Anthem

Medical Policy

Subject: Coblation® Therapies for Musculoskeletal Conditions
Document #: SURG.00088
Status: Reviewed

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Description/Scope

This document addresses the use of Coblation for the treatment of musculoskeletal conditions involving the ankle and foot, elbow, hip, knee, shoulder, and wrist. Coblation (ArthroCare Corporation; Austin, TX) is a type of radiofrequency ablation referred to as *cold* or controlled ablation. Coblation devices direct radiofrequency energy, rupturing target tissue cells, and disintegrating molecules with minimal heat production. Coblation technology can be delivered by a variety of wands, hand pieces and stylette tips used at different anatomic sites.

Note: Please see the following documents for other proposed uses of Coblation technology or other related indications:

- CG-SURG-87 Nasal Surgery for the Treatment of Obstructive Sleep Apnea and Snoring
- SURG.00071 Percutaneous and Endoscopic Spinal Surgery
- SURG.00100 Cryoablation for Plantar Fasciitis and Plantar Fibroma
- SURG.00129 Oral, Pharyngeal and Maxillofacial Surgical Treatment for Obstructive Sleep Apnea or Snoring

Position Statement

Investigational and Not Medically Necessary:

The use of Coblation technology is considered **investigational and not medically necessary** for the treatment of musculoskeletal conditions.

Rationale

No randomized controlled trials (RCTs) evaluating the efficacy of Coblation technology and related devices for treatment of joint or musculoskeletal soft tissue conditions have been published. The available studies are small case series reporting short-term outcomes (Pandolfi, 2021; Tasto, 2005; Weil, 2008). Weil and colleagues (2008) evaluated the effectiveness of a minimally invasive technique using bipolar radiofrequency in 10 individuals with recalcitrant plantar fasciitis who failed conservative care. A percutaneous microtenotomy was performed unilaterally with the TOPAZ MicroDebrider. Outcome measures included a visual analog scale (VAS) and the American Orthopaedic Foot & Ankle Society (AOFAS) Hindfoot and Midfoot Scale. At the 1-year follow-up, participants demonstrated a statistically significant improvement in VAS and AOFAS midfoot scores compared with baseline values ($p<0.0001$). However, a significant improvement was not observed in VAS scores at 6 months compared with the 1-year follow-up. Limitations of this study include the lack of a control group, very small sample size, and short-term follow-up.

A 2021 case series by Pandolfi and colleagues included 18 individuals with cervical discogenic pain that was not responsive to 3 months of conservative care. Individuals were treated with percutaneous disc compression using coblation technology. The mean VAS score was 7.9 (standard deviation [SD], 1.6) before the procedure, 2.5 (SD, 3.1) at the 3- to 4-month follow-up and 2.5 (SD, 2.5) at the 2-year follow-up. As with other case series, the study had a small sample size and lacked a comparison group.

Well-designed RCTs with appropriate controls reporting long-term outcomes are needed to demonstrate the safety and efficacy of Coblation technology compared with established methods of management of musculoskeletal conditions.

Background/Overview

Coblation (that is, cold ablation) is a form of bipolar radiofrequency energy technology in which the current does not pass directly into the tissue, thereby producing minimal thermal injury to surrounding tissues. The mechanism of action involves combining bipolar radiofrequency energy with a conductive solution such as gel or saline. An electrode wand device forms a vapor that subsequently breaks down, producing ions in a gas plasma layer. The formed reactive plasma particles are able to break molecular bonds within the targeted tissue. The ArthroCare Corporation has created Coblation devices for intraoperative use to assist with hemostasis in a number of surgical settings including cosmetic, urology, spine and neurology, ear, nose and throat, gynecology, and laparoscopy/general surgery.

The U.S. Food and Drug Administration (FDA) granted 510(k) clearance to ArthroCare TOPAZ ArthroWands (FDA, 2006) and the Werewolf Coblation System and Coblation Halo Wand (FDA, 2019) as Class II electrosurgical cutting and coagulation devices.

