HYPERHIDROSIS TREATMENT

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.

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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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.
HYPERHIDROSIS TREATMENT (cont.)

Description: (cont.)

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 Type A or Type B:

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 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

- 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 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
HYPERHIDROSIS TREATMENT (cont.)

Criteria: (cont.)

**Botulinum Toxin Type A or Type B:** (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 Type A or Type B: (cont.)

Initial Treatment: (cont.)

Botulinum Toxin Type B: (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.

Botulinum Toxin Type A or Type B: (cont.)

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:

Repeat Treatments:

- 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)\(^1\) 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 Lipectomy 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:


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 Procedures. 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 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 upper limb 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-naïve and previously treated patients. Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity adult patients < 65 years of age.

FDA Product Approval Information for Xeomin® (incobotulinumtoxinA):

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

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

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

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.