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1.0 Description of the Procedure, Product, or Service

1.1 Background

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, 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 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.

Drysol™ (aluminum chloride [hexahydrate] 20% topical solution, Person and Covey, Inc.) is FDA approved as an astringent to be used as an aid in the management of hyperhidrosis (axillae, palmar, plantar, and craniofacial) available by prescription. In 2004 the U.S. Food and Drug Administration (FDA) approved botulinum toxin type A to treat primary axillary hyperhidrosis (severe underarm sweating) that cannot be managed by topical agents such as prescription (Drysol™) and over-the-counter (OTC) (i.e., Certain Dri® 12%) topical agents with aluminum chloride. A typical dosage would be intradermal injections of 50 units per axilla. Efficacy begins in about 7 to 10 days and lasts approximately 4 to 12 months. Contraindications to Botulinum type A toxin include infection at the proposed injection site(s), pregnancy, and lactation. Botulinum toxin type A should be used with caution in recipients with neuromuscular disorders (i.e., myasthenia gravis) and recipients taking medications such as aminoglycosides, pencillamine, quinine, and calcium channel blockers. The safety and effectiveness has been established for recipients 18 years and older. Botulinum toxin has also been investigated as a treatment of hyperhidrosis in body areas other than the axilla and for secondary gustatory hyperhidrosis.

On February 8, 2008, the FDA issued an Early Communication about the Ongoing Safety Review; Botox® and Botox® Cosmetic (botulinum toxin type A) and Myobloc® (botulinum type B). The FDA has received reports of systemic adverse reactions including respiratory compromise and death following the use of Botulinum types A and B for both FDA-approved and unapproved uses. The reactions reported are suggestive of botulism, which occurs when botulinum toxin spreads in the body beyond the site where it was injected. The most serious cases had outcomes that included hospitalization and death, and occurred mostly in children treated for cerebral palsy-associated limb spasticity. Use of botulinum toxins for treatment of limb spasticity (severe arm and leg muscle spasms) in children or adults is not an approved use in the United States. The communication stated; "The safety, efficacy and dosage of botulinum toxins have not been established for the treatment of limb spasticity of cerebral palsy or for use in any condition in children less than 12 years of age." The FDA will update this document when additional information or analyses become available. On July 31, 2009, the FDA approved the following revisions to the prescribing information of Botox®/Botox® Cosmetic and Myobloc®:

- a. "A Boxed Warning highlighting the possibility of experiencing potentially life-threatening distant spread of toxin effect from injection site after local injection.
- b. A Risk Evaluation and Mitigation Strategy (REMS) that includes a Medication Guide to help recipients understand the risk and benefits of botulinum toxin products.
- c. 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.

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.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;

- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Treatment of hyperhidrosis is covered under the NC Health Choice Program when it is determined to be medically necessary when the following criteria are met.

3.2.1 Primary Focal Hyperhidrosis

Primary focal hyperhidrosis is defined as excessive sweating induced by sympathetic hyperactivity in selected areas that is not associated with an underlying disease process. The most common locations are underarms (axillary hyperhidrosis), palms (palmar hyperhidrosis), soles (plantar hyperhidrosis) or face (craniofacial hyperhidrosis).

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

- a. acrocyanosis of the hands;
- b. history of recurrent skin maceration with bacterial or fungal infections;
- c. history of recurrent secondary infections;
- d. history of persistent eczematous dermatitis in spite of medical treatments with topical dermatological or systemic anticholinergic agents.

1. Axillary Hyperhidrosis

The following treatments may be considered medically necessary for recipients with axillary hyperhidrosis:

- (a) aluminum chloride 20% solution*;
- (b) OnabotulinumtoxinA (intradermal injection) for severe primary axillary hyperhidrosis that is inadequately managed with topical agents*, in recipients 18 years and older;
- (c) endoscopic transthoracic sympathectomy (ETS) and surgical excision of axillary sweat glands, if conservative treatment (i.e., aluminum chloride or OnabotulinumtoxinA, individually and in combination) has failed.

