Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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(See policy history boxes for previous effective dates)

Title: Treatment of Hyperhidrosis, Excluding Botulinum

Description/Background

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 scalp or face and predominately over the forehead, lips, and nose. Secondary facial gustatory hyperhidrosis 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.

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, topical anticholinergic medications, oral anticholinergic medications, iontophoresis, 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 versus T4 sympathectomy) result 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 (Appendix Table 1) has had good correlation to other assessment tools and is practical in the clinical setting.

Regulatory Status:

Drysol™ (Person and Covey), an aluminum chloride [hexahydrate] 20% topical solution, was approved by the U.S. Food and Drug Administration (FDA) as an aid in the management of hyperhidrosis (axillae, palmar, plantar, craniofacial); originally available by prescription, it is now sold over-the-counter. Additional topical medicines approved by the FDA include Hypercare Topical and Xerac AC.

Qbrexza™(glycopyrronium) 2.4% topical cloth was FDA-approved for use in the treatment of primary axillary hyperhidrosis in 2018.

In 2011, the miraDry® System (Miramar Labs) was cleared for marketing by the 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 two 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.

In 2023, the Brella® Sweat Control Patch (Candesant Biomedical, Inc.) was approved by the FDA through the 513(f)(2) de novo pathway for the treatment of primary axillary hyperhidrosis in adults. The patch is applied by a clinician and kept in place for up to 3 minutes, during which the patch's sodium layer creates heat after coming into contact with sweat, which leads to temporary inactivation of sweat glands.

Medical Policy Statement

The safety and effectiveness of hyperhidrosis treatments have been established. They may be considered a useful therapeutic option in specified situations.

Inclusionary and Exclusionary Guidelines

Primary Focal Hyperhidrosis (Regions: axillary, palmar, plantar and craniofacial)
Treatment of primary focal hyperhidrosis may be considered **established** with any of the following medical conditions:

- acrocyanosis of the hands; or
- history of recurrent skin maceration with bacterial or fungal infections; or
- history of recurrent secondary infections; or
- history of persistent eczematous dermatitis despite medical treatments with topical dermatologic or systemic anticholinergic agents; or
- any other functional impairment (a restriction or impairment of daily activities or interactions) caused by hyperhidrosis.

Treatments that may be considered **established** by focal region include:
Axillary:

- Aluminum chloride 20% solution
- Surgical options (ie, endoscopic transthoracic sympathectomy [ETS] and surgical excision of axillary sweat glands), if conservative treatment (ie, aluminum chloride or botulinum toxin*, individually and in combination) has failed;

Palmar:

- Aluminum chloride 20% solution
- Endoscopic transthoracic sympathectomy, if conservative treatment (ie, aluminum chloride or botulinum toxin*, individually and in combination) has failed;

Plantar:

- Aluminum chloride 20% solution;

Craniofacial
- Aluminum chloride 20% solution
- Endoscopic transthoracic sympathectomy, if conservative treatment (ie, aluminum chloride) has failed.

***Note:** Refer to the pharmacy Botulinum Toxin policies for use in treating hyperhidrosis.*

Treatments that are considered **experimental/investigational** by focal region include:
Axillary
- Axillary liposuction
- Iontophoresis
- Microwave treatment
- Radiofrequency ablation;

Palmer
- Iontophoresis
- Microwave treatment
- Radiofrequency ablation;

Plantar
- Iontophoresis
- Lumbar sympathectomy
- Microwave treatment
- Radiofrequency ablation;

Craniofacial
- Iontophoresis
- Microwave treatment
- Radiofrequency ablation.

Treatment of hyperhidrosis is **not covered** if the above criteria are not met.

Secondary Gustatory Hyperhidrosis
Secondary gustatory hyperhidrosis is most often related to Frey syndrome (auriculotemporal nerve syndrome); but may also be associated with:
- Encephalitis
- Syringomyelia
- Diabetes
- Facial herpes zoster
- Parotid infection or surgery
- Trauma or injury, etc.

The following treatments may be considered **established** for the treatment of severe secondary gustatory hyperhidrosis (hyperhidrosis disease severity scale 3 or 4 *[appendix table 1]*):
- aluminum chloride 20% solution
- surgical options (ie, tympanic neurectomy), if conservative treatment has failed.

