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Thermal Capsulorrhaphy as a Treatment of Joint Instability

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Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Thermal capsulorrhaphy is **considered experimental, investigational and/or unproven** as a treatment of joint instability, including, but not limited to the shoulder, knee, and elbow.

Policy Guidelines

None.

Description

Thermal capsulorrhaphy uses thermal energy to restructure collagen in the capsule or ligaments to reduce the capsule size. This procedure has primarily been evaluated for shoulder joint instability and proposed to treat capsular laxity in other joints.

Shoulder Instability

Shoulder instability is a relatively common occurrence, reported in between 2% and 8% of the population. The condition may arise from a single traumatic event (i.e., subluxation or dislocation), repeated microtrauma, or constitutional ligamentous laxity, resulting in deformation and/or damage in the glenohumeral capsule and ligaments. Shoulder instability may be categorized according to the movement of the humeral head (i.e., either anterior, posterior, inferior or multidirectional instability). Multidirectional instability most frequently consists of anterior and inferior subluxation or dislocation. Inferior movement is also classified as multidirectional.

Treatment

Initial treatment of shoulder subluxation or dislocation is conservative in nature followed by range-of-motion and strengthening exercises. However, if instability persists, either activity modifications or surgical treatment may be considered. Activity modification may be appropriate for patients who can identify a single motion that aggravates instability, such as overhead throwing motions. Surgical treatment may be considered in those who are unwilling to give up specific activities (i.e., related to sports) or when instability occurs frequently or during daily activities.

Surgery consists of inspection of the shoulder joint with repair, reattachment, or tightening of the labrum, ligaments, or capsule performed either with sutures or sutures attached to absorbable tacks or anchors. While arthroscopic approaches have been investigated over the past decade, their degree of success has been controversial due to a higher rate of recurrent instability compared with open techniques, thought to be related in part to the lack of restoration of capsular tension. Recent reports of arthroscopic techniques have described various suturing techniques for tightening the capsule, which require master of technically difficult arthroscopic intra-articular knot-tying.

Thermal Capsulorrhaphy

Thermal capsulorrhaphy has been proposed as a technically simpler arthroscopic technique for tightening the capsule and ligaments. The technique is based on the observation that the use of nonablative levels of radiofrequency thermal energy can alter the collagen in the glenohumeral ligaments and/or capsule, resulting in their shrinkage and a decrease in capsular volume, both thought to restore capsular tension. Thermal capsulorrhaphy may be used in conjunction with arthroscopic repair of torn ligaments or other structures (i.e., repair of Bankart or superior labrum anterior and posterior lesion). In addition, thermal capsulorrhaphy has been investigated as an arthroscopic treatment of glenohumeral laxity, a common injury among overhead athletes, such as baseball players, resulting in internal impingement of the posterior rotator cuff against the glenoid labrum. Internal impingement is often accompanied by posterior rotator cuff tearing and labral injury. Thermal capsulorrhaphy has also been proposed as a sole arthroscopic treatment. For example, the technique may be considered in patients with chronic shoulder pain without recognized instability, based on the theory that the pain may be related to occult or microinstability. This diagnosis may be considered when a

diagnostic arthroscopy reveals only lax ligaments and is commonly seen among baseball players. Finally, thermal capsulorrhaphy may be considered in patients with congenital ligamentous laxity, such as Ehlers-Danlos or Marfan syndrome.

While thermal capsulorrhaphy was initially investigated using laser energy, the use of radiofrequency probes is now more commonly employed. Devices include Oratec® ORA-50 electrothermal system (Oratec Interventions, Menlo Park, CA), the VULCAN® EAS® electrothermal arthroscopy system (Smith and Nephew, Andover, MA), and the VAPR™ TC Electrode (Mitek Products, Norwood, MA).

Regulatory Status

Thermal capsulorrhaphy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). Previously a number of electrosurgical cutting and coagulation devices were cleared for marketing by the FDA through the 510(k) process. FDA product code: GEI.

