



Louisiana

Treatment of Hyperhidrosis

Policy # 00172

Original Effective Date: 07/15/2005

Current Effective Date: 06/20/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Botulinum Toxins are considered separately in medical policy 00012.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider treatment of primary hyperhidrosis, including endoscopic transthoracic sympathectomy (ETS) and surgical excision of axillary sweat glands to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility will be considered when both of the following criteria are met:

- Medical complications such as persistent skin maceration with recurrent secondary infections or persistent eczematous dermatitis despite medical treatments with topical dermatologic agents; and
- Endoscopic transthoracic sympathectomy or surgical excision of axillary sweat glands will be considered eligible for coverage after a failed conservative trial of botulinum toxin and aluminum chloride.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the treatment of primary hyperhidrosis when patient selection criteria are not met to be **investigational**.*

Based on review of available data, the Company considers iontophoresis, microwave treatment, radiofrequency ablation, lumbar sympathectomy and axillary liposuction as a treatment for primary hyperhidrosis to be **investigational**.*

Background/Overview

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 hyperhidrosis is idiopathic in nature, typically involving the hands (palmar), feet (plantar) or axillae. Secondary hyperhidrosis can result from a variety of drugs, such as tricyclic antidepressants,

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selective serotonin reuptake inhibitors (SSRIs) or underlying diseases/conditions, such as febrile diseases, diabetes mellitus or menopause. Gustatory hyperhidrosis is an unusual iatrogenic cause of facial hyperhidrosis in response to hot or spicy foods, resulting from surgery to the parotid gland and subsequent aberrant regenerating parasympathetic fibers.

The consequences of hyperhidrosis are primarily psychosocial in nature. Excessive sweating may be socially embarrassing (i.e., 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 a day; excessive sweating may 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 ETS and surgical excision of axillary sweat glands. Botulinum toxin has also been investigated as a treatment of secondary gustatory hyperhidrosis.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 2 sessions of approximately one hour in duration. Sessions occur in a physician's office and local anesthetic is used.

Centers for Medicare & Medicaid Services (CMS):

There is no national policy regarding Medicare coverage of ETS as a treatment for hyperhidrosis. The CMS has no national coverage policy regarding the use of botulinum toxin for treatment of hyperhidrosis.

Rationale/Source

Aluminum Chloride

Aluminum chloride is a common component of over-the-counter antiperspirants, although a prescription product is available (Drysol®)[‡]. Although the mechanism is unclear, aluminum chloride is associated with atrophy of the secretory cells seen in eccrine sweat glands. Aluminum chloride is 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.

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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%. However, the published literature regarding iontophoresis as a treatment of hyperhidrosis is sparse. A 2003 Technology Evaluation Centers (TEC) Assessment on iontophoresis concluded that evidence was insufficient to determine whether the effects of iontophoresis for the treatment of hyperhidrosis exceed those of placebo. The 2003 TEC Assessment also concluded that, in the treatment of hyperhidrosis, there is insufficient evidence to show that tap water iontophoresis is as beneficial as topical drug administration. The conclusions of the TEC Assessment form the rationale for the change in the coverage statement, which in the original suggested that iontophoresis could be considered medically necessary.

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 4cm² 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.

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 percent. 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. 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.

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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 cases, the 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 literature search.

