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.
**Condition**

**Medical Necessity**

**Primary focal hyperhidrosis**

Treatment of primary focal hyperhidrosis using the following therapies (see Table 1) may be considered medically necessary 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

**Hyperhidrosis**

Treatment of hyperhidrosis is considered not medically necessary in the absence of functional impairment (see Definition of Terms below) or any of the above medical conditions.

**Severe secondary gustatory hyperhidrosis**

The following treatments may be considered medically necessary 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 and iontophoresis.

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**Table 1** summarizes the treatments that may be considered medically necessary by focal region.

**Table 2** summarizes the treatments that are considered investigational by focal region.

**Table 1. Treatments for Hyperhidrosis Considered Medically Necessary**

<table>
<thead>
<tr>
<th>Focal Regions</th>
<th>Treatments Considered Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axillary</td>
<td>Aluminum chloride 20% solution</td>
</tr>
</tbody>
</table>
### Focal Regions

<table>
<thead>
<tr>
<th>Treatments Considered Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botulinum toxin for severe primary axillary hyperhidrosis inadequately managed with topical agents, in patients ≥18 y</td>
</tr>
<tr>
<td>ETS and surgical excision of axillary sweat glands, if conservative treatment (ie, aluminum chloride or botulinum toxin, individually and in combination) has failed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Palmar</th>
<th>Aluminum chloride 20% solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botulinum toxin type A products for severe primary palmar hyperhidrosis inadequately managed with topical agents, in patients ≥18 y</td>
<td></td>
</tr>
<tr>
<td>ETS, if conservative treatment (ie, aluminum chloride or botulinum toxin type A, individually and in combination) has failed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Plantar</th>
<th>Aluminum chloride 20% solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Craniofacial</td>
<td>Aluminum chloride 20% solution</td>
</tr>
<tr>
<td>ETS, if conservative treatment (ie, aluminum chloride) has failed</td>
<td></td>
</tr>
</tbody>
</table>

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: U.S. Food and Drug Administration.

### Table 2. Treatments for Hyperhidrosis Considered Investigational

<table>
<thead>
<tr>
<th>Focal Regions</th>
<th>Treatments Considered Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axillary</td>
<td>Axillary liposuction</td>
</tr>
<tr>
<td></td>
<td>Iontophoresis</td>
</tr>
<tr>
<td></td>
<td>Microwave treatment</td>
</tr>
<tr>
<td></td>
<td>Radiofrequency ablation</td>
</tr>
<tr>
<td>Palmar</td>
<td>RimabotulinumtoxinB</td>
</tr>
<tr>
<td></td>
<td>Iontophoresis</td>
</tr>
<tr>
<td></td>
<td>Microwave treatment</td>
</tr>
<tr>
<td></td>
<td>Radiofrequency ablation</td>
</tr>
<tr>
<td>Plantar</td>
<td>Botulinum toxin</td>
</tr>
<tr>
<td></td>
<td>Iontophoresis</td>
</tr>
<tr>
<td></td>
<td>Lumbar sympathectomy</td>
</tr>
<tr>
<td></td>
<td>Microwave treatment</td>
</tr>
<tr>
<td></td>
<td>Radiofrequency ablation</td>
</tr>
</tbody>
</table>
Focal Regions | Treatments Considered Investigational
--- | ---
Craniofacial | Botulinum toxin
| Iontophoresis
| Microwave treatment
| Radiofrequency ablation

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) despite 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
- 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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
</tbody>
</table>
### 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.

**Primary focal hyperhidrosis:** 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
- bilateral and relatively symmetric sweating
- cessation of focal sweating during sleep
- frequency of at least once per week
• impairment of daily activities
• positive family history

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 3 below).

Table 3. The Hyperhidrosis Disease Severity Scale

<table>
<thead>
<tr>
<th>Score</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>My underarm sweating is never noticeable and never interferes with my daily activities</td>
</tr>
<tr>
<td>2</td>
<td>My underarm sweating is tolerable but sometimes interferes with my daily activities</td>
</tr>
<tr>
<td>3</td>
<td>My underarm sweating is barely tolerable and frequently interferes with my daily activities</td>
</tr>
<tr>
<td>4</td>
<td>My underarm sweating is intolerable and always interferes with my daily activities</td>
</tr>
</tbody>
</table>

Benefit Application

Nonsurgical agents may be managed under a pharmacy benefit.

Evidence Review

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.
Background

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 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 the treatment of the underlying cause, such as discontinuing certain drugs or hormone replacement therapy as a treatment for menopausal symptoms.
Iontophoresis uses an 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 the 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 event. 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, a randomized controlled trial (RCT), and case series. The 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 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. The 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. 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 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 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. The 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. RCTs 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 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. The relevant outcomes are symptoms, quality of life, and treatment-related morbidity. One small placebo-controlled randomized trials 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. The relevant outcomes are symptoms, quality of life, and treatment-related morbidity. RCTs are needed comparing botulinum toxin with placebo or active treatment in patients who had 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. The 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. 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 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 two small RCTs and a nonrandomized cohort study. The 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 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. The 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. The 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. The 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. The 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. The 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 4.