The following treatment* is considered **experimental/investigational** as a treatment for severe secondary gustatory hyperhidrosis including, but not limited to:
- iontophoresis

***Note:** Refer to the pharmacy Botulinum Toxin policies for use in treating hyperhidrosis.*

Treatment of secondary gustatory hyperhidrosis is **not covered** if the above criteria are not met.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

32664 64999 69676

Other codes (investigational, not medically necessary, etc.):

E1399 64818 97024 97033 97039

RATIONALE

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Iontophoresis for Primary Focal Hyperhidrosis (ie, Axillary, Palmar, Plantar, Craniofacial

Clinical Context and Therapy Purpose

The purpose of iontophoresis of sweat glands in individuals who have primary focal hyperhidrosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with primary focal hyperhidrosis. Primary focal hyperhidrosis is idiopathic, typically involving the hands (palmar), feet (plantar), or axillae (underarms). Topical antiperspirant treatment is typically tried first.

Interventions
The therapy being considered is iontophoresis of sweat glands.

Comparators
A variety of therapies have been investigated for primary hyperhidrosis that does not respond to topical antiperspirants, including topical therapy with anticholinergics (eg, glycopyrronium), oral anticholinergic medications, microwave treatment, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands.

Outcomes
The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

The Wade et al (2017) systematic review identified 10 studies using iontophoresis: 4 RCTs, 5 nonrandomized comparative studies, and a case series.[1] All studies were rated as having a high or unclear risk of bias. Comparators differed across studies: placebo (3 studies), botulinum (2 studies), no treatment (2 studies), and iontophoresis plus anticholinergic therapy (2 studies). Sample sizes ranged from 10 to 112, with the case series having the sample size of 112. Most studies treated hands, with some studies treating hands and feet. A meta-analysis could not be conducted due to the heterogeneity across studies. Reviewers concluded that the evidence was low quality but consistent, showing a potential benefit of iontophoresis compared with no treatment or placebo; however, when compared with botulinum injections, iontophoresis appeared less effective and had a short duration of effect.

Randomized Controlled Trials

A RCT by Rajagopal et al (2014) compared iontophoresis plus topical aluminum chloride hexahydrate with botulinum toxin injection but did not provide data on the efficacy of this therapy compared with placebo.[2] The trial included 60 patients with a baseline HDSS score of 3 or 4.[3] Patients were randomized to treatment with iontophoresis 3 times weekly or to 1 botulinum toxin injection in each hand, with 2 weeks between treatments. HDSS scores were recorded at four weeks; nonresponders were permitted to crossover to the other treatment arm. At the end of the initial 4 weeks, improvement (defined as a decrease of at least 1 point in HDSS score) was identified in 24 (80%) of 30 patients in the botulinum toxin group and 14 (47%) of 30 patients in the iontophoresis group (p=.007). Sixteen patients in the iontophoresis arm crossed over to the botulinum toxin arm, with 12 showing excellent improvement after an additional 4 weeks. In contrast, only 1 of the 6 patients who crossed over to the iontophoresis arm showed improvement after a second 4-week treatment period. In this relatively small sample with a relatively short intervention period, iontophoresis was less effective than botulinum toxin.

Case Series

Among the case series is a retrospective study Dogruk Kacar et al (2014) from Turkey, which included 21 pediatric patients under age 18.[4] Most patients (n=16) had palmoplantar hyperhidrosis. Among study completers, the mean self-report treatment effectiveness score, rated on a 0-to-10 visual analog scale, was 6.36 at the end of treatment. Seventeen (89.5%) of 19 patients reported a 50% or more decrease in sweating at the end of treatment. Another representative series is the McAleer and Collins (2014) study from Ireland, which included 28 patients.[5] Patients received a minimum of 9 treatments over 21 days in a clinical setting. Twenty (80%) of the 25 patients for whom data were available after hospital administration of tap water iontophoresis reported a moderate or great amount of improvement in symptoms and a moderate or great improvement in quality of life.