A literature search for studies published from 2005 through January 2008 indicates continued interest in the use of botulinum toxin to treat hyperhidrosis. Allergan funded a multicenter double-blind, randomized, placebo-controlled efficacy and safety study of Botox (0, 50, or 75U) in 322 subjects with persistent bilateral primary axillary hyperhidrosis (e.g., exhibiting at least two of the following: bilateral sweating, impairment of daily activities, frequency of at least once per week, younger than 25 years of age at onset, positive family history and cessation of focal sweating during sleep). Enrollment criteria included a resting sweat production of at least 50mg/axilla in 5 minutes and a rating of 3 or 4 (underarm sweating barely tolerable or intolerable, and frequently or always interferes with daily activities) on the Hyperhidrosis Disease Severity Scale (HDSS). Retreatment after 4 weeks was allowed in subjects with at least 50mg of sweat (per axilla) over 5 minutes and an HDSS score of 3 or 4. Following the first injection, 75% of subjects in the Botox groups showed at least a 2 point improvement in the HDSS, compared with 25% of subjects in the placebo group. Sweat production decreased by 87% (75U), 82% (50U) and 33% (vehicle). (Similar results were obtained in patients requiring a second treatment). The median duration of effect was 197, 205 and 96 days (75U, 50U, and vehicle, respectively). Seventy-eight percent of subjects (252) completed the 52-week study; 96/110 (87%) in the 75-U group, 83/104 (80%) in the 50-U group and 73/108 (68%) in the control group. Intent-to-treat analysis at 52 weeks showed a responder rate (greater than 2 point improvement on the HDSS) for 54 (49%) subjects in the 75-U group, 57 (55%) in the 50-U group and 6 (6%) in the placebo group. Injection-site pain was reported in about 10% of all groups, with a mean duration of 2.4 days (10 day maximum). A topical preparation of botulinum toxin A was studied in a small (12 patient) vehicle-controlled split-side trial. At 4 weeks, sweat production was reduced by 65% with topical application of Botox vs. 25% on the vehicle-treated side. Additional studies with a larger number of subjects and longer follow-up are needed to assess this new formulation.

A literature search in 2009 found that the use of botulinum type A for glandular hypersecretory disorders and the optimal surgical technique for hyperhidrosis continues to be of interest. However, few long-term, randomized clinical comparative trials exist for the treatment of hyperhidrosis conditions.

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Microwave Treatment

A 2012 RCT evaluated a microwave device for treating primary focal hyperhidrosis. This device applies microwave energy to superficial skin structures with the intent of inducing thermolysis of the eccrine and apocrine sweat glands. This industry-sponsored, double-blind trial randomized 120 adults with primary axillary hyperhidrosis 2:1 to active (n=81) or sham (n=39) treatment. Treatment consisted of 2 sessions, separated by approximately 2 weeks. Patients who responded adequately after 1 session or declined further treatment did not undergo the second session; a third procedure was allowed within 30 days for patients who still had a high level of sweating after 2 sessions. All patients in the sham group had 2 sessions. In the active treatment group, 11 (9%) patients had 1 session, 60 (74%) had 2 sessions, and 10 (8%) patients had 3 sessions. The primary efficacy end point was an HDSS score of 1 or 2 at the 30-day follow-up; HDSS score at 6 months was a secondary outcome. A total of 101 (84%) of 120 patients completed the study. At 30 days, 89% of the active treatment group and 54% of the sham group had an HDSS score of 1 or 2 ($p<0.001$). At 6 months, 67% of the active treatment group versus 44% of the sham group had an HDSS score of 1 or 2 ($p=0.02$). Unblinding occurred at 6 months. Twelve-month data were available for the active treatment group only; 69% reported an HDSS score of 1 or 2. There were 45 procedure-related adverse events in 23 (28%) of the active treatment group versus 5 (13%) of the sham group. The most frequently reported adverse event was altered sensation; no serious adverse events were reported. Compensatory sweating was reported by 2 patients in each group (mean duration, 52 days). The authors noted that study data provided an opportunity to identify areas for improvement in the treatment protocol including waiting longer between treatments and using a higher dose of energy at the second session.

A 2012 industry-sponsored case series reported on 31 patients with primary axillary hyperhidrosis treated with microwave therapy using the miraDry system. All patients had an HDSS score of 3 or 4 at baseline. The primary efficacy outcome (the proportion of patients whose HDSS score decreased to 1 or 2) was 28 (90%) at 6 and 12 months posttreatment. Longer term skin-related adverse effects (that all resolved over time) were altered sensation in the skin of the axillae (65% of patients; median duration, 37 days) and palpable bumps under the skin of the axillae (71% of patients; median duration, 41 days).