**Table 4. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02295891</td>
<td>MiraDry Treatment for Focal Axillary Hyperhidrosis (MiraDry Tx)</td>
<td>24</td>
<td>Jul 2020</td>
</tr>
<tr>
<td>NCT03236012</td>
<td>Hyperhidrosis of the Residual Limb in Patients With Amputations: Developing a Treatment Approach</td>
<td>25</td>
<td>Dec 2023</td>
</tr>
<tr>
<td>NCT03433859</td>
<td>Prospective Multicentric Open Randomised Controlled Trial Comparing Topical Aluminium Chloride to OnabotulinumtoxinA Intradermal Injections in Residual Limb Hyperhidrosis (Lower Limbs)</td>
<td>54</td>
<td>Sep 2020</td>
</tr>
<tr>
<td>NCT03921320</td>
<td>Evaluation of Compensatory Sweating After Unilateral Videothoracoscopic Sympathectomy of the Dominant Side or Sequential Bilateral Videothoracoscopic Sympathectomy: a Multicentric Randomized Trial</td>
<td>200</td>
<td>Dec 2020</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01930604</td>
<td>Botulinum Toxin Treatment in Craniofacial, Inguinal, Palmar, Plantar and Truncal Hyperhidrosis</td>
<td>588</td>
<td>Oct 2019 (status unknown)</td>
</tr>
<tr>
<td>NCT02854540</td>
<td>Management of Palmar Hyperhidrosis with Hydrogel-based Iontophoresis</td>
<td>13</td>
<td>Aug 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
Practice Guidelines and Position Statements

Society of Thoracic Surgeons

In 2011, the Society of Thoracic Surgeons published an expert consensus statement on the surgical treatment of hyperhidrosis.44 The document stated that endoscopic thoracic sympathectomy is the treatment of choice for patients with primary hyperhidrosis. It 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 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 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 the time of surgery
- Body mass index <28 kg/m²
- No sweating during sleep
- No significant comorbidities
- Resting heart rate <55 beats per minute

American Academy of Neurology

In 2008, the American Academy of Neurology issued guidelines on the use of botulinum toxin for the treatment of autonomic disorders and pain.45 These guidelines were updated in 2013.46
Table 5 summarizes the recommendations for botulinum toxin injection as a treatment of hyperhidrosis, by site and type of toxin:

**Table 5. Recommendation Levels by Hyperhidrosis Site and Botulinum Toxin Type**

<table>
<thead>
<tr>
<th>Botulinum Toxin</th>
<th>Axillary</th>
<th>Palmar</th>
<th>Gustatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botulinum neurotoxin type A</td>
<td>A</td>
<td>B</td>
<td>U</td>
</tr>
<tr>
<td>AbobotulinumtoxinA</td>
<td>B</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>IncobotulinumtoxinA</td>
<td>U</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>OnabotulinumtoxinA</td>
<td>B</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>RimabotulinumtoxinB</td>
<td>U</td>
<td>U</td>
<td>U</td>
</tr>
</tbody>
</table>

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**

In 2014, the National Institute for Health and Care Excellence (NICE) issued guidance 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.47

The Institute also issued guidance in 2014 on endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb.48 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.
Regulatory Status

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 onabotulinumtoxinA. Other botulinum toxin products approved by
the 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 is specifically approved for the treatment of
hyperhidrosis.

The FDA (2009) 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 for marketing 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.
References


2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Iontophoresis for Medical Indications. TEC Assessments 2003; Volume 18, Tab 3.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/20</td>
<td>New policy number (8.01.19), approved March 19, 2020, effective April 1, 2020. This policy replaces 8.01.519. Policy statements remain unchanged; this is effectively a policy renumber.</td>
</tr>
</tbody>
</table>

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Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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 S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Email AppealsDepartmentInquiries@Premera.com

Getting Help in Other Languages

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).

Arabic (Arabic): يحيى هذا الإشعار معلومات هامة. قد يكون هذا الإشعار معلومات مهمة للأشخاص الذين يتحدثون لغات مختلفة.

Disney Blue Cross يشمل هذه المعلومات ويحتوي على معلومات تساعد على تطبيقها في اللغة العربية.

Premera Blue Cross يشمل هذه المعلومات ويحتوي على معلومات تساعد على تطبيقها في اللغة العربية.

Call 800-722-1471 (TTY: 800-842-5357).


Kreyòl ayisyen (Creole): Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsèn aplan kisayon w lan oswa konvènt konsènan ak konvènt lòt. You have the right to get information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

This page contains important information. Your right to obtain and use this information and assistance is not affected by your language or ability to speak.

English (Portuguese): This page contains important information. This page may not be understood by everyone.

English (Japanese): This page contains important information. You have the right to obtain this information and assistance in any language and do not need to pay.

Romanian (Russian): You have the right to obtain this information and assistance in any language and do not need to pay.

Vietnamese (Vietnamese): This page contains important information. Your right to obtain and use this information and assistance is not affected by your language or ability to speak.