Section Summary: Iontophoresis for Primary Focal Hyperhidrosis

There is insufficient evidence that iontophoresis is an effective treatment of primary focal hyperhidrosis. A systematic review of 10 studies suggested a potential benefit of iontophoresis; however, the studies had either low or unclear risk of bias. The single RCT among the 10 studies found iontophoresis less effective than botulinum toxin in the short-term treatment of palmar hyperhidrosis. Randomized controlled trials are needed to show that iontophoresis is more effective than placebo treatment or at least as effective as alternative therapies.

Microwave Treatment for Treatment for Primary Focal Hyperhidrosis (ie, Axillary, Palmar, Plantar, Craniofacial)

Clinical Context and Therapy Purpose

The purpose of microwave treatment of sweat glands in individuals who have primary focal hyperhidrosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with primary focal hyperhidrosis. Primary focal hyperhidrosis is idiopathic, typically involving the hands (palmar), feet (plantar), or axillae (underarms).

Interventions
The therapy being considered is microwave treatment of sweat glands. Topical antiperspirant treatment is typically tried first in these patients.

Comparators
A variety of therapies have been investigated for primary hyperhidrosis that does not respond to topical antiperspirants, including topical therapy with anticholinergics (eg, glycopyrronium), oral anticholinergic medications, intradermal injections of botulinum toxin, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands.

Outcomes
The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.

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 HDSS has had a good correlation to other assessment tools and is practical in the clinical setting.

Study Selection Criteria
See information under the first indication.

Review of Evidence

Systematic Reviews
Hsu et al (2017) conducted a systematic review of studies investigating the use of microwave-based therapies for the treatment of axillary hyperhidrosis.[6] The literature search, conducted through June 2016, identified an RCT (described below) and 4 single-arm observational studies (one of which is described below). Studies were published between 2012 and 2016. The total number of patients in the 5 studies was 189 (range, 7 to 120). Administration of microwave therapy differed by frequency (1 to 3 times) and length of treatment intervals (2 weeks to 3 months) among the studies. Follow-up extended to 1 year in 4 of the studies. All studies reported HDSS scores. Additional outcomes included osmidrosis evaluation (3 studies), gravimetric assessments (2 studies), and Dermatologic Life Quality Index (1 study). All studies reported that microwave therapy was effective in reducing sweating in patients with axillary hyperhidrosis, with HDSS scores decreasing by at least 1 point throughout follow-up. The most common adverse events reported were swelling, pain, edema, hair loss, altered sensation, and palpable bumps. Reviewers concluded that while efficacy was indicated and side effects were mild, additional RCTs with larger sample sizes and longer follow-up would be needed.

The Wade et al. (2017)[1] systematic review included only a single RCT in its evaluation (the same RCT included in the Hsu systematic review described above) and detailed below in the RCT section. While the RCT results suggested a benefit of microwave compared with placebo, the evidence was of low quality. Also, evidence of safety was insufficient.

Randomized Controlled Trials
A RCT by Glaser et al (2012) evaluated a microwave device for treating primary focal hyperhidrosis.[7] This device applied 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<.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=.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.

Observational Studies

Hong et al (2012) conducted an industry-sponsored case series of 31 patients with primary axillary hyperhidrosis treated with microwave therapy using the miraDry system.[8] 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 events (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

A systematic review and RCT found a short-term benefit of microwave treatment in reducing hyperhidrosis but also reported skin-related adverse events (eg, pain, altered sensation). The case series also reported reductions in sweating, but sample sizes were small. Additional controlled trials with long-term follow-up in the treatment and control groups, a longer period of blinding, and a consistent treatment protocol would be needed to confirm the efficacy of this treatment and better define the risk-benefit ratio.

Radiofrequency Ablation for Primary Focal Hyperhidrosis (ie, Axillary, Palmar, Plantar, Craniofacial)

Clinical Context and Therapy Purpose

The purpose of radiofrequency ablation (RFA) of sweat glands in individuals who have primary focal hyperhidrosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with primary focal hyperhidrosis. Primary focal hyperhidrosis is idiopathic, typically involving the hands (palmar), feet (plantar), or axillae (underarms).

Interventions

The therapy being considered is RFA of sweat glands. Topical antiperspirant treatment is typically tried first in these patients.

