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 gustatory 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 are met:

A. Primary medical conditions causing secondary hyperhidrosis have been identified and treated where possible

B. The hyperhidrosis is persistent and severe, and has resulted in significant medical complications such as:
   1. Acrocyanosis of the hands
   2. Recurrent skin maceration with secondary bacterial or fungal infection
3. Recurrent secondary infections
4. Persistent eczematous dermatitis despite medical treatments with topical dermatologics or systemic anticholinergics
   C. A trial of nonsurgical treatments has failed or is contraindicated.

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.

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 sympathicolysis 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.

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
- Nonsurgical treatments trialed and documented response

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 localized hyperhidrosis is idiopathic in nature, typically involving the hands (palmar), feet (plantar), or underarms (axillae).

Primary focal hyperhidrosis is defined as 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 hyperhidrosis is usually generalized or craniofacial sweating. It 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, Raynaud’s disease, and Frey’s syndrome.

Secondary gustatory hyperhidrosis is excessive sweating on ingesting highly spiced foods. This trigeminovascular reflex typically occurs symmetrically on scalp or face and predominately over forehead, lips and nose.

Secondary facial gustatory sweating, in contrast, is usually asymmetrical and 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’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, 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) sympathicolysis 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 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.

Since tympanic neurectomy for the treatment of severe gustatory hyperhidrosis when a trial of nonsurgical treatments failed, and excision of sweat glands have evolved into a standard of care, 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.

**ENDOSCOPIC TRANSTHORACIC SYMPATECTOMY**

**Systematic Reviews**

Deng (2011) published a meta-analysis of data from randomized controlled trials and observational studies published to 2010 evaluating thoracoscopic sympathectomy for patients with palmar hyperhidrosis.[1] The authors pooled outcome data from different approaches to sympathectomy, i.e., single-ganglia blockage (T2, T3, or T4), and multi-ganglia blockage (T2-3, T2-4, or T3-4). (Note: T refers to rib). Based on these analyses, they concluded that T3 (11 studies) and T3-4 (2 studies) had the “best” clinical efficacy i.e., 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 was only available from one study with 60 patients; a pooled analysis could not be performed.

**Randomized Controlled Trials**

Youssef (2015) published results from a randomized controlled trail (RCT) that analyzed outcomes for unilateral sequential endoscopic transthoracic sympathectomy (S-ETS) in comparison with simultaneous bilateral endoscopic transthoracic sympathectomy (B-ETS) in treating patients with palmar hyperhidrosis (PH) and compensatory hyperhidrosis (CH). Four hundred seven patients with intractable PH were randomly assigned to the two groups: 203 patients in the S-ETS group, and 204 patients in the B-ETS group. Three hundred sixty-four patients completed the study, and the authors report complication rates were comparable for both groups. Treatment success on the two month follow-up was 97.2% for S-ETS and 96.7% for B-ETS. The incidence of CH was decreased substantially from 131 (71.1%) patients in the B-ETS group compared to 22 (12.2%) patients in the S-ETS group (P<.001). Eighty-four (58.3%) patients in the S-ETS group had simultaneous disappearance or decreased perspiration on the soles. Finally, the authors reported that all patients in the S-ETS group were satisfied, whereas 37.9% of B-ETS patients were unsatisfied with their operation, mostly because of CH and recurrences. The author concluded that although both methods were safe, effective, and minimally invasive methods of treatment for PH.

Heidemann (2013) published results from an RCT that described two groups of consecutive patients with isolated axillary hyperhidrosis who underwent thoracoscopic sympathectomy (n = 49) or local axillary surgery (n = 47) at the same university hospital over a nine-year period, depending on referral or preference. Patients received identical questionnaires to investigate local effect and side effects after surgery. Outcome after surgery for isolated axillary hyperhidrosis was significantly better after local surgical treatment compared with sympathectomy. Local effect was better and side effects fewer, but milder recurrent symptoms were more frequent. Authors suggest that local axillary surgery is preferable for isolated axillary hyperhidrosis and that R2-R3 or R2-R4 sympathicotomy should be discouraged.

Yuncu (2013) published an RCT which compared surgery at the T3 and T3-4 levels. The trial included 60 patients with axillary hyperhidrosis; 17 were assigned to T3-4 surgery and 43 to T3 surgery. There were no significant differences between groups in postoperative satisfaction. At the 1-year follow-up, the incidence of compensatory sweating was lower in the T3 group (79%) than the T3-4 group (100%).

