

**SUBJECT: ELECTROTHERMAL COLLAGEN SHRINKAGE FOR ORTHOPEDIC CONDITIONS**

**POLICY NUMBER: 7.01.46**

**CATEGORY: Technology Assessment**

**EFFECTIVE DATE: 04/19/01**

**REVISED DATE: 12/20/01, 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**

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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

## **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

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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.

**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

**ICD9:**      717.0-717.8      Internal derangement of knee, code range  
718.81      Instability of joint, shoulder

**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

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\* 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.