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**MEDICAL COVERAGE GUIDELINES**
**SECTION: MEDICINE**

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# 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.**

## 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.

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)

**Criteria:**

**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

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

## HYPERHIDROSIS TREATMENT (cont.)

**Criteria:** (cont.)

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

**Initial Treatment:** (cont.)

- 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

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

- 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)

## HYPERHIDROSIS TREATMENT (cont.)

**Criteria:** (cont.)

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

**Initial Treatment:** (cont.)

- 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.

**Botulinum Toxin Type B:**

- 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.

## HYPERHIDROSIS TREATMENT (cont.)

**Criteria:** (cont.)

**Botulinum Toxin Type A or Type B:**

**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

**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.

## HYPERHIDROSIS TREATMENT (cont.)

**Criteria:** (cont.)

**Surgical Excision:**

- 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

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

**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.

- 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.

## HYPERHIDROSIS TREATMENT (cont.)

**Criteria:** (cont.)

**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.

**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.

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

## HYPERHIDROSIS TREATMENT (cont.)

**Resources:**

1. 8.01.19 BCBS Association Medical Policy Reference Manual. Treatment of Hyperhidrosis. Re-issue date 04/12/2012, issue date 07/16/1999.

2. Altman R. Hyperhidrosis. 07/2002, accessed 04/2003.

3. American Academy of Dermatology. Effective Treatments Mean Excessive Sweating Patients No Longer Swimming in Anxiety. Accessed 05/01/2006.

4. American Academy of Dermatology. Don't Sweat It...Treatments Stop Excessive Perspiration. *Dermatology Insights.* Accessed 05/01/2006;3(No.1):12-13.

5. BCBS Association Technology Assessment Program. Iontophoresis for Medical Indications. 06/2003;18(No. 3).

6. Campanati A, Penna L, Guzzo T, et al. Quality-of-life assessment in patients with hyperhidrosis before and after treatment with botulinum toxin: results of an open-label study. *Clin Ther.* Jan 2003;25(1):298-308.

7. Charles PD. Botulinum neurotoxin serotype A: a clinical update on non-cosmetic uses. *Am J Health Syst Pharm.* Nov 15 2004;61(22 Suppl 6):S11-23.

8. Cohen JL, Solish N. Treatment of hyperhidrosis with botulinum toxin. *Facial Plast Surg Clin North Am.* Nov 2003;11(4):493-502.

9. Glogau RG. Botulinum A neurotoxin for axillary hyperhidrosis. No sweat Botox. *Dermatol Surg.* Aug 1998;24(8):817-819.

10. Guntinas-Lichius O. First use of botulinum toxin type B in ENT patients with secondary therapy failure of botulinum toxin type A. *HNO.* Jan 2004;52(1):53-56.

11. Haider A, Solish N. Focal hyperhidrosis: diagnosis and management. *CMAJ.* Jan 4 2005;172(1):69-75.

12. Hexsel D, Dal'forno T, al. e. Inguinal or Hexsel's Hyperhidrosis Review. *Clin Dermatol.* 01-02/2004;22(1):53-59.

13. Institute for Spine Care Chicago Institute of Neurosurgery and Neuroresearch. Hyperhidrosis. 12/2003, accessed 12/10/2003.

14. International Hyperhidrosis Society. Clinical Guidelines for Generalized and Focal Hyperhidrosis. 2004, accessed 01/18/2005.

## HYPERHIDROSIS TREATMENT (cont.)

**Resources:** (cont.)

15. International Hyperhidrosis Society. Diagnosis Guidelines. 11/10/2006.

16. InterQual Care Planning Procedures Adult. Sympathectomy, Endoscopic/Open.

17. Kavanagh GM, Oh C, Shams K. BOTOX delivery by iontophoresis. *Br J Dermatol.* Nov 2004;151(5):1093-1095.

18. Kim WO, Kil HK, Yoon DM, Cho MJ. Treatment of compensatory gustatory hyperhidrosis with topical glycopyrrolate. *Yonsei Med J.* Aug 30 2003;44(4):579-582.

19. Kreyden O, Scheidegger E. Anatomy of the Sweat Glands, Pharmacology of Botulinum Toxin, and Distinctive Syndromes Associated With Hyperhidrosis Review. *Clin Dermatol.* 01-02/2004;22(1):40-44.

20. Laskawi R, Drobik C, al. e. Up-to-Date Report of Botulinum Toxin Type A Treatment in Patients With Gustatory Sweating. *Laryngoscope.* 1998;108:381-384.

21. Lauchli S, Burg G. Treatment of hyperhidrosis with botulinum toxin A. *Skin Therapy Lett.* Nov-Dec 2003;8(7):1-4.

22. Levit F. Treatment of Hyperhidrosis by Tap Water Iontophoresis. *Cutis.* 1980;26:192-194.

23. Lowe N, Campanati A, Bodokh I, et al. The place of botulinum toxin type A in the treatment of focal hyperhidrosis. *Br J Dermatol.* Dec 2004;151(6):1115-1122.

24. Lowe PL, Cerdan-Sanz S, Lowe NJ. Botulinum toxin type A in the treatment of bilateral primary axillary hyperhidrosis: efficacy and duration with repeated treatments. *Dermatol Surg.* May 2003;29(5):545-548.

25. National Organization for Rare Disorders. Hyperhidrosis, Primary. 12/2003.

26. Naumann M, Hofmann U, al. e. Effective Treatment With Intracutaneous Botulinum Toxin, Focal Hyperhidrosis. *Arch Dermatol.* 1998;134:301-304.

27. Naumann M, Jost W. Botulinum toxin treatment of secretory disorders. *Mov Disord.* Mar 2004;19 Suppl 8:S137-141.

28. Rompel R, Peros I, Petres J. Subcutaneous Curettage for the Treatment of Axillary Hyperhidrosis. *European Journal of Dermatology.* January-February 1997;7(1):43-46.

## HYPERHIDROSIS TREATMENT (cont.)

**Resources:** (cont.)

29. Schnider P, Binder M, al. e. Double Blind Trial of Botulinum A Toxin for the Treatment of Focal Hyperhidrosis of the Palms. *Br J Dermatol.* 1997;136:548-545.

30. Schnider P, Moraru E, Kittler H, et al. Treatment of focal hyperhidrosis with botulinum toxin type A: long-term follow-up in 61 patients. *Br J Dermatol.* Aug 2001;145(2):289-293.

31. Sevim S, Dogu O, al. e. Botulinum Toxin-A Therapy for Palmar and Plantar Hyperhidrosis. *Acta Neurol Belg.* 12/2002;102(4):167-170.

32. Shelley W, Talanin N, al. e. Botulinum Toxin Therapy for Palmar Hyperhidrosis. *J Am Acad Dermatol.* 1998;38:227-229.

33. Stolman LP. In hyperhidrosis (excess sweating), look for a pattern and cause. *Cleve Clin J Med.* Oct 2003;70(10):896-898.

34. Swartling C, Naver H, Pihl-Lundin I, Hagforsen E, Vahlquist A. Sweat gland morphology and periglandular innervation in essential palmar hyperhidrosis before and after treatment with intradermal botulinum toxin. *J Am Acad Dermatol.* Nov 2004;51(5):739-745.

35. Swinehart J. Therapy of Hyperhidrosis. 12/2003, accessed 12/11/2003.

FDA Product Approval Information for Botox® (onabotulinumtoxinA):

- FDA-approved indication: 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.