

(80119)

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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is encouraged for reconstructive services.** 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 psychological and social functioning. Various treatments for hyperhidrosis are available, such as topical agents, oral medications, botulinum toxin, and surgical procedures.

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 (SSRIs), 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 scalp or face and predominately over forehead, lips, and nose. Secondary facial gustatory sweating, in contrast, is usually asymmetrical 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's 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 non-surgical treatments. While accepted as an effective treatment, sympathectomy is not without complications. In addition to the immediate surgical complications of pneumothorax or temporary Horner's syndrome, compensatory sweating on the trunk generally occurs in a majority of patients, with different degrees of severity. Medical researchers have investigated whether certain approaches, e.g., T3 versus T4 sympathectomy, result in less compensatory sweating, but there remains a lack of consensus about which approach best minimizes the risk of this side effect. In addition, with lumbar sympathectomy for plantar hyperhidrosis, there has been concern about the risk of post-operative sexual dysfunction in 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 Minor's starch iodine test. Qualitative assessment tools include general health surveys and hyperhidrosis-specific surveys. Of these, the Hyperhidrosis Disease Severity Scale (HDSS) 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, Inc.) is approved by the U.S. Food and Drug Administration (FDA) to be used as an aid in the management of hyperhidrosis (axillae, palmar, plantar, and craniofacial); it is available by prescription.

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. Other FDA-approved botulinum toxin products include:

2000: RimabotulinumtoxinB, marketed as Myobloc® (Solstice Neurosciences)

2009: AbobotulinumtoxinA, marketed as Dysport® (Medicis Pharmaceutical Corporation, 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, the FDA approved the following revisions to the prescribing information of botulinum toxin products:

- "A *Boxed Warning* highlighting the possibility of experiencing potentially life-threatening distant spread of toxin effect from injection site after local injection.
- A Risk Evaluation and Mitigation Strategy (REMS) that includes a *Medication Guide* to help patients understand the risk and benefits of botulinum toxin products.
- Changes to the established drug names to reinforce individual potencies and prevent medication errors. The potency units are specific to each botulinum toxin product, and the doses or units of biological activity

cannot be compared or converted from one product to any other 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, Inc.; Sunnydale, CA) was cleared by the 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.

Policy (Formerly Corporate Medical Guideline)

Primary Focal Hyperhidrosis

Treatment of primary hyperhidrosis may be considered **medically necessary** with any of the following medical complications:

- 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.

Focal Regions	Treatments Considered Medically Necessary	Treatments Considered Investigational
<i>Axillary</i>	<ul style="list-style-type: none"> • aluminum chloride 20% solution*; • pharmacologic management**; • endoscopic transthoracic sympathectomy (ETS) and surgical excision of axillary sweat glands, if conservative treatment (i.e., aluminum chloride or pharmacologic management**, individually and in combination) has failed. 	<ul style="list-style-type: none"> • axillary liposuction • iontophoresis • microwave treatment
<i>Palmar</i>	<ul style="list-style-type: none"> • aluminum chloride 20% solution*; • pharmacologic management**; • endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride or pharmacologic management**, individually and in combination) has failed. 	<ul style="list-style-type: none"> • iontophoresis • pharmacologic management** • microwave treatment • radiofrequency ablation
<i>Plantar</i>	<ul style="list-style-type: none"> • aluminum chloride 20% solution* 	<ul style="list-style-type: none"> • iontophoresis • lumbar sympathectomy • pharmacologic management** • microwave treatment
<i>Craniofacial</i>	<ul style="list-style-type: none"> • aluminum chloride 20% solution*; • endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride) has failed. 	<ul style="list-style-type: none"> • iontophoresis • pharmacologic management** • microwave treatment

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

Secondary Gustatory Hyperhidrosis

The following treatments would be considered **medically necessary** for the treatment of severe gustatory hyperhidrosis:

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

The following treatment is considered **investigational** as a treatment for severe gustatory hyperhidrosis including, but not limited to:

- iontophoresis

See Drug Therapy Guidelines for botulinum toxin products policy for this indication.

*FDA approved indication

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

See also Protocol called Cosmetic vs. Reconstructive Services.

Policy Guideline

A multi-specialty working group defines primary focal hyperhidrosis as a condition that is characterized by visible, excessive sweating of at least six months' 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: (2)

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

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.

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