Section Summary: Microwave Treatment

One RCT and case series provide insufficient evidence that microwave treatment improves the health outcome for primary focal hyperhidrosis. The RCT reported short-term benefit of microwave treatment in reducing hyperhidrosis, but also reported a high rate of skin-related adverse effects (eg, pain, altered sensation). Additional controlled trials with long-term follow-up in the treatment and control groups, a longer period of blinding, and a consistent treatment protocol are needed to confirm the efficacy of this treatment and to better define the risk-benefit ratio.

Radiofrequency Ablation

A 2013 study evaluated radiofrequency ablation (RFA) as a treatment for patients with severe bilateral palmar hyperhidrosis resistant to conservative treatment. The study was conducted in Turkey and retrospectively reviewed outcomes after RFA (n=48) or transthoracic sympathectomy (n=46). Patients were

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not randomized to treatment group. After a mean follow-up of 15 months, palmar hydrosis was absent in 36 (75%) patients in the RFA group versus 44 (96%) patients in the surgery group. The difference in outcomes between groups was statistically significant, favoring the surgical intervention ($p < 0.01$). Six patients in each group reported moderate or severe compensatory sweating ($p = 0.78$).

Section Summary: Radiofrequency Ablation

One nonrandomized comparative study represents insufficient evidence for RFA as a treatment of hyperhidrosis. In this single available study, RFA was inferior to surgical sympathectomy.

Lumbar Sympathectomy

No RCTs on the use of lumbar sympathectomy to treat primary plantar hyperhidrosis were identified, but several case series were identified. A 2009 series by Rieger et al from Austria evaluated surgical results in 90 patients (59 men, 31 women with severe plantar hyperhidrosis). Thirty-seven (41%) patients had only plantar hyperhidrosis and 53 (59%) had plantar and palmar hyperhidrosis. All patients had previously used other treatments including topical antiperspirant (ie aluminum chloride). There were a total of 178 procedures, 90 on the right side and 88 on the left side. The technique involved resecting a segment of the sympathetic trunk between the third and fourth lumbar bodies together with the ganglia (L3 and/or L4). After a mean follow-up of 24 months (range, 3-45 months), hyperhidrosis was eliminated in 87 (97%) of 90 patients. Postoperative neuralgia occurred in 38 (42%) patients between the seventh and eighth day. The pain lasted less than 4 weeks in 11 patients, 1 to 3 months in 19 patients, 4 to 12 months in 5 patients, and more than 12 months in 3 patients. Three men reported temporary sexual symptoms; 1 was incapable of ejaculation for 2 months. None of the women reported postoperative sexual dysfunction.

In 2010, Reisfeld reported on a study of bilateral endoscopic lumbar sympathectomy in 63 patients with focal plantar hyperhidrosis from a specialized hyperhidrosis clinic in the United States. Thirteen (21%) patients were male and 50 (79%) were female. A clamping method was used in which clamps were placed at L3 (47%), L4 (52%), and L2 (1%). There was a learning curve with this procedure, and 5 early cases were converted to an open procedure. Fifty-six (89%) patients had previously undergone some form of thoracic sympathectomy, and all had tried conservative measures. After a mean follow-up of 7 months, all patients considered their plantar hyperhidrosis symptoms to be "cured" or "improved"; 97% reported "cure." All patients with previous thoracic sympathectomy had some degree of compensatory sweating. After lumbar sympathectomy, 51 (91%) of the 56 patients reported that their compensatory sweating was unchanged. In the 7 patients who did not have a previous thoracic sympathectomy, 1 reported mild and 6 reported moderate compensatory sweating. Male patients reported no sexual problems; investigators did not report possible sexual problems among female patients.

