

## MEDICAL POLICY – 8.01.519

## Treatment of Hyperhidrosis

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RELATED MEDICAL POLICIES:

None

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## Introduction

Hyperhidrosis is a medical term that means excessive sweating. There are two types of hyperhidrosis: primary (focal) hyperhidrosis and secondary hyperhidrosis. Primary focal hyperhidrosis is sweating that's not due to another medical condition or is a side effect of medication. This kind of sweating is its own medical condition, and it takes place on specific parts of the body such as the hands, feet, underarms, or head and neck. These specific areas are known as focal areas.

The other type of hyperhidrosis is secondary hyperhidrosis. This is sweating that happens because of another medical reason such as diabetes, menopause, or obesity.

This policy describes when and what types of treatments may be medically necessary for primary focal and secondary hyperhidrosis.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

**Note:** This policy provides medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Unique clinical circumstances may warrant individual consideration, based on a review of applicable medical records.

Condition	Medical Necessity
<p><b>Primary focal hyperhidrosis</b></p>	<p><b>Treatment of primary (focal) hyperhidrosis using the following therapies (see Table 1) may be considered medically necessary when 1 or more of the following medical conditions are present:</b></p> <ul style="list-style-type: none"> <li>• Acrocyanosis of the hands or</li> <li>• History of persistent eczematous dermatitis in spite of medical treatments with topical dermatological or systemic anticholinergic agents or</li> <li>• History of recurrent secondary infections or</li> <li>• History of recurrent skin maceration with bacterial or fungal infections</li> </ul> <p><b>Ongoing/repeat treatments may be considered medically necessary to maintain improvements in physical function.</b></p> <p><b>Treatment of primary (focal) hyperhidrosis is considered not medically necessary in the absence of physical functional impairment (see Definition of Terms below) or any of the medical conditions in the list above.</b></p>

<b>Table 1. Treatment of Primary Hyperhidrosis Considered Medically Necessary or Investigational</b>		
Focal regions	Treatments that may be considered medically necessary (if a medical condition from the list above is present)	Treatments considered investigational (but not limited to):
Axillary (underarm)	<ul style="list-style-type: none"> <li>• Aluminum chloride 20% topical solution*</li> <li>• Botulinum toxin (if not adequately managed with topical agents, in patients 18 years old and older)</li> <li>• Endoscopic transthoracic sympathectomy [ETS] if conservative treatment has failed (ie, aluminum chloride or botulinum toxin, individually and in</li> </ul>	<ul style="list-style-type: none"> <li>• Axillary liposuction</li> <li>• Microwave treatment</li> <li>• Iontophoresis</li> <li>• Radiofrequency ablation</li> </ul>



**Table 1. Treatment of Primary Hyperhidrosis Considered Medically Necessary or Investigational**

Focal regions	Treatments that may be considered medically necessary (if a medical condition from the list above is present)	Treatments considered investigational (but not limited to):
	combination) • Surgical excision of axillary sweat glands, if conservative treatment has failed (ie, aluminum chloride or botulinum toxin, individually and in combination)	
Palmar (palm of hand)	• Aluminum chloride 20% topical solution* • Botulinum toxin type A products (if not adequately managed with topical agents, in patients 18 years and older) • ETS, if conservative treatment has failed (ie, aluminum chloride or botulinum toxin type A, individually and in combination)	• RimabotulinumtoxinB • Iontophoresis • Microwave treatment • Radiofrequency ablation
Plantar (sole of foot)	• Aluminum chloride 20% topical solution*	• Botulinum toxin • Iontophoresis • Lumbar sympathectomy • Microwave treatment • Radiofrequency ablation
Craniofacial (head/face)	• Aluminum chloride 20% topical solution* • ETS, if conservative treatment has failed (ie, aluminum chloride)	• Botulinum toxin • Iontophoresis • Microwave treatment • Radiofrequency ablation

\*Aluminum chloride solution is approved by FDA for treatment of primary hyperhidrosis. At least 1 botulinum toxin product is FDA-approved for treatment in adults of severe axillary hyperhidrosis inadequately managed by topical agents.

