Preauthorization is encouraged for reconstructive services.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Hyperhidrosis, or excessive sweating, can lead to impairments in psychologic and social functioning. Various treatments for hyperhidrosis are available, such as topical agents, oral medications, botulinum toxin, and surgical procedures.

Summary of Evidence

There is insufficient evidence on the efficacy and safety of iontophoresis or microwave treatment for treating hyperhidrosis and on radiofrequency ablation for palmar hyperhidrosis. There is evidence from randomized trials that botulinum toxin improves the net health outcome for patients with axillary hyperhidrosis and evidence that botulinum toxin A products improve the net health outcome for palmar hyperhidrosis. Because of the limited number of studies and high rates of adverse effects, there is insufficient evidence that botulinum toxin B improves the net health outcome for patients with primary palmar hyperhidrosis. There is insufficient evidence on the efficacy of any botulinum toxin products for other types of primary hyperhidrosis, including plantar and secondary hyperhidrosis.

Regarding surgical treatments for hyperhidrosis, data from randomized controlled trials and observational studies show high rates of efficacy of endoscopic transthoracic sympathectomy for primary focal hyperhidrosis, with the exception of plantar hyperhidrosis. There are, however, high rates of compensatory hyperhidrosis which must be considered in the treatment decision. There are insufficient data to draw conclusions on the efficacy of endoscopic lumbar sympathectomy in patients with primary plantar hyperhidrosis.

Policy

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 in spite of medical treatments with topical dermatologicals or systemic anticholinergics.
Table 1. Treatments Considered Medically Necessary and Investigational

<table>
<thead>
<tr>
<th>Focal Regions</th>
<th>Treatments Considered Medically Necessary</th>
<th>Treatments Considered Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axillary</td>
<td>• Aluminum chloride 20% solution;</td>
<td>• Axillary liposuction</td>
</tr>
<tr>
<td></td>
<td>• Botulinum toxin for severe primary axillary hyperhidrosis that is inadequately managed with topical agents, in patients 18 y or older**;</td>
<td>• Iontophoresis</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
<td>• Microwave treatment</td>
</tr>
<tr>
<td>Palmar</td>
<td>• Aluminum chloride 20% solution;</td>
<td>• Rimabotulinumtoxinb**</td>
</tr>
<tr>
<td></td>
<td>• Botulinum toxin A products for severe primary palmar hyperhidrosis that is inadequately managed with topical agents, in patients 18 y or older**;</td>
<td>• Iontophoresis</td>
</tr>
<tr>
<td></td>
<td>• Endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride or botulinum toxin type A**, individually and in combination) has failed.</td>
<td>• Microwave treatment</td>
</tr>
<tr>
<td></td>
<td>• Rimabotulinumtoxinb**</td>
<td>• Radiofrequency ablation</td>
</tr>
<tr>
<td>Plantar</td>
<td>• aluminum chloride 20% solution</td>
<td>• Botulinum toxin**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Iontophoresis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lumbar Sympathectomy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Microwave treatment</td>
</tr>
<tr>
<td>Craniofacial</td>
<td>• aluminum chloride 20% solution;</td>
<td>• Botulinum toxin**</td>
</tr>
<tr>
<td></td>
<td>• endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride) has failed.</td>
<td>• Iontophoresis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Microwave treatment</td>
</tr>
</tbody>
</table>

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

**For guidelines on use of botulinum toxin products refer to the Drug Therapy Guidelines.

The following treatments may be considered medically necessary for the treatment of severe secondary gustatory hyperhidrosis (see Policy Guidelines for list of gustatory hyperhidrosis conditions):

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

Other treatments are considered investigational as a treatment for severe gustatory hyperhidrosis including, but not limited to:

- iontophoresis

Treatment of hyperhidrosis is considered not medically necessary in the absence of functional impairment or any of the above medical complications.

Policy Guidelines

See also the Cosmetic vs. Reconstructive Services Protocol.

See Drug Therapy Guidelines for botulinum toxin products policy.

A multi-specialty working group defines primary focal hyperhidrosis as a condition that is characterized by visible, excessive sweating of at least six months’ in duration without apparent cause and with at least two of the following features: bilateral and relatively symmetric sweating, impairment of daily activities, frequency of at least once per week, age at onset younger than 25 years, positive family history, and cessation of focal sweating during sleep.1
In the Hyperhidrosis Disease Severity Scale, patients rate the severity of symptoms on a scale of 1-4:
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.

Gustatory hyperhidrosis conditions
- Frey’s syndrome
- encephalitis
- syringomyelia
- diabetic neuropathies
- herpes zoster parotitis
- parotid abscess.

Medicare Advantage
For Medicare Advantage members the above guidelines will apply, except in regards to iontophoresis.

Iontophoresis will be considered medically necessary for treatment of intractable, disabling primary focal hyperhidrosis that has not been responsive to recognized standard therapy.

Medicare Advantage Policy Guidelines
Good hygiene measures, extra-strength antiperspirants (for axillary hyperhidrosis), and topical aluminum chloride should initially be tried.

