

Clinical Policy: Hyperhidrosis Treatments

Reference Number: WNC.CP.162 Last Review Date: Coding Implications Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description

Hyperhidrosis is defined as excessive sweating beyond a level required to maintain normal body temperature in response to heat exposure or exercise.

Policy/Criteria

- I. It is the policy of WellCare of North Carolina[®] that treatment with *iontophoresis* (electrophoresis, Drionic device) is medically necessary when **all** of the following criteria are met:
 - A. Diagnosis of primary hyperhidrosis;
 - **B.** Development of medical complications, such as skin maceration with secondary skin infections; *OR* has a significant constant disruption of professional and/or social life (e.g., recurrent changing of clothes, affecting job/social function, etc.) which has occurred because of excessive sweating;
 - **C.** Unresponsive or unable to tolerate at least one of the pharmacotherapies prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines);
 - **D.** Failed a 6-month trial of conservative management including the adherent application of aluminum chloride hexahydrate [Drysol by prescription] or topical agents have resulted in a severe rash;
 - E. Has none of the following contraindications:
 - 1. Cardiac pacemaker;
 - 2. Cardiac arrhythmias;
 - 3. Pregnancy
 - 4. Metal implants, depending on size and position (may divert the electric current);
 - 5. Epilepsy.
- **II.** It is the policy of health plans affiliated with WellCare of North Carolina[®] that surgical excision of axillary sweat glands for axillary hyperhidrosis are **medically necessary** when *all* of the following criteria are met:
 - A. Meets all of the iontophoresis criteria in I.A. through I.E.;
 - **B.** Has persistent and severe primary hyperhidrosis;
 - **C.** Has failed one of the following:
 - 1. Iontophoresis;
 - 2. Trial of botulinum toxin.



- **III.** It is the policy of WellCare of North Carolina[®] that *endoscopic thoracic sympathectomy* (ETS) for palmar or palmar and axillary hyperhidrosis is medically necessary when **all** of the following criteria are met:
 - A. Meets all of the iontophoresis criteria in I.A. through I.E.;
 - **B.** Member has a resting heart rate > 55 beats per minute;
 - **C.** Hyperhidrosis symptoms started at an early age (usually < 16 years), and surgery is requested for a young member (usually < 25 years of age);
 - **D.** Body mass index <28;
 - E. Reports no sweating during sleep;
 - F. Member has no significant comorbidities;
 - G. Member has persistent and severe primary hyperhidrosis;
 - **H.** Member has failed **one** of the following:
 - 1. Iontophoresis;
 - 2. Trial of botulinum toxin for predominantly axillary hyperhidrosis.
 - I. The member has been counseled on risks of procedure.
 - *Note: The standard line of medical therapy is:*
 - 1. Drysol, then Botox or topical glycopyrronium for axillary hyperhidrosis;
 - 2. Drysol, then iontophoresis for palmoplantar hyperhidrosis;
 - 3. Third-line therapies such as iontophoresis and surgery for axillary hyperhidrosis, and Botox and surgery for palmoplantar hyperhidrosis.
- **IV.** There is insufficient evidence in published peer-reviewed literature to support all other treatments for hyperhidrosis, including, but not limited to, microwave therapy, or liposuction as the sole method of removing axillary sweat glands.

Background

Hyperhidrosis can be classified as either primary or secondary.¹ Primary focal hyperhidrosis is idiopathic in nature and is defined as excessive sweating induced by sympathetic hyperactivity in selected areas that is not associated with an underlying disease process.² The most common locations are underarms (axillary hyperhidrosis), hands (palmar hyperhidrosis), and feet (plantar hyperhidrosis). Primary focal hyperhidrosis is a condition that is characterized by visible, excessive sweating of at least six months' duration without apparent cause. Hyperhidrosis can ruin clothing, produce emotional distress, and lead to occupational disability.¹

Secondary hyperhidrosis can result from a variety of drugs, such as tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs), or underlying diseases/conditions, such as febrile diseases, diabetes mellitus, or 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 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.

A variety of therapies have been investigated for primary hyperhidrosis, including topical therapy with aluminum chloride, iontophoresis, intradermal injections of botulinum toxin type A, endoscopic transthoracic sympathectomy (ETS), and surgical excision of axillary sweat glands.^{1,3,4} ETS is an invasive procedure intended to arrest the symptoms of hyperhidrosis and involves interrupting the upper thoracic sympathetic chain through clipping, cauterization, or cutting.¹. ETS is considered a last resort due to potential serious, irreversible compensatory sweating (excessive sweating on large areas of the body or all over as well as other effects, such as, extreme hypotension, arrhythmia, and heat intolerance.⁵ Treatment of secondary hyperhidrosis focuses on the treatment of the underlying cause, such as discontinuing certain drugs or hormone replacement therapy as a treatment of menopausal symptoms.