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

Condition	Medical Necessity
<b>Secondary hyperhidrosis</b>	<p><b>Treatment of severe secondary gustatory hyperhidrosis may be considered medically necessary (see Table 2) when 1 or more of the following medical conditions are present:</b></p> <ul style="list-style-type: none"> <li>• Diabetic neuropathies</li> <li>• Encephalitis</li> <li>• Frey syndrome</li> <li>• Herpes zoster parotitis</li> <li>• Parotid abscess</li> <li>• Syringomyelia</li> </ul>



Condition	Medical Necessity
	<p><b>Treatment of secondary hyperhidrosis is considered not medically necessary in the absence of a physical functional impairment (see <a href="#">Definition of Terms</a> below) or for other medical conditions not listed above.</b></p>

**Table 2. Treatment of Secondary Gustatory Hyperhidrosis Considered Medically Necessary or Investigational**

Treatments that may be considered medically necessary if a medical condition from the list above is present)	Treatments considered investigational (but not limited to):
<ul style="list-style-type: none"> <li>Aluminum chloride 20% topical solution*</li> <li>Surgical options, (ie tympanic neurectomy), if conservative treatment has failed</li> </ul>	<ul style="list-style-type: none"> <li>Botulinum toxin</li> <li>Iontophoresis</li> </ul>

\*FDA approved indication.

**Documentation Requirements**

**For Primary focal hyperhidrosis (excessive sweating)**  
**Clinical documentation supporting one or more medical conditions below and documentation of significant functional impairment:**

- Acrocyanosis of the hands (a bluish or purplish color to the hands)

**OR**

- History of persistent eczematous dermatitis (red, itchy skin) in spite of medical treatments with topical dermatological or systemic anticholinergic agents

**OR**

- History of recurrent secondary infections

**OR**

- History of recurrent skin maceration (skin that softens) and with bacterial or fungal infections

**For Secondary hyperhidrosis (excessive sweating)**  
**Clinical documentation supporting one or more medical conditions below and documentation of significant functional impairment:**

- Diabetic neuropathies



## Documentation Requirements

- Encephalitis
- Frey syndrome (injury to a specific nerve that causes sweating on the head and neck while eating, among other symptoms)
- Herpes zoster parotitis (inflammation of the main saliva glands due to shingles)
- Parotid abscess (infection of the main saliva glands)
- Syringomyelia (cyst within the spinal cord)

## Coding

Code	Description
CPT	
32664	Thoracoscopy, surgical; with thoracic sympathectomy

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Definition of Terms

- **Cosmetic:** In this policy, cosmetic services are those which are primarily intended to preserve or improve appearance. Cosmetic surgery is performed to reshape normal structures of the body in order to improve the patient's appearance or self-esteem.
- **Physical functional impairment:** In this policy, physical functional impairment means a limitation from normal (or baseline level) of physical functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of nearby body parts or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments.
- **Reconstructive surgery:** In this policy, reconstructive surgery refers to surgeries performed on abnormal structures of the body, caused by congenital defects, developmental



abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function.

A multispecialty working group 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:

- Age at onset younger than 25 years old
- Bilateral and relatively symmetric sweating
- Family history of focal hyperhidrosis
- Focal sweating stops during sleep
- Frequency of focal hyperhidrosis is at least once per week
- Impairment of daily activities

## Benefit Application

Nonsurgical agents may be covered under a pharmacy benefit.

## Evidence Review

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### Description

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

### Background

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 in nature, 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 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 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, 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.



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.

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 (eg, 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. Also, 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 [Appendix Table 1](#)) has had a good correlation to other assessment tools and is practical in the clinical setting.





