhidrosis when it results from another condition. Treatment of secondary hyperhidrosis focuses on treating the underlying cause.

Secondary Gustatory Hyperhidrosis: An unusual cause of facial hyperhidrosis in response to hot or spicy foods that may develop after parotid gland trauma or surgical removal.

Iontophoresis: Use of electricity to temporarily turn off the sweat gland. The hands or feet are placed into water and a gentle current of electricity is passed through the water. The therapy requires several sessions.

Microwave Treatment: The application of microwave energy to superficial skin structures with the intent of inducing thermolysis of the sweat glands.

Radiofrequency Ablation: The use of electrodes to generate heat and destroy abnormal tissue.

Sympathectomy: Involves the surgical destruction of the ganglia responsible for hyperhidrosis.

Tympanic Neurectomy: Excision of the tympanic nerve to treat a variety of conditions, including but not limited to, facial sweating, sialorrhea, recurrent parotid fistulas and chronic ear pain.

Botulinum Toxin: Botulinum Toxin Type A formulations include Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA) and Xeomin® (incobotulinumtoxinA).

Botulinum Toxin Type B is marketed as Myobloc® (rimabotulinumtoxinB)
HYPERHIDROSIS TREATMENT (cont.)

Criteria:

COVERAGE FOR TREATMENT TO CORRECT A CONGENITAL DEFECT OR BIRTH ABNORMALITY IS DEPENDENT UPON BENEFIT PLAN LANGUAGE AND IS SUBJECT TO THE PROVISIONS OF THE RECONSTRUCTIVE BENEFIT AND THE COSMETIC BENEFIT EXCLUSION. REFER TO MEMBER’S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS AND THE FUNCTIONAL IMPAIRMENT REQUIREMENT.

Botulinum Toxin:

Initial Treatment:

- Botulinum toxin Type A (Botox, Dysport, Xeomin) or Type B (Myobloc) is considered medically necessary for individuals 18 years of age or older for the treatment of primary axillary hyperhidrosis with documentation of ONE of the following:
  
  1. Skin maceration with secondary infection
  2. Acrocyanosis of the hands
  3. Severe, persistent eczematous dermatitis that impairs activities of daily living (ADLs) despite medical treatment with topical dermatological or systemic anticholinergic agents
  4. Functional impairments by history and physical examination as documented by ALL of the following:
     - Excessive sweating interfering with instrumental ADLs¹ that impedes an individual’s ability to effectively work in certain professions (e.g., fine motor skills or intricate work activities)
     - Continued symptoms after treatment with prescription topical antiperspirant 4 weeks or longer

- Botulinum toxin Type A (Botox, Dysport, Xeomin) is considered medically necessary for individuals 18 years of age or older for the treatment of primary palmar hyperhidrosis with documentation of ONE of the following:
  
  1. Skin maceration with secondary infection
  2. Acrocyanosis of the hands
  3. Severe, persistent eczematous dermatitis that impairs activities of daily living (ADLs) despite medical treatment with topical dermatological or systemic anticholinergic agents
  4. Functional impairments by history and physical examination as documented by ALL of the following:
     - Excessive sweating interfering with instrumental ADLs¹ that impedes an individual’s ability to effectively work in certain professions (e.g., fine motor skills or intricate work activities)
     - Continued symptoms after treatment with prescription topical antiperspirant 4 weeks or longer
HYPERHIDROSIS TREATMENT (cont.)

Criteria: (cont.)

Botulinum Toxin: (cont.)

Initial Treatment: (cont.)

- Botulinum toxin Type A (Botox) is considered *medically necessary* for the trial treatment of secondary gustatory hyperhidrosis with documentation of ALL of the following:

  1. Previous parotid gland trauma or surgery
  2. Thoracic sympathectomy would improve or restore impaired function that currently impedes the individual's ability to perform a job function, manage their daily life, or tend to their personal hygiene. (The intent of a trial treatment with Botulinum toxin Type A is to prevent the invasive procedure, transthoracic sympathectomy).

- Botulinum toxin Type A (Botox, Dysport, Xeomin) or Type B (Myobloc) for treatment of hyperhidrosis or excessive sweating that does not meet the above criteria is considered *cosmetic* and *not eligible for coverage*, even when the procedure will improve emotional, psychological or mental condition or performance, based upon ANY of the following:

  1. Intent to enhance or improve appearance
  2. Absence of a functional physical impairment

- Botulinum toxin Type A (Botox, Dysport, Xeomin) or Type B (Myobloc) for the treatment of, plantar and craniofacial hyperhidrosis 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.
HYPERHIDROSIS TREATMENT (cont.)

Criteria: (cont.)

Botulinum Toxin: (cont.)

Initial Treatment: (cont.)

- Botulinum toxin Type B for the treatment of palmar hyperhidrosis 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.

Repeat Treatments:

- Botulinum toxin Type A (Botox, Dysport, Xeomin) or Type B (Myobloc) is considered medically necessary for repeat treatment of primary axillary hyperhidrosis with documentation of ALL of the following:

  1. Initial treatment criteria must have been met
  2. Good response was achieved with initial treatment

- Botulinum toxin Type A (Botox, Dysport, Xeomin) is considered medically necessary for repeat treatment of primary palmar hyperhidrosis with documentation of ALL of the following:

  1. Initial treatment criteria must have been met
  2. Good response was achieved with initial treatment

- Botulinum toxin Type A (Botox) is considered medically necessary for repeat treatment of secondary gustatory hyperhidrosis with documentation of ALL of the following:

  1. Initial treatment criteria must have been met
  2. Good response was achieved with initial treatment
HYPERhidrosis treatment (cont.)

