Guidelines for Medical Necessity Determination for Botulinum Toxin in the Treatment of Hyperhidrosis

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for botulinum toxin in the treatment of hyperhidrosis (described by CPT® codes 64650 and 64653). These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 433.000: *Physician Services*; 130 CMR 410.000: *Outpatient Hospital Services*; 130 CMR 450.000: *Administrative and Billing Regulations*; Subchapter 6 of the *Physician Manual*; and Subchapter 6 of the *Acute Outpatient Hospital Manual* for information about coverage, limitations, service conditions, and other prior authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Options (SCO), or Program of All-Inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for the use of botulinum toxin in the treatment of any condition, including in the treatment of hyperhidrosis. MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

SECTION 1. GENERAL INFORMATION

Hyperhidrosis is a medical condition defined by excessive sweating. Primary hyperhidrosis is defined by sweating that is not caused by another disease, while secondary hyperhidrosis is defined by sweating that occurs as a result of another medical condition (including, but not limited to, acromegaly, anxiety, cancer, or carcinoid syndrome) or as a result of a medication.[1]

Botulinum toxins are neurotoxins produced by the *Clostridium botulinum* bacterium. When injected into skeletal muscle, these toxins act by inhibiting the release of acetylcholine from peripheral nerve cells into neuromuscular junctions, thereby acting as a neuromuscular blocker and causing muscle weakness or paralysis.[2]

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1 U.S. National Library of Medicine. Hyperhidrosis. https://medlineplus.gov/ency/article/007259.htm. Accessed October 19, 2021.

2 Carruthers J. Overview of botulinum toxin for cosmetic indications. UpToDate. UpToDate; 2019. Accessed October 19, 2021.

Botulinum toxins are used for the treatment of a variety of medical conditions including, but not limited to, blepharospasm, cervical dystonia, hyperhidrosis, overactive bladder, strabismus, upper-limb spasticity, and urinary incontinence associated with neurologic conditions. These Guidelines pertain solely to the use of botulinum toxins in the treatment of hyperhidrosis, and do not pertain to the use of botulinum toxins in the treatment of other medical conditions.

Different serotypes of botulinum toxin (i.e., A, B, C1, D, E, F) are produced by different strains of the bacterium, and the pharmacologic properties of the serotypes differ. In the United States, only serotypes A and B are available or clinical use.[3]

These Guidelines pertain to the use of botulinum toxins in the indications for which they are approved by the Federal Drug Administration (FDA), which are also referred to as "on-label indications." PA requests for the use of botulinum toxins in "off-label" indications may be considered for approval on a case-by-case basis. Botox® (onabotulinumtoxinA) is the only botulinum toxin that has FDA approval for the treatment of hyperhidrosis. Specifically, onabotulinumtoxinA is FDA-approved for the treatment of hyperhidrosis solely for patients 18 years and older with severe primary axillary hyperhidrosis. OnabotulinumtoxinA is not FDA-approved for other types of hyperhidrosis, such as secondary hyperhidrosis, palmar hyperhidrosis, or plantar hyperhidrosis.

SECTION II. CLINICAL GUIDELINES

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A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for botulinum toxins in the treatment of severe primary axillary hyperhidrosis on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the treatment. These criteria include *all* of the following.

- The member has a diagnosis of severe primary axillary hyperhidrosis.
- The prescriber is a dermatologist or neurologist.
- Clinical documentation of the member's inadequate response, adverse reaction, or contraindication to aluminum chloride solution.
- The dose is appropriate for stated indication.

B. NONCOVERAGE

MassHealth does not consider botulinum toxins to be medically necessary in the treatment of hyperhidrosis under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

- Treatment is being done for mild or moderate hyperhidrosis.
- Treatment is being done for cosmetic purpose.

[3] Carruthers J. Overview of botulinum toxin for cosmetic indications. UpToDate. UpToDate; 2019. Accessed October 19, 2021.

MassHealth does not approve the use of botulinum toxin for the treatment of hyperhidrosis where safety risks or contraindications to the use of botulinum toxin exist, which include, but are not limited to, the following conditions or situations.

- Current use of aminoglycoside therapy
- Infection at the proposed injection site
- Sensitivity or allergy to any botulinum toxin preparation or to any of the components in the formulation

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

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A. Requests for PA of botulinum toxins in the treatment of hyperhidrosis must be accompanied by clinical documentation that supports the medical necessity for this procedure.

B. Documentation of medical necessity must include all of the following.

- Diagnosis (i.e., what type of hyperhidrosis) and severity of the condition
- Proof that prescriber is a dermatologist or neurologist
- Inadequate response, adverse reaction, or contraindication to aluminum chloride solution
- Name, dose, number, and frequency of treatments recommended by the prescriber

Clinical information must be submitted by the MassHealth-enrolled qualified health professional performing the procedure. Providers are strongly encouraged to submit requests for PA electronically. Providers must submit the request for PA and all supporting documentation using the Provider Online Service Center (POSC), or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at https://www.mass.gov/lists/masshealth-provider-forms-used-by-multiple-provider-types) and attaching all supporting documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900.

APPLICABLE CPT® CODES

The Current Procedural Terminology (CPT®) codes provided below are for informational purposes only. CPT® coding is the sole responsibility of the billing party. Inclusion of a CPT® code in these Guidelines does not imply that the service described by this code is a covered service. This list of codes may not be all-inclusive.

CPT CODE	DESCRIPTION
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck)

SELECT REFERENCES

1. Galadari H, Galadari I, Smit R, Prygova I, Redaelli A. Treatment approaches and outcomes associated with the use of abobotulinumtoxinA for the treatment of hyperhidrosis: A systematic review. J Am Acad Dermatol. 2021 Nov;85(5):1121-1129. doi: 10.1016/j.jaad.2020.07.123. Epub 2020 Aug 8. PMID: 32781184

2. Ibrahim O, Kakar R, Bolotin D, et al. The comparative effectiveness of suction-curettage and onabotulinumtoxin-A injections for the treatment of primary focal axillary hyperhidrosis: a randomized control trial. J Am Acad Dermatol. 2013; 69(1):88-95.

3. Lowe NJ, Glaser DA, Eadie N, et al.; North American Botox in Primary Axillary Hyperhidrosis Clinical Study Group. 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. 2007; 56(4):604-611.

4. 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. 2002; 28(9):822-827.

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12. Smith CC, Pariser D. Primary focal hyperhidrosis. UpToDate. UpToDate; 2020. Accessed October 19, 2021.

These Guidelines are based on review of the medical literature and current practice in the use of botulinum toxins in the treatment of hyperhidrosis. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; MassHealth encourages such readers to contact their health care provider for guidance or explanation.

Policy Effective Date: October 21, 2022 Approved by: 

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