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.
This policy outlines when the treatment of hyperhidrosis is considered medically necessary (click condition to navigate to that section):

- **Primary focal hyperhidrosis**
- **Severe secondary gustatory hyperhidrosis**

*Note:  See Definition of Terms below*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Indications</th>
</tr>
</thead>
</table>
| Hyperhidrosis      | Treatment of hyperhidrosis in the absence of a functional impairment* as described in this policy is considered not medically necessary.  
*Note:  See Definition of Terms below* |
| Primary focal hyperhidrosis | Treatment of primary focal hyperhidrosis may be considered medically necessary for treatment of a functional impairment* as seen in any of the following medical conditions:  
- Acrocyanosis (bluish discoloration) of the hands;  
- History of recurrent skin maceration with bacterial or fungal infections;  
- History of recurrent secondary infections;  
- History of persistent eczematous dermatitis despite medical treatments with topical dermatologic or systemic anticholinergic agents  
*Note:  See Definition of Terms below* |

Use links below to navigate to treatment options by region:
- **Axillary**
- **Palmar**
- **Plantar**
- **Craniofacial**

<table>
<thead>
<tr>
<th>Focal region</th>
<th>Treatment</th>
</tr>
</thead>
</table>
| Primary focal hyperhidrosis | The following treatments may be considered medically necessary for individuals ≥ 18 years of age to treat the axillary region when treatment of a functional impairment* criteria have been met (see above):  
- Aluminum chloride 20% solution  
- Botulinum toxin for severe primary axillary hyperhidrosis inadequately managed with topical agents (e.g., OTC aluminum chloride antiperspirant, glycopyrronium tosylate wipes)  
- ETS and surgical excision of axillary sweat glands, if conservative treatment (i.e., aluminum chloride 20% solution or botulinum toxin, individually and in combination) has failed |
<table>
<thead>
<tr>
<th>Condition</th>
<th>Indications</th>
</tr>
</thead>
</table>
| Primary focal hyperhidrosis | **The following treatments are considered investigational for the treatment of axillary regions:**  
  - Axillary liposuction  
  - Iontophoresis  
  - Microwave treatment  
  - Radiofrequency ablation |
| Primary focal hyperhidrosis | **The following treatments may be considered medically necessary for individuals ≥ 18 years of age to treat the palmar region when treatment of a functional impairment* criteria have been met (see above):**  
  - Aluminum chloride 20% solution  
  - Botulinum toxin type A products for severe primary palmar hyperhidrosis inadequately managed with topical agents (e.g., OTC aluminum chloride antiperspirant)  
  - ETS, if conservative treatment (i.e., aluminum chloride 20% solution or botulinum toxin type A, individually and in combination) has failed |
| Primary focal hyperhidrosis | **The following treatments are considered investigational for the treatment of the palmar region:**  
  - RimabotulinumtoxinB  
  - Iontophoresis  
  - Microwave treatment  
  - Radiofrequency ablation |
| Primary focal hyperhidrosis | **The following treatments may be considered medically necessary to treat the plantar region when treatment of a functional impairment* criteria have been met (see above):**  
  - Aluminum chloride 20% solution |
| Primary focal hyperhidrosis | **The following treatments are considered investigational for treatment of the plantar region:**  
  - Botulinum toxin  
  - Iontophoresis  
  - Lumbar sympathectomy  
  - Microwave treatment |
| Condition                        | Indications                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 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; OTC: over-the-counter. |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| **Primary focal hyperhidrosis** | **Craniofacial**                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                                 | The following treatments may be considered medically necessary to treat the craniofacial region when treatment of a functional impairment* criteria have been met (see above):  
  • Aluminum chloride 20% solution  
  • ETS, if conservative treatment (i.e., aluminum chloride 20% solution) has failed  |
|                                 | The following treatments are considered investigational for the treatment of the craniofacial region:  
  • Botulinum toxin  
  • Iontophoresis  
  • Microwave treatment  
  • Radiofrequency ablation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| **Severe secondary gustatory hyperhidrosis** | The following treatments may be considered medically necessary to treat severe secondary gustatory hyperhidrosis:  
  • Aluminum chloride 20% solution  
  • Surgical options (i.e., tympanic neurectomy) if conservative treatment has failed  |
|                                 | The following treatments are considered investigational as a treatment for severe secondary gustatory hyperhidrosis including, but not limited to:  
  • Botulinum toxin  
  • Iontophoresis  

