| Title               | Treatment of Hyperhidrosis   |  |
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| Number              | CP.MP.PR.8.01.519  |  |
| Revision<br>Date(s) | 06/12/07; 03/08/05; 06/08/04; 03/09/04; 09/12/03; 11/12/02; 09/07/99 |  |
| Effective Date      | June 12, 2007  |  |
| Replaces            | N/A  |  |
| Cross<br>References | CP.MP.PR.5.01.512 Botulinum Toxin                                    |  |

| Description | Hyperhidrosis may be defined as excessive sweating, beyond a level required to maintain<br>normal body temperature in response to heat exposure or exercise. In some patients with<br>hyperhidrosis, sweat production is so profound that it can exceed greater than 40<br>mL/m <sup>2</sup> /min, forty times the normal defined rate. Hyperhidrosis can be classified as   |
|-------------|--|
|             | either primary or secondary. Primary hyperhidrosis is idiopathic in nature, typically<br>involving the hands (palmar), feet (plantar), or axillae. Secondary hyperhidrosis can<br>result from a variety of drugs, such as tricyclic antidepressants, selective serotonin<br>reuptake inhibitors (SSRIs), or underlying diseases/conditions such as febrile diseases,<br>diabetes mellitus, or menopause. Gustatory hyperhidrosis is an unusual iatrogenic cause<br>of facial hyperhidrosis in response to hot or spicy foods, resulting from surgery to the<br>parotid gland and subsequent aberrant regenerating parasympathetic fibers.  |
|             | Primary (focal) hyperhidrosis can be extremely disabling socially and professionally and<br>can dramatically reduce the quality of life. The excessive moisture can lead to<br>maceration of the skin, which can result in secondary skin infections or odor<br>(bromhidrosis). When validated scales of quality of life are used to measure disease<br>burden, the effects of hyperhidrosis are comparable with those of severe psoriasis, end-<br>stage renal disease, rheumatoid arthritis, and multiple sclerosis. In addition,<br>hyperhidrosis may require several changes of clothing a day; excessive sweating may<br>also result in staining of clothing or shoes.  |
|             | Treatment of secondary hyperhidrosis naturally focuses on treatment of the underlying cause, such as discontinuing certain drugs or hormone replacement therapy as a treatment of menopausal symptoms. A variety of therapies have been investigated for primary hyperhidrosis, including topical therapy with aluminum chloride or tanning agents, iontophoresis, botulinum toxin, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands. Botulinum toxin (botox) has also been investigated as a treatment of secondary gustatory hyperhidrosis. In terms of botox, this policy discusses its use only as a treatment of hyperhidrosis. Other indications for botox are discussed in a separate medical policy. |

| Scope  | Medical policies are systematically developed guidelines that serve as a resource for<br>Company staff when determining coverage for specific medical procedures, drugs or<br>devices. Coverage for medical services is subject to the limits and conditions of the<br>member benefit plan. Members and their providers should consult the member benefit<br>booklet or contact a customer service representative to determine whether there are any<br>benefit limitations applicable to this service or supply. |
|--------|---|
| Policy | Primary Hyperhidrosis   |
|        | Treatment of primary (focal) hyperhidrosis may be considered <b>medically necessary</b> when the condition causes physical functional impairments such as skin maceration with secondary infections.  |
|        | Treatment of primary(focal) hyperhidrosis, including aluminum chloride, iontophoresis, botulinum toxin, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands is considered <b>cosmetic</b> in the absence of physical functional impairment or medical complications associated with the condition.   |
|        | According to evidence-based literature axillary liposuction is considered <b>investigational</b> as a treatment for primary hyperhidrosis.  |
|        | Secondary Gustatory Hyperhidrosis   |
|        | Botulinum toxin may be considered <b>medically necessary</b> as a treatment for secondary gustatory hyperhidrosis.  |
|        |   |

| Policy<br>Guidelines   | A variety of iontophoretic devices can be purchased for use in the home. There are no specific HCPCS codes for these pieces of DME. Code E1399 (Durable medical equipment, miscellaneous)<br>Botulinum toxin may be coded for using HCPCS code J0585 (Botulinum toxin, type A, per unit).  |
|------------------------|--|
| Benefit<br>Application | For the purposes of this policy, the following terms are defined below:<br><b>Cosmetic</b> : In this policy, cosmetic services are those which are primarily intended to<br>preserve or improve appearance. Cosmetic surgery is performed to reshape normal<br>structures of the body in order to improve the patient's appearance or self-esteem.   |
|                        | <b>Physical Functional Impairment</b> : In this policy, physical functional impairment means a limitation from normal (or baseline level) of physical functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of nearby body parts or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments. |