## 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, an 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 to sham or active treatment in patients with various types of primary focal hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### **Botulinum Toxins**

For individuals who have primary axillary hyperhidrosis who receive botulinum toxin type A or B, the evidence includes RCTs and a meta-analysis. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Placebo-controlled RCTs have generally found better outcomes in the botulinum toxin groups. A meta-analysis 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 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 suggest 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 a meaningful 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. Placebo-controlled RCTs have generally found better outcomes in the botulinum toxin groups. RCTs comparing botulinum toxin type A formulations in patients with primary palmar hyperhidrosis have generally found no significant difference in outcomes. Although these studies had small sample sizes, their findings suggest 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 a meaningful 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 RCT 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 the effects of the technology on health outcomes.

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. RCTs are needed comparing botulinum toxin with placebo or active treatment in patients with primary plantar hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **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 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 versus sham therapy, but there was a high rate of skin-related adverse effects. Additional RCTs are needed comparing microwave with sham or active treatment in patients with various types of primary focal hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Radiofrequency Ablation**

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive radiofrequency ablation, the evidence includes a nonrandomized cohort study. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The cohort study, conducted in patients with palmar hyperhidrosis, found a higher cure rate in the surgery group than in the radiofrequency ablation group, and found a similar rate of compensatory sweating in both groups. RCTs are needed comparing radiofrequency ablation with sham or active treatment in patients with various types of primary focal hyperhidrosis. 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 qualitatively 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 qualitatively 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 case series. 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. Moreover, there have been substantial rates of compensatory sweating and concerns about adverse effects 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.

## Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in [Table 3](#).

**Table 3. Summary of Key Trials**

NCT No	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT01930604</a>	Botulinum Toxin Treatment in Craniofacial, Inguinal, Palmar, Plantar and Truncal Hyperhidrosis	588	Oct 2017 (ongoing)
<a href="#">NCT02854540</a>	Management of Palmar Hyperhidrosis with Hydrogel-based Iontophoresis	18	Aug 2018
<a href="#">NCT02295891</a>	MiraDry Treatment for Focal Axillary Hyperhidrosis (MiraDry Tx)	24	Jan 2019

NCT: national clinical trial

## Practice Guidelines and Position Statements

### *Society of Thoracic Surgeons*

The Society of Thoracic Surgeons published an expert consensus statement (2011) on the surgical treatment of hyperhidrosis.<sup>41</sup> The document states that endoscopic thoracic sympathectomy is the treatment of choice for patients with primary hyperhidrosis. They further recommended the following treatment strategies (with R referring to “rib” and the number to which rib):

- R3 interruption for palmar hyperhidrosis; an R4 interruption is also reasonable. The authors note a slightly higher rate of compensatory sweating with an R3, but R3 is also more effective at treating hyperhidrosis.



- R4 or R5 interruption for palmar-axillary, palmar-axillary-plantar or axillary hyperhidrosis alone; R5 interruption is also an option for axillary hyperhidrosis alone.
- R3 interruption for craniofacial hyperhidrosis without blushing; an R2 and R3 procedure is an option but may lead to a higher rate of compensatory sweating, and also increases the risk of Horner’s syndrome.

According to the statement, endoscopic thoracic sympathectomy has been recommended for patients with severe symptoms that cannot be managed with other therapies who meet the following criteria:

- Onset of hyperhidrosis at an early age (before 16 years)
- <25 years of age at time of surgery
- Body mass index <28 kg/m<sup>2</sup>
- No sweating during sleep
- No significant comorbidities
- Resting heart rate <55 beats per minute

### *American Academy of Neurology (AAN)*

The American Academy of Neurology issued guidelines (2008) on the use of botulinum toxin for the treatment of autonomic disorders and pain.<sup>42</sup> These guidelines were updated in 2013.<sup>43</sup>

**Table 4** summarizes the recommendations for botulinum toxin injection as a treatment of hyperhidrosis, by site and type of toxin:

**Table 4. Recommendation Levels<sup>a</sup> by Hyperhidrosis Site and Botulinum Toxin Type**

Botulinum Toxin	Axillary	Palmar	Gustatory
Botulinum neurotoxin type A	A	B	U
AbobotulinumtoxinA	B	U	U
IncobotulinumtoxinA	U	U	U
OnabotulinumtoxinA	B	U	U
RimabotulinumtoxinB	U	U	U



<sup>a</sup> A: established as effective, has at least 2 consistent Class I studies; B: probably effective, has at least 1 class I study or at least 2 consistent class II studies; C: possibly effective, has at least 1 class II study or at least 2 consistent class II studies; U: inadequate or conflicting data, treatment is unproven.