Microwave energy has been proposed for the treatment of primary axillary hyperhidrosis. The miraDry System (Mirimar Labs, Inc) is a Food and Drug Administration (FDA) approved device indicated for treatment of primary axillary hyperhidrosis. It is not indicated for treating hyperhidrosis related to other body areas or generalized hyperhidrosis.

According to the National Institute for Health and Care Excellence (NICE), "Current evidence on the safety and efficacy of transcutaneous microwave ablation for severe primary axillary hyperhidrosis is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into transcutaneous microwave ablation for severe primary axillary hyperhidrosis and may update the guidance on publication of further evidence."⁶

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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



CPT ^{®*} Codes	Description
32664	Thoracoscopy, surgical; with thoracic sympathectomy
97024* NIA	Application of a modality to 1 or more areas; diathermy (e.g., microwave)
97033 NIA	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes

* Insufficient evidence in published peer-reviewed literature to support suction assisted liposuction or diathermy as the sole method of removing axillary sweat glands.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original Approval date.	03/21	05/21
Reviewed CPT and ICD-10-CM codes.		02/22
Annual review. "Experimental/investigational" verbiage replaced with descriptive language in policy statement and background References reviewed and updated.	08/22	11/22
Annual review. Updated Criteria II.B. to greater than 55 beats per minute. Removed "is relatively healthy" in criteria II.F. Background updated with no impact on criteria. Updated verbiage under ICD-10 code table to "Insufficient evidence in published peer-reviewed literature to support suction assisted liposuction as the sole method of removing axillary sweat glands" ICD-10 codes removed. References reviewed and updated. NCHC verbiage removed from NC Guidance Verbiage.	05/23	05/23
Annual review. Changed order of criteria. Added criteria point III.I. "The member/enrollee has been counseled on risks of procedure." And deleted verbiage " <i>Note</i> : The normal line of medical therapy is: Drysol, then Botox or topical glycopyrronium for axillary hyperhidrosis Drysol, then iontophoresis for palmoplantar hyperhidrosis Other treatments are third-line therapies (iontophoresis and surgery for axillary hyperhidrosis, and Botox and surgery for palmoplantar hyperhidrosis). Background updated with no clinical significance, added "ETS is considered a last resort due to potential serious, irreversible compensatory sweating (excessive sweating on large areas of the body or all over as well as other effects, i.e., extreme hypotension, arrhythmia, and heat intolerance. ¹⁸ " Removed CPT codes 64802 through 64823. References reviewed and updated. Removed HCPCS table.	02/24	02/24
Added note regarding the normal line of medical therapy back into policy after erroneously removing during January 2024 annual policy review.	05/24	05/24
Annual Review. Updated criteria I.E.3. by removing text (hyperhidrosis often improves during pregnancy). Changed Criteria I.E.5. from 'cracked skin near the treatment area' to 'epilepsy.'		



Reviews, Revisions, and Approvals	Revision Date	Approval Date
Criteria II. Changed verbiage to WellCare of North Carolina. Criteria		
II.A. and Criteria III.A. changed 'through D' to 'I.E.' Criteria III.B,G,		
H, added "member," with no effect on criteria. Updated verbiage in		
Note section at the end of Criteria III. with no impact to criteria. Minor		
verbiage update in Criteria IV. Added NICE information to		
Background, with no impact to criteria. Note Under CPT code box,		
added "or diathermy." CPT codes and References reviewed.		