---

**Approval**

<table>
<thead>
<tr>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial authorization</strong></td>
</tr>
</tbody>
</table>
Authorization criteria

Future re-authorization of Botox (onabotulinumtoxinA), Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), and Xeomin (incobotulinumtoxinA) for all covered indications in this policy may be approved up to 3 years as long as the drug-specific coverage criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.

Documentation Requirements

For primary focal hyperhidrosis (excessive sweating)
Clinical documentation supporting treatment of a functional impairment as seen in one or more of the medical conditions noted below along with the affected focal region (axillary, palmar, plantar, or craniofacial) and the requested treatment (aluminum chloride 20% solution, botulinum toxin/botulinum toxin type A, or endoscopic transthoracic sympathectomy):

- 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 severe secondary gustatory hyperhidrosis (excessive sweating after eating spicy foods)
Clinical documentation noting the affected area of excessive sweating and the requested treatment:

- Aluminum chloride 20% solution; or
- Surgical options (i.e., tympanic neurectomy) if conservative treatment has failed

Coding guidelines for this policy: When HCPCS code J0585, J0586, J0587, or J0588 is denied, the related injection codes(s) will also be subject to denial.
### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>32664</td>
<td>Thoracoscopy, surgical; with thoracic sympathectomy</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>J0585</td>
<td>Injection, onabotulinumtoxinA, (Botox) 1 unit</td>
</tr>
<tr>
<td>J0586</td>
<td>Injection, abobotulinumtoxinA, (Dysport) 5 units</td>
</tr>
<tr>
<td>J0587</td>
<td>Injection, rimabotulinumtoxinB, (Myobloc) 100 units</td>
</tr>
<tr>
<td>J0588</td>
<td>Injection, incobotulinumtoxinA, (Xeomin) 1 unit</td>
</tr>
<tr>
<td>64650</td>
<td>Chemodenervation of eccrine glands; both axillae</td>
</tr>
<tr>
<td>64653</td>
<td>Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day</td>
</tr>
<tr>
<td>64818</td>
<td>Sympathectomy, lumbar</td>
</tr>
</tbody>
</table>

**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 individual’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 (HDSS) is used by individuals to rate the severity of their symptoms on a scale of 1 to 4 (see Table 1 below).

<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 psychological and social functioning. Various treatments for hyperhidrosis are available, such as topical antiperspirant agents (e.g., 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 (e.g., tricyclic antidepressants, selective serotonin reuptake inhibitors) or underlying diseases/conditions (e.g., 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, topical anticholinergic medications, 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 has 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 individuals 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
individuals, 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 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 (HDSS) (see 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 (i.e., 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 individuals with various types of primary focal hyperhidrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Botulinum Toxins**

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

For individuals who have primary palmar hyperhidrosis who receive botulinum toxin type A, the evidence includes RCTs. 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 individuals with primary palmar hyperhidrosis have generally found no significant differences in outcomes. Although these studies had small sample sizes, their findings suggested that, with appropriate dosage adjustments, there are similar levels of efficacy and adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary palmar hyperhidrosis who receive botulinum toxin type B, the evidence includes an RCT. The relevant outcomes are symptoms, quality of life, and treatment-related morbidity. One small placebo-controlled randomized trial did not clearly demonstrate the efficacy of botulinum toxin type B in individuals with palmar hyperhidrosis. Also, a high rate of adverse events was reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

**Microwave**

For individuals who have primary focal hyperhidrosis (i.e., 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 systematic review and RCT found a short-term benefit of microwave treatment in reducing hyperhidrosis but also reported skin-related adverse events (e.g., pain, altered sensation). Additional RCTs are needed comparing microwave treatment with sham or active treatment in
individuals with various types of primary focal hyperhidrosis. The evidence is insufficient to
determine that the technology results in an improvement in the net health outcome.

