

# MEDICAL POLICY

<b>SUBJECT: ELECTROTHERMAL COLLAGEN SHRINKAGE FOR ORTHOPEDIC CONDITIONS</b>	<b>EFFECTIVE DATE: 12/20/01</b> <b>REVISED DATE: 12/19/02, 11/20/03, 07/15/04, 05/18/05, 04/20/06, 04/19/07, 03/20/08, 02/19/09, 09/17/09, 08/19/10</b> <b>ARCHIVED DATE: 07/21/11</b> <b>EDITED DATE: 07/19/12, 07/18/13, 07/17/14, 07/16/15, 07/21/16, 07/20/17, 10/18/18</b>
<b>POLICY NUMBER: 7.01.46</b> <b>CATEGORY: Technology Assessment</b>	<b>PAGE: 1 OF: 3</b>
<ul style="list-style-type: none"><li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li><li>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i></li><li>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i></li></ul>	

## **POLICY STATEMENT:**

Based upon our criteria and assessment of the peer-reviewed literature, electrothermal collagen shrinkage does not improve patient outcomes and therefore is considered **not medically necessary** for the treatment of joint instability, including but not limited to, the shoulder, knee or elbow.

## **POLICY GUIDELINES:**

Other arthroscopic treatments performed concomitantly with thermal capsulorrhaphy are considered as separate procedures, and coverage is not affected by the not medically necessary status of thermal capsulorrhaphy.

## **DESCRIPTION:**

Electrothermal collagen shrinkage of tissues has been proposed as a means to treat selected orthopedic conditions; including but not limited to, shoulder instability and anterior cruciate ligament laxity in the knee. Thermal capsulorrhaphy uses an arthroscopic approach to heat collagen causing it to contract and shrink. The healing of the effected tissues is said to result in shorter collagen fibers and a more stable joint. The procedure is performed as a primary treatment or as a supplement to suture techniques for ligamentous laxity in the shoulder and has been performed as a component of a multiple procedure approach to shoulder instability.

## **RATIONALE:**

The FDA has given 510k approval to a number of devices designed to heat soft tissues including, but not limited to: Oratec's VULCAN™ and EAS™ Electrothermal Arthroscopy System and Mitek's VAPR™ System.

The current published literature does not support the use of thermal capsulorrhaphy alone or in combination with other arthroscopic procedures. In a review of pathophysiology, clinical features and treatment of shoulder instability in patients with joint hyperlaxity, SM Johnson and colleagues (2010) concluded that operative treatment provides reproducibly good results for patients with hyperlaxity who do not respond to a prolonged program of nonoperative measures. Open inferior capsular shift remains the gold standard of operative treatment, although arthroscopic capsular shift and plication procedures are now producing comparable results. Thermal capsulorrhaphy is associated with unacceptably high failure rates and postoperative complications and cannot be recommended as a treatment.

Y Engelsma, et al. (2010) conducted a case series to evaluate the result of arthroscopic stabilization procedures in patients with posterior shoulder instability. In this case series, they treated eighteen patients (19 shoulders) with posterior shoulder instability with either arthroscopic thermal capsular shrinkage (9 patients), capsulorrhaphy (3) or labral refixation (7). The Rowe-score and DASH-score as well as subjective and objective evaluations of the patients function, range of motion, pain and instability were used as clinical outcome measurements. At a mean follow-up of 50 months, the Rowe-score improved significantly from 46 to 74 (P = 0.005). Four patients (21%) had recurrent instability after arthroscopic treatment (2 with generalized ligamentous laxity; 3 after thermal shrinkage). Analysis of postoperative DASH-scores showed a tendency toward inferior outcomes after thermal shrinkage and in patients with an a-traumatic origin of shoulder instability. The authors concluded that arthroscopic shoulder stabilization by either labral refixation or capsulorrhaphy is a safe and effective treatment for posterior shoulder instability. Thermal capsular shrinkage however showed poor results and should be abandoned for this indication.

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**CODES:**      Number                      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

**CPT:**                      No specific code(s)

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**HCPCS:**                S2300 (NMN)              Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy

**ICD10:**                M22.2x1-M22.92        Patellofemoral disorders knee (code range)  
M23.000-M23.069        Cystic meniscus knee (code range)  
M23.200-M23.369        Meniscus derangements (code range)  
M23.40-M23.92            Internal derangement of knee (code range)  
M24.811-M24.819        Other specific joint derangements of shoulder, not elsewhere classified (code range)  
M25.211-M25.219        Flail joint, shoulder (code range)  
M25.311-M25.319        Other instability, shoulder (code range)  
Q68.6                        Discoid meniscus

**REFERENCES:**

BlueCross BlueShield Association. Thermal capsulorrhaphy as a treatment of joint instability - archived. Medical Policy Reference Manual #7.01.82. archived 2016 Mar 10.

