# MEDICAL POLICY

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| **POLICY TITLE** | **OTHER THERAPIES OF HYPERHIDROSIS** |
| **POLICY NUMBER** | **MP 2.005** |

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| **CLINICAL BENEFIT** | ☐ MINIMIZE SAFETY RISK OR CONCERN.<br>☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.<br>☐ ASSURE APPROPRIATE LEVEL OF CARE.<br>☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.<br>☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.<br>☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| **Effective Date:** | **3/1/2025** |



## I. POLICY

Treatment of primary hyperhidrosis using the therapies in Table PG1 may be considered **medically necessary** for individuals with any of the following:

- 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 dermatological or systemic anticholinergic agents.

**Table PG1. Treatments for Hyperhidrosis**

| Focal Regions | Treatments Considered **Medically Necessary** | Treatments Considered **Investigational** |
|---|---|---|
| Axillary | • Aluminum chloride 20% solution<br>• ETS, Iontophoresis or surgical excision of axillary sweat glands, if conservative treatment (i.e., aluminum chloride or botulinum toxin, individually and in combination) has failed | • Axillary liposuction<br>• Microwave Treatment<br>• Radiofrequency Ablation |
| Palmar | • Aluminum chloride 20% solution<br>• ETS, Iontophoresis if conservative treatment (i.e., aluminum chloride or botulinum toxin type A, individually and in combination) has failed | • Microwave Treatment<br>• Radiofrequency Ablation |

| | | |
|---|---|---|
| Plantar | • Aluminum chloride 20% solution<br>• Iontophoresis | • Lumbar sympathectomy<br>• Microwave treatment<br>• Radiofrequency ablation |
| Craniofacial | • Aluminum chloride 20% solution<br>• ETS, if conservative treatment (i.e., aluminum chloride) has failed | • Iontophoresis<br>• Microwave Treatment<br>• Radiofrequency Ablation |

ETS: endoscopic transthoracic sympathectomy; FDA: Food and Drug Administration.

Treatment of primary hyperhidrosis is considered **investigational** in the absence of functional impairment or medical conditions as there is insufficient evidence to support a general conclusion supporting the health outcomes or benefits associated with this procedure.

### Secondary Gustatory Hyperhidrosis

The following treatments may be considered **medically necessary** for the treatment of severe secondary gustatory hyperhidrosis. (See Policy Guidelines section for examples of gustatory hyperhidrosis conditions):

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

Other treatments for severe secondary gustatory hyperhidrosis including, but not limited to iontophoresis, are considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure for this condition.

*Botulinum Toxin as a treatment for hyperhidrosis is addressed in Capital policy titled **Botox**.*

## POLICY GUIDELINES

### Primary Focal Hyperhidrosis

Primary focal hyperhidrosis is defined as excessive sweating induced by sympathetic hyperactivity in selected areas that is not associated with an underlying disease process. The most common locations are underarms (axillary hyperhidrosis), palms (palmar hyperhidrosis), soles (plantar hyperhidrosis), or face (craniofacial hyperhidrosis).

A multispecialty working group defines primary focal hyperhidrosis as a condition that is characterized by visible, excessive sweating of at least 6 months' 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 patients to rate the severity of their symptoms on a scale of 1 to 4 (see **Table PG2**):

**Table PG2. 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 |

### Secondary Hyperhidrosis

Secondary hyperhidrosis is excessive sweating that can be generalized or craniofacial sweating and may occur as a result of olfactory or gustatory stimuli, neurologic lesions, intrathoracic neoplasms, Raynaud's disease, and Frey's syndrome.

**Gustatory hyperhidrosis conditions include, but aren't limited to, the following:**

- Frey syndrome
- Encephalitis
- Syringomyelia
- Diabetic neuropathies
- Herpes zoster parotitis
- Parotid abscess

***Cross-references:***

**MP 4.013 Iontophoresis/Phonophoresis**

## II. PRODUCT VARIATIONS

Top

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

**FEP PPO** - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

## III. DESCRIPTION/BACKGROUND

Top

### 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 (e.g., tricyclic antidepressants, selective serotonin reuptake inhibitors) or underlying diseases/conditions (e.g., febrile diseases, diabetes mellitus, 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, 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 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, oral anticholinergic medications, iontophoresis, intradermal injections of botulinum toxin, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands. Treatment of secondary hyperhidrosis focuses on treatment of the underlying cause, such as discontinuing certain drugs or hormone replacement therapy as a treatment of menopausal symptoms.

