



Medical Coverage Policy

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Surgical Treatment for Hyperhidrosis

Table of Contents

Overview	1
Coverage Policy.....	1
General Background.....	2
Coding/Billing Information.....	7
References	7

Related Coverage Resources

- [Acupuncture](#)
- [Biofeedback](#)
- [Botulinum Therapy](#)
- [Complementary and Alternative Medicine](#)
- [Physical Therapy](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses surgical treatments for hyperhidrosis.

Coverage Policy

Coverage for the treatment of hyperhidrosis may vary across plans. Refer to the customer's benefit plan document for coverage details.

Endoscopic thoracic sympathectomy (ETS) for the treatment of primary palmar and axillary hyperhidrosis is considered medically necessary when EITHER:

- the individual has medical complications secondary to hyperhidrosis (e.g., skin maceration with secondary infection)
- OR**
- the individual is experiencing a significant impact on age-appropriate activities of daily living as a result of hyperhidrosis
- AND**
- failure of at least two nonsurgical treatments (e.g. prescription topical agent, oral medication, Botox® injection, or iontophoresis).

Surgical removal of axillary sweat glands (including use of curettage and liposuction) for the treatment of primary axillary hyperhidrosis is considered medically necessary when ALL of the above medical necessity criteria have been met.

Surgical treatment of secondary hyperhidrosis is considered not medically necessary since appropriate therapy involves treatment of the underlying condition (e.g., hyperthyroidism, diabetes mellitus and hyperpituitarism).

The following treatments for hyperhidrosis are considered experimental, investigational or unproven:

- liposuction as the sole method of removing axillary sweat glands
- repeat/reversal of ETS
- sympathectomy for craniofacial hyperhidrosis
- sympathectomy for plantar hyperhidrosis

Note: Nonprescription and over-the-counter drugs are excluded under many medical benefit plans. Please refer to the applicable pharmacy benefit to determine benefit availability and the terms and conditions of coverage related to the treatment of hyperhidrosis.

General Background

Hyperhidrosis, or excessive sweating, is a medical condition that is defined as sweating beyond what is necessary to maintain thermal regulation. Hyperhidrosis can be classified as primary focal or secondary, depending on its cause or origin. Primary focal hyperhidrosis, also known as essential or idiopathic hyperhidrosis, is caused by an overactive sympathetic nervous system. Primary focal hyperhidrosis can lead to intractable and profuse sweating in several locations typically affecting the feet (plantar), armpits (axillae), and hands (palmar). Hyperhidrosis can be accompanied by facial blushing. Secondary hyperhidrosis usually affects the whole body and is due to some underlying cause such as malignancy, infection, spinal cord injury, neurologic and endocrine disorders. Craniofacial hyperhidrosis is uncommon and can be provoked by heat, emotion, or spicy foods (i.e., gustatory hyperhidrosis or Frey's syndrome).

Hyperhidrosis symptoms typically begin in adolescence or in the early twenties and may affect one or more anatomic regions. There is some evidence to suggest that there may be genetic and familial elements to hyperhidrosis. Hyperhidrosis may result in multiple complications, including bacterial/fungal overgrowth and eczematous dermatitis. Sweating that interferes with an individual's activities of daily living is generally viewed as abnormal. Individuals may endure functional limitations such as difficulty handling necessary papers or tools, impeding their ability to perform jobs and activities of daily living. The Hyperhidrosis Disease Severity Scale (HDSS) is a diagnostic tool that provides a qualitative measure of the severity of the patient's condition based on how it affects daily activities. Treatment options available to patients with primary hyperhidrosis can be categorized as non-surgical, minimally invasive, and surgical. Each therapeutic option differs by duration of efficacy, side effects, and response rate in the various anatomic areas treated (International Hyperhidrosis Society [IHHS], 2019).

Non-surgical Treatments

- Topical treatments for hyperhidrosis include aluminum chloride, anticholinergics and local anesthetics (including topical anticholinergic wipes), and astringent agents.
- Botulinum Toxin (Botox®) injection therapy has been used in all of the body areas affected in primary hyperhidrosis.
- miraDry® uses a non-invasive handheld device to deliver precisely controlled electromagnetic energy beneath the underarm skin to the area where sweat glands are located, resulting in thermolysis of the sweat glands.
- Iontophoresis directs electrical current through water to pass an ionized substance through intact skin to treat palmar and plantar hyperhidrosis. In some cases clinicians may need to use iontophoresis to deliver anticholinergics or other medications to hyperhidrotic areas affected.