Rationale

This medical policy was created in July 2020 and has been updated regularly with searches of the PubMed database. The most recent literature search was conducted through March 12, 2024.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice

Thermal Capsulorrhaphy

Shoulder

In 2006, a Canadian workgroup reported a multicenter RCT that had been recruiting subjects since 1999. (1) Enrollment was slower than anticipated; 19 patients treated with thermal capsulorrhaphy, and 15 subjects treated with surgical repair had completed 2-year follow-up as of publication. This trial was completed in February 2010 with an enrollment of 58 patients.

In 2001, Levitz et al. reported a study of 82 baseball players undergoing arthroscopic surgery for internal impingement. (2) The first 51 patients underwent traditional arthroscopic surgery, consisting of débridement of tears in the rotator cuff and attachment of labral tears. There was no attempt to reduce the capsular laxity. The next 31 patients underwent traditional arthroscopic surgery and also underwent thermal capsulorrhaphy. The main outcome measure was time to return to competition. Among those who did not undergo thermal capsulorrhaphy, 80% returned to competition at a mean time of 7.2 months, with 67% still competing after 30 months. Among those who did undergo thermal capsulorrhaphy, 93% returned to competition at a mean time of 8.4 months, with 90% still competing after 30 months.

In 2000, Savoie and Field compared the outcomes of patients with multidirectional instability who were treated with either thermal capsulorrhaphy (n=30) or arthroscopic capsular shift (i.e., suture repair) (n=26). (3) Additional arthroscopic procedures were performed in both groups, as needed. Two patients treated with thermal capsulorrhaphy had an unsatisfactory outcome compared with 3 patients in the suture repair group.

In 2005, Chen et al. reported on 40 patients who underwent combined arthroscopic labral repair and thermal capsulorrhaphy from 1999 to 2002; the results were compared with a historical control group of 32 patients who underwent the same surgery without capsulorrhaphy during 1996 to 1999. (4) There was no difference in outcomes in the 2 groups, leading the authors to conclude that thermal capsulorrhaphy neither improved nor compromised the results of conventional arthroscopic treatment.

In 2001, Levy et al. reported on 90 patients (99 shoulders) with shoulder instability treated with thermal capsulorrhaphy using either radiofrequency (34 patients, 38 shoulders) or laser energy (56 patients, 61 shoulders) and followed for means of 23 and 40.5 months, respectively. (5) In the laser-treated group, 59% of the patients considered their shoulder(s) to be “better” or “much better;” the failure rate in this group was 36.1%. In the radiofrequency-treated group, 76.3% of patients felt better or much better; the failure rate was a 23.7%.

In 2004, D’Alessandro et al. published the results of a prospective study of 84 patients (84 shoulders) who underwent thermal capsulorrhaphy for various indications. (6) With an average follow-up of 38 months, 37% of patients reported unsatisfactory results, based on reports of pain, instability, return to work, and the American Shoulder and Elbow Surgeons Shoulder Assessment score. The authors reported that the high rate of unsatisfactory results was of great concern. Levine et al. reported that the initial wave of enthusiasm for thermal capsulorrhaphy has largely subsided, given the negative results reported by in this study. (7)

In 2007, 2- to 6-year follow-up was reported on 85 of 100 consecutive patients treated with thermal capsulorrhaphy for glenohumeral instability. (8) Thirty-seven patients (43.5%) were considered to have had a failed procedure, defined as recurrent instability, revision of surgery, and recalcitrant pain or stiffness requiring manipulation. Deterioration of efficacy over time was reported from a series of 12 overhead athletes (volleyball, tennis, baseball, swimming) who presented with internal impingement at an average age of 27 years (range, 23-34 years). (9) At 2 years after surgery, average modified Rowe score had increased from 45.8 to 90.4; at 7 years postoperatively, the Rowe score had decreased to 70.4 and visual analog scale (VAS) score for pain was 4.8. At 7 years, 25% of athletes reported that they had returned to their preinjury level of competition, 25% played at a lower level, and 50% had stopped because of their shoulder pain.