2. Palmar Hyperhidrosis

The following treatments may be considered medically necessary for recipients with palmar hyperhidrosis:

- (a) aluminum chloride 20% solution*;
- (b) OnabotulinumtoxinA (intradermal injection) for severe primary palmar hyperhidrosis that is inadequately managed with topical agents, in recipients 18 years and older;
- (c) endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride or botulinum type A, individually and in combination) has failed.

3. Plantar Hyperhidrosis

Treatment with aluminum chloride 20% solution* may be considered medically necessary for recipients with plantar hyperhidrosis.

4. Craniofacial Hyperhidrosis

The following treatments may be considered medically necessary for recipients with craniofacial hyperhidrosis:

- (a) aluminum chloride 20% solution*;
- (b) endoscopic transthoracic sympathectomy (ETS), if conservative treatment (i.e., aluminum chloride) has failed.

3.2.2 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.

a. Secondary Gustatory Hyperhidrosis

The following treatments may be considered medically necessary for recipients with severe gustatory hyperhidrosis:

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

*FDA approved indication.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Treatment of hyperhidrosis not covered under the NC Health Choice Program in the following situations:

In the majority of recipients, treatment of primary hyperhidrosis would be considered not medically necessary based on the lack of functional impairment or medical complications associated with the condition.

a. Primary Focal Hyperhidrosis

The following treatments are considered investigational in the treatment of hyperhidrosis in the specified focal regions:

1. Axillary
 - (a) axillary liposuction
 - (b) RimabotulinumtoxinB

- (c) Iontophoresis
- 2. Palmar
 - (a) RimabotulinumtoxinB
 - (b) Iontophoresis
- 3. Plantar
 - (a) OnabotulinumtoxinA
 - (b) RimabotulinumtoxinB
 - (c) Iontophoresis
 - (d) lumbar sympathectomy
- 4. Craniofacial
 - (a) OnabotulinumtoxinA
 - (b) RimabotulinumtoxinB
 - (c) Iontophoresis
- b. Secondary Hyperhidrosis

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

- 1. OnabotulinumtoxinA
- 2. RimabotulinumtoxinB
- 3. iontophoresis.

Gustatory Hyperhidrosis conditions:

- (a) Frey's syndrome
- (b) Encephalitis
- (c) Syringomyelia
- (d) diabetic neuropathies
- (e) herpes zoster parotitis
- (f) parotid abscess

4.3 Policy Guidelines

Primary focal hyperhidrosis is a condition that is characterized by visible, excessive sweating of at least six (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, recipients 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.

On July 31, 2009, the FDA approved the following revisions to the prescribing information of Botox®/Botox® Cosmetic and Myobloc® that include changes to the

established drug name. The information detailed below has not been modified. 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.

4.3.1 Aluminum chloride

Antiperspirants containing aluminum salts, Drysol™ (aluminum chloride hexahydrate 20% topical solution, Person and Covey, Inc.), are considered the most effective topical agents for mild focal axillary hyperhidrosis and are used as first-line agents for focal hyperhidrosis in all locations.

4.3.2 Iontophoresis

Iontophoresis in conjunction with tap water or anticholinergic agents is a longstanding treatment of palmar or plantar and more recently axillary idiopathic hyperhidrosis, with a reported success rate of up to 85%. However, the published literature regarding iontophoresis as a treatment of hyperhidrosis is sparse. A 2003, BCBS Association Technology Evaluation on Center Assessment concludes that the evidence was insufficient to determine whether the effects of iontophoresis for the treatment of hyperhidrosis exceed those of placebo. The 2003 BCBS Association Technology Evaluation on Center Assessment also concluded that in the treatment of hyperhidrosis, evidence is insufficient to show that tap water iontophoresis is as beneficial as topical drug administration.

4.3.3 Botulinum Toxin Injections

Botulinum toxin type A (Botox®, Allergan Inc.) 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. A considerable body of published literature addresses botulinum toxin injection in the treatment of axillary hyperhidrosis, all of which substantiates its effectiveness. The drawback of this approach is the need for repeated injections, which have led some to consider surgical approaches.