|            | <b>Reconstructive Surgery</b> : In this policy, reconstructive surgery refers to surgeries performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function.  |
|------------|---|
| Rationale/ | Aluminum Chloride   |
| Source     | Topical products are the first line of therapy in treating primary (focal) hyperhidrosis.<br>Aluminum chloride, like other metallic salts, exerts its anhidrotic effect by obstructing<br>the distal sweat ducts within the acrosyringium by facilitating the formation of a<br>precipitate. Common side effects usually limit the efficacy of the modality to mild cases<br>of hyperhidrosis. For those patients who respond to antiperspirants, long-term use can<br>sometimes result in degeneration of the eccrine unit and resolution of the localized<br>hyperhidrosis. A prescription product is available (Drysol). Aluminum chloride is<br>predominantly used to treat axillary hyperhidrosis and not palmar or volar hyperhidrosis. |
|            | Iontophoresis   |
|            | Iontophoresis is a technique that involves the use of an electric current to introduce various ions through the skin. Published literature regarding iontophoresis as a treatment of hyperhidrosis is sparse.   |
|            | The mechanism of action is not precisely known, but is thought to be related to plugging of the sweat gland pores. The typical device consists of trays containing electrodes. Prior to using, the trays are filled with tap water, the patient inserts the hands or feet or positions the device in the axilla, and the current is turned on. Patients are treated for approximately 20 minutes, with treatments every 2 to 3 days for 5 to 10 sessions before an effect is observed. Maintenance therapy may be applied every two weeks after initial therapy.  |
|            | 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%.  |
|            | In one controlled blinded study, treatment of palmar hyperhidrosis by alternating current (AC) or by AC with DC-offset (AC/DC) was compared with the conventional DC method. Palmar hyperhidrosis was completely controlled after an average of 11 treatments by either AC/DA iontophoresis or the conventional DC method. Virtually no effect was seen when AC without DC-offset was used for TWI. The authors state AC/DC iontophoresis should become the treatment of choice for palmoplantar hyperhidrosis.   |
|            | Iontophoresis became more recognized as a practical approach in the treatment of hyperhidrosis in 1968. No large randomized trials have been performed, but several smaller trials suggest significant benefit. Irritation is a significant problem with this technique as well. It causes dry, peeling, and cracked skin at the treatment site, especially in the axillae treatment site.  |

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After topical aluminum chloride, tap water iontophoresis is traditionally thought of as the second line in treating palmar or plantar hyperhidrosis, but it is frequently too irritating for regular use in the axillae.

## **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. Laskawi and colleagues reported on the outcomes of 19 patients with gustatory hyperhidrosis treated with botulinum toxin injected into every 4 cm<sup>2</sup> of involved skin. In all cases, gustatory sweating ceased within two days, with a mean duration of effect of 17 months. There is a considerable body of published literature regarding botulinum toxin injection in the treatment of axillary hyperhidrosis, all of which substantiates its effectiveness. Two of these were double-blind, randomized trials that demonstrated that botulinum toxin was more effective than placebo in patients with palmar hyperhidrosis. The drawback of this approach is the need for repeated injections, which have led some to consider surgical approaches, discussed below.

## **Endoscopic Transthoracic Sympathectomy**

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. Therefore, various surgical techniques of thoracic sympathectomy have been investigated as a curative procedure, primarily for combined palmar and axillary hyperhidrosis. Large case series have reported success rates of up to 98% in large case series. A variety of approaches have been reported, but endoscopic techniques have emerged as a minimally invasive alternative to either transaxillary, supraclavicular, or anterior thoracic approaches. 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 can occur in up to 55% of patients, reducing patient satisfaction with the procedure. Gustatory sweating may also occur. Sympathectomy also results in cardiac sympathetic denervation, which in turn can lead to a 10% reduction in the heart rate.

