

Geisinger Health Plan Policies and Procedure Manual

Policy: MP040

Section: Medical Benefit Policy

Subject: Somnoplasty™, Coblation™ (Radiofrequency Ablation)

Applicable Lines of Business

Commercial	Х	CHIP	Х
Medicare	Х	ACA	X
Medicaid	Х		

I. Policy: Somnoplasty™, Coblation™ (Radiofrequency Ablation)

II. Purpose/Objective:

To provide a policy of coverage regarding Somnoplasty™, Coblation™ (Radiofrequency Ablation)

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury.
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

- illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking
 into account both the functional capacity of the Member and those functional capacities that are appropriate for
 Members of the same age

DESCRIPTION:

Somnoplasty utilizes low-power, low-temperature radiofrequency energy as a treatment for nasal airway obstruction, obstructive sleep apnea and/or snoring. By means of a partially insulated electrode, radiofrequency energy is delivered into the soft palate, uvula and/or turbinates, through the submucosal tissue to make one or several coagulation lesions. The treated tissue is naturally absorbed over the following several weeks, thus reducing tissue volume.

Coblation is a method of non-thermal volumetric tissue removal through molecular dissociation, using the electrically conductive fluid employed in the gap between the electrode and tissue. When electrical current is applied to this fluid, it turns into a charged layer of particles, called a plasma layer. Charged particles accelerate through the plasma and gain sufficient energy to break the molecular bonds within cells. This causes the cells to disintegrate molecule by molecule, so that tissue is volumetrically removed.

For other related policies please see:

- MP 72 Percutaneous Disc Decompression (Nucleoplasty)
- MP 201 Obstructive Sleep Apnea

COVERED INDICATIONS:

Coblation tonsillectomy may be considered medical necessary for the treatment of any of the following:

- Recurrent or chronic tonsillar infection; or
- Tonsillar hypertrophy leading to respiratory symptoms or airway obstruction; or
- Peri-tonsillar abscess; or
- Recurrent middle ear infection where tonsillar hypertrophy is believed to be an exacerbating factor.

EXCLUSIONS:

Somnoplasty/coblation for the treatment of socially disruptive snoring is considered **not medically necessary** and is **NOT COVERED.**

Somnoplasty / coblation for the treatment of obstructive sleep apnea is considered **experimental**, **investigational or Unproven** and is **NOT COVERED**. There is inconclusive evidence in the published, peer-reviewed medical literature that the service has a beneficial effect on health outcomes.

Somnoplasty /coblation of the inferior turbinates for treatment of chronic nasal obstruction is considered **experimental**, **investigational or unproven** and is **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature directly comparing somnoplasty to the established alternatives of electrocautery or submucosal surgical resection of the turbinates. In addition, there are no published clinical studies reporting on the long-term outcomes of individuals with mucosal hypertrophy that have been treated with radiofrequency volumetric tissue reduction.

Coblation tenotomy for the treatment of musculoskeletal conditions is considered **experimental**, **investigational or unproven** and is **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature directly comparing coblation tenotomy to the established alternatives.

Coblation adenoidectomy is considered **experimental**, **investigational or unproven** and is **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature directly comparing coblation to the established alternatives

Videolaryngoscope-assisted Coblation for the treatment of epiglottic cysts is **considered experimental**, **investigational or unproven** and is **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature directly comparing coblation to the established alternatives

Coblation for the treatment of laryngopharyngeal vascular lesions is considered **experimental**, **investigational or unproven** and is **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature directly comparing coblation to the established alternatives

Coblation for the treatment of glottis cancer or laryngeal cancer is considered **experimental**, **investigational or unproven** and is **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature directly comparing coblation to the established alternatives

Computed tomography (CT)-guided percutaneous Coblation of the thoracic nerve root for the treatment of post-herpetic neuralgia is considered experimental, investigational or unproven and is NOT COVERED. There is insufficient evidence in the peer-reviewed published medical literature directly comparing coblation to the established alternatives.

Coblation for the treatment of headache and/or nerve pain is considered **experimental**, **investigational or unproven** and is **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature directly comparing coblation tenotomy to the established alternatives.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Somnoplasty™, Coblation™ (Radiofrequency Ablation)

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

30999 Unlisted procedure, nose

42299 Unlisted procedure, palate, uvula

41530 Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session

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

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Powell, NB, Riley RW, et.al., "Radiofrequency Volumetric Reduction of the Palate in Subjects With Sleep-Disordered Breathing", *Chest*, 113(5):1163-1174, May 1998.

Hukins CA, Mitchell IC, Hillman DR, "Radiofrequency Tissue Volume Reduction of the Soft Palate in Simple Snoring", *Archives of Otolaryngology-Head & Neck Surgery*, 126(5):602-606, May 2000.

