

# Regence

Medical Policy Manual

Surgery, Policy No. 165

## ***Surgical Treatments for Hyperhidrosis***

**Effective:** May 1, 2023

**Next Review:** March 2024

**Last Review:** March 2023

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

This policy addresses surgical treatments for hyperhidrosis, excessive sweating beyond a level required to maintain normal body temperature.

### **MEDICAL POLICY CRITERIA**

**Note:** This policy only addresses the surgical treatment of hyperhidrosis.

- I. Surgical treatment of hyperhidrosis, including craniofacial hyperhidrosis, via endoscopic transthoracic sympathectomy or excision of axillary sweat glands may be considered **medically necessary** when there is clinical documentation that all of the following Criteria (A. – C.) are met:
  - A. Primary medical conditions causing hyperhidrosis have been identified and treated where possible; and
  - B. The hyperhidrosis is persistent and severe, and has resulted in one or more of the significant medical complications below (see Policy Guidelines):
    1. Acrocyanosis of the hands; or
    2. Recurrent skin maceration with secondary bacterial or fungal infection; or

3. Recurrent secondary infections; or
  4. Persistent eczematous dermatitis; or
  5. Documentation of inability to perform critical activities of daily living or demands of employment (such as impaired grip and writing ability for employment, or impaired walking) due to symptoms of hyperhidrosis; and
- C. A trial of all of the following nonsurgical treatments has been ineffective, not tolerated, or are contraindicated:
1. Prescription antiperspirants (e.g. aluminum chloride hexahydrate 20%) and/or anticholinergics (e.g. glycopyrrolate or oxybutynin); and
  2. If the treatment is for axillary or palmar hyperhidrosis and the patient is age 18 years or older, a trial of botulinum toxin type A [Botox] injection is completed OR the patient does not have axillary or palmar hyperhidrosis.
- II. Tympanic neurectomy may be considered **medically necessary** for the treatment of severe gustatory hyperhidrosis if a trial of nonsurgical treatments failed or is contraindicated.
- III. Surgical treatment of hyperhidrosis via endoscopic transthoracic sympathectomy, excision of axillary sweat glands, or tympanic neurectomy is considered **not medically necessary** when the Criteria in I. or II. above are not met (see Policy Guidelines).
- IV. All other surgical treatments of hyperhidrosis are considered **investigational**, including but not limited to lumbar sympathectomy; axillary liposuction or curettage performed alone or in combination with any other procedure; subdermal laser-assisted axillary hyperhidrosis treatment; percutaneous radiofrequency sympathiccolysis or sympathectomy; and radiofrequency ablation for palmar hyperhidrosis.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## POLICY GUIDELINES

Medical treatment of persistent hyperhidrosis is considered not medically necessary in the absence of significant medical complications associated with the condition. Skin irritation, skin maceration without secondary infection, need for frequent changing of clothing, or psychosocial distress alone are not considered to be significant medical complications.

## LIST OF INFORMATION NEEDED FOR REVIEW

### REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes including the following:
  - Type of hyperhidrosis
  - Documentation primary medical conditions causing hyperhidrosis have been identified and treated where possible

- Documentation hyperhidrosis is persistent and severe and has resulted in significant medical complications including inability to perform critical activities of daily living or demands of employment, if relevant
- Documentation of specific nonsurgical treatments trialed and documented response including use of prescription antiperspirants and/or anticholinergics, and botulinum toxin type A [Botox] injection trial when appropriate per policy.

## CROSS REFERENCES

1. [Botulinum toxin Type A injection](#), Medication Policy Manual, Drugs, Policy No. 006

## BACKGROUND

### HYPERHIDROSIS

Hyperhidrosis may be defined as excessive sweating, beyond a level required to maintain normal body temperature in response to heat exposure or exercise. Hyperhidrosis can be classified as either primary or secondary.

#### Primary Hyperhidrosis

Primary focal hyperhidrosis is defined as idiopathic bilateral, relatively symmetric, excessive sweating of at least six months' duration induced by sympathetic hyperactivity in selected areas that is not associated with an underlying disease process. The most common locations are underarms (axillary hyperhidrosis), palms (palmar hyperhidrosis), soles of the feet (plantar hyperhidrosis) or face and scalp (craniofacial hyperhidrosis). The second (T2) and third (T3) thoracic ganglia are responsible for palmar hyperhidrosis, the fourth (T4) thoracic ganglia controls axillary hyperhidrosis, and the first (T1) thoracic ganglia controls facial hyperhidrosis.

#### Secondary Hyperhidrosis

Secondary generalized hyperhidrosis is a type of excessive sweating that is caused by another medical condition or is a side effect of a medication. Secondary hyperhidrosis can result from a variety of drugs, [e.g., tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs)], olfactory stimuli, or underlying diseases/conditions, such as febrile diseases, diabetes mellitus, anxiety, menopause, neurologic lesions, intrathoracic neoplasms, and Raynaud's disease.