Iontophoresis 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. Iontophoresis used in conjunction with tap water or anticholinergic agents is a long-standing treatment of palmar (palms) or plantar (soles) and more recently axillary (underarm) idiopathic hyperhidrosis. The mechanism of action is not precisely known, but it is thought to be related to plugging of the sweat glands. During this procedure, trays are filled with tap water and the patient inserts the hands or feet or positions the device in the axilla, and the current is turned on. Patients are treated for approximately twenty (20) minutes, with treatments every two (2) to three (3) days for five (5) to ten (10) sessions before an effect is observed. Maintenance therapy may be required every two (2) weeks after normal sweating is achieved.

Surgical treatment options include removal of the eccrine glands and/or interruption of the sympathetic nerves. Eccrine sweat glands produce an aqueous secretion, the overproduction of which is primarily responsible for hyperhidrosis. These glands are innervated by the sympathetic nervous system. Surgical removal has been performed in patients with severe isolated axillary hyperhidrosis.

Various surgical techniques of sympathectomy have been tested. The second (T2) and third (T3) thoracic ganglia are responsible for palmar hyperhidrosis, the fourth (T4) thoracic ganglion controls axillary hyperhidrosis, and the first (T1) thoracic ganglion controls craniofacial hyperhidrosis. Thoracic sympathectomy has been investigated as a potentially curative procedure, primarily for combined palmar and axillary hyperhidrosis unresponsive to nonsurgical treatments. While accepted as an effective treatment, sympathectomy is not without complications. In addition to the immediate surgical complications of pneumothorax or temporary Horner syndrome, compensatory sweating on the trunk generally occurs in most patients, with different degrees of severity. Medical researchers have investigated whether certain approaches (e.g., T3 sympathectomy vs T4 sympathectomy) result in less compensatory sweating, but there remains a lack of consensus about which approach best minimizes the risk of this adverse effect. In addition, with lumbar sympathectomy for plantar hyperhidrosis, there has been concern about the risk of postoperative sexual dysfunction in both men and women.

### 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 (see Table PG2) has had good correlation to other assessment tools and is practical in the clinical setting.

## REGULATORY STATUS

Drysol™ (Person and Covey), an aluminum chloride (hexahydrate) 20% topical solution, was approved by the U.S. Food and Drug Administration (FDA) as an aid in the management of hyperhidrosis (axillae, palmar, plantar, craniofacial); it is available by prescription. Additional topical medicines approved by the FDA include Hypercare Topical and Xerac AC.

In 2011, the miraDry® System (Miramar Labs) was cleared for marketing by FDA through the 510(k) process for treating primary axillary hyperhidrosis. This microwave device is designed to heat tissue at the dermal-hypodermal interface, the location of the sweat glands. Treatment consists of 2 sessions for a total duration of approximately 1 hour. Sessions occur in a physician's office, and a local anesthetic is used. The device is currently not approved for the treatment of palmar or plantar hyperhidrosis.

## IV. RATIONALE

TOP

### Summary of Evidence

#### PRIMARY FOCAL HYPERHIDROSIS

### Iontophoresis

For individuals who have primary focal hyperhidrosis (i.e., 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. For axillary, palmar and plantar hyperhidrosis, the evidence is sufficient to determine the effects of the technology on health outcomes.

### Microwave

For individuals who have primary focal hyperhidrosis (i.e., axillary, palmar, plantar, craniofacial) who receive microwave treatment, the evidence includes a systematic review, an RCT, and case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The RCT, conducted in patients with primary axillary hyperhidrosis, found a short-term benefit of microwave treatment vs sham therapy, but there was a high rate of skin-related adverse events. However, these adverse events did resolve completely overtime.

In a systematic review, Hsu and colleagues (2017) evaluated the literature on the use of the microwave-based device for subdermal thermolysis of the axilla and its effectiveness for the treatment of axillary hyperhidrosis. They performed the review using PubMed, Embase, SCOPUS, and Cochrane databases on June 2, 2016. These investigators reviewed 5 clinical trials and 189 patients, all of which were published between 2012 and 2016. There was 1 randomized controlled trial (RCT), 1 retrospective study, and the remainder were prospective studies. Although all of the studies were conducted with a small sample size, the results indicated that microwave-based device treatment of axillary hyperhidrosis had long-term effectiveness with mild AEs. In addition, most patients were satisfied with the outcomes in these studies. The authors concluded that microwave-based device treatment may be an effective alternative treatment for axillary hyperhidrosis; however, further investigation is needed to ascertain its long-term safety and effectiveness. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Radiofrequency Ablation

For individuals who have primary focal hyperhidrosis (i.e., axillary, palmar, plantar, craniofacial) who receive radiofrequency ablation, the evidence includes 2 small RCTs and a nonrandomized cohort study. 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 the effects of the technology on health outcomes.