Radiofrequency Ablation

For individuals who have primary focal hyperhidrosis (i.e., axillary, palmar, plantar, craniofacial) who receive radiofrequency ablation (RFA), 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 individuals with severe bilateral palmar hyperhidrosis resistant to conservative treatment. Two small RCTs that compared RFA to botulinum toxin A in individuals with palmar or axillary hyperhidrosis had conflicting results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 an 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 an 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 that the technology results in an improvement in the net health outcome.

**Secondary Gustatory Hyperhidrosis**

For individuals who have severe secondary gustatory hyperhidrosis who receive iontophoresis or botulinum toxin, the evidence includes uncontrolled studies and systematic reviews. 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 that the technology results in an improvement in the net health outcome.

For individuals who have severe secondary gustatory hyperhidrosis who receive tympanic neurectomy, the evidence includes uncontrolled studies and systematic reviews. 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 an improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

**Table 2. 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>Microwave Energy-induced Thermolysis of Axillary Apocrine Glands and Hair Follicles Will Result in Improvement of Secondary Psychopathology Related to Hyperhidrosis</td>
<td>24</td>
<td>Nov 2023</td>
</tr>
<tr>
<td>NCT03921320</td>
<td>Evaluation of Compensatory Sweating After Unilateral Videothoracoscopic Sympathectomy of the Dominant Side</td>
<td>200</td>
<td>Dec 2023</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT05737914</td>
<td>Bilateral Endoscopic Thoracic T3 Sympathectomy Versus T3 Radiofrequency Ablation for Treatment of Primary Palmar Hyperhidrosis</td>
<td>68</td>
<td>Oct 2023</td>
</tr>
<tr>
<td>NCT05057117</td>
<td>Longevity of Microwave Thermolysis and Botulinum Toxin A for Treatment of Axillary Hyperhidrosis: a Randomized Intra-Individual Trial</td>
<td>30</td>
<td>Jul 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>Mar 2021</td>
</tr>
<tr>
<td>NCT01930604</td>
<td>Botulinum Toxin Treatment in Craniofacial, Inguinal, Palmar, Plantar and Truncal Hyperhidrosis, a Randomized, Double Blind, Placebo Controlled Study</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>
<tr>
<td>NCT03236012</td>
<td>Hyperhidrosis of the Residual Limb in Patients With Amputations: Developing a Treatment Approach</td>
<td>25</td>
<td>Feb 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

**Practice Guidelines and Position Statements**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.
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. These guidelines were updated in 2013 and retired in 2017. Table 3 summarizes the recommendations for botulinum toxin injection as a treatment of hyperhidrosis, by site and type of toxin:

Table 3. 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 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.

The Institute also issued guidance in 2014 on endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb. 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 individuals suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments.”

For severe primary axillary hyperhidrosis, NICE issued guidance in 2017 on the use of transcutaneous microwave ablation. The guidance stated that there is inadequate evidence in both quantity and quality to evaluate the safety and efficacy of microwave ablation.
Society of Thoracic Surgeons

In 2011, the Society of Thoracic Surgeons published an expert consensus statement on the surgical treatment of hyperhidrosis. The document stated that endoscopic thoracic sympathectomy is the treatment of choice for individuals 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 individuals 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

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 U.S. Food and Drug Administration (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 non-cosmetic indications, but not specifically approved for treatment of hyperhidrosis include:

2000: RimabotulinumtoxinB (Myobloc; Solstice Neurosciences)

2009: AbobotulinumtoxinA (Dysport; Medicis Pharmaceutical)

2010: IncobotulinumtoxinA (Xeomin; Merz Pharmaceuticals).

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 individuals 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.”

The REMS requirement, provision of the medication guide, has since been removed and there are no current REMS requirements for botulinum toxin products.¹

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.


