Clinical Policy Title: Treatment of hyperhidrosis

Clinical Policy Number: 16.02.01

Effective Date: September 1, 2013
Initial Review Date: December 10, 2012
Most Recent Review Date: November 18, 2015
Next Review Date: November, 2016

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the treatment of hyperhidrosis to be clinically proven and, therefore, medically necessary when the following criteria are met:

A. Primary focal hyperhidrosis

Treatment of primary hyperhidrosis may be considered medically necessary when one of the following medical complications is present:

- Acrocyanosis of the hands.
- History of recurrent skin maceration with bacterial or fungal infections.
- History of recurrent secondary infections.
- History of persistent eczematous dermatitis in spite of medical treatments with topical dermatological or systemic anticholinergic agents.
Focal regions | Treatments considered medically necessary:
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Axillary | • Aluminum chloride 20% solution.*
• Botulinum toxin (BTX)* (see Select Health of South Carolina clinical policy for botulinum toxin) for severe primary axillary hyperhidrosis that is inadequately managed with topical agents* in patients 18 years and older.
• Endoscopic transthoracic sympathectomy (ETS) and surgical excision of axillary sweat glands, if conservative treatment (i.e., aluminum chloride or botulinum toxin, individually and in combination) has failed.
Palmar | • Aluminum chloride 20% solution.*
• BTX* in the affected areas for severe primary palmar hyperhidrosis that is inadequately managed with topical agents* in patients 18 years and older.
• ETS if conservative treatment (i.e., aluminum chloride or botulinum toxin, individually and in combination) has failed.
Plantar | • Aluminum chloride 20% solution.*
Craniofacial | • Aluminum chloride 20% solution.*
• ETS if conservative treatment (i.e., aluminum chloride) has failed.

*U.S. Food and Drug Administration (FDA) approved indication.

B. Secondary hyperhidrosis

Secondary hyperhidrosis is a medical condition characterized by excessive sweating, which may be generalized. This condition may also include craniofacial sweating. Secondary hyperhidrosis can occur as a result of olfactory or gustatory stimuli, neurologic lesions, intrathoracic neoplasms, Raynaud’s disease, and Frey’s syndrome.

The following treatments may be considered medically necessary for patients with severe gustatory hyperhidrosis:

a. Aluminum chloride 20% solution.*

b. Surgical options (i.e., tympanic neurotomy), if conservative treatment has failed.

*FDA-approved indication.

Limitations:

All other treatment for hyperhidrosis is not medically necessary. Additionally, the following treatments are considered not medically necessary:

• Axillary liposuction.
• Iontophoresis.
• RimabotulinumtoxinB (palmar).
• BTX-A or BTX-B (plantar, craniofacial, or secondary).
• Lumbar sympathectomy (plantar).
• Microwave thermolysis (Miradry).

The following treatments (non-exhaustive) are considered investigational for treatment of severe gustatory hyperhidrosis:

• BTX-A or BTX-B.
• Iontophoresis.

**Alternative covered services:**

Physician office consultations.

**Background**

Hyperhidrosis is a medical condition that causes a patient to perspire in excess of the level required to maintain a normal body temperature. Hyperhidrosis is categorized as either primary or secondary. Primary hyperhidrosis is induced by sympathetic hyperactivity and is idiopathic in nature, beginning during adolescence or earlier and typically involving the hands (palmar), feet (plantar), underarms (axillar), or face (craniofacial). Secondary hyperhidrosis can occur at any time in life and may result from a variety of medications, such as tricyclic antidepressants or selective serotonin reuptake inhibitors (SSRIs), or other underlying diseases/conditions, such as febrile illnesses, thyroid or pituitary glandular disorders, tumors, gout, diabetes mellitus or menopause. Secondary hyperhidrosis is usually classified as generalized or craniofacial, although it may also be palmpoplantar and gustatory.

Symptoms of primary hyperhidrosis include visible, excessive sweating of at least six months’ duration without apparent cause and with at least two of the following additional characteristics: bilateral and relatively symmetric sweating, frequency of at least once per week, impairment of daily activities, age at onset younger than 25 years, cessation of focal sweating during sleep, and positive family history. In the Hyperhidrosis Disease Severity Scale (HDSS), patients rate the severity of symptoms on a scale of one to four:

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.

