

MEDICAL POLICY	Electrothermal Capsular Shrinkage
Effective Date: 3/1/2021  <div style="text-align: right;">3/1/2021</div>	Medical Policy Number: 2 Technology Assessment Committee Approved Date: 7/03; 7/04; 7/05 Medical Policy Committee Approved Date: 9/07; 7/09; 4/11; 2/13; 3/14; 5/15; 3/16; 4/17; 9/17; 12/18; 1/19; 2/2020; 2/2021
Medical Officer Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Electrothermal capsular shrinkage (i.e., electrothermal arthroscopic capsulorrhaphy, electrothermally-assisted capsule shift, electrothermal shrinkage) is considered **not medically necessary and is not covered** for all indications, including, but not limited to, the treatment of joint instability.

Link to [Policy Summary](#)

CPT/HCPCS CODES

All Lines of Business

Not Covered

S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy
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Unlisted Codes

All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as **Not Covered**.

29999	Unlisted procedure, arthroscopy
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DESCRIPTION

Joint Instability

Joint instability occurs when these tissues weaken and no longer hold bones in proper place.¹ Instability is commonly due to injury (e.g., dislocation), overuse, or multidirectional instability (i.e., being “double jointed”). Symptoms of joint instability include pain, repeated dislocation, tenderness, or a feeling that the joint “gives out”. Conservative treatment includes rest, splinting, or anti-inflammatory drugs; however, surgery may be required to repair the joint, ligament, or tendon if conservative therapy fails.

Electrothermal Arthroscopic Capsulorrhaphy (ETAC)

ETAC was developed as a minimally invasive alternative to open surgery for treating joint instability. The procedure, “utilizes a radiofrequency probe or laser to deliver nonablative heat, which is intended to cause shrinkage of the collagen fibers comprising the ligaments or joint capsule, thereby tightening the capsule and stabilizing the joint.”¹ ETAC is commonly performed as an outpatient procedure and recovery takes 3 to 6 weeks.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of electrothermal arthroscopic capsulorrhaphy (ETAC) as a treatment for joint instability. Below is a summary of the available evidence identified through December 2021.

Systematic Reviews

In 2016, Chen and colleagues conducted a systematic review and meta-analysis to evaluate the effects of surgical management on multidirectional instability (MDI).² Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The primary outcome of interest was recurrent instability, including recurrent subluxation or dislocation. Secondary outcome measures included reoperation, range of motion, and pain.

The final selected studies were pooled into three surgical technique groups: open capsular shift (OCS), arthroscopic capsular plication (ACP), and arthroscopic thermal capsular shrinkage (TCS). The authors identified 36 studies as eligible for inclusion; thus producing a total sample size of 1,053 patients (n=383 OCS, n=326 ACP, n=344 TCS). The results of meta-analysis indicated the TCS group experienced the highest recurrent instability rate (23.9%), compared to the OCS (9.9%) and ACP (6.08%) groups. In regards to reoperation, the TCS group also experienced the highest reoperation rate (16.9%). There was

insufficient data to permit conclusions for the outcome of range of motion in the TCS groups. Patients in the TCS group reported pain as the main cause of poor outcome scores.

Strengths of this systematic review include the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers, large sample size, contacting study authors for additional information, assessment of heterogeneity, and sensitivity analyses. Limitations were present in the lower methodological quality of some selected studies and the heterogeneity present between studies. The authors concluded, "it is suggestible to avoid thermal capsular shrinkage (TCS) in the treatment of multidirectional instability (MDI)."²

Randomized Controlled Trials (RCTs)

- In 2016, McRae et al. conducted a RCT to evaluate arthroscopic electrothermal capsulorrhaphy (ETAC) with Bankart repair and isolated arthroscopic Bankart repair for instability of the medial glenohumeral ligament and the anterior band of the inferior glenohumeral ligament.³ A total of 88 patients were recruited and randomized to receive arthroscopic Bankart repair with (n=44) or without ETAC (n=44). Post-operative follow-up occurred at 3 months, 6 months, 12 months, and 24 months. The primary outcomes of interest were the Western Ontario Shoulder Instability (WOSI) Index, American Shoulder and Elbow Surgeons (ASES) score, the Constant score, and rates of dislocation/subluxation.

A total of 14 patients were lost to follow-up by 24 months. Of the 74 patients remaining, no statistically significant differences were identified between groups at any post-operative follow-up for any of the outcome measures. The results indicated no benefit in patient-reported outcome or recurrence rates using ETAC. The mean WOSI scores at 2 years post-operative were "virtually identical for the two groups."³ A total of 7 patients in the ETAC group were considered treatment failures.

