



Louisiana

Treatment of Hyperhidrosis

Policy # 00172

Original Effective Date: 07/15/2005

Current Effective Date: 10/12/2020

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 endoscopic transthoracic sympathectomy (ETS) and surgical excision of axillary sweat glands (applicable only to axillary hyperhidrosis) **eligible for coverage**** for the treatment of primary focal hyperhidrosis (i.e. axillary, palmar, craniofacial regions) when both of the following criteria (1 and 2) are met:

1. Patient has one of the following medical conditions (a-c):
 - a. History of recurrent skin maceration with bacterial or fungal infections; or
 - b. History of recurrent secondary infections; or
 - c. History of persistent eczematous dermatitis despite medical treatments with topical dermatologic or systemic anticholinergic agents; and
2. Patient has failed conservative treatment with aluminum chloride 20% solution and botulinum toxin (applicable only to axillary and palmar hyperhidrosis) used individually and in combination.

Note: Botulinum toxin coverage criteria for axillary and palmar primary hyperhidrosis are noted in MP 00012.

Based on review of available data, the Company considers surgical tympanic neurectomy to be **eligible for coverage**** for the treatment of severe secondary gustatory hyperhidrosis when conservative treatment with aluminum chloride 20% solution has failed.

When Services Are Considered Not Medically Necessary

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Treatment of primary focal hyperhidrosis in the absence of functional impairment and any of the medical conditions noted above (a-c) is considered to be **not medically necessary.****

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 other treatments for focal hyperhidrosis and when coverage criteria are not met **investigational***, including but not limited to axillary liposuction, iontophoresis, microwave treatment, radiofrequency ablation, and lumbar sympathectomy for plantar hyperhidrosis.

All other treatments for severe secondary gustatory hyperhidrosis are considered **investigational***, including but not limited to iontophoresis.

Policy Guidelines

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.

Absent evidence to the contrary, botulinum toxin products are considered to have a class effect. A multispecialty working group have defined primary focal hyperhidrosis as a condition characterized by 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, 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.

The Hyperhidrosis Disease Severity Scale is used by patients to rate the severity of their symptoms on a scale of 1 to 4 (see Table PG1):

Table PG1. The Hyperhidrosis Disease Severity Scale

Score	Definition
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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

Background/Overview

Hyperhidrosis

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, 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, 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 the 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.

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The consequences of hyperhidrosis are primarily psychosocial. 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.

Treatment

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 for menopausal symptoms.

Iontophoresis uses electrical current to deliver medication transdermally. A charged ionic drug is placed on the skin with an electrode of the same charge, which drives the drug into the skin, with the purpose of achieving better penetration of the drug into underlying tissue. The benefits of this method would be an enhancement of treatment effects and a reduction in adverse events associated with systemic administration of the drug.

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

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in less compensatory sweating, but there remains a lack of consensus about which approach best minimizes the risk of this adverse event. Also, with lumbar sympathectomy for plantar hyperhidrosis, there has been concern about the risk of postoperative sexual dysfunction in both men and women.

Outcome Measures

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 (see Appendix Table 1) has had a good correlation to other assessment tools and is practical in the clinical setting.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2011, the miraDry[®] System (Miramar Labs) was cleared for marketing by FDA through the 510(k) process for treating primary axillary hyperhidrosis. This microwave device is designed to heat tissue at the dermal-hypodermal interface, the location of the sweat glands. Treatment consists of 2 sessions for a total duration of approximately 1 hour. Sessions occur in a physician's office, and a local anesthetic is used. The device is currently not approved for the treatment of palmar or plantar hyperhidrosis.

Rationale/Source

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.

Primary Focal Hyperhidrosis

Iontophoresis

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive iontophoresis, the evidence includes a systematic review, a 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-

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term treatment of palmar hyperhidrosis. Additional RCTs are needed comparing iontophoresis with 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.

Microwave

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive microwave treatment, the evidence includes a systematic review, an RCT, and case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The RCT, conducted in patients with primary axillary hyperhidrosis, found a short-term benefit of microwave treatment vs sham therapy, but there was a high rate of skin-related adverse events. Additional RCTs are needed comparing microwave treatment with 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.

Radiofrequency Ablation

For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive radiofrequency ablation, the evidence includes 2 small RCTs and a nonrandomized cohort study. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. One nonrandomized comparative study found RFA inferior to surgical sympathectomy for patients with severe bilateral palmar hyperhidrosis resistant to conservative treatment. Two small RCTs that compared RFA to botulinum toxin A in patients with palmar or axillary hyperhidrosis had conflicting results. The evidence is insufficient to determine the effects of the technology on health outcomes.