Secondary gustatory hyperhidrosis is excessive sweating related to ingesting or thinking about the ingesting food. This trigeminovascular reflex typically occurs symmetrically on scalp or face and predominately over forehead, lips and nose and can include flushing, redness, and general discomfort felt at the cheek level. This phenomenon is associated with conditions including encephalitis, syringomyelia, diabetic neuropathies, and, most commonly, conditions resulting from damage to the parotid gland (sometimes referred to as Frey's syndrome) including herpes zoster parotitis and parotid abscess. Other conditions and diseases also can cause hyperhidrosis, including those listed at [sweathelp.org](http://sweathelp.org).<sup>[1]</sup>

Frey's 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 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 in nature. Excessive sweating may be socially embarrassing or may interfere with certain professions. 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.

A variety of medical therapies have been investigated for treating primary hyperhidrosis, including topical therapy with aluminum chloride or tanning agents, oral anticholinergic medications, iontophoresis, intradermal injections of botulinum toxin, and microwave treatment. Treatment of secondary hyperhidrosis naturally focuses on treatment of the underlying cause.

## **SURGICAL TREATMENT**

This medical policy addresses only surgical treatment of hyperhidrosis. Surgical treatments for axillary hyperhidrosis include transthoracic sympathectomy and surgical excision of axillary sweat glands. Transthoracic sympathectomy may also be used for palmar hyperhidrosis. Surgical removal of axillary sweat glands has been performed in patients with severe isolated axillary hyperhidrosis. Removal may involve removal of the subcutaneous sweat glands without removal of any skin, limited excision of skin and removal of surrounding subcutaneous sweat glands, or a more radical excision of skin and subcutaneous tissue en bloc.

A variety of approaches have been reported for sympathectomy. For transthoracic sympathectomy, transthoracic endoscopic techniques have emerged as minimally invasive alternatives to transaxillary, supraclavicular, or anterior thoracic approaches. Percutaneous radiofrequency (RF) sympathectomy has also been proposed as a sympathectomy technique in which RF lesions are made in the thoracic sympathetic chain under fluoroscopic guidance without the need for general anesthesia, intubation, or risk of lung collapse. Lumbar sympathectomy may be performed as a surgical treatment of plantar hyperhidrosis and may also be done endoscopically.

While accepted as an effective treatment, sympathectomy is not without complications. In addition to the immediate surgical complications of pneumothorax or temporary Horner's syndrome, compensatory sweating on the trunk can occur in up to 55% of patients, reducing patient satisfaction with the procedure. Gustatory sweating may also occur. Sympathectomy also results in cardiac sympathetic denervation, which in turn can lead to a 10% reduction in the heart rate. In addition to the complications associated with transthoracic sympathectomy, lumbar sympathectomy for plantar hyperhidrosis may have the additional risk of permanent sexual dysfunction in men and women. Medical researchers have investigated whether certain approaches, e.g., T3 versus T4 sympathectomy, result in less compensatory sweating, but there remains a lack of consensus about which approach best minimizes the risk of this side effect.

Tympanic neurectomy is a surgical technique that may be used for treatment of severe gustatory hyperhidrosis. The nerves are transected in the middle ear through a flap created in the ear drum. Possible risks from this surgery include rupture of the tympanic membrane, infection, hearing loss, and loss of taste in certain parts of the tongue.

## EVIDENCE SUMMARY

In order to determine whether surgical treatment of hyperhidrosis results in sustained improvements in clinically meaningful health outcomes, comparisons to conventional therapies in well-designed comparative studies (ideally randomized controlled trials) are needed using standardized functional measurement tools.

For individuals who have primary axillary or palmar hyperhidrosis, a high rate of clinical efficacy after endoscopic transthoracic sympathectomy has been demonstrated,<sup>[2-10]</sup> although the rate of postoperative compensatory sweating was substantial.<sup>[11]</sup> Surgical excision of axillary sweat glands in individuals who have primary axillary hyperhidrosis has been shown to be highly effective. The evidence is sufficient to determine that endoscopic transthoracic sympathectomy and surgical excision of axillary sweat glands results in a meaningful improvement in the net health outcome for individuals who have primary axillary or palmar hyperhidrosis. These procedures are considered standard of care for these indications when a trial of non-surgical treatment has failed.

For individuals who have severe secondary gustatory hyperhidrosis who receive tympanic neurectomy, this treatment has been shown to have high success rates, without the need for repeated interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome and this treatment is considered standard of care for this indication when a trial of non-surgical treatment has failed.

The focus of the following evidence summary is on systematic reviews (SRs), technology assessments (TAs), randomized controlled trials (RCT), and comparative nonrandomized studies for the investigational indications listed in the policy criteria.