Loube D," Radiofrequency Ablation for Sleep-Disordered Breathing", Chest, 113(5):1151-1152, May 1998.

Piccirillo JF, Duntley S, Schotland H, "Obstructive Sleep Apnea", JAMA, 284(12):1492-1494, 27 Sept 2000.

Exar EN, Collop NA, "The Upper Airway Resistance Syndrome", Chest, 115(4):1127-1139, April 1999.

Krug, P, "Snoring and Obstructive Sleep Apnea", AORN Journal, 69(4):792-801, April 1999.

Geisinger Technology Assessment Committee Review, <u>Radio-ablation of Turbonates for Nasal Obstruction</u>, July 12, 2000.

Powell NB, Riley RW, Guilleminault C. Radiofrequency tongue base reduction in sleep-disordered breathing: A pilot study. Otolaryngol Head Neck Surg 1999;120:656-64.

Li KK, Powell NB, Riley RW, Troell RJ, Guilleminault C. Radiofrequency volumetric tissue reduction for treatment of turbinate hypertrophy: A pilot study. Otolaryngol Head Neck Surg 1998;119:569-73.

Nease CJ and Krempl GA. Radiofrequency treatment of turbinate hypertrophy: A randomized, blinded, placebo-controlled clinical trial. Otolaryngol Head Neck Surg 2004;130:291-9.

Blue Cross and Blue Shield Association Technology Evaluation Center. radiofrequency volumetric tissue reduction for sleep-related breathing disorders. TEC Assessment program December 2000 15 (15); 1-27.

ECRI. Custom Hotline Response (online) Radiofrequency volumetric tissue reduction (Somnoplasty) for obstructive sleep apnea or snoring. Current as of July 27,2006.

Troell RJ, Powell NB, Riley RW, Li KK. Comparison of postoperative pain between laser-assisted uvulopalatoplasty, uvulopalatophayngoplasty, and radiofrequency volumetric tissue reduction of the palate. Otolaryngol Head Neck Surg 2000;122:402-9.

Woodson BT, Steward DL, Weaver EM, Javaheri S. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2003;128:848-61.

Coticchia JM, Yun RD, Nelson L, Koempel J. Temperature-controlled radiofrequency treatment of tonsillar hypertrophy for reduction of upper airway obstruction in pediatric patients. arch Otolaryngol Head Neck Surg. 2006;132:425-431.

Cavaliere M, Mottola G, Iemma M. Comparison of the effectiveness and safety of radiofrequency turbinoplasty and traditional surgical technique in treatment of inferior turbinate hypertrophy. Otolaryngol Head Neck Surg 2005;133:972-978.

Woodson BT, Nelson L, Mickelson S, Huntley T, Sher A. A multi-institutional study of radiofrequency volumetric tissue reduction for OSAS. Otolaryngol Head Neck Surg 2001;125:303-11.

Winifred S. Hayes. Hayes directory (online) Radiofrequency tissue volume reduction (RFTVR) for the treatment of upper airway obstruction. Winfred S. Hayes Inc: Lansdale Pa. Current as of January 30, 2006.

"Coblation in Brief", The Coblation Process, http://www.arthrocare.com

Coblation, http://www.snorenet.com/coblation

Otolaryngology - Houston, "New Options for Tonsil Problems", http://www.homestead.com/otolaryngology

Winifred S. Hayes. Hayes Inc. Online. Radiofrequency Volumetric Tissue Reduction for the Treatment of Upper Airway Obstruction. Nov. 2000. Updated 10/18/04.

ECRI, HTAIS Hotline. Radiofrequency mediated tongue tissue reduction (somnoplasty) for sleep apnea. 8/9/2004.

ArthroCare Corporation. Coblation [website]. Sunnyvale, CA: Arthrocare; 1999. Available at: http://www.arthrocare.com/. Accessed August 2006.

Bhattacharyya N, Kepnes LJ. Clinical effectiveness of coblation inferior turbinate reduction. Otolaryngol Head Neck Surg. 2003;129(4):365-371.

National Institute for Clinical Excellence (NICE). Coblation tonsillectomy. Interventional Procedure Guidance 9. London, UK: NICE; September 2003, Available at: http://www.nice.org.uk/pdf/ip/IPG009guidance.pdf.

Philpott CM, Wild DC, Mehta D, Daniel M, Banerjee AR. A double-blinded randomized controlled trial of coblation versus conventional dissection tonsillectomy on post-operative symptoms. Clin Otolaryngol. 2005 Oct;30(5):477-8.

Glade RS, Pearson SE, Zalzal GH, Choi SS. Coblation adenotonsillectomy: An improvement over electrocautery technique? Otolaryngol Head Neck Surg 2006;134:852-855.