\*Bisson L. Thermal capsulorrhaphy for isolated posterior instability of the glenohumeral joint without labral detachment. Amer J Sport Med 2005;33(12):1898-904.

\*Carter TR, et al. Radiofrequency electrothermal shrinkage of the anterior cruciate ligament. Am J Sports Med 2002;30(2):221-6.

\*Chen S, et al. The effects of thermal capsular shrinkage on the outcomes of arthroscopic stabilization for primary anterior shoulder instability. Am J Sports Med 2004 May;33(5):705-11.

Chu PJ, et al. Electrothermal treatment of thumb basal joint instability. Arthroscopy 2009 Mar;25(3):290-5.

Coons DA and Barber FA, Thermal medical retinaculum shrinkage and lateral release for the treatment of recurrent patellar instability. Arthrosc 2006;22(2):166-71.

\*D'Alessandro DF, et al. Prospective evaluation of thermal capsulorrhaphy for shoulder instability – indications and results, two- to five-year follow-up. Am J Sports Med 2004;32(1):21-33.

\*Enad JG, et al. Electrothermal capsulorrhaphy in glenohumeral instability without Bankart tear. Arthrosc 2003;19(7):740-5.

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Engelsma Y, et al. Arthroscopic stabilization of posterior shoulder instability. Knee Surg Sports Traumatol Arthrosc 2010 Dec;18(12):1762-1766.

\*Farnig E, et al. Anterior cruciate ligament radiofrequency thermal shrinkage: a short-term follow-up. Arthrosc 2005;21(9):1027-33.

Hawkins RJ, et al. Electrothermal arthroscopic shoulder capsulorrhaphy: a minimum 2-year follow-up. Am J Sport Med 2007 Sep;35(9):1484-8.

\*Indelli PF, et al. Monopolar thermal treatment of symptomatic anterior cruciate ligament instability. Clin Orthopaed Rel Res 2003;407:139-47.

Johnson SM, et al. Shoulder instability in patients with joint hyperlaxity. J Bone Joint Surg Am 2010 Jun;92(6):1545-57.

\*Maiotti M, et al. The use of arthroscopic thermal shrinkage to treat chronic lateral ankle instability in young athletes. Arthrosc 2005 Jun;21(6):751-7.

Mason WT, et al. Arthroscopic thermal capsulorrhaphy for palmer midcarpal instability. J Hand Surg Eur Vol 2007 Aug;32(4):411-416.

Massoud SN, et al. Radiofrequency capsular shrinkage for voluntary shoulder instability. J Shoulder Elbow Surg 2007 Jan-Feb;16(1):43-8.

\*Miniaci A, et al. Thermal capsular shrinkage for treatment of multidirectional instability of the shoulder. Bone Joint Surg 2003 Dec;85-A(12):2283-7.

Mohtadi NG, et al. A multi-centre randomized controlled trial comparing electrothermal arthroscopic capsulorrhaphy versus open inferior capsular shift for patients with shoulder instability: protocol implementation and interim performance: lessons learned from conducting a multi-centre RCT. Trials 2006 Feb 2;7:4.

\*Sekiya JK, et al. Thermal capsulorrhaphy for shoulder instability. AAOS Instructional Course Lectures 2003;52:65-80.

Virk SS, et al. Adoption of new technology in sports medicine: case studies of the Gore-Tex prosthetic ligament and of thermal capsulorrhaphy. Arthroscopy 2011 Jan;27(1):113-212.

\*Wong KL, et al. Treatment of glenohumeral subluxation using electrothermal capsulorrhaphy. Arthrosc 2005 Aug;21(8):985-91.

Zheng N, et al. The effects of thermal capsulorrhaphy of medial parapatellar capsule on patellar lateral displacement. J Orthop Surg 2008 Sep 30;3:45.

\* key article

**KEY WORDS:**

Capsulorrhaphy, Thermal capsulorrhaphy, Thermal collagen shrinkage.

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, electrothermal collagen shrinkage is not specifically addressed in National or Regional Medicare coverage determinations or policies.