Comparators

A variety of therapies have been investigated for primary hyperhidrosis that does not respond to topical antiperspirants, including topical therapy with anticholinergics (eg, glycopyrronium), oral anticholinergic medications, intradermal injections of botulinum toxin, microwave treatment, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands.

Outcomes

The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.

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 HDSS has had a good correlation to other assessment tools and is practical in the clinical setting.

Study Selection Criteria

See information under the first indication.

Review of Evidence

Randomized Controlled Trials

Mostafa et al (2019) conducted a RCT of RFA compared to botulinum toxin type A in 80 patients with primary palmar hyperhidrosis.[9] Both groups showed improvements from baseline in HDSS scores at 1 week, 1 month, and 2 months after treatment, but scores in the RFA group were significantly lower (indicating more improvement with RFA) than in the botulinum toxin group at 1 week, 1 month, and 2, 6, and 12 months after treatment.

Rummaneethorn et al 2019 compared RFA to botulinum toxin A in 20 patients with primary axillary hyperhidrosis.[10] At the endpoint visit (week 12), the botulinum toxin A group had

significantly lower reduction of mean HDSS score than the RFA group with 1.60 (0.59) versus 2.05 (0.68), respectively (p=.0332).

Nonrandomized Comparative Studies
Zhong et al (2024) published a multicenter retrospective cohort study that compared RFA and video-assisted thoracoscopic sympathectomy in 807 patients with palmar hyperhidrosis.[11] The study was conducted in China and all patients were followed for a median of 1.5 to 1.7 years. At baseline, the study population underwent propensity score matching. At 1 year postoperatively, clinical efficacy (defined as complete remission after treatment) was observed in 80.1% of patients who underwent RFA compared to 91% of patients who underwent video-assisted thoracoscopic sympathectomy (p<.001). Patients in the RFA group also had significantly more symptom recurrence and compensatory hyperhidrosis compared to the video-assisted thoracoscopic sympathectomy group.

Purtuloglu et al (2013) evaluated radiofrequency ablation (RFA) as a treatment for patients with severe bilateral palmar hyperhidrosis resistant to conservative treatment.[12] The study was conducted in Turkey and retrospectively reviewed outcomes after RFA (n=48) or transthoracic sympathectomy (n=46). Patients were 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 and 44 (96%) patients in the surgery group. The difference in outcomes between groups was statistically significant, favoring the surgical intervention (p<.01). Six patients in each group reported moderate or severe compensatory sweating (p=.78).

Section Summary: Radiofrequency Ablation
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 body of evidence is insufficient to assess the use of RFA as a treatment for hyperhidrosis.

Primary Axillary Hyperhidrosis Treated With Surgical Excision of Axillary Sweat Glands

Clinical Context and Therapy Purpose
The purpose of surgical excision of axillary sweat glands in individuals who have primary axillary hyperhidrosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with primary axillary hyperhidrosis. Primary axillary hyperhidrosis is idiopathic and involves the axillae (underarms).

Interventions
The therapy being considered is surgical excision of the axillary sweat glands. Topical antiperspirant treatment is typically tried first in these patients.

Comparators

A variety of therapies have been investigated for primary hyperhidrosis that does not respond to topical antiperspirants, including topical therapy with anticholinergics (eg, glycopyrronium), oral anticholinergic medications, and intradermal injections of botulinum toxin.

Outcomes
The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.

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 HDSS has had a good correlation to other assessment tools and is practical in the clinical setting.

Study Selection Criteria
See information under the first indication.

Review of Evidence
Surgical Excision of Axillary Sweat Glands
Surgery may involve removal of the subcutaneous axillary 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.[13] Depending on the completeness of surgical excision, the treatment is effective in 50% to 95% of patients.

Section Summary: Surgical Excision of Axillary Sweat Glands
Sweat gland excision has been found to be effective in 50% to 95% of appropriately selected patients.

Endoscopic Transthoracic Sympathectomy for Primary Axillary, Palmar, and Craniofacial Hyperhidrosis

Clinical Context and Therapy Purpose
The purpose of endoscopic transthoracic sympathectomy of sweat glands in individuals who have primary focal hyperhidrosis, within the axillary, palmar, or craniofacial area, is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with primary focal hyperhidrosis, within the axillary, palmar, or craniofacial area. Primary focal hyperhidrosis is idiopathic, typically involving the hands (palmar), head/face (craniofacial), or axillae (underarms).

