

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy Treatment of Hyperhidrosis

Table of Contents

- Policy: Commercial
- Policy: Medicare
 - Authorization Information
- <u>Coding Information</u>

Description

Policy History

- Information Pertaining to All Policies
- References

Policy Number: 406

BCBSA Reference Number: 8.01.19 (For Plan internal use only)

Related Policies

Botulinum Toxin Injections, (#006)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Treatment of primary focal hyperhidrosis using aluminum chloride 20% solution, botulinum toxin for severe primary axillary hyperhidrosis inadequately managed with topical agents, in individuals ≥18 years, may be considered <u>MEDICALLY NECESSARY</u> with **ANY** of the following medical conditions:

- acrocyanosis of the hands; OR
- history of recurrent skin maceration with bacterial or fungal infections; OR
- history of recurrent secondary infections; OR
- history of persistent eczematous dermatitis despite medical treatments with topical dermatologic or systemic anticholinergic agents.

Treatment of hyperhidrosis is considered **INVESTIGATIONAL** in the absence of functional impairment or any of the above medical conditions.

The following treatments may be considered <u>MEDICALLY NECESSARY</u> for the treatment of severe secondary gustatory hyperhidrosis:

- aluminum chloride 20% solution
- surgical options (ie, tympanic neurectomy) if conservative treatment has failed.

Other treatments are considered **INVESTIGATIONAL** as a treatment for severe secondary gustatory hyperhidrosis including, but not limited to:

- botulinum toxin
- iontophoresis.

Treatments that may be considered **MEDICALLY NECESSARY** by focal region include:

Axillary

- Aluminum chloride 20% solution
- Botulinum toxin for severe primary axillary hyperhidrosis inadequately managed with topical agents, in individuals ≥18 years.
- Palmar
 - Aluminum chloride 20% solution
 - Botulinum toxin type A products for severe primary palmar hyperhidrosis inadequately menaged with topical agenta in individuals >18 years
 - managed with topical agents, in individuals ≥18 years.
- Plantar
 - o Aluminum chloride 20% solution.
- Craniofacial
 - Aluminum chloride 20% solution.

Treatments that are considered **INVESTIGATIONAL** by focal region include:

- Axillary
 - Axillary liposuction
 - Iontophoresis
 - Microwave treatment
 - Radiofrequency ablation.
- Palmar
 - o RimabotulinumtoxinB
 - o lontophoresis
 - Microwave treatment
 - Radiofrequency ablation.
- Plantar
 - Botulinum toxin
 - o lontophoresis
 - Microwave treatment
 - o Radiofrequency ablation.
- Craniofacial
 - o Botulinum toxin
 - o lontophoresis
 - Microwave treatment
 - $\circ \quad \mbox{Radiofrequency ablation.}$

A multispecialty working group has defined primary focal hyperhidrosis as a condition characterized by visible, excessive sweating of at least 6 months in duration without apparent cause and with at least 2 of the following features: bilateral and relatively symmetric sweating, impairment of daily activities, frequency of at least once per week, age at onset younger than 25 years, positive family history, and cessation of focal sweating during sleep.

The Hyperhidrosis Disease Severity Scale is used by individuals to rate the severity of their symptoms on a scale of 1 to 4 (Table PG1):

Table PG1. The Hyperhidrosis Disease Severity Scale

| Score | Definition |
|-------|---|
| 1 | My underarm sweating is never noticeable and never interferes with my daily activities |
| 2 | My underarm sweating is tolerable but sometimes interferes with my daily activities |
| 3 | My underarm sweating is barely tolerable and frequently interferes with my daily activities |
| 4 | My underarm sweating is intolerable and always interferes with my daily activities |

Prior Authorization Information

Inpatient

For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> if the procedure is performed inpatient.