In 2007, Good et al. conducted a retrospective chart review on patients who had been referred for shoulder stiffness and had developed glenohumeral chondrolysis. (10) Of the 8 patients who had developed glenohumeral chondrolysis after shoulder arthroscopy, 5 had undergone thermal capsulorrhaphy for shoulder instability, and 3 had a thermal procedure with labral repair or synovectomy. The onset was described as early and rapid, with repeat arthroscopy to confirm the diagnosis of chondrolysis and rule out infection at an average of 8 months after the initial shoulder arthroscopy. The mean age of the patients was 23 years (range, 15-39 years). None of the patients had evidence of chondral damage at the index arthroscopy, and none had received postoperative intra-articular pain pumps, a procedure which has also been associated with chondrolysis. The patients required between 1 and 6 procedures after the onset of chondrolysis to manage their pain, including glenoid allograft, humeral head arthroplasty, and total shoulder arthroplasty. Good et al. identified an additional 10 reported cases of glenohumeral chondrolysis following shoulder arthroscopy in the English-language literature. Five of the 10 cases occurred after the use of gentian violet dye injection into the joint to identify a rotator cuff tear; this technique has since been abandoned. Of the remaining 5 reported cases, 4 involved the use of a thermal device during the procedure. An accompanying editorial by the journal's editors concluded that "...pending evidence to the contrary, shoulder thermal capsulorrhaphy is a procedure in which these and other reported risks outweigh any potential benefits." (11)

A 2010 review of shoulder instability in patients with joint hyperlaxity indicates that although initial results with thermal capsulorrhaphy seemed promising, subsequent studies with longer follow-up showed "...unacceptably high failure rates and postoperative complications..." including cases of postoperative axillary nerve palsy and transient deltoid weakness. (12) Abnormal capsular tissue has also been observed in the areas of previous thermal treatment, with either severe thickening or thin, friable deficient capsule. In a 2011 review, Virk and Kocher described thermal capsulorrhaphy as a failed new technology in sports medicine. (13)

Radiofrequency technology for shoulder instability was rapidly adopted despite limited clinical evidence and a poor understanding of its indications. (14) Reports of serious adverse events followed, leading to its abandonment. In their 2014 paper, Mohtadi et al. presented findings from a multicenter randomized clinical trial evaluating the safety and efficacy of electrothermal

arthroscopic capsulorrhaphy (ETAC) compared with open inferior capsular shift (ICS) and reviewed the role of randomized trials in adopting new technology. Fifty-four subjects with multidirectional instability or multidirectional laxity with anteroinferior instability and failed nonoperative treatment were randomized to ETAC (n = 28) or open ICS (n = 26). The groups were comparable at baseline, except for external rotation at the side. At 2 years postoperatively, quality of life and functional outcomes between groups were not clinically different. However, ETAC had fewer complications and episodes of recurrence compared with open surgery. This evidence reinforces the need to critically evaluate new technology before widespread clinical use.

Rolfes (2015) performed a systematic review comparing the effectiveness of two arthroscopic techniques used to reduce shoulder instability: capsular plication and thermal capsulorrhaphy. (15) The overall success rates of the 12 reviewed studies were 91% for arthroscopic capsular plication and 76.5% for thermal capsulorrhaphy. The reviewer concluded that arthroscopic capsular plication had a higher rate of success than thermal capsulorrhaphy.

McRae et al. (2016) compared arthroscopic Bankart repair with ETAC of the medial glenohumeral ligament and anterior band of the inferior glenohumeral ligament versus undergoing arthroscopic Bankart repair alone. (16) Eighty-eight patients were randomly assigned to receive arthroscopic Bankart repair with (n=44) or without ETAC (n=44). Data on 74 patients were analyzed, with the rest lost to follow-up. There were no differences between groups at any post-surgery time points for Western Ontario Shoulder Instability Index (WOSI), American Shoulder and Elbow Surgeons (ASES), or Constant-Murley scores. Eight patients in the non-ETAC group and 7 in the ETAC group were considered failures. No benefits in patient-reported outcome or recurrence rates using ETAC were found. Mean WOSI scores 2 years post-surgery was virtually identical for the two groups. ETAC could not be shown to provide benefit or detriment when combined with arthroscopic labral repair for traumatic anterior instability of the shoulder.