## ***National Institute for Health and Care Excellence (NICE)***

The National Institute for Health and Care Excellence issued guidance in 2014 stating that there was sufficient evidence for the efficacy and safety of endoscopic thoracic sympathectomy for primary facial blushing to support the use of the procedure.<sup>44</sup>

The Institute also issued guidance in 2014 on endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb.<sup>45</sup> The guidance stated that “current evidence on the efficacy and safety of endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb is adequate to support the use of this procedure.” Also: “Due to the risk of side effects, this procedure should only be considered in patients suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments.”

## **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

## **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, and craniofacial); it is available by prescription. Additional topical medicines approved by the FDA include Hypercare Topical and Xerac AC.

In 2004 botulinum toxin type A (Botox®; Allergan Pharmaceuticals Ireland) was approved by the FDA through the biologic license application process for use to treat primary axillary hyperhidrosis (severe underarm sweating) that cannot be managed by topical agents. In 2009, this product was renamed to onabotulinumtoxinA. Other botulinum toxin products approved by FDA for treatment of hyperhidrosis through the biologic license application process include:

- 2000: RimabotulinumtoxinB (Myobloc®; Solstice Neurosciences)



- 2009: AbobotulinumtoxinA (Dysport®; Medicis Pharmaceutical)
- 2010: IncobotulinumtoxinA (Xeomin®; Merz Pharmaceuticals)

None of the other botulinum toxin products are specifically approved for treatment of hyperhidrosis.

In 2009, the FDA approved the following revisions to the prescribing information of botulinum toxin products:

- "A Boxed Warning highlighting the possibility of experiencing potentially life-threatening distant spread of toxin effect from injection site after local injection.
- A Risk Evaluation and Mitigation Strategy (REMS) that includes a Medication Guide to help patients understand the risk and benefits of botulinum toxin products.
- Changes to the established drug names to reinforce individual potencies and prevent medication errors. The potency units are specific to each botulinum toxin product, and the doses or units of biological activity cannot be compared or converted from one product to another botulinum toxin product. The new established names reinforce these differences and the lack of interchangeability among products."

In 2011, the miraDry® System (Miramar Labs) was cleared by the 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 two sessions for a total duration of approximately one 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

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## Appendix

**Appendix Table 1. 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

## History

Date	Comments
09/07/99	Add to Therapy Section - New Policy
11/12/02	Replace Policy - Policy reviewed without literature review; new review date only.
09/12/03	Replace Policy - Policy updated regarding iontophoresis as a treatment for hyperhidrosis based on 2003 TEC Assessment; policy statement revised to indicate that this is considered investigational (previously considered medically necessary). Policy changed from "AR" to "BC."
03/09/04	Replace Policy - Policy revised regarding surgical treatments of axillary hyperhidrosis; surgical excision considered medically necessary, axillary liposuction considered investigational.
06/08/04	Replace Policy - Correction to policy statement to remove surgical excision of axillary sweat glands from investigative statement in Policy Section.
03/08/05	Replace Policy - Policy updated with literature search; policy statement unchanged.
02/06/06	Codes updated - No other changes.



