BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Hyperhidrosis, Treatment of

File Name:	hyperhidrosis_treatment_of
Origination:	9/2004
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Description of Procedure or Service

Hyperhidrosis may be defined as excessive sweating, beyond a level required to maintain normal body temperature in response to heat exposure or exercise. Hyperhidrosis can be classified as either primary or secondary. Primary localized hyperhidrosis is idiopathic in nature (the exact cause is unable to be determined), typically involving the hands (palmar), feet (plantar), or underarms (axillae). Secondary hyperhidrosis can result from a variety of medications, such as tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs), or underlying diseases/conditions, such as febrile illnesses, diabetes mellitus, or menopause.

Secondary hyperhidrosis is usually generalized or craniofacial sweating. Secondary gustatory hyperhidrosis is excessive sweating in response to eating 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 type A, 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.

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 and 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) as an astringent to be used as an aid in the management of hyperhidrosis (axillae, palmar, plantar, and craniofacial) available by prescription.

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.

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®
2009: AbobotulinumtoxinA, marketed as Dysport®
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 Botox®/Botox® Cosmetic and Myobloc®:

- "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."

Abobotulinumtoxin A, Marketed as Dysport®, was approved on April 29, 2009 and prescribing information included the Boxed Warning, REMS and new drug name at the time of approval.

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Table 1: Summary of FDA-Approved Botulinum Toxin Products

Trade Name	NEW Drug Name	OLD Drug Name	Indication
Botox®	OnabotulinumtoxinA	Botulinum toxin type A	cervical dystonia, severe primary axillary hyperhidrosis, strabismus, blepharospasm
Botox® Cosmetic	OnabotulinumtoxinA	Botulinum toxin type A	temporary improvement in the appearance of moderate to severe glabellar lines
Dysport®	AbobotulinumtoxinA	Botulinum toxin type A	cervical dystonia, temporary improvement in the appearance of moderate to severe glabellar lines
Myobloc®	RimabotulinumtoxinB	Botulinum toxin type B	cervical dystonia

*The marketed trade names and the product formulations have not changed.

In terms of botulinum toxin products, this policy only discusses their use as a treatment of hyperhidrosis.

Other indications for botulinum toxin are discussed separately in the policy titled "Botulinum Toxin Injection".

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Treatment of Hyperhidrosis when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits and for the definition of cosmetic and reconstructive services. Services or procedures performed for psychological or emotional reasons are considered cosmetic, and therefore are typically excluded by the member's health benefit plan.

Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Treatment of Hyperhidrosis is covered

A. Primary Focal Hyperhidrosis

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Hyperhidrosis, Treatment of

Treatment of primary hyperhidrosis using the following therapies may be considered medically necessary for functional impairment or with 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 dermatological or systemic anticholinergic agents.

Table 1. Treatments Considered Medically Necessary

Focal Regions	**Treatments Considered Medically Necessary**
Axillary	• aluminum chloride 20% solution*; • 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., both aluminum chloride and botulinum toxin, individuallyor in combination) has failed.
Palmar	• aluminum chloride 20% solution*; • Botulinum toxin A products for severe primary palmar hyperhidrosis that is inadequately managed with topical agents, in patients 18 years and older; • endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., both aluminum chloride and botulinum toxin type A, individually or in combination) has failed.
Plantar	• aluminum chloride 20% solution*
Craniofacial	• aluminum chloride 20% solution*; • endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride) has failed.

Aluminum chloride solution is approved by U.S. Food and Drug Administration (FDA) for treatment of primary hyperhydrosis. At least 1 botulinum toxin product is FDA approved for treatment in adults of severe axillary hyperhydrosis that is inadequately managed by topical agents.

B. Secondary Hyperhidrosis

Secondary hyperhidrosis is excessive sweating that can be generalized or craniofacial sweating and may occur as a result of olfactory or gustatory stimuli, neurologic lesions, intrathoracic neoplasms, Raynaud's disease and Frey's syndrome.

1. Secondary Gustatory Hyperhidrosis

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

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a. aluminum chloride 20% solution*;

b. surgical options (i.e., tympanic neurectomy), if conservative treatment has failed.

*FDA approved indication.

When Treatment of Hyperhidrosis is not covered

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

The following treatments are considered investigational for treatment of primary focal hyperhidrosis, including but not limited to:

A. Primary Focal Hyperhidrosis

Focal Regions	Treatments Considered Investigational
Axillary	• axillary liposuction • iontophoresis • microwave treatment
Palmar	• RimabotulinumtoxinB • iontophoresis • microwave treatment • radiofrequency ablation
Plantar	• botulinum toxin • iontophoresis • lumbar sympathectomy microwave treatment
Craniofacial	• botulinum toxin • iontophoresis • microwave treatment

B. Secondary Hyperhidrosis

1. The following treatments are considered investigational for treatment of severe gustatory hyperhidrosis including, but not limited to:
   a. Botulinum toxin,
   b. iontophoresis.

Secondary Gustatory Hyperhidrosis conditions:

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

Policy Guidelines

In the absence of evidence to the contrary, botulinum toxin products are considered to have a class effect. This approach is consistent with the BCBSNC policy titled "Botulinum Toxin Injection."

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All botulinum toxin products may require prior review.

Functional impairment refers to the inability to perform activities of daily living and/or manual tasks in a professional setting.

A multi-specialty working group defines primary focal hyperhidrosis as a condition that is characterized by visible, excessive sweating of at least 6 months' duration without apparent cause and with at least two (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.

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.

Hyperhidrosis treatments include topical, systemic, nonsurgical, and surgical methods. Treatment options vary in their indication for use, therapeutic efficacy, duration of effect, and side effects.