### Surgery

For individuals who have primary axillary hyperhidrosis who receive surgical excision of axillary sweat glands, the evidence includes review articles. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The evidence has shown that excision is highly effective,

and this treatment is considered standard of care for this indication. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary axillary and palmar hyperhidrosis who receive endoscopic transthoracic sympathectomy, the evidence includes several RCTs, a meta-analysis, and case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The meta-analysis found a high rate of clinical efficacy after endoscopic transthoracic sympathectomy, although the rate of postoperative compensatory sweating was substantial. Subsequent studies have supported these findings. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary plantar hyperhidrosis who receive lumbar sympathectomy, the evidence includes one RCT conducted at a single center in Brazil, case series, and a systematic review. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Case series have reported high rates of clinical efficacy, but findings are inconclusive due to lack of control groups. The RCT was limited by its small sample size and lack of blinded outcome assessment. Moreover, there have been substantial rates of compensatory sweating and concerns about adverse events on sexual functioning. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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. RCTs are needed to evaluate the safety and efficacy of these treatments for severe secondary gustatory hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 a meaningful improvement in the net health outcome.

## V. DEFINITIONS

TOP

**ACROCYANOSIS** is a blue or purple mottled discoloration of the extremities, especially the fingers, toes and/or nose.

**BASIC ACTIVITIES OF DAILY LIVING** include and are limited to walking in the home, eating, bathing, dressing, and homemaking

**BOTOX®** is a therapeutic muscle-relaxing agent that works at motor nerve endings (nerves that lead to muscles). It belongs to a class of drugs called neurotoxins.

**CERVICAL DYSTONIA** IS a movement disorder (nervous system disease) characterized by sustained muscle contractions. This results in involuntary, abnormal, squeezing and twisting

muscle contractions in the head and neck region. These muscle contractions result in sustained abnormal positions or posturing. Sideways or lateral rotation of the head and twisting of the neck is the most common finding in cervical dystonia. Muscle hypertrophy occurs in most patients.

**DYSTONIA** is a series of involuntary prolonged muscle contractions, often distorting body posture. Dystonia may be primary (idiopathic) or secondary to degenerative or metabolic central nervous system disorders (e.g., Wilson's disease, various lipidoses, multiple sclerosis, cerebral palsy, stroke, brain hypoxia) or drugs (most often phenothaizines, thioxanthenes, butyrophenones, and antiemetics).

**FUNCTIONAL IMPAIRMENT** A condition that describes a state where an individual is limited in the performance of basic activities of daily living**.**

**GUSTATORY** pertains to taste**.**

**IONTOPHORESIS** is a technique that involves the use of an electric current to introduce various ions through the skin. The mechanism of action is not precisely known, but it is thought to be related to plugging of the sweat glands.

**MACERATION** is the process of softening a solid by steeping in a fluid.

**PRIMARY FOCAL HYPERHIDROSIS** is a condition that is characterized by visible, excessive sweating of a least 6 months' duration without apparent cause and with at least 2 of the following features: bilateral and relatively symmetric sweating, impairment of daily activities, frequency of a least once per week, age at onset younger than 25 years, positive family history, and cessation of focal sweating during sleep.

## VI. BENEFIT VARIATIONS

Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

## VII. DISCLAIMER

Top

*Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the*

*information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION

Top

This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Investigational; therefore, not covered:**

| Procedure Codes | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 15877 | 15878 | 97024 | | | | | | |

**Covered when medically necessary:**

| Procedure Codes | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 11450 | 11451 | 32664 | 69676 | 97033 | | | | |

**Covered when medically necessary:**

| ICD-10-CM Diagnosis Code | Description |
|---|---|
| L74.510 | Primary focal hyperhidrosis, axilla |
| L74.511 | Primary focal hyperhidrosis, face |
| L74.512 | Primary focal hyperhidrosis, palms |
| L74.513 | Primary focal hyperhidrosis, soles |
| L74.519 | Primary focal hyperhidrosis, unspecified |
| L74.52 | Secondary focal hyperhidrosis |
| R61 | Generalized hyperhidrosis |

## IX. REFERENCES

Top

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## X. POLICY HISTORY

Top

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| **MP 2.005** | **02/11/2020 Consensus Review.** Policy statements unchanged. |
| | **04/06/2021 Minor Review.** Iontophoresis changed to medically necessary for axillary, palmar and plantar hyperhidrosis. Background, Rationale, References and coding updated. |
| | **07/19/2022 Consensus Review**. Title changes to Other Therapies of Hyperhidrosis (formerly Non-Pharmacological Treatments of Hyperhidrosis) Formatting changes to policy and PG1. Updates to policy guidelines, and rationale. Coding and literature review. Updated references. |
| | **08/31/2023 Consensus Review.** Reformatted policy stance and policy guidelines. Intent unchanged. Literature and coding review. Updated references. |
| | **01/19/2024 Administrative Update.** Clinical benefit added. |
| | **12/02/2024 Consensus Review.** No change to intent. Updated references. |

Top