In May 2008, a report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology was published. The assessment is an evidence-based review of the safety and efficacy of botulinum neurotoxin type A in the treatment of autonomic and urologic disorders and low back and head pain. These guidelines include the following recommendations for hyperhidrosis: axillary hyperhidrosis, strong evidence supports botulinum toxin type A should be offered as a treatment option; palmar hyperhidrosis, good evidence supports botulinum toxin type A should be considered as a treatment option to patients who are unresponsive to topical treatment as an alternative to iontophoresis or sympathectomy; and gustatory hyperhidrosis; weak

evidence supports botulinum toxin type A as a treatment option for gustatory sweating.

Given the insufficient evidence available to evaluate the net health outcomes in comparison with alternative therapies, the use of intradermal injections of botulinum toxin type A for secondary gustatory hyperhidrosis, plantar, and craniofacial hyperhidrosis is considered investigational. In addition, botulinum type B is considered investigational due to insufficient evidence to evaluate the net health outcome of this treatment.

4.3.4 Endoscopic Transthoracic Sympathectomy

Endoscopic transthoracic sympathectomy (ETS) is an outpatient procedure that interrupts the overactive sympathetic nerves that cause excessive sweating, primarily for combined palmar and axillary hyperhidrosis that is unresponsive to topical, systemic and botulinum toxin type A therapy. A variety of approaches have been reported but endoscopic techniques have emerged as a minimally invasive alternative to a transaxillary, supraclavicular, or anterior thoracic approach. In addition to a variety of approaches, various surgical techniques of thoracic sympathectomy (e.g., resection, transection, ablation and clipping) have been investigated as a curative procedure, primarily for combined palmar and axillary hyperhidrosis that is unresponsive to topical, systemic and botulinum toxin type A therapy. While accepted as an effective treatment, the potential complications of this surgery should not be taken lightly and all other conservative measures should be attempted prior to consideration of sympathectomy.

Future clinical trials comparing surgical techniques will need to ensure that the procedures are standardized and outcome measures validated for both symptoms of the disease and surgical complications. The studies must have large numbers of patients and adequate long-term follow-up, if they are to detect differences in results among procedures with very high technical success rates and include head-to-head comparisons with other treatment options.

4.3.5 Lumbar Sympathectomy

In addition to complications associated with sympathectomy, lumbar sympathectomy is not employed for plantar hyperhidrosis because of the additional risk of permanent sexual dysfunction in men and women.

4.3.6 Tympanic Neurectomy

Review articles by Clayman et al. and de Bree et al. describe the various medical and surgical treatments for Frey's syndrome. Tympanic neurectomy is described as a treatment for Frey's syndrome with satisfactory control reported in 82% of recipients. In addition, this surgical treatment is generally definitive without a need for repeated interventions.

4.3.7 Surgical Removal of Axillary Sweat Glands

Surgical removal has been performed in recipients with severe isolated axillary hyperhidrosis. Removal may involve removal of the subcutaneous sweat glands without removal of any skin, limited excision of skin and removal of surrounding subcutaneous sweat glands, or a more radical excision of skin and subcutaneous tissue en bloc. Depending on the completeness of surgical excision, the treatment is effective in from 50%–95% of recipients.

4.3.8 Liposuction

Liposuction, a minimally invasive technique, has also been investigated as an alternative to surgical excision of the axillary sweat glands. Compared to surgical removal of axillary sweat glands, liposuction results in less disruption to the overlying skin resulting in smaller surgical scars and a diminished area of hair loss. Only scattered reports and case studies regarding this procedure were identified in the literature. The efficacy of liposuction for hyperhidrosis is not well-supported.

Note: Although similar in certain aspects, botulinum toxin products 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 preparations.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for the use of Botulinum toxin injection and for all Botulinum toxin products.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
September 30, 2011	Throughout	Policy Date of Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes
32664
64650
64653

HCPCS Code
J0585
J0587

Note: Codes 64650, 64653, J0585 and J0587 require prior approval. Claims will deny if prior approval has not been obtained.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital, Outpatient Hospital, and Office

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.