Other Joints

Literature on thermal capsulorrhaphy for joints other than the shoulder is limited, consisting mainly of small case series and uncontrolled studies. (17-23) Recent studies are outlined below.

Ankle

In a retrospective study from Ventura et al. (2021), fifty-four patients (out of an original group of 90) with isolated anterior talo-fibular ligament (ATFL) lesion suffering from chronic ankle instability (CAI) who underwent surgical treatment between 2000 and 2009 were assessed. (24) All the patients underwent a four-step protocol including synovectomy, debridement of ATFL lesion borders, capsular shrinkage, and 21-day immobilization and non-weightbearing. Clinical assessment included the American Orthopaedic Foot and Ankle Society (AOFAS) ankle and hindfoot scoring system, Karlsson-Peterson score, Tegner activity level, and objective examination comprehending range-of-motion (ROM) and manual laxity tests. AOFAS (preoperative, 64.8; postoperative, 92.4; $p < 0.001$) and Karlsson-Peterson score (preoperative, 62.5; postoperative, 88.8; $p < 0.001$) significantly improved after a median 11-years follow-up

(7-16 years). Similarly median Tegner activity level significantly increased at follow-up compared to pre-operative status (6.0 and 4.0 respectively, $p < 0.001$). Objective examination documented a statistically significant improvement in terms of ankle stability compared to pre-operative manual laxity tests, with negative anterior drawer test observed in 48 (88.9%) patients ($p < 0.001$). Sagittal ROM was full in 50 patients (92%). Nine patients had subsequent ankle sprains (15.6%), two patients required further surgery, while 7 were treated conservatively. No major complications were reported.

Hand and Wrist

Wong and Ho (2019) performed a retrospective review of 8 patients with chronic thumb metacarpal phalangeal joint (MCPJ) volar plate instability treated with the novel technique of thermal shrinkage of the volar plate via thumb MCPJ arthroscopy. (25) The mean follow-up period was 41.4 months (range, 2-134 months). One case had recurrence of instability requiring open volar plate capsulodesis. All other cases had their thumb hyperextensibility resolved and maintained throughout the entire follow up period, up to 134 months for the case with the longest duration of follow up.

In a retrospective study, Helsper et al. (2020) investigated the clinical outcomes of patients treated for chronic distal radioulnar joint instability with arthroscopic thermal annealing of the superficial radioulnar ligaments, ulnar palmar wrist ligaments, and dorsoulnar wrist capsule using a radiofrequency probe. (26) Sixty patients (62 wrists) were treated over an 18-year period. At mean follow-up of 10 years (range 3 to 19), 30 of 33 patients were satisfied with their surgical outcomes. There were statistically significant improvements in ulnar-sided wrist pain on a visual analogue scale and in distal radioulnar joint stability on the dorsopalmar stress test after surgery compared with preoperative status. The modified Mayo Wrist (MMW) Score and Quick Disabilities of the Arm, Shoulder, and Hand score of the patients were favorable. Early failure occurred in 11 of 62 wrists. Nine of these 11 wrists needed a secondary procedure.

Burn et al. (2020) conducted a retrospective review of 9 patients who underwent arthroscopic electrothermal treatment of low-grade Geissler's scapholunate interosseous ligament (SLIL) tears. (27) Symptom resolution, return to activity, postoperative complications, ROM, grip strength, and subsequent treatment were recorded. Each patient completed Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH), MMW, and Patient-Rated Wrist Evaluation (PRWE) questionnaires. Mean follow-up was 7 years (range: 5-11 years). Wrist motion was near symmetric with a mean of 76 (± 14), 74 (± 8), 21 (± 13), and 40 degrees (± 13) for wrist flexion, extension, radial deviation, and ulnar deviation. QuickDASH improved significantly by a mean 39 points (50 (preoperative)-11 [postoperative], $p = 0.009$). Postoperative MMW and PRWE scores were 83 and 14, respectively. VAS score was 1.4. A total of 90% returned to their preinjury level of function or higher.

