

**EFFECTIVE DATE: XXXX**

**POLICY LAST UPDATED: XXXX**

## OVERVIEW

Hyperhidrosis, or excessive sweating, can lead to impairments in psychologic and social functioning. Various treatments for hyperhidrosis are available, such as topical antiperspirant agents (eg, aluminum chloride 20% solution), oral medications, botulinum toxin, and surgical procedures.

## MEDICAL CRITERIA

### BlueCHiP for Medicare

#### Severe Primary Axillary Hyperhidrosis (primary focal hyperhidrosis)

Treatment is considered medically necessary with any of the following criteria:

- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical therapy.
- Focal, visible, severe sweating of at least six (6) months duration without apparent cause with at least 2 of the following characteristics:
  - Bilateral and relatively symmetric significant impairment in daily activities
  - Age of onset less than 25 years
  - Positive family history
  - Cessation of focal sweating during sleep

#### Primary Focal Hyperhidrosis

##### Commercial Products

Treatment of primary focal hyperhidrosis is considered medically necessary when any of the following medical conditions;

- 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;

Inadequately managed with topical agents for the following;

- Palmar focal region
- Axillary focal region
  - impairment of daily activities;
  - frequency of at least once per week;
  - positive family history;
  - cessation of focal sweating during sleep.
- Visible, excessive sweating of at least 6 months in duration without apparent cause and with at least 2 of the following features
  - bilateral and relatively symmetric sweating;
  - significant impairment in daily activities
  - age of onset less than 25 years
  - positive family history
  - cessation of focal sweating during sleep

## Hyperhidrosis Disease Severity Scale

The Hyperhidrosis Disease Severity Scale (HDSS) is used by patients to rate the severity of their symptoms on a scale of 1 to 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.

## PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products for the treatment of hyperhidrosis.

## POLICY STATEMENT

### BlueCHiP for Medicare

#### Severe Primary Axillary Hyperhidrosis (primary focal hyperhidrosis)

Treatment of primary axillary hyperhidrosis is medically necessary when the criteria above is met.

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

## Commercial Products

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

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

The treatments listed below are considered **not medically necessary** as a treatment for severe secondary gustatory hyperhidrosis as the evidence is insufficient to determine the effects of the technology on health outcomes.

- botulinum toxin
- iontophoresis.

Treatment of primary focal hyperhidrosis using the therapies in the list below 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 despite medical treatments with topical dermatologic or systemic anticholinergic agents.

## Therapies

- Axillary
  - Aluminum chloride 20% solution
  - Botulinum toxin for severe primary axillary hyperhidrosis inadequately managed with topical agents, in patients  $\geq 18$  y

- ETS and surgical excision of axillary sweat glands, if conservative treatment (ie, aluminum chloride or botulinum toxin, individually and in combination) has failed
- Palmar
  - Aluminum chloride 20% solution
  - Botulinum toxin type A products for severe primary palmar hyperhidrosis inadequately managed with topical agents, in patients  $\geq 18$  y
  - ETS, if conservative treatment (ie, aluminum chloride or Botulinum toxin type A, individually and in combination) has failed
- Plantar
  - Aluminum chloride 20% solution
- Craniofacial
  - Aluminum chloride 20% solution

Treatments using aluminum chloride 20% solution or surgical options (ie tympanic neurectomy) if conservative treatment has failed may be considered **medically necessary** for the treatment of severe secondary gustatory hyperhidrosis including the following conditions;

- Frey syndrome
- encephalitis
- syringomyelia
- diabetic neuropathies
- herpes zoster parotitis
- parotid abscess.

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: Food and Drug Administration.

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

## COVERAGE

### BlueCHiP for Medicare and Commercial Products

Benefits may vary between groups/contracts. Please refer to the appropriate Member Certificate, Subscriber Agreement, and Benefits Booklet for applicable physician office injection coverage/benefits and for services not medically necessary.

Botulinum toxin is covered under the member's medical benefit for those contracts with no specialty pharmacy benefit and is subject to any applicable copayment/coinsurance and/or deductible.

## BACKGROUND

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 in nature, typically involving the hands (palmar), feet (plantar), or axillae (underarms). Secondary hyperhidrosis can result from a variety of drugs (eg, tricyclic antidepressants, selective serotonin reuptake inhibitors) or underlying diseases/conditions (eg, febrile diseases, diabetes mellitus, 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 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.

### **Therapeutic Options**

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 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 patients, with different degrees of severity. Medical researchers have investigated whether certain approaches (eg, 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 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.

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 has had good correlation to other assessment tools and is practical in the clinical setting.

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive iontophoresis, the evidence includes 1 randomized controlled trial (RCT) and case series.

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 to sham or active treatment in patients with various types of primary focal hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have primary axillary hyperhidrosis who receive botulinum toxin type A or B, the evidence includes RCTs. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Placebo-controlled RCTs have generally found better outcomes in the botulinum toxin groups. Several RCTs have compared botulinum toxin type A formulations in patients with primary axillary hyperhidrosis and have compared botulinum toxin type A and B formulations in patients with axillary hyperhidrosis. Although these studies had small sample sizes, their findings suggest that, with appropriate dosage adjustments, there are similar levels of efficacy and adverse events. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary palmar hyperhidrosis who receive botulinum toxin type A, the evidence includes RCTs. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Placebo-controlled RCTs have generally found better outcomes in the botulinum toxin groups. RCTs comparing botulinum toxin type A formulations in patients with primary palmar hyperhidrosis have generally found no significant difference in outcomes. Although these studies had small sample sizes, their findings suggest that, with appropriate dosage adjustments, there are similar levels of efficacy and adverse events. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary palmar hyperhidrosis who receive botulinum toxin type B, the evidence includes 1 RCT. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. One small placebo-controlled RCT did not clearly demonstrate the efficacy of botulinum toxin type B in patients with palmar hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

#### Iontophoresis

For individuals who have primary focal hyperhidrosis, a 2003 TEC Assessment on iontophoresis for a variety of medical conditions concluded that the evidence was insufficient to determine whether iontophoresis for the treatment of any type of hyperhidrosis improves outcomes. Neither the TEC Assessment nor subsequent literature searches have identified any RCTs evaluating iontophoresis for gustatory hyperhidrosis.

For individuals who have severe secondary gustatory hyperhidrosis who receive iontophoresis or botulinum toxin, the evidence includes uncontrolled studies and systematic reviews that did not identify any relevant RCTs to evaluate the safety and efficacy of these conditions for treatment of severe secondary gustatory hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

## CODING

### BlueCHIP for Medicare and Commercial Products

Botulinum Toxin: The HCPC codes below require pre-authorization for hyperhidrosis

- 32664 Thoracoscopy, surgical; with thoracic sympathectomy
- 64650 Chemodenervation of eccrine glands; both axillae
- 64653 Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day
- 69676 Tympanic neurectomy
- J0585 Injection, Onabotulinumtoxin A, 1 unit (A)
- J0586 Injection, Abobotulinumtoxin A, 5 units (A)
- J0587 Injection, rimabotulinumtoxin B100 units (B):
- J0588 Injection, Incobotulinumtoxin A, 1 unit

## RELATED POLICIES

Botulinum Toxin Injections

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Provider Update,

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