- Systemic medications may be used for the treatment of generalized or focal hyperhidrosis. Many of the drugs reported useful for hyperhidrosis have not been studied in controlled trials. At the doses likely to inhibit hyperhidrosis, side effects can be limiting. In addition, some of these drugs are not approved by the US Food and Drug Administration specifically for the treatment of hyperhidrosis. The most commonly used agents are anticholinergics.

Local Surgical Procedures

Surgical treatment of severe hyperhidrosis by excision of sweat glands is only feasible for axillary disease. The eccrine sweat glands are located in the deep dermis and in the upper subcutaneous layer. There have been many different procedures used to remove axillary sweat glands; they can be grouped into three major categories:

- Excision of both skin and underlying sweat glands is the most radical approach. Radical sweat gland removal can be done with excisions of various shapes and sizes. Complete excision of underarm tissue containing sweat glands is no longer recommended because scarring can cause range of motion limitations.
- Removing subcutaneous glands through a small incision by scraping the glands from the undersurface of the dermis with a curette or by liposuction are two major variants of the same approach. Since some of the eccrine glands are in the dermis, these procedures are less likely to remove all of the glands. However, this less radical approach will lead to smaller scars.
- The third category is a mixture of the first two—a limited central excision is combined with curettage of the surrounding axillary subcutaneous glands.

Endoscopic Thoracic Sympathectomy (ETS)

The most invasive treatment for hyperhidrosis is the surgical interruption of the thoracic sympathetic chain, a procedure done with the goal of permanently stopping sweating in the area innervated by the involved ganglia. Open surgery became obsolete as endoscopy was perfected. Endoscopic thoracic sympathectomy (ETS) is now done as a minimally invasive technique using video-assisted endoscopy (video-assisted thoracoscopic sympathectomy [VTS]). Referral may be made to a neurosurgeon or vascular surgeon for evaluation. Interrupting the transmission of nerve signals can be done by destroying the ganglia (sympathectomy) or by dividing the sympathetic trunk, including the postganglionic fibers (sympathotomy or sympathicotomy). Destruction can be done with local excision of the ganglia or by ablation using electrocautery, laser or chemically (sympathicolysis). Sympathicotomy also can be carried out with electrocautery or laser; less frequently clipping is used. Recurrence of excessive sweating occurs in about 1% of patients in the first year following the procedure and in about 2% to 5% in subsequent years.

The most common complication of sympathectomy is compensatory sweating, excessive sweating of the abdomen, chest, back, thighs, and face, reported to occur at an average rate of about 60%, with a range of 3% to 98%. The mechanism for compensatory sweating is unclear; the most likely explanation is that sweating in the trunk increases to compensate for the lack of sweating from the denervated areas in order to maintain thermoregulation. The occurrence of decreased sweating in other areas not innervated by the ganglia treated by ETS suggests that the response to ETS is more complex. Some studies suggest that the extent of sympathectomy may be related to the incidence of compensatory sweating. The technology used in ETS has been continually improving, allowing surgeons to use smaller thoroscopes and video assistance. But despite these advances, compensatory hyperhidrosis has not changed in incidence and continues to be the most common reason for lack of satisfaction with ETS.

Other possible complications include Horner's syndrome, pneumothorax, hemothorax, wound infection and rare cardiac arrest or arrhythmias. Contraindications for ETS include untreated thyroid diseases; pleural adhesions, which can make accurate identification and dissection of the sympathetic ganglia difficult; and any underlying condition that, would pose a danger to the patient in the presence of pneumothorax. The procedure is associated with complications that lead most clinicians to reserve this procedure for patients with severe symptoms who have failed to improve with more conservative treatment (IHHS, 2019).

Literature Review - Local Surgical Procedures

Surgical removal of the axillary sweat glands is an accepted treatment for severe axillary hyperhidrosis. Many of the reports of local procedures in the literature focus on varying operative techniques to remove axillary sweat glands and offer less information on outcome and patient satisfaction. Local surgery is considered only after failure of less invasive treatment regimens and avoids complications seen with ETS, such as compensatory sweating. Liposuction results seem comparable to those seen with curettage, but there are fewer long-term reports of patients treated with liposuction. With combined excision and curettage, small scars and high patient satisfaction are reported. Findings from small studies indicate better effect of tumescent suction curettage (a variant of liposuction) than curettage only. Overall, satisfaction rates that have been reported for local surgery are generally higher than the rates of 37% to 68% reported for the treatment of axillary hyperhidrosis by ETS (IHHS, 2019; Nasr, et al., 2017; Tronstad, et al., 2014; Commons, et al., 2009; Wollina, et al., 2008; Seo, et al., 2008; Lawrence and Eccles, 2006; Boni, 2006; Lee, et al., 2006).