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


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**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/07/99</td>
<td>Add to Therapy Section - New Policy</td>
</tr>
<tr>
<td>11/12/02</td>
<td>Replace Policy - Policy reviewed without literature review; new review date only.</td>
</tr>
<tr>
<td>09/12/03</td>
<td>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.”</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>03/09/04</td>
<td>Replace Policy - Policy revised regarding surgical treatments of axillary hyperhidrosis; surgical excision considered medically necessary, axillary liposuction considered investigational.</td>
</tr>
<tr>
<td>06/08/04</td>
<td>Replace Policy - Correction to policy statement to remove surgical excision of axillary sweat glands from investigative statement in Policy Section.</td>
</tr>
<tr>
<td>03/08/05</td>
<td>Replace Policy - Policy updated with literature search; policy statement unchanged.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>06/02/06</td>
<td>Disclaimer and Scope updates - No other changes.</td>
</tr>
<tr>
<td>06/12/07</td>
<td>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. Botulinum toxin is indicated as medically necessary treatment for secondary gustatory hyperhidrosis. Definitions of physical functional impairment, cosmetic and reconstructive surgery added to Benefit Application section.</td>
</tr>
<tr>
<td>11/12/07</td>
<td>Code updated - CPT code 89230 removed as directed by RPIW 11/8/07.</td>
</tr>
<tr>
<td>04/08/08</td>
<td>Replace Policy - Policy statement regarding aluminum chloride, iontophoresis, botulinum toxin, endoscopic transthoracic sympathectomy and surgical excision of axillary sweat glands changed from &quot;cosmetic&quot; to &quot;not medically necessary&quot; when there is no physical functional impairment. Description, Rationale and Reference sections updated.</td>
</tr>
<tr>
<td>05/12/09</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement. References added.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Code update - 68409 &amp; 64818 added, no other changes.</td>
</tr>
<tr>
<td>12/08/09</td>
<td>Code Update - 89230 added back to policy.</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Code Update - New 2010 code added.</td>
</tr>
<tr>
<td>04/13/10</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement.</td>
</tr>
<tr>
<td>11/15/10</td>
<td>Codes Updated - Additional J Codes added.</td>
</tr>
<tr>
<td>05/10/11</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement. References added.</td>
</tr>
<tr>
<td>07/10/12</td>
<td>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.</td>
</tr>
<tr>
<td>10/09/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>07/08/13</td>
<td>Replace policy. Policy statement has addition of <em>radiofrequency ablation</em> 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.</td>
</tr>
<tr>
<td>07/14/15</td>
<td>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 &amp; 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.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>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.</td>
</tr>
<tr>
<td>12/01/17</td>
<td>Annual Review, approved November 9, 2017. Literature review completed through October 2017. No new references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>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</td>
</tr>
<tr>
<td>09/01/19</td>
<td>Annual Review, approved August 6, 2019. Policy updated with literature review through October 2018; reference added. Policy statements unchanged.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>Delete policy, approved March 19, 2020, effective April 1, 2020. This policy is replaced with 8.01.19, Policy statements remain unchanged; this is effectively a policy renumber.</td>
</tr>
<tr>
<td>09/01/21</td>
<td>Annual Review, approved August 3, 2021. Policy updated with literature review through May 6, 2021; references added. Format of policy statements edited from tabular to list, but intent unchanged.</td>
</tr>
<tr>
<td>09/01/22</td>
<td>Policy renumbered, approved August 9, 2022 from 8.01.19 Treatment of Hyperhidrosis to 8.01.519 Treatment of Hyperhidrosis. Policy updated with literature review through April 29, 2022; no references added. Policy statements unchanged. Added HCPCS codes J0585, J0586, J0587 and J0588.</td>
</tr>
</tbody>
</table>
### Date | Comments
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03/01/23 | Interim Review, approved February 14, 2023. Policy criteria has been reformatted for greater ease of understanding. Policy intent unchanged. Initial and re-authorization criteria added. Changed the wording from "patient" to "individual" throughout the policy for standardization. Added CPT codes 64650, 64653, 64818.
09/01/23 | Annual Review, approved August 7, 2023. Policy updated with literature review through May 3, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.

**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). ©2023 Premera All Rights Reserved.

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ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).


注意事項: 如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY: 711)。

注意: 如果您使用簡體中文,您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY: 711)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телефон: 711).

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Language Assistance