References

- 1. Smith CC, Pariser, D. Primary focal hyperhidrosis. UpToDate. www.uptodate.com. Published May 13, 2024. Accessed November 01, 2024
- 2. Glaser DA. The use of botulinum toxins to treat hyperhidrosis and gustatory sweating syndrome. Neurotox Res. 2006;9(2 to 3):173 to 177. doi:10.1007/BF03033936
- 3. Cerfolio RJ, De Campos JR, Bryant AS, et al. The Society of Thoracic Surgeons expert consensus for the surgical treatment of hyperhidrosis. Ann Thorac Surg. 2011;91(5):1642 to 1648 doi:10.1016/j.athoracsur.2011.01.105
- 4. Eisenach JH, Atkinson JL, Fealey RD. Hyperhidrosis: evolving therapies for a wellestablished phenomenon [published correction appears in Mayo Clin Proc. 2005 Jun;80(6):828]. Mayo Clin Proc. 2005;80(5):657 to 666. doi:10.4065/80.5.657
- 5. International Hyperhidrosis Society. Endoscopic thoracic sympathectomy (ETS). https://www.sweathelp.org/hyperhidrosis-treatments/ets-surgery.html. Accessed October 31, 2024.
- National Institute for Health and Care Excellence. Transcutaneous microwave ablation for severe primary axillary hyperhidrosis. Interventional procedures guidance [IPG601]. https://www.nice.org.uk/guidance/ipg601. Published December 20, 2017. Accessed November 04, 2024.
- International Hyperhidrosis Society. Hyperhidrosis Treatment Overview. https://www.sweathelp.org/hyperhidrosis-treatments/treatment-overview.html. Accessed October 31, 2024.
- 8. Arora G, Kassir M, Patil A, et al. Treatment of Axillary hyperhidrosis. J Cosmet Dermatol. 2022;21(1):62-70. doi:10.1111/jocd.14378
- 9. Lakraj, AA, Moghimi N, Jabbari B. Hyperhidrosis: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxins. Toxins (Basel). 2013;5(4):821 to 840. Published 2013 Apr 23. doi:10.3390/toxins5040821
- 10. Oakley A. Hyperhidrosis. DermNet NZ. <u>https://dermnetnz.org/topics/hyperhidrosis</u>. Updated July 2015. Accessed November 04, 2024.
- 11. Cole A, Oakley A. DermNet NZ. https://dermnetnz.org/topics/iontophoresis. Updated April 2015. Accessed November 01, 2024.
- 12. Glaser DA, Coleman WP 3rd, Fan LK, et al. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: the dermatologic reduction



in underarm perspiration study. Dermatol Surg. 2012;38(2):185 to 191. doi:10.1111/j.1524-4725.2011.02250.x

- Pariser DM, Hebert AA, Drew J, Quiring J, Gopalan R, Glaser DA. Topical Glycopyrronium Tosylate for the Treatment of Primary Axillary Hyperhidrosis: Patient Reported Outcomes from the ATMOS-1 and ATMOS-2 Phase III Randomized Controlled Trials. Am J Clin Dermatol. 2019;20(1):135 to 145. doi:10.1007/s40257-018-0395-0
- 14. Glaser DA, Hebert AA, Nast A, et al. Topical glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis: Results from the ATMOS-1 and ATMOS-2 phase 3 randomized controlled trials. J Am Acad Dermatol. 2019;80(1):128 to 138.e2. doi:10.1016/j.jaad.2018.07.002
- 15. Sheikh NK, Dua A. Iontophoresis Analgesic Medications. In: StatPearls. Treasure Island (FL): StatPearls Publishing; July 31, 2023. Accessed November 3, 2023.
- Vannucci F, Araújo JA. Thoracic sympathectomy for hyperhidrosis: from surgical indications to clinical results. J Thorac Dis. 2017;9(Suppl 3):S178 to S192. doi:10.21037/jtd.2017.04.04
- 17. Dunlap L, Clifton AV, Stephenson J, et al. Interventions for hyperhidrosis. Cochrane Database of Syst Rev. 2022(2). doi: 10.1002/14651858.CD015135
- Hong HC, Lupin M, O'Shaughnessy KF. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. Dermatol Surg. 2012;38(5):728 to 735. doi:10.1111/j.1524-4725.2012.02375.x
- 19. International Hyperhidrosis Society. BrellaTM Sweat Control PatchTM. https://www.sweathelp.org/hyperhidrosis-treatments/brella.html. Accessed October 31, 2024.
- International Hyperhidrosis Society. Iontophoresis. https://www.sweathelp.org/treatments-hcp/iontophoresis.html. Accessed November 04, 2024.
- 21. Evidence Analysis Research Brief. Microwave therapy for management of hyperhidrosis. Hayes. www.hayesinc.com. Published April 19, 2022. Accessed November 04, 2024.
- 22. Hsu TH, Chen YT, Tu YK, Li CN. A systematic review of microwave-based therapy for axillary hyperhidrosis. J Cosmet Laser Ther. 2017;19(5):275 to 282. doi:10.1080/14764172.2017.1303168
- 23. International Hyperhidrosis Society. Sofdra[™] Topical Gel for Primary Axillary Hyperhidrosis. https://www.sweathelp.org/hyperhidrosis-treatments/sofdra.html. Accessed November 04, 2024.

North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.



EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act] Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

- 1. that is unsafe, ineffective, or experimental or investigational.
- 2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- 1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
- 2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:



NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

- a. Claim Type as applicable to the service provided: Professional (CMS-1500/837P transaction) Institutional (UB-04/837I transaction) Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
- c. Code(s) Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report



the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

- d. Modifiers Providers shall follow applicable modifier guidelines.
- e. Billing Units Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments -For Medicaid refer to Medicaid State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
- g. Reimbursement Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: <u>https://medicaid.ncdhhs.gov/</u>.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or



regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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