A systematic review of literature published through February 2015 was conducted to compare microwave ablation (MA), botulinum toxin (BT) injection, and liposuction-curettage (LC) in the treatment of primary axillary hyperhidrosis based on subjective and objective criteria. A total of 16 of 775 articles were selected based on relevance and criteria of inclusion and exclusion. The three methods proved to be efficient and safe; however, MA and BT had better results when compared to LC in the short term. Both MA and LC showed longer lasting results when compared to BT. However, in the long term, MA was superior to LC (Nasr, et al., 2017).

Literature Review - Endoscopic Thoracic Sympathectomy (ETS)

Sympathectomy has been shown to be very effective for palmar sweating, but is less effective for axillary symptoms. Sympathectomy is not indicated for craniofacial or plantar hyperhidrosis. Although now done as a minimally invasive technique (video-assisted thoracoscopic sympathectomy [VTS]), the procedure is still associated with complications that lead most clinicians to reserve this procedure for patients with severe symptoms who have failed to improve with more conservative treatments.

Most studies involve palmar and axillary hyperhidrosis patients who had failed previous nonsurgical therapies and have severe hyperhidrosis that is causing social, psychological, or work-related disability. Most of the studies also used various methods of ablation, resection or clipping, under direct endoscopic or video guidance (Horslen, et al., 2018; Sang, et al., 2017; Zhang, et al., 2016; Yunca, et al., 2013; Wolosker, et al., 2012; Ishy, et al., 2011; Baumgartner, et al., 2011; Boscardim, et al., 2011; Atkinson, et al., 2011; Wait, et al., 2010).

Recent studies evaluate the appropriate level of sympathectomy. A 2016 meta-analysis of eight randomized controlled trials involving 1200 patients concluded level T4 VTS showed better efficacy in limiting compensatory hyperhidrosis compared with other segments (Zhang, et al., 2016).

Literature Review - Reversal/Repeat ETS/VTS Surgery

There is a paucity of evidence in the peer-reviewed scientific literature to support that reversal or repeated sympathectomy is safe and effective in reversing compensatory sweating and other complications of ETS/VTS.

Literature Review - Sympathectomy for Craniofacial or Plantar Hyperhidrosis

Primary craniofacial hyperhidrosis is more difficult to diagnose than other forms of focal hyperhidrosis because many secondary causes must be considered such as menopause, diabetes mellitus, endocrine disorders, and certain medications. Few studies have evaluated ETS/VTS for primary craniofacial hyperhidrosis. In a systematic review of the literature, Nicholas et al. (2015) concluded clinical evidence supporting the effective treatment of craniofacial hyperhidrosis is weak due to a lack of published randomized controlled trials. The authors recommend topical glycopyrrolate, oral oxybutynin and intradermal botulinum toxin A as first-line therapies due to their high efficacy and favorable safety profiles, noting that T2 sympathectomy should be reserved for patients who are refractory to first-line therapy due to the high incidence of postoperative compensatory sweating and rare yet significant postoperative complications.

There is insufficient evidence in the published peer-reviewed literature to support ETS/VTS or endoscopic lumbar sympathectomy (ELS)/ retroperitoneoscopic lumbar sympathectomy (RLS)/ chemical lumbar sympathetic block (CLSB) for the treatment of plantar hyperhidrosis. Larger, well-designed trials are needed to determine the long term safety and efficacy of the various proposed techniques. Possible surgical complications may include

compensatory sweating, neuralgia, paresthesia, and retrograde ejaculation. Additionally, the target patient population is yet to be defined; some patient populations have included patients who had previously undergone thoracic sympathectomy (Lima, et al., 2017; Rieger, et al., 2016; Reisfeld, et al., 2010; Coelho, et al., 2010; Kim, et al., 2008). The IHHS Treatment guidelines for Primary Focal Plantar Hyperhidrosis state ETS Surgery is not recommended for sweaty feet, "not even as a last resort" (IHHS, 2019).