Outpatient

• For services described in this policy, see below for situations where prior authorization **might be** required if the procedure is performed **outpatient**.

| | Outpatient |
|---------------------------------------|--|
| Commercial Managed Care (HMO and POS) | Prior authorization is not required . |
| Commercial PPO and Indemnity | Prior authorization is not required . |

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

| CPT codes: | Code Description |
|------------|---------------------|
| 69676 | Tympanic neurectomy |

Description

Hyperhidrosis

Hyperhidrosis has been defined as excessive sweating, beyond a level required to maintain normal body temperature, in response to heat exposure or exercise. It can be classified as primary or secondary. Primary focal hyperhidrosis is idiopathic, typically involving the hands (palmar), feet (plantar), or axillae (underarms). Secondary hyperhidrosis can result from a variety of drugs (eg, tricyclic antidepressants, selective serotonin reuptake inhibitors) or underlying diseases/conditions (eg, febrile diseases, diabetes, menopause). Secondary hyperhidrosis is usually generalized or craniofacial sweating.

Secondary gustatory hyperhidrosis is excessive sweating on ingesting highly spiced foods. This trigeminovascular reflex typically occurs symmetrically on the scalp or face and predominately over the forehead, lips, and nose. Secondary facial gustatory hyperhidrosis occurs independently of the nature of the ingested food. This phenomenon frequently occurs after injury or surgery in the region of the parotid gland. Frey syndrome is an uncommon type of secondary gustatory hyperhidrosis that arises from injury to or surgery near the parotid gland resulting in damage to the secretory parasympathetic fibers of the facial nerve. After the injury, these fibers regenerate, and miscommunication occurs between them and the severed postganglionic sympathetic fibers that supply the cutaneous sweat glands and blood vessels. The aberrant connection results in gustatory sweating and facial flushing with mastication. Aberrant secondary gustatory sweating follows up to 73% of surgical sympathectomies and is particularly common after bilateral procedures.

The consequences of hyperhidrosis are primarily psychosocial. Symptoms such as fever, night sweats, or weight loss require further investigation to rule out secondary causes. Sweat production can be assessed with the Minor starch-iodine test, which is a simple qualitative measure to identify specific sites of involvement.

Treatment

A variety of therapies have been investigated for primary hyperhidrosis, including topical therapy with aluminum chloride, topical anticholinergic medications, oral anticholinergic medications, iontophoresis, intradermal injections of botulinum toxin. Treatment of secondary hyperhidrosis focuses on treatment of the underlying cause, such as discontinuing certain drugs or hormone replacement therapy as a treatment for menopausal symptoms.

lontophoresis uses electrical current to deliver medication transdermally. A charged ionic drug is placed on the skin with an electrode of the same charge, which drives the drug into the skin, with the purpose of achieving better penetration of the drug into underlying tissue. The benefits of this method would be an

enhancement of treatment effects and a reduction in adverse events associated with systemic administration of the drug.

Botulinum toxin is a potent neurotoxin that blocks cholinergic nerve terminals, which prevents hyperstimulation of eccrine sweat glands that lead to excessive sweating. Therefore, intracutaneous injections have been investigated as a treatment of gustatory hyperhidrosis and focal primary hyperhidrosis, most frequently involving the axillae or palms. The drawback of this approach is the need for repeated injections, which have led some to consider surgical approaches.

Outcome Measures

Outcomes from different surgical and medical treatment modalities are best assessed using a combination of tools. Quantitative tools include gravimetry, evaporimetry, and the Minor starch-iodine test. Qualitative assessment tools include general health surveys and hyperhidrosis-specific surveys. Of these, the Hyperhidrosis Disease Severity Scale (Appendix Table 1) has had a good correlation to other assessment tools and is practical in the clinical setting.

Summary

Description

Hyperhidrosis, or excessive sweating, can lead to impairments in psychologic and social functioning. Various treatments for hyperhidrosis are available, such as topical antiperspirant agents (eg, aluminum chloride 20% solution), oral medications, botulinum toxin, and surgical procedures.