The physiological consequences of hyperhidrosis may include cold and clammy hands, dehydration and skin infections secondary to maceration of the skin, although the primary impact to patients is 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, a simple
A qualitative measure to identify specific sites of involvement. The cause of primary hyperhidrosis is unknown, although some clinicians suspect that it is caused by sympathetic over activity. Nervousness or excitement, as well as certain foods and drinks, nicotine, caffeine, and smells can trigger and/or exacerbate a response.

A variety of therapies has been used to treat primary hyperhidrosis, including iontophoresis, topical aluminum chloride, intradermal injections of botulinum toxin type A, ETS and surgical excision of axillary sweat glands. By contrast, treatment of secondary hyperhidrosis concentrates on treatment of the underlying cause of the condition, e.g., discontinuation of the iatrogenic agents or administration of hormone replacement therapy to treat menopause. Treatment options vary in their indication for use, therapeutic efficacy, duration of effect, and side effects.

Sympathectomy involves the dissection of the main sympathetic trunk in the upper thoracic region of the sympathetic nervous system, severing or disrupting autonomic nerves involved in maintaining physiological homeostasis. While ETS is generally accepted as an effective treatment, the surgical procedure is associated with various risks and complications. A report by the Finnish Office of Health Technology Assessment (FINOHTA) evaluating the literature on the safety and effectiveness of thoracoscopic sympathectomy for treatment of sweating, reported acute postoperative complications in as many as 10 percent of subjects (Malmivaara et al., 2005). The most common secondary effect of ETS is compensatory sweating in areas that are different than those prior to the surgery. In some instances these may be major and disabling in nature. Less frequent side effects may include pneumothorax, temporary Horner’s Syndrome, gustatory sweating, and “sandpaper hands.” Several fatalities occurring during the procedure have also been reported.

Medical outcomes can be assessed by a combination of quantitative tools, including gravimetry, evaporimetry and the Minor’s starch and iodine test. Qualitative assessment tools include general health surveys and hyperhidrosis-specific surveys, including the (HDSS).

Drysol Dab-O-Matic™ (DOM), Drysol 37.5cc (aluminum chloride hexahydrate 20% w/v topical solution; Person and Covey Inc.) and Hypercare™ (aluminum chloride hexahydrate 20% w/v topical solution; Stratus Pharmaceuticals) are approved by the FDA as astringents to assist in the management of severe hyperhidrosis (axillar, palmar, plantar, and craniofacial) and are available by prescription. Xerac AC (aluminum chloride hexahydrate 20% w/v topical solution; Person and Covey Inc.) has been approved for milder cases of hyperhidrosis.

In 2004, the FDA approved botulinum toxin type A (Botox®) to treat primary axillary hyperhidrosis (severe underarm sweating) that cannot be managed by topical agents. In 2009, this product was renamed to onabotulinumtoxinA.

Microwave hemolysis (Miradry) is a new technology that uses microwave energy to selectively heat the subcutaneous fat where the axillary sweat glands are located. Studies have been limited. Hong et al., in a study funded by Miramar Labs, noted that duration of positive effect was not studied. Miradry is an
investigational procedure that requires larger and longer duration of study.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on October 3, 2015. Searched terms were: "hyperhidrosis (MeSH"

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Severe hyperhidrosis can cause extreme embarrassment that may lead to social and professional isolation. Therapeutic strategies to hyperhidrosis should employ the least invasive treatment that provides effective symptom control. The treatment options available for control of hyperhidrosis, non-surgical or surgical, differ in their invasiveness and efficacy. Mechanisms of action of antiperspirants, iontophoresis, cholinergic inhibitor drugs, BTX, and surgical sympathectomy are reviewed. There is little published evidence in the form of randomized controlled trials (RCTs) to support the use of one treatment over another. Authors have tended to recommend those therapies that are available to their speciality. Specific therapies should be tailored to the patient's symptoms to gain maximum symptomatic improvement with minimum invasiveness and side effects. To achieve this, the full range of treatment options should be available to or accessible by the consulting doctor in order for the patient to have a meaningful choice (Nyamekey 2004).
### Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Reisfeld R. et al., (2006) | **Key points:** Evidence-based review of the nonsurgical management of hyperhidrosis.  
- The most common nonsurgical modern treatments for hyperhidrosis include topical treatments, such as aluminum chloride, iontophoresis (usually with tap water), oral medications such as anticholinergics and BTX-A. Topical treatments should always be first-line therapy. For those who fail such treatment, iontophoresis is typically recommended for those with palmar or plantar hyperhidrosis, whereas BTX is often considered as first- or second-line therapy in severe axillary hyperhidrosis. Oral anticholinergics are considered after failure of all other nonsurgical treatments. |
| Hong H et al., (2012)     | **Key points:** Clinical evaluation of a microwave device for treating axillary hyperhidrosis.  
- **Background** — A third-generation microwave-based device has been developed to treat axillary hyperhidrosis by selectively heating the interface between the skin and underlying fat where the sweat glands reside.  
- **Materials and methods** — Thirty-one adults were enrolled with primary axillary hyperhidrosis. All subjects had one to three procedure sessions over a six-month period to treat both axillae fully. Efficacy was assessed using the HDSS, gravimetric weight of sweat and the Dermatologic Life Quality Index (DLQI), a dermatology-specific quality-of-life scale. Subject safety was assessed at each visit. Subjects were followed for 12 months after all procedure sessions were complete.  
- **Results** — At the 12-month follow-up visit, 90.3% had HDSS scores of 1 or 2, 90.3% had at least a 50% reduction in axillary sweat from baseline, and 85.2% had a reduction of at least 5 points on the DLQI. All subjects experienced transient effects in the treatment area, such as swelling, discomfort, and numbness. The most common adverse event (12 subjects) was the presence of altered sensation in the skin of the arm that resolved in all subjects.  
- **Conclusion** — The device tested provided efficacious and durable treatment for axillary hyperhidrosis. |