### LUMBAR SYMPATHECTOMY

#### Systematic Review

Chudry (2022) published a systematic review (SR) evaluating the effectiveness of interventions for primary palmar hyperhidrosis (PH).<sup>[12]</sup> Six studies were included in the review. Two of these studies addressed the use of endoscopic thoracic sympathectomy (ETS) in PH, and both reported over 95% patient symptom improvement. The authors conclude that ETS was reported as successful as other interventions in the reduction of PH, however, ETS carries significant adverse effects such as compensatory sweating and the potential of complications associated with surgery.

Lima (2020) conducted a SR and meta-analysis of lumbar sympathectomy for plantar hyperhidrosis.<sup>[13]</sup> 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 of six months of follow-up. The RCT was conducted in 30 women at a single hospital in Brazil. The primary outcome measure was a quality-of-life questionnaire that was developed for use in patients undergoing thoracic sympathectomy. After six 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.

Lima (2017) published a SR evaluating the efficacy of lumbar sympathectomy in plantar hyperhidrosis. Among the nine studies included, eight were retrospective studies, and one was a RCT.<sup>[14]</sup> None of the eight retrospective studies were considered to be of high quality, assessed by the Newcastle Ottawa Scale. The protocol was highly variable across trials, with respect to intervention site (ranging from L2/L3 to L5) and surgical technique (seven studies used mechanical clipping or resection sympathectomy, two used chemical sympathectomy). Across all studies, the percent of patients with resolution of symptoms ranged from 5 to 98%. There was a high variation in the incidence of complications across studies, including neuralgia (range, 3% to 42.2%), compensatory sweating, (1.5% to 90%), and sexual dysfunction (not reported by all studies). There is not enough evidence of the safety or long-term clinical outcomes of lumbar sympathectomy in the treatment of plantar hyperhidrosis. Additional RCTs with standardized protocols are needed.

### **Randomized Controlled Trials**

No RCTs beyond those summarized in the SR above were identified.

### **Nonrandomized Studies**

In addition to the nonrandomized studies summarized in the SR above, there have been case series published, however, these observations are not generalizable due to lack of randomization, lack of a control group for comparison, heterogeneous patient characteristics, lack of long-term follow-up, subjective outcomes, and the use of different surgical techniques.<sup>[15-17]</sup> In addition to low success rates, concerns have been reported for side effects in sexual functioning in both males and females.

## **REMOVAL OF AXILLARY SWEAT GLANDS BY LIPOSUCTION OR CURETTAGE**

There is insufficient evidence to determine whether liposuction or curettage of sweat glands is safe or effective as a treatment of axillary hyperhidrosis. In a SR of treatments available in secondary care for the management of primary hyperhidrosis, Wade (2018) evaluated studies on curettage for axillary hyperhidrosis.<sup>[18]</sup> Nine studies were identified including four RCTs and five nonrandomized studies. All were considered to be at high risk for bias. Meta-analysis was not possible due to methodological differences. In four studies, curettage was compared to botulinum treatment and only one small RCT found a statistically significant improvement in symptoms, favoring botulinum.<sup>[19]</sup> No differences were found in sweating, quality-of-life or satisfaction outcomes, although, where reported, the incidence of adverse events was higher with curettage than with botulinum. Although this procedure has been performed for several decades, only scattered reports regarding its effectiveness were identified in a PubMed literature search.<sup>[20-25]</sup>

## **AXILLARY SUBDERMAL LASER TREATMENT**

### **Systematic Reviews and Technology Assessments**

In 2015, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a rapid response review on the clinical effectiveness of laser therapy in axillary hyperhidrosis.<sup>[26]</sup> Five publications were included in the review, three RCTs and two nonrandomized studies. No relevant evidence-based guidelines were identified for inclusion. The authors reported that

although the evidence suggests laser therapy may reduce sweating in cases of axillary hyperhidrosis, these results should be interpreted with caution due to the methodological limitations of the studies, which include but are not limited to, small sample sizes, a lack of reporting on efficacy and safety outcomes, potential selection bias, and a lack of long term follow-up data.

### **Randomized Controlled Trials**

**No RCTs beyond those summarized in the review above were identified.**

### **Nonrandomized Studies**

No studies beyond those summarized in the review above were identified.