Date	Comments
06/02/06	Disclaimer and Scope updates - No other changes.
06/12/07	New PR Policy - Policy replaces BC.8.01.19. In the treatment of primary hyperhidrosis, treatment is considered medically necessary when physical functional impairment exists; and cosmetic when no physical functional impairment is present; axillary liposuction is considered investigational. Botox is indicated as medically necessary treatment for secondary gustatory hyperhidrosis. Definitions of physical functional impairment, cosmetic and reconstructive surgery added to Benefit Application section.
11/12/07	Code updated - CPT code 89230 removed as directed by RPIW 11/8/07.
04/08/08	Replace Policy - Policy statement regarding aluminum chloride, iontophoresis, botulinum toxin, endoscopic transthoracic sympathectomy and surgical excision of axillary sweat glands changed from "cosmetic" to "not medically necessary" when there is no physical functional impairment. Description, Rationale and Reference sections updated.
05/12/09	Replace Policy - Policy updated with literature search; no change to policy statement. References added.
08/11/09	Code update - 68409 & 64818 added, no other changes.
12/08/09	Code Update - 89230 added back to policy.
02/09/10	Code Update - New 2010 code added.
04/13/10	Replace Policy - Policy updated with literature search; no change to policy statement.
11/15/10	Codes Updated - Additional J Codes added.
05/10/11	Replace Policy - Policy updated with literature search; no change to policy statement. Reference added.
07/10/12	Replace policy. An extensive reformatting of policy statement was done to mirror the layout of Blue Cross Policy 8.01.19 Treatment of Hyperhidrosis. Added Microwave treatment as investigational for primary focal hyperhidrosis. The Description and Rationale sections have been updated. Reference 2 replaced. Added CPT 69676 tympanic neurectomy and 97033 application of modality iontophoresis. Added ICD-9 procedure 99.27 Iontophoresis, added J3490 unclassified drugs, J0588 Injection, incobotulinumtoxinA, 1 unit.
10/09/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
07/08/13	Replace policy. Policy statement has addition of <i>radiofrequency ablation</i> as investigational for treatment of palmer hyperhidrosis. Rationale updated based on a literature review through May 2013. References 4, 19, 20 and 32 added; other references renumbered or removed. Some policy sections reformatted for readability. Policy statement changed as noted.
07/31/14	Annual Review. Policy updated with literature search through May, 2014. References 5, 15, 20, 41 added; others renumbered/removed. Policy statements unchanged.



Date	Comments
07/14/15	Annual Review. Policy updated with literature search through April, 2015. Policy statements reformatted and edited for clarity. The word "complications" changed to "conditions" in the policy statements. References 5, 33 added, reference 30 removed; others renumbered. Policy statements clarified, intent is unchanged. Coding update: CPT codes 64650, 64653, 64809, 64818, 95923, 97033, and HCPCS codes J0585, J0586, J0587, J0588 & J3490 removed. Retained only CPT code 32664 that specifically relates to this policy. ICD-9 and ICD-10 procedure codes removed; they were listed for informational purposes only. Policy 5.01.512 removed from Related Policies section.
08/01/16	Annual Review, approved July 12, 2016. Policy updated with literature review through March 22, 2016; references 14, 30 and 37 added. Policy statements unchanged. Code table revised in the Policy Guidelines section, only CPT 32664 is retained for review purposes.
12/01/17	Annual Review, approved November 9, 2017. Literature review completed through October 2017. No new references added. Policy statements unchanged.
07/01/18	Annual Review, approved June 12, 2018, effective October 5, 2018. Policy updated with literature review through February 2018; references 1, 7, 20, 32-34, and 43 added. Policy section revised to align with evidence summary; Policy statements for iontophoresis and radiofrequency ablation changed to investigational for all categories. Botulinum toxin changed to investigational for plantar, craniofacial and secondary gustatory hyperhidrosis

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

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PO Box 91102, Seattle, WA 98111  
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357  
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You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services  
200 Independence Avenue SW, Room 509F, HHH Building  
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)  
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**This Notice has Important Information.** This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

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ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀዳሾች ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፋፈል እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

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ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ឆ្លើយតបនូវសំណួរ ឬប្រាកដន្នយុទ្ធសាស្ត្រ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដំណោះស្រាយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).