Criteria: (cont.)

Iontophoresis:

- Iontophoresis for the treatment of hyperhidrosis 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.

Surgical Excision:

Coverage for surgical treatment of hyperhidrosis is dependent upon benefit plan language. Refer to member's specific benefit plan booklet to verify benefits.

- Surgical excision of axillary sweat glands is considered medically necessary for the treatment of primary hyperhidrosis with documentation of one of the following:
  1. Skin maceration with secondary infection
  2. Functional impairments by history and physical examination as documented by all of the following:
     • Excessive sweating interfering with instrumental activities of daily living (ADLs) that impedes an individual's ability to effectively work in certain professions (e.g., fine motor skills or intricate work activities)
     • Continued symptoms after treatment with prescription topical antiperspirant 4 weeks or longer

Sympathectomy, Open or Endoscopic:

- Open or endoscopic sympathectomy for the treatment of primary axillary, palmar and craniofacial (gustatory) hyperhidrosis is considered medically necessary with documentation of all of the following:
  1. Excessive sweating by history and physical
  2. Symptoms interfere with ADLs
  3. Continued symptoms after treatment with prescription topical antiperspirant 4 weeks or longer.
HYPERHIDROSIS TREATMENT (cont.)

Criteria: (cont.)

Sympathectomy, Open or Endoscopic:

- Lumbar sympathectomy for the treatment of plantar hyperhidrosis 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.

Microwave Treatment:

- Microwave treatment for the treatment of hyperhidrosis 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.

Radiofrequency Ablation:

- Radiofrequency ablation for the treatment of palmar hyperhidrosis 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.
HYPERHIDROSIS TREATMENT (cont.)

Criteria: (cont.)

**Tympanic Neurectomy:**

- Tympanic neurectomy for the treatment of severe gustatory hyperhidrosis is considered *medically necessary* with documentation that conservative treatment has failed.

**Subcutaneous Suction Assisted Lipectomy² or Liposuction:**

- Subcutaneous suction assisted lipectomy or liposuction for the treatment of hyperhidrosis is considered *experimental or investigational* based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.

1. Instrumental ADLs are defined as complex, functional interactions with others and the environment.

2. This procedure may be referred to as bilateral retrodermal curettage by a provider.

Resources:

Literature reviewed 06/14/16. 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.


6. BCBS Association Technology Assessment Program. Iontophoresis for Medical Indications. 06/2003 2003;18(No. 3).
HYPERHIDROSIS TREATMENT (cont.)

Resources: (cont.)


17. InterQual® Care Planning P. Sympathectomy.


HYPERHIDROSIS TREATMENT (cont.)

Resources: (cont.)


HYPERHIDROSIS TREATMENT (cont.)

Resources: (cont.)


FDA Product Approval Information for Botox® (onabotulinumtoxinA):

- FDA-approved indication: Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

  Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

  Prophylaxis of headaches in adult patients with chronic migraine (> = 15 days per month with headache lasting 4 hours a day or longer).

  Treatment of spasticity in adult patients.

  Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain.

  Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients.

  Treatment of blepharospasm associated with dystonia in patients > = 12 years of age. Treatment of strabismus in patients > = 12 years of age.
HYPERHIDROSIS TREATMENT (cont.)

Resources: (cont.)

FDA Product Approval Information for Dysport® (abobotulinumtoxinA):

- FDA-approved indication: Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naive and previously treated patients.

  Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age.

  Treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors.

FDA Product Approval Information for Xeomin® (incobotulinumtoxinA):

- FDA-approved indication: Treatment of adults with cervical dystonia

  Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA (Botox).

  Temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity

  Treatment of adults with upper limb spasticity

FDA Product Approval Information for Myobloc® (rimabotulinumtoxinB):

- FDA-approved indication: Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated cervical dystonia.
HYPERHIDROSIS TREATMENT (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 filling 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 interprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah nílínígíí Blue Cross Blue Shield of Arizona haada yít’éego bína’ídíkidgo éí doodago Háida bíjá aniyeedííí t’àadoo le’e yína’ídíkidgo bee haza’áání hólo díí t’àá hazaad’ehí’ háká a’doowolggo bee haza’á doo bąąh ilínígóó. Ata’ halne’ígíí kojí bích’é’ 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 thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعده أسئلة بخصوص الضرورية بلغتك من دون أية تكلفة. للتحدث مع مرجع الترجمة ب 877-475-4799.
HYPERHIDROSIS TREATMENT (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuangan, 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 makeusap ang isang tagsalog, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 매기기 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 به شما یا درباره می‌گوید، سوال‌ها مربوط به Blue Cross Blue Shield of Arizona یا اطلاعات نیاز دارید، می‌توانید با تماس حاصل نمایید.

Assyrian: Blue Cross Blue Shield of Arizona ئەمەنی نە، سەرەکی دهە سەرەکیە لە ئەمەنی. 877-475-4799 ئەمەنیکەیە.

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: หากคุณ หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถโทรได้ในภาษาที่คุณสะดวก ที่ 877-475-4799.