Interventions
The therapy being considered is endoscopic transthoracic sympathectomy of sweat glands. Topical antiperspirant treatment is typically tried first in these patients.

Comparators

A variety of therapies have been investigated for primary hyperhidrosis that does not respond to topical antiperspirants, including topical therapy with anticholinergics (eg, glycopyrronium), oral anticholinergic medications, intradermal injections of botulinum toxin, microwave treatment, iontophoresis, and surgical excision of axillary sweat glands.

Outcomes

The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.

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 HDSS has had a good correlation to other assessment tools and is practical in the clinical setting.

Study Selection Criteria

See information under the first indication.

Review of Evidence

Systematic Reviews

Several RCTs and a meta-analysis have compared different surgical approaches; there were no sham-controlled randomized trials identified. Deng et al (2011) published a meta-analysis of data from RCTs and observational studies published through 2010 that evaluated endoscopic thoracoscopic sympathectomy for patients with palmar hyperhidrosis.[14] Reviewers pooled outcomes data from different approaches to sympathectomy (ie, single-ganglia blockage [T2, T3, T4], multiganglia blockage [T2-3, T2-4, T3-4]). (Note that T refers to the rib.) Based on these analyses, reviewers concluded that T3 (11 studies) approaches and T3-4 (2 studies) had the “best” clinical efficacy (ie, postoperative resolution of symptoms). The T3 approach resulted in a 97.9% pooled efficacy rate, and the T3-4 approach resulted in a 100% pooled efficacy rate. In the studies for which data were available, the pooled rate of postoperative compensatory sweating was 40% after T3 surgery. Data on compensatory sweating after T3-4 surgery were available from only 1 study (60 patients); a pooled analysis could not be performed.

Randomized Controlled Trials

Subsequent RCTs have compared levels (rib location) of sympathectomy. These trials tended to have relatively small sample sizes (ie, <100 patients). For example, Baumgartner et al (2011) in the United States studied 121 patients with disabling palmoplantar hyperhidrosis.[15] Patients were randomized to bilateral sympathectomy over T2 (n=61 patients) or T3 (n=60 patients). Six (5%) of 121 patients (3 in each group) were considered treatment failures (ie, had recurrent palmar sweating to a bothersome level). There were no significant differences between groups in the reported subjective change in plantar or axillary sweating after surgery. At 6 months, the mean level of compensatory sweating (0 to 10 severity scale) was 4.7 for the T2 group and 3.8 for the T3 group (p value was not significant). Similarly, at 1 year, the mean severity rating of compensatory sweating was 4.7 in the T2 group and 3.7 in the T3 group (p=.09). Yuncu et al (2013) in Turkey randomized 60 patients with axillary hyperhidrosis to T3-4 surgery (n=17) or to T3 surgery (n=43).[16] There were no significant differences between groups in postoperative satisfaction. At 1-year follow-up, the incidence of compensatory sweating was lower in the T3 group (79%) than in the T3-4 group (100%).

Case Series

There also are case series on transthoracic sympathectomy for treating primary focal hyperhidrosis.[17,18,19,20] Case series have generally reported high success rates for palmar and axillary hyperhidrosis, although there are potential adverse events, most commonly compensatory sweating. For example, Karamustafouglu et al (2014) in Turkey reported on 80 patients with primary hyperhidrosis (axillary and/or palmar).[18] All 80 patients responded to a questionnaire a mean of 35 months after surgery. Seventy-one (89%) of the 80 patients were very satisfied with the surgical outcome, and the other 11% were dissatisfied. Compensatory sweating was reported by 62 (78%) patients. Moreover, a series by de Andrade Filho et al (2013) reported on complications after thoracic sympathectomy in 1731 patients with palmar, axillary, or craniofacial hyperhidrosis.[17] Thirty days after surgery, 1531 (88%) of patients reported compensatory sweating. Among the 1531 patients, compensatory sweating was mild in 473 (31%), moderate in 642 (42%), and severe in 416 (27%). Gustatory sweating was reported by 334 (19%) of the 1731 patients.