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**Glossary**

**Hyperhidrosis** — A condition of excess sweating beyond that which is necessary for thermal regulation. Hyperhidrosis may be primary or secondary. In the former, the condition is intrinsic to the sweat glands and is generally restricted to the axilla, hands, and feet. In the latter, the condition is secondary to medications or other diseases such as hyperthyroidism, fever, alcohol, metabolic conditions, Hodgkin’s Disease, and other neoplasms or medications.
**Sympathectomy** — A surgical procedure that destroys specific nerve fibers in the sympathetic nervous system. This may dilate blood vessels and reduce sweating.

**Suction-curettage** — A method in which the doctor will insert a suction tool into two small incisions in order to suction out the sweat-producing glands. It is similar to liposuction, but instead of suctioning out fat, the doctor suctions out the layer of the deep skin where the sweat glands are located. This method has been shown in some studies to effectively reduce underarm sweating for months at a time.

**Botox** — An FDA-approved drug that is most commonly used in the treatment of facial wrinkles, as it paralyzes muscles, when used in small doses. It has also been approved to treat excessive sweating. When injected in areas that sweat excessively, sweating can be significantly reduced in that area for months at a time. This study is a pilot study designed to determine feasibility of these procedures.

**References**

**Professional society guidelines/others:**


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on November 1, 2015 using terms excessive underarm sweating | Open Studies. 11 studies found, four relevant.


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No NCDs identified as of the writing of this policy.


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>11450</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, axillary; with simple or intermediate repair.</td>
<td></td>
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<tr>
<td>11451</td>
<td>Excision of skin and subcutaneous tissue for hidradenitis, axillary; with complex repair.</td>
<td></td>
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<tr>
<td>Code</td>
<td>Description</td>
<td></td>
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<tr>
<td>--------</td>
<td>------------------------------------------------------------</td>
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<tr>
<td>32664</td>
<td>Thoracoscopy with thoracic sympathectomy.</td>
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<tr>
<td>64650</td>
<td>Chemodenervation of eccrine glands, both axillae.</td>
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<tr>
<td>64653</td>
<td>Chemodenervation of other area(s) (e.g., scalp, face, neck), per day.</td>
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<table>
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<th>ICD-9 Code</th>
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<tr>
<td>705.21</td>
<td>Primary focal hyperhidrosis.</td>
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<tr>
<td>705.22</td>
<td>Secondary focal hyperhidrosis.</td>
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<td>L74.510</td>
<td>Primary focal hyperhidrosis, axilla</td>
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<td>L74.511</td>
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<td>L74.512</td>
<td>Primary focal hyperhidrosis, palms</td>
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<td>L74.513</td>
<td>Primary focal hyperhidrosis, soles</td>
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<tr>
<td>L74.519</td>
<td>Primary focal hyperhidrosis, unspecified</td>
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<tr>
<td>L74.52</td>
<td>Secondary focal hyperhidrosis</td>
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<th>HCPCS Level II</th>
<th>Description</th>
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<tr>
<td>J0585</td>
<td>Botulinum toxin type A, per unit.</td>
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<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous (used for iontophoretic device).</td>
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