Summary of Evidence

Primary Focal Hyperhidrosis

Iontophoresis

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive iontophoresis, the evidence includes a systematic review, a randomized controlled trial (RCT), and case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The RCT found that iontophoresis was less effective than botulinum toxin in the short-term treatment of palmar hyperhidrosis. Additional RCTs are needed comparing iontophoresis with sham or active treatment in patients with various types of primary focal hyperhidrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Botulinum Toxins

For individuals who have primary axillary hyperhidrosis who receive botulinum toxin type A or B, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Placebo-controlled randomized trials have generally found better outcomes in the botulinum toxin groups. Meta-analyses have showed that botulinum toxin injections significantly decreased sweating in the short (2 to 4 weeks) and long term (16 weeks), and significantly improved Hyperhidrosis Disease Severity Scale (HDSS) scores. Several RCTs have compared different botulinum toxin type A formulations with botulinum toxin type A and B formulations in patients with axillary hyperhidrosis. Although these studies had small sample sizes, their findings suggested that, with appropriate dosage adjustments, there are similar levels of efficacy and adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary palmar hyperhidrosis who receive botulinum toxin type A, the evidence includes RCTs. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Placebocontrolled randomized trials have generally found better outcomes in the botulinum toxin groups. Randomized controlled trials comparing botulinum toxin type A formulations in patients with primary palmar hyperhidrosis have generally found no significant differences in outcomes. Although these studies had small sample sizes, their findings suggested that, with appropriate dosage adjustments, there are similar levels of efficacy and adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For individuals who have primary palmar hyperhidrosis who receive botulinum toxin type B, the evidence includes an RCT. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. One small placebo-controlled randomized trial did not clearly demonstrate the efficacy of botulinum toxin type B in patients with palmar hyperhidrosis. Also, a high rate of adverse events was reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary plantar hyperhidrosis who receive botulinum toxin type A or B, the evidence includes no RCTs. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Randomized controlled trials are needed comparing botulinum toxin with placebo or active treatment in patients with primary plantar hyperhidrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Microwave

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive microwave treatment, the evidence includes a systematic review, an RCT, and a case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The systematic review and RCT found a short-term benefit of microwave treatment in reducing hyperhidrosis but also reported skin-related adverse events (eg, pain, altered sensation). Additional RCTs are needed comparing microwave treatment with sham or active treatment in patients with various types of primary focal hyperhidrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Radiofrequency Ablation

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive radiofrequency ablation (RFA), the evidence includes 2 small RCTs and a nonrandomized cohort study. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. One nonrandomized comparative study found RFA inferior to surgical sympathectomy for patients with severe bilateral palmar hyperhidrosis resistant to conservative treatment. Two small RCTs that compared RFA to botulinum toxin A in patients with palmar or axillary hyperhidrosis had conflicting results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Secondary Gustatory Hyperhidrosis

For individuals who have severe secondary gustatory hyperhidrosis who receive iontophoresis or botulinum toxin, the evidence includes uncontrolled studies and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The systematic reviews did not identify any relevant RCTs. Randomized controlled trials are needed to evaluate the safety and efficacy of these treatments for severe secondary gustatory hyperhidrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe secondary gustatory hyperhidrosis who receive tympanic neurectomy, the evidence includes uncontrolled studies and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. This treatment has high success rates, without the need for repeated interventions, and is considered standard of care for this indication. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

| T oncy matory | | |
|---------------|---|--|
| Date | Action | |
| 10/2024 | Annual policy review. Policy clarified. Endoscopic transthoracic sympathectomy and surgical excision of axillary sweat glands (32664) Thoracoscopy, surgical; with thoracic sympathectomy retired and removed from the policy. Code 32664 is a covered service. | |
| 8/2024 | Annual policy review. Policy updated with literature review through April 26, 2024; references added. Policy statements unchanged. | |
| 12/2023 | Note added to coding section. | |
| 8/2023 | Annual policy review. References added. Minor editorial refinements to policy statements; intent unchanged. | |

Policy History

| 1/2023 | Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference. |
|---------|---|
| 8/2022 | Annual policy review. Minor editorial refinements to policy statements; intent unchanged. |
| 8/2020 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 8/2019 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 6/2018 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. Prior Authorization Information reformatted. |
| 7/2016 | Annual policy review. New references added. |
| 8/2014 | Clarified coding information. |
| 11/2013 | Annual policy review. New investigational indications described. Effective 11/1/2013. |
| 10/2012 | Updated Treatment of Hyperhidrosis excluding Botulinum Toxin transferred from medical policy 144, Treatment of Hyperhidrosis. |
| 11/2011 | Reviewed at MPG – Plastic Surgery and Dermatology, no changes in coverage. |
| 12/2010 | Reviewed at MPG-Plastic Surgery and Dermatology, no coverage changes were made. |
| 12/2009 | Reviewed at MPG Plastic Surgery and Dermatology, no changes in coverage were made. |
| 12/2009 | New medical policy. Effective 12/1/2009. |