Several retrospective chart reviews evaluated the effects of the procedure on subgroups of patients with hyperhidrosis. Lembranca et al (2017) reviewed the charts of patients with palmar or axillary hyperhidrosis who did not respond to oxybutynin chloride treatment who then underwent thoracic sympathectomy (n=167) and patients who were referred directly to surgical treatment (n=570).[21] Both groups showed improvements in hyperhidrosis and quality of life (>90%). De Campos et al (2017) assessed the quality of life among 15 patients with palmar hyperhidrosis who were unresponsive following a thoracic sympathectomy and underwent a resympathectomy.[22] Quality of life scores improved from “poor” or “very poor” to “excellent” or “very good” in 14 of the 15 patients. Fukuda et al (2018) reviewed charts of patients with craniofacial hyperhidrosis as a primary complaint (n=40) and patients with craniofacial hyperhidrosis as a secondary complaint (n=136).[23] Over 90% of patients in both groups reported a moderate or great reduction in hyperhidrosis following the procedure. Greater improvements in quality of life were reported among the patients with craniofacial hyperhidrosis that was a secondary complaint, though both groups had improved quality of life. A large proportion of patients (92%) reported compensatory hyperhidrosis. Vasconcelos-Castro et al (2019) reported a case series of 23 pediatric patients (ages 11 to 19 years) with primary palmar hyperhidrosis who underwent bilateral thoracoscopic sympathectomy. Sweating severity improved in all patients, with a mean decrease from baseline of 1.95 on the HDSS ($p<.05$ compared to baseline). Compensatory sweating occurred in 47.8% of patients.[24]

Section Summary: Endoscopic Transthoracic Sympathectomy

RCTs and a meta-analysis of RCTs have supported the efficacy of endoscopic transthoracic sympathectomy at various levels for palmar, axillary, and craniofacial hyperhidrosis. These data are complemented by case series, which have found high efficacy rates, but also high rates of compensatory sweating for these conditions.

Lumbar Sympathectomy for Primary Plantar Hyperhidrosis

Clinical Context and Therapy Purpose

The purpose of lumbar sympathectomy of plantar sweat glands in individuals who have primary plantar hyperhidrosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with primary plantar hyperhidrosis. Primary plantar hyperhidrosis is idiopathic and involves the feet.

Interventions
The therapy being considered is lumbar sympathectomy of plantar sweat glands. Topical antiperspirant treatment is typically tried first in these patients.

Comparators
A variety of therapies have been investigated for primary plantar hyperhidrosis that does not respond to topical antiperspirants, including topical therapy with anticholinergics (eg, glycopyrronium), oral anticholinergic medications, iontophoresis, and intradermal injections of botulinum toxin.

Outcomes
The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.

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 HDSS has had a good correlation to other assessment tools and is practical in the clinical setting.

Study Selection Criteria
See information under the first indication.

Review of Evidence

Systematic Reviews
Lima et al (2020) conducted a systematic review and meta-analysis of lumbar sympathectomy for plantar hyperhidrosis.[25] Eight studies were identified, including a total of 517 patients. One RCT met inclusion criteria; the other studies were case series. In all of the studies, lumbar sympathectomy was conducted following transthoracic sympathectomy. Resolution of symptoms occurred in 92% of patients when mechanical sympathectomy was used with clipping or resection of the lymph nodes between L2 and L5, with similar results regardless of resection level. Overall, 44% of patients had mild to severe compensatory sweating after a mean 6 months of follow-up. The RCT was conducted in 30 women at a single hospital in Brazil.[26] The primary outcome measure was a quality of life questionnaire that was developed for use in patients undergoing thoracic sympathectomy. After 6 months, patients in the intervention group had a greater improvement in quality of life relative to the control group patients; 53% reported worsening compensatory sweating. This study was limited by its small sample size, use of an unvalidated outcome measure, and lack of blinded outcome assessment.

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; this article did not cite any data documenting sexual dysfunction.[27] To date, there

are very few studies on endoscopic lumbar sympathectomy for focal plantar hyperhidrosis and only 1 small comparative study with methodological limitations.