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. Due to 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *32664, 64650, 64653, 64999, 69676, J0585, J0586, J0587, J0588, 96999*

ICD-9 Codes: 705.21, 705.22

ICD-10 Codes: L74.510, L74.511, L74.512, L74.513, L74.519, L74.52

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

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Medical Director review 1/2015

Specialty Matched Consultant Advisory Panel review 1/2016

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Policy Implementation/Update Information

10/14/04 Specialty Matched Consultant Advisory Panel review 8/27/04. Original policy issued.

11/11/04 Removed reference to "use of or inability to tolerate pharmacotherapy for excessive sweating (e.g., anti-cholinergics, beta-blockers, or benzodiazapines)" from "When Covered" section re: Botulinum toxin treatment or endoscopic transthoracic sympathectomy or surgical excision of axillary sweat glands. Reference added.

4/7/05 Added CPT code 64614 to Billing/Coding section.

9/15/05 Added statement "Botulinum Toxin Type A (Botox®) may require prior approval." to Benefits Application and Policy Guidelines sections. Also under Policy Guidelines, added the following statement: "Although similar in certain aspects, Botulinum toxin type A and Botulinum toxin type B are not interchangeable. Each of these products differs from the other in preparation and potency. Treatment regimens that were developed and tested for one should not be assumed to be valid for the other preparation." Under When covered section, specified "Botulinum Toxin Type A (Botox®)" where botulinum toxin is mentioned for treatment of primary hyperhidrosis. Reference sources added.

1/5/06 Removed CPT code 64614 from Billing/Coding section and added new 2006 CPT codes 64650 & 64653.

11/27/06 Specialty Matched Consultant Advisory Panel review 8/30/2006. No changes to criteria. Reference sources added. (pmo)

10/6/08 Policy Guidelines revised to include definition of primary focal hyperhidrosis and the hyperhidrosis disease severity scale. Reference sources added. Specialty Matched Consultant Advisory Panel review 9/4/08. (pmo)

12/21/09 Description, When Covered and When Not Covered sections revised with information re: FDA approved revisions to prescribing information for botulinum toxin products that included drug name changes. Policy Guidelines revised based on current information. Added 69676, J0586 and J0587 to Billing/Coding section. Reference sources added. (pmo)

6/22/10 Policy Number(s) removed (amw)

3/1/11 Specialty Matched Consultant Advisory Panel review 2-2011. No changes to Policy Statement. (mco)

6/21/11 Medical Director review 6/2011. Policy Guidelines revised. The following statement added to Policy Guidelines: "In the absence of evidence to the contrary, botulinum toxin products are considered to have a class effect. This approach is consistent with the BCBSNC policy titled "Botulinum Toxin Injection." Therefore, all references to OnabotulinumtoxinA and RimabotulinumtoxinB replaced with the general term, Botulinum Toxin. RimabotulinumtoxinB removed as an investigational treatment for primary axillary hyperhidrosis. Medically necessary and investigational treatments for primary hyperhidrosis revised into a table format. Description section updated. References updated. (mco)

2/7/12 Specialty Matched Consultant Advisory Panel review 1/2012. No changes to Policy Statements. (mco)

8/7/12 Description section updated to include the miraDry System, a microwave device designed to heat tissue at the dermal-hypodermal interface, the location of the sweat glands. "When Covered" section revised to include the following statement: "Treatment of primary hyperhidrosis may be considered medically necessary for functional impairment or with 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 dermatological or systemic anticholinergic agents." "When not Covered" section updated to include "microwave treatment" as a procedure considered investigational for all focal areas. CPT code J0588 and 96999 added to Billing/Coding section. Benefit Application section updated to include following statements: "Please refer to the Member's Benefit Booklet for availability of benefits and for the definition of cosmetic and reconstructive services. Services or procedures performed for psychological or emotional reasons are considered cosmetic, and therefore are typically excluded by the member's health benefit plan.." The following statement added to Policy Guidelines: "Functional impairment refers to the inability to perform activities of daily living and/or manual tasks in a professional setting." References updated. Medical Director review 7/2012. (mco)

2/12/13 Specialty Matched Consultant Advisory Panel review 1/2013. No changes to Policy Statements. (mco)

7/16/13 Added the follow treatment for Palmer Hyperhidrosis under the "When not Covered" section: "Radiofrequency Ablation." References updated. Policy Guidelines updated. Medical Director review 6/2013. (mco)

10/15/13 Revised "When Covered" section. Coverage for endoscopic transthroacic sympathectomy (ETS) for axillary and palmer hyperhidrosis is considered medically

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necessary if conservative treatment (i.e., aluminum chloride **and** botulinum toxin, individually **or** in combination) has failed. Medical Director review 10/2013. (mco)

2/11/14 Specialty Matched Consultant Advisory Panel review 1/2014. Medical Director review 1/2014. No changes to Policy Statements. (mco)

7/15/14 References updated. No changes to Policy Statements. (mco)

1/27/15 Billing/Coding section updated to include CPT code 64999; ICD-9 codes: 705.21, 705.22; and ICD-10 Codes: L74.510, L74.511, L74.512, L74.513, L74.519 and L74.52. No changes to Policy Statements. Notification given 1/27/15 for effective date 4/1/15. (td)

9/1/15 References updated. When Covered and When Not Covered sections reformatted and edited for clarity. When Covered section revised to replace "complications" with "conditions". Policy Statement intent unchanged. (td)

2/29/16 Specialty Matched Consultant Advisory Panel review 1/2016. Medical Director review 1/2016. (td)

1/27/17 Specialty Matched Consultant Advisory Panel review 1/2017. No change to policy statement. (an)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.