It is worth noting that, in contrast to earlier concerns about this procedure being associated with risks of permanent sexual dysfunction in men and women, these case series found no instances of permanent sexual dysfunction. A 2004 review from a multispecialty working group on hyperhidrosis stated that lumbar sympathectomy is not recommended for plantar hyperhidrosis because of associated sexual dysfunction;

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this article did not cite any data documenting sexual dysfunction. To date, there are very few studies on endoscopic lumbar sympathectomy for focal plantar hyperhidrosis and no comparative studies.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Treatment of Hyperhidrosis", 8.01.19,4:2018.
2. Eisenach J; Atkinson J; Fealey R: Hyperhidrosis: evolving therapies for a well-established phenomenon. *Mayo Clinic Proceedings* 2005 May; 80 (5):657-66.

Policy History

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| | |
|------------|---|
| 06/07/2005 | Medical Director review |
| 06/21/2005 | Medical Policy Committee review |
| 07/15/2005 | Managed Care Advisory Council approval |
| 07/12/2006 | Medical Director review |
| 07/19/2006 | Medical Policy Committee review. Format revisions. FDA information added. No change in policy statement. |
| 08/01/2007 | Medical Director review |
| 08/15/2007 | Medical Policy Committee approval. No change to coverage eligibility. |
| 08/06/2008 | Medical Director review |
| 08/20/2008 | Medical Policy Committee approval. Updated rationale. No change to coverage eligibility. |
| 08/06/2009 | Medical Policy Committee approval |
| 08/26/2009 | Medical Policy Implementation Committee approval. No change to coverage eligibility. |
| 11/12/2009 | Medical Policy Committee approval. |
| 11/18/2009 | Medical Policy Implementation Committee approval. Deleted the "When Services Are Considered Not Medically Necessary" section. Added that when patient selection criteria are not met, to deny investigational. |
| 11/04/2010 | Medical Policy Committee review |
| 11/16/2010 | Medical Policy Implementation Committee approval. Added to the coverage section <i>Note</i> that <i>incobotulinumtoxinA (Xeomin)[®] ‡</i> is not indicated for hyperhidrosis. Coverage eligibility unchanged. |
| 11/03/2011 | Medical Policy Committee review |
| 11/16/2011 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 11/01/2012 | Medical Policy Committee review |
| 11/28/2012 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 04/01/2013 | Coding updated |
| 06/04/2013 | Criteria clarified. Changed from "any" to "both". |
| 08/01/2013 | Medical Policy Committee review |
| 08/21/2013 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 03/06/2014 | Medical Policy Committee review |
| 03/19/2014 | Medical Policy Implementation Committee approval. Changed "Botox" to botulinum toxin type A products to coincide with the updates to the Botox policy. Also added a statement reflecting use of botulinum toxin type B to be investigational for primary hyperhidrosis. |
| 06/04/2015 | Medical Policy Committee review |
| 06/20/2015 | Medical Policy Implementation Committee approval. No change to coverage. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |

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- 06/02/2016 Medical Policy Committee review
- 06/20/2016 Medical Policy Implementation Committee approval. No change to coverage.
- 06/01/2017 Medical Policy Committee review
- 06/21/2017 Medical Policy Implementation Committee approval. Revised the eligible for coverage statement by removing “the use of aluminum chloride, botulinum toxin type A products (Botox, Xeomin, Dysport)”. Revised the first criteria bullet to state “Medical complications such as persistent skin maceration with recurrent secondary infections or persistent eczematous dermatitis despite medical treatments with topical dermatologic agents.” Removed the second investigational statement regarding the treatment of primary hyperhidrosis with botulinum toxin type B (Myobloc). Added “microwave treatment, radiofrequency ablation, lumbar sympathectomy” to investigational statement.
- 06/07/2018 Medical Policy Committee review
- 06/20/2018 Medical Policy Implementation Committee approval. No change to coverage.
- Next Scheduled Review Date: 06/2019

Coding

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| Code Type | Code |
|------------------|--|
| CPT | 11450, 11451, 15839, 32664, 64632, 64650, 64653, 64818 |
| HCPCS | J0585, J0586, J0587, J0588 |
| ICD-10 Diagnosis | L74.510 L74.511 L74.512 L74.513 L74.519 L74.52 R61 |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary (or "Medical Necessity")** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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