Background
Hyperhidrosis may be 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 either primary or secondary. Primary focal hyperhidrosis is idiopathic in nature, typically involving the hands (palmar), feet (plantar), or axillae (underarms). Secondary hyperhidrosis can result from a variety of drugs, such as tricyclic antidepressants, selective serotonin reuptake inhibitors, or underlying diseases/conditions, such as febrile diseases, diabetes mellitus, or 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 sweating, in contrast, is usually asymmetric and occurs independently of the nature of the ingested food. This phenomenon frequently occurs after injury or surgery in the region of the parotid gland. Frey syndrome is an uncommon type of secondary gustatory hyperhidrosis that arises from injury to or surgery near the parotid gland resulting in damage to the secretory parasympathetic fibers of the facial nerve. After injury, these fibers regenerate, and miscommunication occurs between them and the severed postganglionic sympathetic fibers that supply the cutaneous sweat glands and blood vessels. The aberrant connection results in gustatory sweating and facial flushing with mastication. Aberrant secondary gustatory sweating follows up to 73% of surgical sympathectomies and is particularly common after bilateral procedures.
The consequences of hyperhidrosis are primarily psychosocial in nature. 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.

A variety of therapies have been investigated for primary hyperhidrosis, including topical therapy with aluminum chloride, oral anticholinergic medications, iontophoresis, intradermal injections of botulinum toxin, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands. Treatment of secondary hyperhidrosis focuses on treatment of the underlying cause, such as discontinuing certain drugs or hormone replacement therapy as a treatment of menopausal symptoms.

Botulinum toxin is a potent neurotoxin that blocks cholinergic nerve terminals; symptoms of botulism include cessation of 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 may also be tried. 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 facial hyperhidrosis. Thoracic sympathectomy has been investigated as a potentially curative procedure, primarily for combined palmar and axillary hyperhidrosis that is unresponsive to nonsurgical treatments. While accepted as an effective treatment, sympathectomy is not without complications. In addition to the immediate surgical complications of pneumothorax or temporary Horner syndrome, compensatory sweating on the trunk generally occurs in most patients, with different degrees of severity. Medical researchers have investigated whether certain approaches (e.g., T3 vs. T4 sympathectomy) result in less compensatory sweating, but there remains a lack of consensus about which approach best minimizes the risk of this adverse effect. In addition, with lumbar sympathectomy for plantar hyperhidrosis, there has been concern about the risk of postoperative sexual dysfunction in both men and women.

The outcome of different surgical and medical treatment modalities is best assessed by 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 has been found to have a good correlation to other assessment tools and to be practical in the clinical setting.

**Regulatory Status**

Drysol™ (aluminum chloride [hexahydrate] 20% topical solution, Person and Covey) is approved by the Food and Drug Administration (FDA) to be used as an aid in the management of hyperhidrosis (axillae, palmar, plantar, craniofacial); it is available by prescription.

In 2004, FDA approved botulinum toxin type A (Botox®; Allergan Pharmaceuticals Ireland) to treat primary axillary hyperhidrosis (severe underarm sweating) that cannot be managed by topical agents. In 2009, this product was renamed to OnabotulinumtoxinA. Other FDA-approved botulinum toxin products include:

- 2000: RimabotulinumtoxinB, marketed as Myobloc® (Solstice Neurosciences)
- 2009: AbobotulinumtoxinA, marketed as Dysport® (Medicis Pharmaceutical, Scottsdale, AZ)
- 2010: IncobotulinumtoxinA, marketed as Xeomin® (Merz Pharmaceuticals)
None of these other botulinum toxin products are indicated for treatment of hyperhidrosis.

On July 31, 2009, FDA approved the following revisions to the prescribing information of botulinum toxin products:

• “A Boxed Warning highlighting the possibility of experiencing potentially life-threatening distant spread of toxin effect from injection site after local injection.

• A Risk Evaluation and Mitigation Strategy (REMS) that includes a Medication Guide to help patients understand the risk and benefits of botulinum toxin products.

• Changes to the established drug names to reinforce individual potencies and prevent medication errors. The potency units are specific to each botulinum toxin product, and the doses or units of biological activity cannot be compared or converted from one product to another botulinum toxin product. The new established names reinforce these differences and the lack of interchangeability among products.”

In January 2011, the miraDry® System (Miramar Labs, Sunnydale, CA) was cleared by FDA through the 510(k) process for treating primary axillary hyperhidrosis. This is a microwave device designed to heat tissue at the dermal-hypodermal interface, the location of the sweat glands. Treatment consists of two sessions of approximately one hour in duration. Sessions occur in a physician’s office and local anesthetic is used. FDA Product Code: NEY.

During the process of reviewing the literature, the TEC team noted that the internet site address listed in reference 5 was no longer active as of January 2011. A search of the database did not reveal a replacement article. Therefore, reference 5 was not included in this Protocol.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References
We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


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


