Medical Coverage Policy

Botulinum Toxin for the Treatment of Hyperhidrosis

☐ Device/Equipment  ☒ Drug  ☒ Medical  ☐ Surgery  ☒ Test  ☐ Other

Effective Date:  9/19/2012  Policy Last Updated:  9/19/2012

☒ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☐ Prospective review is not required.

Description:
Hyperhidrosis may be defined as excessive sweating, beyond a level required to maintain normal body temperature, in response to heat exposure or exercise. It may be classified as either primary or secondary.

Primary focal hyperhidrosis:
Primary focal hyperhidrosis is idiopathic in nature, typically involving the hands (palmar), feet (plantar), or axillae (underarms). Primary focal hyperhidrosis is a condition characterized by visible, excessive sweating of at least 6 months’ duration without apparent cause and with at least 2 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.

Secondary hyperhidrosis:
Secondary hyperhidrosis may 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:
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.

Frey’s syndrome:
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.

**Other gustatory hyperhidrosis conditions:**
Other gustatory hyperhidrosis conditions include encephalitis, syringomyelia, diabetic neuropathies, herpes zoster parotitis, parotid abscess.

**Secondary facial gustatory sweating:**
Secondary facial gustatory sweating 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.

The consequences of hyperhidrosis are primarily psychosocial in nature. Excessive perspiration may be socially embarrassing (e.g., limiting the ability to shake hands) or interfere with certain professions. For example, palmar hyperhidrosis may preclude artwork, working with electrical components, or playing certain musical instruments. In addition, hyperhidrosis may require several changes of clothing daily and may cause staining of clothing and/or shoes.

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, 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.

**Treatments:**

**Botulinum toxin:**
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:**
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.

**Thoracic sympathectomy**
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. Various surgical techniques of thoracic sympathectomy have been investigated as a 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.

Hyperhidrosis Disease Severity Scale
Using the hyperhidrosis disease severity scale, patients rate the severity of symptoms on a scale of 1-4:
- I. My underarm sweating is never noticeable and never interferes with my daily activities.
- II. My underarm sweating is tolerable but sometimes interferes with my daily activities.
- III. My underarm sweating is barely tolerable and frequently interferes with my daily activities.
- IV. My underarm sweating is intolerable and always interferes with my daily activities.

This policy refers **only** to botulinum toxin as a treatment for levels 3 and 4 on the severity scale.

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

**Primary Focal Hyperhidrosis**
Treatment of primary focal hyperhidrosis is considered **medically necessary** with any of the following complications:
- I. acrocyanosis of the hands; OR
- II. history of recurrent skin maceration with bacterial or fungal infections; OR
- III. history of recurrent secondary infections; OR
- IV. history of persistent eczematous dermatitis in spite of medical treatments with topical dermatological or systemic anticholinergic agents.

Botulinum toxin is **medically necessary** in patients 18 years and older, when inadequately managed with topical agents for the:
- axillary focal region
- palmar focal region (botulinum toxin A)
- axillary focal region:

Botulinum toxin is **not covered** as a treatment for the plantar or craniofacial focal region.

**Secondary Hyperhidrosis**

**Secondary Gustatory Hyperhidrosis**
Botulinum toxin is **not covered** as a treatment for severe gustatory hyperhidrosis.

**Policy:**
The use of Botulinum Toxin for the Treatment of Hyperhidrosis is medically necessary when the above criteria are met. **Preauthorization is required for BlueCHiP for Medicare and recommended for all other lines of business.**

**When botulinum toxin is used, please note the following:**
Reimbursement is provided only for the portion of medication used for a patient's treatment. Reimbursement is not provided for any wastage or unused portion. If a vial is divided between two patients, the billing must be for the exact amount of botulinum toxin used on each individual patient.

**Limitations of coverage:**
- The appropriate injection/destruction codes (e.g., 64612; 64613; 67345) may be submitted in conjunction with J0585, J0586, and J0587. Reimbursement for the injection code will be on a one
time basis only, per operative session, regardless of the number of injections unless the procedure is bilateral or more than one body region is injected.

- Electromyographic guidance (CPT codes 95860; 95861; 95869; 92265) may be used to ensure the proper needle location within the muscle. Again, only one unit of EMG service may be submitted per session unless the procedure is bilateral or more than one body region is being treated.
- Cost for special syringes is considered part of the surgical procedure and not separately reimbursable.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Member Certificate, Subscriber Agreement, and Benefits Booklet for applicable coverage/benefits.

Botulinum toxin is covered under the member's medical benefit and is subject to any applicable copay/coinsurance and/or deductible.

Specialty Pharmacy
Botulinum toxin is available for member purchase at community pharmacies; however physicians may order Botulinum Toxin through the network specialty pharmacy. For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

Coding:
J0585 Injection, Onabolulinumtoxina, 1 unit (A)
J0586 Injection, Abobotulinumtoxina, 5 units (A)
J0587 Injection, Abotulinumtoxina, 100 units (B)
J0588 Injection, Incobotulinumtoxin A, 1 unit (effective 1/1/12)
C9278 Injection, incobotulinumtoxinA, 1 unit

ICD-9-CM Codes:
705.2 Focal hyperhidrosis
705.21 Primary focal hyperhidrosis
705.22 Secondary focal hyperhidrosis

ICD-10-CM Codes:
L74.510 Primary focal hyperhidrosis, axilla
L74.511 Primary focal hyperhidrosis, face
L74.512 Primary focal hyperhidrosis, palms
L74.513 Primary focal hyperhidrosis, soles
L74.519 Primary focal hyperhidrosis, unspecified
L74.52 Secondary focal hyperhidrosis

Also known as:
Not applicable

Related topics
Not applicable

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