Crespo Romero et al. (2021) performed a prospective study of 20 patients with symptomatic instability of scapholunate (SL) ligament (14 of them also with triangular fibrocartilage complex [TFCC] wrist injuries) treated with arthroscopic electrothermal shrinkage was conducted using a monopolar radiofrequency probe. (28) All patients underwent follow-up regularly for an

average of 50.6 months (range 29-80 months). The MMW score improved from a mean of 59 ± 17.1 points preoperatively to 88.3 ± 16.2 points at the final follow-up. At the final clinical examination, a painful Watson scaphoid shift test was found in 3 patients (15%). The mean flexion-extension arc was unchanged ($132^\circ \pm 19^\circ$), and mean grip strength improved 12 kg. No patient showed radiologic signs of arthritis or instability after surgery (mean SLIL interval 1.9 ± 0.7 mm; mean SLIL angle $42.7^\circ \pm 7.3^\circ$). Of the 14 patients with combined TFCC injuries, 3 patients continued complaining of ulnar-sided point tenderness. At the end of the follow-up, 80% of the subjects were satisfied or very satisfied.

Ricks et al. (2021) assessed the long-term results of arthroscopic capsular shrinkage when used for palmar midcarpal instability (PMCI) of the wrist in a prospective cohort study. (29) All patients were followed up and reviewed independently from the operating surgeon. Assessment included a structured questionnaire, disabilities of the arm, shoulder and hand (DASH) questionnaire, and clinical examination using a goniometer. PMCI was assessed objectively with the anterior drawer test and radiological imaging was only performed if clinically relevant to the residual symptoms. Thirteen patients (15 wrists) underwent arthroscopic capsular shrinkage for PMCI. Twelve patients (14 wrists) were available for clinical review with a follow-up rate of 92.3%. The mean time from index procedure to final review was 12 years (range: 10-14 years). The symptoms of instability had completely resolved in nine wrists (7 patients). Only 2 of the 14 wrists had symptoms that were reproduced with a positive anterior drawer test. All other wrists were stable on objective assessment. The mean DASH score had improved from presurgery of 34 to postsurgery of 12.1 and at 12-year follow-up this had deteriorated minimally to 15.3. Assessment of the ROM showed an average increase in range of flexion/extension by 22 degrees. Patient satisfaction was excellent. The patients rated, that nine wrists were much better than presurgery, three as better, one unchanged, and one worse.

Summary of Evidence

For individuals with joint instability who receive thermal capsulorrhaphy of the shoulder, the evidence includes randomized controlled trials, systematic reviews, and case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. The literature does not definitively support that this procedure is an efficacious treatment for shoulder instability and reports a high rate of unsatisfactory results and complications, raising the potential for a net harm. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with joint instability who receive thermal capsulorrhaphy of joints other than the shoulder, the evidence consists mainly of small case series and uncontrolled studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

In 2010, the American Academy of Orthopaedic Surgeons published patient information on thermal capsular shrinkage. (30) The information provided stated that thermal capsular

shrinkage was developed as a less invasive way to treat a shoulder that is loose and frequently dislocates. Early short-term results were promising, and the procedure gained in popularity. However, more recent results over a longer follow-up period have shown a much higher failure rate and more complications than were first reported. As a result, the procedure is used less frequently. To date, thermal capsulorrhaphy is rarely performed as it has been virtually abandoned. (31)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	29999
HCPCS Codes	S2300

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
05/15/2024	Document updated with literature review. Coverage unchanged. Added reference 31.
06/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. The following references were added: 24-29.
09/01/2021	Reviewed. No changes.
07/15/2020	New medical document originating from SUR701.014; Coverage unchanged. Thermal capsulorrhaphy is considered experimental, investigational and/or unproven as a treatment of joint instability, including, but not limited to the shoulder, knee, and elbow.