Methodological strengths included the prospective, multi-center, randomized, controlled design and comparing ETAC to another surgical treatment for joint instability. The extended follow-up analysis was also a methodological strength; however, losses to follow-up occurred so potential bias cannot be excluded. Limitations were identified in the small sample sizes, lack of blinding, and lack of intention-to-treat analysis. Ultimately, the authors concluded, "ETAC could not be shown to provide benefit or detriment when combined with arthroscopic labral repair for traumatic anterior instability of the shoulder."³

- In 2014, Mohtadi and colleagues conducted a RCT to evaluate the safety and efficacy of electrothermal arthroscopic capsulorrhaphy (ETAC) compared to open inferior capsular shift (ICS).⁴ Patients with joint instability were recruited between 1999 and 2008 from 9 Canadian orthopedic practices. A total of 54 patients were randomized intraoperatively to either ETAC (n=28) or ICS (n=26). Post-operative follow-up occurred at 7 days, 14 days, 6 weeks, 8 weeks, 3 months, 6 months, 12 months, and 24 months. The primary outcome of interest was the difference in disease-specific quality of life at 2 years post-operative (measured using the Western Ontario Shoulder Instability [WOSI] Index). Secondary outcome measures included the American Shoulder and Elbow Surgeons (ASES) score (a shoulder-specific functional assessment tool), and the Constant score (an overall functional assessment of the shoulder).

The trial was prematurely stopped due to slow recruitment, a high exclusion rate (45.5%), and patients withdrawing (n=3) or declining (n=7) consent. Of the 54 patients who underwent ETAC or ICS, 7 patients (n=3 ETAC and n=4 ICS) were lost to follow-up at 2 years. For all outcomes, both groups showed statistically significant improvements from baseline to 2 years; however, “no statistically or clinically significant differences in mean WOSI Index, ASES, or Constant scores between groups at any postoperative interval.”⁴ There were also no statistically or clinically significant differences between groups at any postoperative interval for range of motion or recurrent instability.

Methodological strengths of this study include the prospective, multi-center, randomized, controlled design, use of a comparator group, and intention-to-treat analysis. The extended follow-up analysis was also a methodological strength; however, 13% of the original cohort was lost to follow-up so potential bias cannot be excluded. Significant limitations are present in the small sample size, lack of blinding, and early termination of the study. Due to the early termination of recruitment, the sample size was too small for the study to be adequately powered; therefore, bias cannot be excluded. Also, the strict inclusion criteria make the results of this study ungeneralizable to a broader patient population. The authors concluded, “at 2 years postoperatively, quality of life and functional outcomes between groups were not clinically different.”⁴

EVIDENCE SUMMARY

The current evidence indicates electrothermal arthroscopic capsulorrhaphy (ETAC) is not an effective treatment of joint instability. Identified studies did not demonstrate a statistically or clinically significant difference between treatment groups. In addition, the systematic review by Chen et al. noted a higher rate of joint instability with ETAC compared to other standard of care treatments.

CLINICAL PRACTICE GUIDELINES

No evidence-based clinical practice guidelines were identified that specifically addressed electrothermal arthroscopic capsulorrhaphy (ETAC) for the treatment of joint instability. However, in 2010 the American Association of Orthopedic Surgeons (AAOS) released a statement regarding ETAC that concluded the following:

“Early short-term results with thermal capsulorrhaphy were encouraging, and the procedure rapidly gained in popularity. However, more recent results with patients over a longer follow-up period have shown a much higher failure rate than was first seen. Also, more complications have been reported. As a result, doctors are performing thermal capsular shrinkage less frequently.”⁵

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

As of 12/29/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses electrothermal capsular shrinkage.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

Electrothermal arthroscopic capsulorrhaphy is a procedure, and therefore is not regulated by the FDA. However, the thermal probe device used during the surgery is under FDA regulation. Several thermal probe devices have been granted 510(k) approval, including, but not limited to:

- Arthrocare System 2000 CAPS® X ArthroWand® (Arthrocare Corporation, Sunnyvale, CA)
- Oratec ORA-50 Electrothermal System and Accessories (Oratec Interventions, Menlo Park, CA)
- VAPR™ TC Electrode (Mitek Products, Norwood, MA)
- VULCAN® EAS® Electrothermal Arthroscopy System and Accessories (Smith and Nephew, Memphis, TN)

More information regarding these devices can be found by searching the FDA 510(k) database for product code GEI and GEX.⁶

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Hayes. Thermal Capsulorrhaphy For Shoulder Instability. Published 10/4/2006. Archived 11/3/2011. <https://evidence.hayesinc.com/report/dir.ther0005>. Accessed 12/29/2020.
2. Chen D, Goldberg J, Herald J, Critchley I, Barmare A. Effects of surgical management on multidirectional instability of the shoulder: a meta-analysis. *Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA*. 2016;24(2):630-639.

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6. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>. Accessed 12/29/2020.