Professional Societies/Organizations

In the United States, there are no official guidelines for the treatment of hyperhidrosis. Therefore, most practitioners use the clinical guidelines of the International Hyperhidrosis Society (IHHS) with treatment algorithms for primary axillary, facial, gustatory, palmar, plantar, and generalized hyperhidrosis. The IHHS recommends a step-therapy approach in which patients would use conservative therapies first and step up to more invasive treatments depending on their responses (Jacob, 2018).

International Hyperhidrosis Society Treatment guidelines for Primary Focal Axillary Hyperhidrosis

- For many patients, treatment will begin with topical antiperspirants starting with over-the-counter products, "clinical strength" over-the-counter products (active ingredient often zirconium salts), and then prescription products (active ingredient often aluminum chloride hexahydrate). If a patient does not adequately respond to topical antiperspirant therapy, or if the side effects of such therapy are intolerable, onabotulinumtoxinA injections are one of the next lines of treatment.
- miraDry is an electromagnetic energy/microwave technology device that, in a noninvasive manner, results in thermolysis of the sweat glands.
- Qbrexza (glycopyrronium) cloths are a more recent addition to the potential arsenal and received FDA approval in June 2018 for the treatment of primary axillary hyperhidrosis in patients aged 9 years and older.
- Oral systemic medications including anticholinergics (glycopyrrolate, oxybutynin, and propantheline), propranolol, clonidine, and diltiazem may be used to treat primary axillary hyperhidrosis but require patient education regarding potential side effects (such as dry mouth, blurred vision, urinary retention, tachycardia and constipation). These side effects may limit the use anticholinergics in many patients but sometimes can be managed by adjusting the individual's dose.
- Local surgical procedures: Combinations of curettage and central excision, or of curettage and liposuction may be used, as well as combinations of liposuction and laser treatments. Complete excision of underarm tissue containing sweat glands is no longer recommended because scarring can cause range of motion limitations. If sweat reduction has not been sufficient after local surgical treatment, a procedure may be repeated or onabotulinumtoxinA or antiperspirants may be used to control sweating from remaining sweat glands
- Finally, for carefully selected patients, endoscopic thoracic sympathectomy (ETS) may be an option if all other treatment options have been exhausted (including rounds of treatment regimen adjustments, retreatment, and combination therapies). It should be recognized, however, that sympathectomy has been shown to be effective for palmar sweating, but is less effective for axillary symptoms. If ETS is to be pursued, patients must be educated to fully understand the possibility of limited efficacy and the risk of complications including, but not limited to, compensatory sweating.

International Hyperhidrosis Society Treatment guidelines for Primary Focal Palmar Hyperhidrosis

- For many patients, treatment will begin with topical antiperspirants (active ingredient often aluminum chloride hexahydrate).
- Many experts also consider tap water iontophoresis to be a first line treatment for palmar sweating.
- If the patient's excessive sweating symptoms occur during, or are exacerbated by known anxiety-provoking situations, the patient may be treated prior to such events with an anticholinergic or a short course benzodiazepine.
- While only FDA-approved for axillary hyperhidrosis in adults, onabotulinumtoxinA can be used for any area of focal hyperhidrosis and is commonly used in pediatric patients.
- Oral systemic medications including anticholinergics (glycopyrrolate, oxybutynin, and propantheline), propranolol, clonidine, and diltiazem may be used to treat primary palmar hyperhidrosis, but require patient education regarding potential side effects (such as dry mouth, blurred vision, urinary retention,

tachycardia and constipation). These side effects may limit the use of anticholinergics in many patients but sometimes can be managed by adjusting the individual's dose.

- Finally, for carefully selected patients, ETS may be an option if all other treatment options have been exhausted (including rounds of treatment regimen adjustments, retreatment, and combination therapies). If ETS is to be pursued, patients must be educated to fully understand the risk of complications including, but not limited to, compensatory sweating. Compensatory sweating is the most common reason for lack of satisfaction with ETS.

International Hyperhidrosis Society Treatment guidelines for Primary Focal Plantar Hyperhidrosis

- ETS Surgery is NOT recommended for sweaty feet. NOT even as a last resort.