Back L, Paloheimo M, Ylikoski J. Traditional Tonsillectomy compared with bipolar radiofrequency thermal ablation tonsillectomy in adults: a pilot study. Arch Otolaryngol Head Neck Surg 2001;127:1106-1112.

Belloso A, Chidambaram A, Morar P, Timms MS. Coblation tonsillectomy versus dissection tonsillectomy: postoperative hemorrhage. Laryngoscope 2003 Nov;113 (11):2010-3.

Geisinger Technology Assessment Triage Committee Review, Radiofrequency Volumetric Tissue Reduction, October 30, 2006.

Geisinger Technology Assessment Triage Committee Review, Non-thermal Volumetric Tissue Reduction October 30, 2006.

Shah AN, Brewster D, Mitzen K, Mullin D. Radiofrequency coblation versus intramural bipolar cautery for the treatment of inferior turbinate hypertrophy. Ann Otol Rhinol Laryngol. 2015;124(9):691-697

Casale M, Bottaro V, Sabatino L, et al. The efficacy of radiofrequency volumetric tissue reduction of hypertrophied inferior turbinate in simple snoring. Eur Rev Med Pharmacol Sci. 2014;18(15):2160-2168.

Amali A, Motiee-Langroudi M, Saedi B, Rahavi-Ezabadi S, et al. A comparison of uvulopalatopharyngoplasty and modified radiofrequency tissue ablation in mild to moderate obstructive sleep apnea: a randomized clinical trial. J Clin Sleep Med. 2017 Sep 15;13(9):1089-1096.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: #08-2009-017; Submucosal ablation of tongue base. Option #4

Al-Ani Z, Jacobsen EW, Kartus JT et al. Radiofrequency microtenotomy: a promising method for treatment of rotator cuff tendinopathy.. Knee Surg Sports Traumatol Arthrosc, 2019 Sep 2.

Shibuya N, Thorud JC, Humphers JM et al. Is percutaneous radiofrequency coblation for treatment of Achilles tendinosis safe and effective?. J Foot Ankle Surg, 2012 Sep 15;51(6).

Lu Y, Zhang Q, Zhu Y et al. Is radiofrequency treatment effective for shoulder impingement syndrome? A prospective randomized controlled study.. J Shoulder Elbow Surg, 2013 Sep 3;22(11)

Hamlin K, Munro C, Barker SL et al. Open release versus radiofrequency microtenotomy in the treatment of lateral epicondylitis: a prospective randomized controlled trial. Shoulder Elbow, 2017 Dec 26;10(1).

Wang W, Rikhraj IS, Chou ACC et al. Endoscopic Plantar Fasciotomy vs Open Radiofrequency Microtenotomy for Recalcitrant Plantar Fasciitis.. Foot Ankle Int, 2017 Nov 29:39(1).

Wu B, Yue L, Sun F, et al. The feasibility and efficacy of ultrasound-guided C2 nerve root Coblation for cervicogenic headache. Pain Med. 2019;20(6):1219-1226.

Yang X-H , Li Y, Yang L-Q, et al., Nerve Coblation for treatment of trigeminal neuralgia: A case report. World J Clin Cases. 2019;7(9):1060-1065

Singh J, Bhardwaj B. The comparison between microdebrider assisted adenoidectomy and Coblation adenoidectomy: Analyzing the intraoperative parameters and post-operative recovery. Indian J Otolaryngol Head Neck Surg. 2020;72(1):59-65

Meng X, Wen Q, Gu J, Wang Y. Videolaryngoscope-assisted coblation of epiglottic cysts. Eur Arch Otorhinolaryngol. 2020;277(4):1129-1132.

Luo C, Yang B, Yang L-Q, et al. Computed tomography-guided percutaneous Coblation of the thoracic nerve root for treatment of postherpetic neuralgia. Pain Physician. 2020;23(5):E487-E496.

Jia J, Zhang J, Xiao S. Clinical effects of radiofrequency Coblation for adult laryngopharyngeal vascular lesions. Laryngoscope. 2021;131(3):566-570.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/01

Revised: 12/01 (Coding), 11/02 (add Coblation, reverse prior auth); 1/04 (definition, indication criteria) 11/06 (added indications and exclusions), 1/09 (coding), 05/09 (Medicare coverage mandate), 5/14 (removal of Medicare coverage); 4/20 (add musculoskeletal exclusion); 4/21 (add pain mgt exclusion) 4/22 (add laryngeal cancer, glottis cancer, laryngeal vascular lesions, epiglottic cysts, and coblation adenoidectomy exclusions)

Reviewed: 1/08, 5/10, 5/11, 5/12, 5/13, 5/15, 5/16, 4/17, 4/18, 4/19, 4/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.