## **PERCUTANEOUS RADIOFREQUENCY TREATMENTS**

### **Systematic Reviews**

Hasimoto (2020) published a SR with meta-analysis of nine studies (N=378) evaluating the effectiveness of radiofrequency (RF) treatment of primary hyperhidrosis, including radiofrequency ablation (RFA) sympathectomy (N=238) and fractionated microneedle radiofrequency (FMRF) of the axillary (N=75) compared to video-assisted thoracic sympathectomy (VATS) (N=65).<sup>[27]</sup> In seven of the nine studies, patients were subjected to RF only, and in two of nine studies RF was compared to VATS. Across the three studies evaluating FMRF, there was a reduction in the severity of hyperhidrosis (mean difference - 1.24, 95% CI -1.44 to -1.03) and minor improvement in reported quality of life (QoL) (-9.0, 95% CI -9.15 to -8.85). There was improvement in QoL found after RFA (two studies, mean difference -15.92, 95% CI -17.61 to -14.24), although the one study comparing QoL improvement after RFA or VATS found that VATS showed superior results. In the one study that evaluated symptom recurrence between VATS and RF found higher recurrence rates in RF (5% vs. 25%, respectively,  $p < 0.01$ ). There were no RCTs identified for inclusion, and of the two studies comparing RFA to VATS, one was a non-randomized controlled study and the other was a retrospective observational study. The authors concluded that there is a need for high-quality prospective studies comparing RF to current standard practice, particularly VATS.

### **Randomized Controlled Trials**

Mostafa (2019) conducted a randomized controlled trial (RCT) of radiofrequency ablation compared to botulinum toxin type A in 80 patients with primary palmar hyperhidrosis.<sup>[28]</sup> Both groups showed improvements from baseline in HDSS scores at one week, one month, and two months after treatment, but scores in the radiofrequency ablation group were significantly lower (indicating more improvement with RFA) than in the botulinum toxin group at one week, one month, and two, six, and 12 months after treatment.

Rummaneethorn (2019) compared RFA to botulinum toxin A in 20 patients with primary axillary hyperhidrosis.<sup>[29]</sup> At the endpoint visit (week 12), the botulinum toxin A group had significantly greater reduction of mean HDSS score than the RFA group with 1.60 (0.59) versus 2.05 (0.68), respectively ( $p = 0.0332$ ). At week 12, the botulinum toxin A group also had significantly higher satisfaction score by quartile rating scale than the microneedle RF group (2.55 + 0.69 versus 1.70 + 1.03, respectively,  $p = 0.004$ ).

### **Nonrandomized Studies**

No studies beyond those summarized in the SR above were identified.

## PRACTICE GUIDELINE SUMMARY

In 2011, an expert consensus statement on the surgical treatment of hyperhidrosis was published by a task force of the Society of Thoracic Surgeons.<sup>[30]</sup> The document stated that endoscopic thoracic sympathectomy is the treatment of choice for patients with primary hyperhidrosis. They further recommend the following treatment strategies (with R referring to rib and the number to the specific rib):

- R3 interruption for palmar hyperhidrosis; an R4 interruption is also reasonable. The authors note a slightly higher rate of compensatory sweating with an 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's syndrome.

## SUMMARY

There is enough evidence to determine that endoscopic transthoracic sympathectomy and surgical excision of axillary sweat glands results in a meaningful improvement in the net health outcome for individuals who have primary axillary, craniofacial, or palmar hyperhidrosis. These procedures are considered standard of care for these indications when a trial of non-surgical treatment has failed. Clinical guidelines based on research recommend surgical treatment for primary hyperhidrosis. Therefore, endoscopic transthoracic sympathectomy and surgical excision of axillary sweat glands is considered medically necessary when policy criteria are met.

For individuals who have severe secondary gustatory hyperhidrosis who receive tympanic neurectomy, this treatment has been shown to have high success rates without the need for repeated interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome and this treatment is considered standard of care for this indication when a trial of non-surgical treatment has failed. Therefore, tympanic neurectomy is considered medically necessary for the treatment of secondary gustatory hyperhidrosis when policy criteria are met.

There is not enough research to show surgical treatment for hyperhidrosis improves health outcomes for all other conditions and/or complications. Therefore, surgical treatment for hyperhidrosis is considered not medically necessary when policy criteria are not met.

There is not enough research to show that surgical treatments of hyperhidrosis including, but not limited to lumbar sympathectomy, axillary liposuction or curettage performed alone or in combination with any other procedure, subdermal laser-assisted axillary hyperhidrosis treatment, percutaneous radiofrequency sympathiclysis or sympathectomy and radiofrequency ablation for palmar hyperhidrosis improves health outcomes for people with hyperhidrosis. There are no evidence-based clinical practice guidelines recommending these

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procedures for the treatment of hyperhidrosis. Therefore, these techniques are considered investigational.

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## CODES

**NOTE:** Codes 11450 and 11451 should not be reported when there is a diagnosis of hyperhidrosis.

Codes	Number	Description
CPT	32664	Thoracoscopy, surgical; with thoracic sympathectomy

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<b>Codes</b>	<b>Number</b>	<b>Description</b>
	64818	Sympathectomy, lumbar
	69676	Tympanic neurectomy
HCPCS	None	

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**Date of Origin:** November 1999