Surgery

For individuals who have primary axillary hyperhidrosis who receive surgical excision of axillary sweat glands, the evidence includes review articles. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The evidence has shown that excision is highly effective, and this treatment is considered standard of care for this indication. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary axillary and palmar hyperhidrosis who receive endoscopic transthoracic sympathectomy, the evidence includes several RCTs, a meta-analysis, and case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The meta-analysis

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found a high rate of clinical efficacy after endoscopic transthoracic sympathectomy, although the rate of postoperative compensatory sweating was substantial. Subsequent studies have supported these findings. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary plantar hyperhidrosis who receive lumbar sympathectomy, the evidence includes one RCT conducted at a single center in Brazil, case series, and a systematic review. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Case series have reported high rates of clinical efficacy, but findings are inconclusive due to lack of control groups. The RCT was limited by its small sample size and lack of blinded outcome assessment. Moreover, there have been substantial rates of compensatory sweating and concerns about adverse events on sexual functioning. The evidence is insufficient to determine the effects of the technology on health outcomes.

Secondary Gustatory Hyperhidrosis

For individuals who have severe secondary gustatory hyperhidrosis who receive iontophoresis or botulinum toxin, the evidence includes uncontrolled studies and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The systematic reviews did not identify any relevant RCTs. RCTs are needed to evaluate the safety and efficacy of these treatments for severe secondary gustatory hyperhidrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have severe secondary gustatory hyperhidrosis who receive tympanic neurectomy, the evidence includes uncontrolled studies and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. This treatment has high success rates, without the need for repeated interventions, and is considered standard of care for this indication. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Society of Thoracic Surgeons

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In 2011, the Society of Thoracic Surgeons published an expert consensus statement on the surgical treatment of hyperhidrosis. The document stated that endoscopic thoracic sympathectomy is the treatment of choice for patients with primary hyperhidrosis. It further recommended the following treatment strategies (with R referring to rib and the number to which rib):

- R3 interruption for palmar hyperhidrosis; an R4 interruption is also reasonable. The authors note a slightly higher rate of compensatory sweating with R3, but R3 is also more effective at treating hyperhidrosis.
- R4 or R5 interruption for palmar-axillary, palmar-axillary-plantar, or axillary hyperhidrosis alone; R5 interruption is also an option for axillary hyperhidrosis alone.
- R3 interruption for craniofacial hyperhidrosis without blushing; an R2 and R3 procedure is an option but may lead to a higher rate of compensatory sweating, and also increases the risk of Horner syndrome.

According to the statement, endoscopic thoracic sympathectomy has been recommended for patients with severe symptoms that cannot be managed with other therapies who meet the following criteria:

- Onset of hyperhidrosis at an early age (before 16 years)
- <25 years of age at time of surgery
- Body mass index <28 kg/m²
- No sweating during sleep
- No significant comorbidities
- Resting heart rate <55 beats per minute

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence issued guidance stating that there was sufficient evidence for the efficacy and safety of endoscopic thoracic sympathectomy for primary facial blushing to support the use of the procedure.

The Institute also issued guidance in 2014 on endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb. The guidance stated that "current evidence on the efficacy and safety of endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb is adequate to support the use of this procedure." Also: "Due to the risk of side effects, this procedure should only be considered in patients suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments."

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U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT02854540	Management of Palmar Hyperhidrosis with Hydrogel-based Iontophoresis	13	Aug 2018
<i>Ongoing</i>			
NCT02295891	MiraDry Treatment for Focal Axillary Hyperhidrosis (MiraDry Tx)	24	Jul 2020
NCT03236012	Hyperhidrosis of the Residual Limb in Patients With Amputations: Developing a Treatment Approach	25	Dec 2023
NCT03921320	Evaluation of Compensatory Sweating After Unilateral Videothoracoscopic Sympathectomy of the Dominant Side or Sequential Bilateral Videothoracoscopic Sympathectomy: a Multicentric Randomized Trial	200	Dec 2020

NCT: national clinical trial.

References

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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.
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08/20/2008 Medical Policy Committee approval. Updated rationale. No change to coverage eligibility.
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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 *Note that incobotulinumtoxinA (Xeomin®) ‡ 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

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Louisiana

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Policy # 00172

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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.

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.

06/06/2019 Medical Policy Committee review

06/19/2019 Medical Policy Implementation Committee approval. No change to coverage.

09/03/2020 Medical Policy Committee review

09/09/2020 Medical Policy Implementation Committee approval. Botox products removed from this policy. Revised to track BCBSA.

Next Scheduled Review Date: 09/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	11450, 11451, 15839, 32664, 64632, 64650, 64653, 64818
HCPCS	No codes
ICD-10 Diagnosis	L74.510-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:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (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

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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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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