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use Managed Care Guidelines Indemnity/PPO Guidelines Clinical Exception Process Medical Technology Assessment Guidelines

References

- 1. Food and Drug Administration. Approved risk evaluation and mitigation strategies. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. Accessed May 1, 2024.
- Wade R, Rice S, Llewellyn A, et al. Interventions for hyperhidrosis in secondary care: a systematic review and value-of-information analysis. Health Technol Assess. Dec 2017; 21(80): 1-280. PMID 29271741
- Rajagopal R, Mallya NB. Comparative evaluation of botulinum toxin versus iontophoresis with topical aluminium chloride hexahydrate in treatment of palmar hyperhidrosis. Med J Armed Forces India. Jul 2014; 70(3): 247-52. PMID 25378778
- 4. Solish N, Bertucci V, Dansereau A, et al. A comprehensive approach to the recognition, diagnosis, and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. Dermatol Surg. Aug 2007; 33(8): 908-23. PMID 17661933
- Dogruk Kacar S, Ozuguz P, Eroglu S, et al. Treatment of primary hyperhidrosis with tap water iontophoresis in paediatric patients: a retrospective analysis. Cutan Ocul Toxicol. Dec 2014; 33(4): 313-6. PMID 24405389
- 6. McAleer MA, Collins P. A study investigating patients' experience of hospital and home iontophoresis for hyperhidrosis. J Dermatolog Treat. Aug 2014; 25(4): 342-4. PMID 23356798
- Obed D, Salim M, Bingoel AS, et al. Botulinum Toxin Versus Placebo: A Meta-Analysis of Treatment and Quality-of-life Outcomes for Hyperhidrosis. Aesthetic Plast Surg. Aug 2021; 45(4): 1783-1791. PMID 33619611
- 8. Lowe NJ, Glaser DA, Eadie N, et al. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol. Apr 2007; 56(4): 604-11. PMID 17306417
- Baumann L, Slezinger A, Halem M, et al. Pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for treatment of axillary hyperhidrosis. Int J Dermatol. May 2005; 44(5): 418-24. PMID 15869543