Commercially available Coblation devices (ArthroCare Sports Medicine) include a broad range of surgical wands used by orthopedic surgeons to perform minimally invasive arthroscopic procedures to the ankle and foot, elbow, hip, knee, shoulder, and wrist, and may involve soft tissue debridement, subacromial decompression, meniscal removal and sculpting, or tendon debridement.

Definitions

Bipolar radiofrequency: A radiofrequency device that contains both the active and return electrodes in the probe.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
20999	Unlisted procedure, musculoskeletal system, general [No specific code for surgery using Coblation technology]
29999	Unlisted procedure, arthroscopy [when specified as surgery using Coblation technology]
ICD-10 Diagnosis	
	All musculoskeletal conditions

References

Peer Reviewed Publications:

1. Khan AM, Fanton GS. Thermal energy in the knee. Techniques in Knee Surgery. 2004; 3(3):180-186.
2. Levine MJ, Shaffer B. Basic science applications of thermal energy in arthroscopic surgery. Sports Med Arthro Rev. 2005; 13(4):186-192.
3. Owens BD, Stickles BJ, Balikian P, Busconi BD. Prospective analysis of radiofrequency versus mechanical debridement of isolated patellar chondral lesions. Arthroscopy. 2002; 18(2):151-155.
4. Pandolfi M, Galli F, Borelli A et al. Percutaneous cervical coblation as therapeutic technique in the treatment of algo-dysfunctional pain of discal herniation. Radiol Med. 2021; 126(6):860-868.
5. Sherk HH, Vangsness CT, Thabit G III, Jackson RW. Electromagnetic surgical devices in orthopaedics. Lasers and radiofrequency. J Bone Joint Surg Am. 2002; 84-A(4):675-681.
6. Tasto JP, Cummings J, Medlock V, et al. Microtenotomy using a radiofrequency probe to treat lateral epicondylitis. Arthroscopy. 2005; 21(7):851-860.
7. Weil L Jr, Glover JP, Weil LS Sr. A new minimally invasive technique for treating plantar fasciosis using bipolar radiofrequency: a prospective analysis. Foot Ankle Spec. 2008; 1(1):13-18.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. ArthroCare® Topaz™ ArthroWands® Device Summary. No. K053567. Rockville, MD: FDA. March 6, 2006. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf5/K053567.pdf. Accessed on June 20, 2023.
2. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. Werewolf™ Coblation™ System and Coblation™ Halo™ Wand Device Summary. No. K192027. Rockville, MD: FDA. December 20, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192027.pdf. Accessed on June 20, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Reviewed	08/11/2022	MPTAC review. Updated References section.
Reviewed	08/12/2021	MPTAC review. Updated Rationale, Background/Overview, References and Index sections.
Reviewed	08/13/2020	MPTAC review. Updated References section.
Reviewed	08/22/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	11/08/2018	MPTAC review. Updated Description, Rationale, and References sections.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale and References sections.
Reviewed	02/02/2017	MPTAC review. Updated References section.
Reviewed	02/04/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Description, Rationale, and References sections.
Reviewed	02/13/2014	MPTAC review. Updated Description, Rationale, References, and Index.
Reviewed	02/14/2013	MPTAC review. Updated Description, Rationale, Background, Coding, References, and Index.
Reviewed	02/16/2012	MPTAC review. Updated Description, Rationale, and References.
Reviewed	02/17/2011	MPTAC review. Updated Description, Coding, References, and Index.
Reviewed	02/25/2010	MPTAC review. Revised title to: Coblation® Therapies for Musculoskeletal Conditions. Updated Description, Background, Rationale, References, and Index.
Reviewed	02/26/2009	MPTAC review. Rationale and References updated.
Reviewed	02/21/2008	MPTAC review. Updated Rationale, Background, References, and Index. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” This change was approved at the November 29, 2007 MPTAC meeting.

Reviewed	03/08/2007	MPTAC review. References and Index updated.
New	03/23/2006	MPTAC initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.