International Hyperhidrosis Society Treatment guidelines for Primary Craniofacial Hyperhidrosis

- ETS may be attempted as treatment for primary craniofacial sweating. It is, however, a treatment of last resort. The surgery is not as effective for facial/cranial sweating as for palmar sweating. The most frequent and important complication is compensatory hyperhidrosis. Especially in patients who have undergone resection of the second thoracic ganglion, the risk of severe compensatory hyperhidrosis is higher, which may cause dissatisfaction with the procedure.

American Academy of Dermatology (AAD)

The AAD Clinical Guidelines or Appropriate Use Criteria do not address hyperhidrosis.

American Academy of Neurological Surgeons

The American Academy of Neurological Surgeons (AANS) position statement on sympathectomy for hyperhidrosis states that “Nonsurgical measures (botox injections, topical agents i.e.: drysol, certain dry, anticholinergic medications, and iontophoresis [drionics]) are usually ineffective for severe forms of palmar and axillary hyperhidrosis. They usually provide temporary or partial relief of symptoms for a limited duration. Frequent maintenance of treatment is required. Thoracoscopic sympathectomy provides permanent relief of palmar and axillary hyperhidrosis with a very high surgical success rate (99% palmar, 85% axillary). The results of surgery are durable; recurrent symptoms are extremely rare (less than 0.5 %). The procedure may be performed on an outpatient basis. Endoscopic sympathectomy is safe and highly effective for providing a permanent cure for palmar and axillary hyperhidrosis. These disorders impair the function and activities of daily living of affected individuals. Insurance reimbursement for this procedure is appropriate and justified” (AANS, reaffirmed 2009).

Society of Thoracic Surgeons

The 2011 Society of Thoracic Surgeons expert consensus for the surgical treatment of hyperhidrosis concludes that endoscopic thoracic sympathectomy with interruption of the sympathetic chain is the treatment of choice for patients with primary hyperhidrosis. The authors report that “For palmar hyperhidrosis, the optimal operation is a rib level (R) 3 interruption (cauterizing or clipping the sympathetic chain on top of the third rib) because it yields the driest hands; however, an R4 interruption is also reasonable. The patient should be aware of the differences and the slightly higher risk of compensatory hyperhidrosis (CH) with an R3 but the risk of moister hands with an R4. An R4 and R5 sympathetic chain interruption should be used for palmar-axillary, palmar-axillary-plantar, or axillary hyperhidrosis alone. An R5 interruption alone is also a viable option for patients who have axillary hyperhidrosis only. Finally, an R3 interruption is suggested for patients with craniofacial hyperhidrosis without blushing. An R2 and R3 procedure may be performed for these patients, but it may lead to a higher incidence of CH, and it increases the risk of Horner’s syndrome, especially on the left side” (Cerfoio, et al., 2011).

The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative

No information found.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): No applicable NCD found.
- Local Coverage Determinations (LCDs): No applicable LCD found.

Use Outside of the US

National Institute for Health and Clinical Excellence (NICE): NICE published a guideline on Endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb (May 2014) recommended that current evidence on the efficacy and safety of endoscopic thoracic sympathectomy (ETS) for primary hyperhidrosis of the upper limb is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.

NICE guidance on endoscopic thoracic sympathectomy for primary facial blushing (February 2014) recommended that current evidence on the efficacy and safety of endoscopic thoracic sympathectomy (ETS) for primary facial blushing is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary for primary palmar and axillary hyperhidrosis:

CPT®* Codes	Description
32664†	Thoracoscopy, surgical; with thoracic sympathectomy

†**Note:** Experimental/Investigational/Unproven for craniofacial and plantar hyperhidrosis

Considered Medically Necessary for primary axillary hyperhidrosis:

CPT®* Codes	Description
11450	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with simple or intermediate repair
11451	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with complex repair
15877†	Suction assisted lipectomy; trunk
15878†	Suction assisted lipectomy; upper extremity
17999††	Unlisted procedure, skin, mucous membrane and subcutaneous tissue

†**Note:** Considered Experimental/Investigational/Unproven when used to report liposuction as the sole method of removing axillary sweat glands

††**Note:** Considered Medically Necessary when used to report surgical removal of axillary sweat glands by curettage

Considered Experimental/Investigational/Unproven when used to report craniofacial or plantar hyperhidrosis or endoscopic lumbar sympathectomy:

CPT®* Codes	Description
64818	Sympathectomy, lumbar
64999	Unlisted procedure, nervous system

*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.

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