Section Summary: Lumbar Sympathectomy
There is insufficient evidence in support of lumbar sympathectomy for treating plantar hyperhidrosis; case series have found lower rates of efficacy for plantar compared with axillary or palmar hyperhidrosis, and there are concerns for adverse events in sexual functioning. One RCT conducted among 30 women at a single center in Brazil was limited by its small sample size and lack of blinded outcome assessment. There are insufficient data to conclude that any particular approach to surgery results in lower rates of compensatory sweating.

Iontophoresis and Botulinum Toxin for Severe Secondary Gustatory Hyperhidrosis

Clinical Context and Therapy Purpose
The purpose of iontophoresis and intradermal injections of botulinum toxin in individuals who have severe secondary gustatory hyperhidrosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with severe secondary gustatory hyperhidrosis.

Secondary gustatory hyperhidrosis is excessive sweating on ingesting highly spiced foods. 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.

Interventions
The therapies being considered are iontophoresis and intradermal injections of botulinum toxin.

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.

Comparators
Alternatives for treatment of secondary gustatory hyperhidrosis include topical therapy (eg, aluminum chloride) and treatment of the underlying cause (eg, dietary changes).

Outcomes
The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.

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 HDSS has had a good correlation to other assessment tools and is practical in the clinical setting.

Study Selection Criteria
See information under the first indication.

Review of Evidence

Iontophoresis
TEC Assessment (2003) assessing iontophoresis for a variety of medical conditions concluded that the evidence was insufficient to determine whether iontophoresis for the treatment of any hyperhidrosis improves outcomes.[28] Neither the TEC Assessment nor subsequent literature searches have identified any RCTs evaluating iontophoresis for gustatory hyperhidrosis.

Section Summary: Iontophoresis for Secondary Gustatory Hyperhidrosis
Systematic reviews for iontophoresis for gustatory hyperhidrosis have not found evidence supporting these methods.

Tympanic Neurectomy for Severe Secondary Gustatory Hyperhidrosis

Clinical Context and Therapy Purpose
The purpose of tympanic neurectomy in individuals who have severe secondary gustatory hyperhidrosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with severe secondary gustatory hyperhidrosis.

Secondary gustatory hyperhidrosis is excessive sweating on ingesting highly spiced foods. 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.

Interventions
The therapy being considered is tympanic neurectomy.

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.

Comparators
Alternatives for treatment of secondary gustatory hyperhidrosis include topical therapy (eg, glycopyrronium, aluminum chloride) and treatment of the underlying cause (eg, dietary changes).

Outcomes

The general outcomes of interest are symptoms, quality of life, and treatment-related morbidity.
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 HDSS has had a good correlation to other assessment tools and is practical in the clinical setting.

Study Selection Criteria
See information under the first indication.

Review of Evidence
Review articles by Clayman et al (2006)[29] and de Bree et al (2007)[30] have described various medical and surgical treatments for Frey syndrome. Tympanic neurectomy has been described as a treatment, with satisfactory control reported in 82% of patients. Also, this surgical treatment is generally definitive without a need for repeated interventions.

Section Summary: Tympanic Neurectomy for Secondary Gustatory Hyperhidrosis
Review articles have supported the use of tympanic neurectomy for patients with severe gustatory sweating.

SUMMARY OF EVIDENCE

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-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 that the technology results in an improvement in the net health outcome.

Microwave
For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive microwave treatment, the evidence includes a systematic review, a RCT, and a case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The systematic review and RCT found a short-term benefit of microwave treatment in reducing hyperhidrosis but also reported skin-related adverse events (eg, pain, altered sensation). Additional RCTs are needed comparing radiofrequency ablation with sham or active treatment in patients with various types of primary focal hyperhidrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Radiofrequency Ablation
For individuals who have primary focal hyperhidrosis (ie, axillary, palmar, plantar, craniofacial) who receive radiofrequency ablation (RFA) , 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 that the technology results in an improvement in the net health outcome.

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 an 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 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 an improvement in the net health outcome.

For individuals who have primary plantar hyperhidrosis who receive lumbar sympathectomy, the evidence includes 1 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 technology results in an improvement in the net health outcome.

Secondary Gustatory Hyperhidrosis
For individuals who have severe secondary gustatory hyperhidrosis who receive iontophoresis and 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 that the technology results in an improvement in the net health outcome.