## Surgical Removal of Axillary Sweat Glands

Both eccrine and apocrine axillary sweat glands are predominantly located in the superficial subcutis and dermal subcutaneous interface, with scattered eccrine glands located completely in the dermis. Surgical removal has been performed in patients 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 patients. Liposuction has also been investigated as a minimally invasive technique to surgical excision. In some case, the

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procedure has been performed to remove the apocrine sweat glands, located deeper in the dermis, and responsible for axillary malodor, which may be referred to as osmidrosis, or bromidrosis if the malodor is also associated with hyperhidrosis. Although this procedure has been performed for several decades, only scattered case reports regarding its effectiveness were identified in a MEDLINE literature search. References: 1. Levit F. Treatment of hyperhidrosis by tap water iontophoresis. *Cutis* 1980; 26(2):192-4. 2. 2003 TEC Assessment; Tab 3, Iontophoresis for Medical Indications. 3. Laskawi R, Drobik C, Schonebeck C. Up-to-date report of botulinum toxin type A treatment in patients with gustatory sweating (Frey's syndrome). Laryngoscope 1998; 108(3):381-84. 4. Schnider P, Binder M, Auff E, et al. Double blind trial of botulinum A toxin for the treatment of focal hyperhidrosis of the palms. Br J Dermatol 1997; 136(4):548-52. 5. Shelley WB, Talanin NY, Shelley ED. Botulinum toxin therapy for palmar hyperhidrosis. J Am Acad Dermatol 1998; 38(2 pt 1):227-9. 6. Naumann M, Hofmann U, Bergman I, et al. Focal hyperhidrosis: effective treatment with intracutaneous botulinum toxin. Arch Dermatol 1998; 134(3):301-04. 7. Naumann MK, Hamm H, Lowe NJ. Effect of botulinum toxin type A on quality of life measures in patients with excessive axillary sweating: a randomized controlled trial. Br J Dermatol 2002; 147(6):1218-26. 8. Naumann M, Lowe NJ, Kumar CR, et al. Botulinum toxin type A is a safe and effective treatment for axillary hyperhidrosis over 16 months: a prospective study. Arch Dermatol 2003; 139(6):731-6. 9. Campanati A, Penna L, Guzzo T, et al. Quality-of-life assessment in patients with hyperhidrosis before and after treatment with botulinum toxin: results of an openlabel study. Clin Ther 2003; 25(1):298-308. 10. Lowe NJ, Yamauchi PS, Lask GP, et al. Efficacy and safety of botulinum toxin type A in the treatment of palmar hyperhidrosis: a double-blind, randomized, placebocontrolled study. Dermatol Surg 2002; 28(9):822-7. 11. Saadia D, Voustianiouk A, Wang AK, et al. Botulinum toxin type A in primary palmar hyperhidrosis: randomized, single-blind, two dose study. *Neurology* 2001; 57(11):2095-9. 12. Naumann M, Lowe NJ. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomized, parallel group, double blind, placebo controlled trial. BMJ 2001; 323(7313):596-9. 13. Heckmann M, Ceballow-Baumann AO, Plewig G. Botulinum toxin A for axillary hyperhidrosis (excessive sweating). N Engl J Med 2001; 344(7):488-93. 14. Drott C, Gothberg G, Claes G. Endoscopic transthoracic sympathectomy: an efficient and safe method for the treatment of hyperhidrosis. J Am Acad Dermatol 1995 July; 33(1):78-81

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| Codes | Number | Description  |
|-------|--------|--|
| CPT   | 32664  | Thoracoscopy; with thoracic sympathectomy          |
|       | 64650  | Chemodenervation of eccrine glands; both axillae   |
|       | 64653  | ; other area(s) (e.g., scalp, face, neck), per day |

| Codes              | Number             | Description                             |  |
|--------------------|--------------------|---|--|
|                    | 89230              | Sweat collection by iontophoresis       |  |
| ICD-9<br>Procedure |                    |   |  |
| ICD-9<br>Diagnosis | 705.21             | Primary focal hyperhidrosis             |  |
|                    | 705.22             | Secondary focal hyperhidrosis           |  |
|                    | 780.8              | Hyperhidrosis                           |  |
| HCPCS              | J0585              | Botulinum toxin, type A, per 100 units  |  |
| Type of<br>Service | Medicine / Surgery |   |  |
| Place of           | Inpatient (t       | Inpatient (thoracoscopic sympathectomy) |  |
| Service Outpatient |                    |   |  |