- 10. Dressler D. Comparing Botox and Xeomin for axillar hyperhidrosis. J Neural Transm (Vienna). Mar 2010; 117(3): 317-9. PMID 20143241
- 11. Talarico-Filho S, Mendonça DO Nascimento M, Sperandeo DE Macedo F, et al. A double-blind, randomized, comparative study of two type A botulinum toxins in the treatment of primary axillary hyperhidrosis. Dermatol Surg. Jan 2007; 33(1 Spec No.): S44-50. PMID 17241414
- 12. Frasson E, Brigo F, Acler M, et al. Botulinum toxin type A vs type B for axillary hyperhidrosis in a case series of patients observed for 6 months. Arch Dermatol. Jan 2011; 147(1): 122-3. PMID 21242408
- 13. An JS, Hyun Won C, Si Han J, et al. Comparison of onabotulinumtoxinA and rimabotulinumtoxinB for the treatment of axillary hyperhidrosis. Dermatol Surg. Aug 2015; 41(8): 960-7. PMID 26218729
- 14. Grove GL, Togsverd-Bo K, Zachariae C, et al. Botulinum toxin A versus microwave thermolysis for primary axillary hyperhidrosis: A randomized controlled trial. JAAD Int. Jun 2024; 15: 91-99. PMID 38495540
- Mirkovic SE, Rystedt A, Balling M, et al. Hyperhidrosis Substantially Reduces Quality of Life in Children: A Retrospective Study Describing Symptoms, Consequences and Treatment with Botulinum Toxin. Acta Derm Venereol. Jan 12 2018; 98(1): 103-107. PMID 28761964
- 16. Lowe NJ, Yamauchi PS, Lask GP, et al. Efficacy and safety of botulinum toxin type a in the treatment of palmar hyperhidrosis: a double-blind, randomized, placebo-controlled study. Dermatol Surg. Sep 2002; 28(9): 822-7. PMID 12269876
- 17. Saadia D, Voustianiouk A, Wang AK, et al. Botulinum toxin type A in primary palmar hyperhidrosis: randomized, single-blind, two-dose study. Neurology. Dec 11 2001; 57(11): 2095-9. PMID 11739832
- Campanati A, Giuliodori K, Martina E, et al. Onabotulinumtoxin type A (Botox(®)) versus Incobotulinumtoxin type A (Xeomin(®)) in the treatment of focal idiopathic palmar hyperhidrosis: results of a comparative double-blind clinical trial. J Neural Transm (Vienna). Jan 2014; 121(1): 21-6. PMID 24052109
- Baumann L, Slezinger A, Halem M, et al. Double-blind, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for the treatment of palmar hyperhidrosis. Dermatol Surg. Mar 2005; 31(3): 263-70. PMID 15841624
- 20. Hsu TH, Chen YT, Tu YK, et al. A systematic review of microwave-based therapy for axillary hyperhidrosis. J Cosmet Laser Ther. Oct 2017; 19(5): 275-282. PMID 28281850
- Glaser DA, Coleman WP, Fan LK, et al. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: the dermatologic reduction in underarm perspiration study. Dermatol Surg. Feb 2012; 38(2): 185-91. PMID 22289389
- 22. Hong HC, Lupin M, O'Shaughnessy KF. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. Dermatol Surg. May 2012; 38(5): 728-35. PMID 22452511
- Mostafa TAH, Hamed AA, Mohammed BM, et al. C-Arm Guided Percutaneous Radiofrequency Thoracic Sympathectomy for Treatment of Primary Palmar Hyperhidrosis in Comparison with Local Botulinum Toxin Type A Injection, Randomized Trial. Pain Physician. Nov 2019; 22(6): 591-599. PMID 31775406
- 24. Rummaneethorn P, Chalermchai T. A comparative study between intradermal botulinum toxin A and fractional microneedle radiofrequency (FMR) for the treatment of primary axillary hyperhidrosis. Lasers Med Sci. Jul 2020; 35(5): 1179-1184. PMID 31939036
- 25. Hafner J, Beer GM. Axillary sweat gland excision. Curr Probl Dermatol. 2002; 30: 57-63. PMID 12471699
- 26. Hornberger J, Grimes K, Naumann M, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. J Am Acad Dermatol. Aug 2004; 51(2): 274-86. PMID 15280848
- 27. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Iontophoresis for Medical Indications. TEC Assessments 2003;Volume 18, Tab 3.
- 28. Li C, Wu F, Zhang Q, et al. Interventions for the treatment of Frey's syndrome. Cochrane Database Syst Rev. Mar 17 2015; 2015(3): CD009959. PMID 25781421
- 29. Clayman MA, Clayman SM, Seagle MB. A review of the surgical and medical treatment of Frey syndrome. Ann Plast Surg. Nov 2006; 57(5): 581-4. PMID 17060744
- 30. de Bree R, van der Waal I, Leemans CR. Management of Frey syndrome. Head Neck. Aug 2007; 29(8): 773-8. PMID 17230557
- 31. Naumann M, So Y, Argoff CE, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review): report of the Therapeutics and Technology

Assessment Subcommittee of the American Academy of Neurology. Neurology. May 06 2008; 70(19): 1707-14. PMID 18458231

- 32. Naumann M, Dressler D, Hallett M, et al. Evidence-based review and assessment of botulinum neurotoxin for the treatment of secretory disorders. Toxicon. Jun 01 2013; 67: 141-52. PMID 23178324
- 33. National Institute of Health and Care Excellence (NICE). Transcutaneous microwave ablation for severe primary axillary hyperhidrosis [IPG601]. 2017; https://www.nice.org.uk/guidance/ipg601. Accessed May 3, 2024.
- 34. Cerfolio RJ, De Campos JR, Bryant AS, et al. The Society of Thoracic Surgeons expert consensus for the surgical treatment of hyperhidrosis. Ann Thorac Surg. May 2011; 91(5): 1642-8. PMID 21524489