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 an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2014, the NICE 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.[31]

The Institute also issued guidance in 2014 on endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb.[32] 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."

For severe primary axillary hyperhidrosis, NICE issued guidance in 2017 on the use of transcutaneous microwave ablation.[33] The guidance stated that there is inadequate evidence in both quantity and quality to evaluate the safety and efficacy of microwave ablation.

Society of Thoracic Surgeons

In 2011, the Society of Thoracic Surgeons published an expert consensus statement on the surgical treatment of hyperhidrosis.[33] 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/m^2
- No sweating during sleep
- No significant comorbidities
- Resting heart rate <55 beats per minute

U.S. Preventive Services Task Force Recommendations

Not applicable.

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
Published			
NCT02854540	Management of Palmar Hyperhidrosis with Hydrogel-based Iontophoresis	13	Aug 2018
Unpublished			
NCT03236012	Hyperhidrosis of the Residual Limb in Patients With Amputations: Developing a Treatment Approach	25	Feb 2022
Ongoing			
NCT02295891	Microwave Energy-induced Thermolysis of Axillary Apocrine Glands and Hair Follicles Will Result in Improvement of Secondary Psychopathology Related to Hyperhidrosis	24	Aug 2022
NCT03921320	Evaluation of Compensatory Sweating After Unilateral Videothoracoscopic Sympathectomy of the Dominant Side or Sequential Bilateral Videothoracoscopic Sympathectomy: a Multicentric Randomized Trial	200	Dec 2023
NCT05737914	Bilateral Endoscopic Thoracic T3 Sympathectomy Versus T3 Radiofrequency Ablation for Treatment of Primary Palmar Hyperhidrosis	68	Oct 2023

NCT: national clinical trial

Government Regulations

National:

There is no national coverage determination (NCD) on the topic of treatment for hyperhidrosis.

Local:

There is no local coverage determination (LCD) on the topic of treatment for hyperhidrosis, excluding botulinum toxin.

The 2024 Medicare Physician Fee Schedule has assigned fees for codes 32664, 69676. An assigned fee is not a guarantee of payment.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Botulinum Toxins – BCN Only (Retired – replaced by pharmacy policy)
Botulinum Toxin Type A Injection (Pharmacy)
Botulinum Toxin Type B Injection (Pharmacy)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/3/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/7/04	5/7/04	5/17/04	Joint policy established (Iontophoresis; policy retired)
1/1/07	11/1/06	11/6/06	Joint policy updated
1/1/09	10/13/08	12/30/08	Routine maintenance
11/1/11	8/16/11	8/16/11	Routine maintenance
3/1/13	12/11/12	12/31/12	Routine maintenance
1/1/15	10/21/14	11/3/14	Adopted Blue Cross Blue Shield Association's policy "Treatment of Hyperhidrosis." This updated policy replaces the JUMP policy "Tap Water Iontophoresis Treatment for Hyperhidrosis" and retired JUMP policy "Endoscopic Thoracic Sympathectomy for Hyperhidrosis." Treatment of hyperhidrosis using Botulinum is addressed on the BCN policy titled Botulinum Toxins and the BCBSM pharmacy policies titled Botulinum Toxin Type A Injection and Botulinum Toxin Type B Injection.
7/1/16	4/19/16	4/19/16	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance • Removed codes 64650 & 64653 • Added code 97033 • Updated Rationale & References
1/1/18	10/19/17	10/19/17	Routine maintenance • Updated Rationale & References
1/1/19	10/16/18	10/16/18	Routine maintenance • Updated Rationale & References
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance Ref 11,12,24,25,26 added
1/1/22	10/19/21		Routine maintenance

			Inc/Excl format updated; some clarifications. Codes 64818, 97024 added.
1/1/23	10/18/22		Routine maintenance (ls)
1/1/24	10/17/23		Routine maintenance (jf) Vendor Managed: eviCore Added ref 32 and 33
1/1/25	10/15/24		Routine maintenance (jf) Vendor Managed: NA Ref added 11

Next Review Date: 4th Qtr, 2025

APPENDIX

Appendix Table 1. The Hyperhidrosis Disease Severity Scale

Score	Definition
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

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TREATMENT OF HYPERHIDROSIS, EXCLUDING BOTULINUM

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.