Ibrahim (2013) evaluated the operative and postoperative results of two-stage unilateral vs one-stage bilateral thoracoscopic sympathectomy. Two hundred and seventy patients with severe palmar and/or axillary hyperhidrosis were included in the study. One hundred and thirty patients received one-stage bilateral, single-port video-assisted thoracoscopic sympathectomy (one-stage group) and 140, two-stage unilateral, single-port video-assisted thoracoscopic sympathectomy, with a mean time interval of four months between the procedures (two-stage group). The mean postoperative follow-up period was 12.5 (range: 1-24 months). Sixteen (12%) patients of the one-stage group and 15 (11%) of the two-stage group suffered from mild/moderate pain (P = 0.8482). Pneumothorax occurred in 8 (6%) patients of the one-stage group and in 11 (8%) of the two-stage group. Compensatory sweating occurred in 25 (19%) patients of the one-stage group and in 6 (4%) of the two-stage group (P = 0.0001). The authors concluded that both two-stage unilateral and one-stage bilateral single-port video-assisted thoracoscopic sympathectomies were effective, safe and minimally invasive procedures.
A 2011 study by Baumgartner included 121 patients with disabling palmoplantar hyperhidrosis.\[6\] Patients were randomized to receive bilateral sympathectomy over T2 (n=61 patients) or T3 (n=60 patients). Six of 121 (5%) patients, three in each group, were considered treatment failures, (i.e., 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 six months, the mean level of compensatory sweating (0 to 10 severity scale) was 4.7 (standard deviation [SD]=2.7) for the T2 group and 3.8 (SD=2.8) for the T3 group (p=not significant). Similarly, at 1 year, the mean severity rating of compensatory sweating was 4.7 (SD=2.5) in the T2 group and 3.7 (SD=2.8) in the T3 group; p=0.09.

In 2011, an additional study was published by Ishy in Brazil in which surgery at the T3 and T4 levels was compared.\[7\] This study included 20 patients with palmar hyperhidrosis. All patients experienced complete bilateral remission of palmar sweating after 1 year of follow-up. The level of compensatory sweating did not differ significantly between groups at 1 week, 1 month, or 6 months, but at 1 year, there was a significantly higher rate in the T3 compared to the T4 group (20/20, 100% in the T3 group and 15/20, 75% in the T4 group, p=0.47).

Inan (2011) published results from an additional RCT comparing different surgical techniques for hyperhidrosis. The authors reported primary success rates of 96.3% for isolated palmar hyperhidrosis, 95.7% for palmar and axillary hyperhidrosis, and 66.7% for palmar and face/scalp hyperhidrosis.\[8\] Complication rates were similar among the groups and included pneumothorax which required no intervention. RCTs continue to be published comparing levels of sympathectomy.\[6,7\] Large case series on endoscopic transthoracic sympathectomy (ETS) have reported success rates for of up to 98% for treatment of axillary and/or palmar hyperhidrosis.\[9-18\]

**COMPLICATIONS**

A 2013 series reported on complications after thoracic sympathectomy in 1731 patients with palmar, axillary or craniofacial hyperhidrosis.\[19\] Thirty days after surgery, 1531 (88.4%) 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 of the 1731 (19%) patients.

**PLANTAR HYPERHIDROSIS**

**Systematic Reviews**

No SRs were identified

**Randomized Controlled Trials**

No RCTs were identified

**Nonrandomized Studies**

Case series have found lower rates of efficacy for plantar compared to axillary or palmar hyperhidrosis. In a retrospective analysis of prospectively collected data on patients who underwent ETS for primary focal hyperhidrosis, Wait reported complete resolution of symptoms in 19 of 197 (9.6%) plantar hyperhidrosis patients compared to 99.7% and 73% for palmar and axillary hyperhidrosis, respectively.\[17\] In addition to low success rates, concerns have been reported for side effects in sexual functioning in both males and females.
LUMBAR SYMPATHECTOMY

Systematic Review

No SRs were identified.

Randomized Controlled Trials

No RCTs were identified.

Nonrandomized Studies

The evidence is limited to several case series trials that are unreliable due to the following: 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.[20-25]

SURGICAL REMOVAL OF AXILLARY SWEAT GLANDS (INCLUDING LIPOSUCTION AND CURETTAGE)

There is sufficient evidence to suggest that excisional removal of sweat glands may be safe and effective as a treatment of severe, refractory axillary hyperhidrosis and this technique is considered a standard of care for surgical candidates.

There is insufficient evidence to determine whether liposuction or curettage of sweat gland is safe or effective as a treatment of axillary hyperhidrosis. Although this procedure has been performed for several decades, only scattered reports regarding its effectiveness were identified in a PubMed literature search.[26-31]

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.[32] 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 were identified.

Nonrandomized Studies

No studies were identified.

PERCUTANEOUS RADIOFREQUENCY (RF) SYMPATHICOLYSIS

Systematic Reviews
No SRs were identified

**Randomized Controlled Trials**

No RCTs were identified.

**Nonrandomized Studies**

No studies were identified.

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**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.[33] 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.**

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**SUMMARY**

There is enough research to show that surgical treatment, including gustatory hyperhidrosis, via endoscopic transthoracic sympathectomy or excision of axillary sweat glands improves health outcomes for people with primary hyperhidrosis and certain medical complications. In addition, tympanic neurectomy for the treatment of severe gustatory hyperhidrosis if a trial of nonsurgical treatments failed and excision of sweat glands have evolved into a standard of care. Clinical guidelines based on research recommend surgical treatment for primary hyperhidrosis. Therefore, surgical treatments for people with hyperhidrosis may be considered medically necessary 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 sympathicolysis or sympathectomy and radiofrequency ablation for palmar hyperhidrosis improves health outcomes for people with hyperhidrosis. Therefore, these techniques are considered investigational.
REFERENCES


15. Han, PP, Gottfried, ON, Kenny, KJ, Dickman, CA. Biportal thoracoscopic sympathectomy: surgical techniques and clinical results for the treatment of


32. 2015 Apr 29 Guidelines. PMID: 26180877


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*Date of Origin: November 1999*