



Louisiana

Thermal Capsulorrhaphy as a Treatment of Joint Instability

Policy # 00033

Original Effective Date: 05/12/2003

Current Effective Date: 03/21/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers thermal capsulorrhaphy as a treatment of joint instability, including, but not limited to the shoulder, knee and elbow, to be **not medically necessary**.**

Background/Overview

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.

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 mastery of technically difficult arthroscopic intra-articular knot-tying.

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

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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 Monopolar RF Generator (Oratec Interventions, Menlo Park, CA) and ArthroCare^{®‡} (ArthroCare, Sunnyvale, CA).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Thermal Capsulorrhaphy of the Shoulder

The evidence on thermal capsulorrhaphy of the shoulder is derived from 1 small randomized controlled trial (RCT) several nonrandomized comparative studies, and 2 large case series with midterm follow-up. Reports of adverse events are also reviewed.

Randomized Controlled Trials

In 2006, a Canadian workgroup reported a multicenter RCT that had been recruiting subjects since 1999. 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 (see Table 1).

Nonrandomized Comparative Studies

In 2001, Levitz et al reported a study of 82 baseball players undergoing arthroscopic surgery for internal impingement. 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

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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). 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. 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. 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%.

Case Series

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. 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.

In 2007, 2- to 6-year follow-up was reported on 85 of 100 consecutive patients treated with thermal capsulorrhaphy for glenohumeral instability. 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). 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 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.

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Other Joints

Literature on thermal capsulorrhaphy for joints other than the shoulder is limited. One small case series (13 patients) from 2007 reported use of thermal capsulorrhaphy for palmar midcarpal instability. A 2008 publication describes thermal capsulorrhaphy for the parapatellar capsule as controversial.

Adverse Events

In 2007, Good et al conducted a retrospective chart review on patients who had been referred for shoulder stiffness and had developed glenohumeral chondrolysis. 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."

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. 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT00251160 ^a	Electrothermal Arthroscopic Capsulorrhaphy (ETAC) and Of 58 Inferior Capsular Shift in Patients With Shoulder Instability		Feb 2010 (completed)

NCT: national clinical trial.

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^a Denotes industry-sponsored or cosponsored trial.

Summary of Evidence

The literature does not support use of thermal capsulorrhaphy. The few available comparative studies do not support that this procedure is an efficacious treatment for shoulder instability. The case series report a high rate of unsatisfactory results and complications, raising the potential for a net harm. Because of the lack of efficacy and potential for harm, this procedure is considered not medically necessary.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Thermal Capsulorrhaphy as a Treatment of Joint Instability", 7.01.82, Archived 3:2016.
2. Abrams JS. Thermal capsulorrhaphy for instability of the shoulder: concerns and applications of the heat probe. *Instr Course Lect*. 2001;50:29-36. PMID 11372327
3. Gryler EC, Greis PE, Burks RT, et al. Axillary nerve temperatures during radiofrequency capsulorrhaphy of the shoulder. *Arthroscopy*. Jul 2001;17(6):567-572. PMID 11447541
4. Mohtadi NG, Hollinshead RM, Ceponis PJ, 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 [ISRCTN68224911; NCT00251160]. *Trials*. 2006;7:4. PMID 16542033
5. Levitz CL, Dugas J, Andrews JR. The use of arthroscopic thermal capsulorrhaphy to treat internal impingement in baseball players. *Arthroscopy*. Jul 2001;17(6):573-577. PMID 11447542
6. Savoie FH, 3rd, Field LD. Thermal versus suture treatment of symptomatic capsular laxity. *Clin Sports Med*. Jan 2000;19(1):63-75, vi. PMID 10652665
7. Chen S, Haen PS, Walton J, et al. The effects of thermal capsular shrinkage on the outcomes of arthroscopic stabilization for primary anterior shoulder instability. *Am J Sports Med*. May 2005;33(5):705-711. PMID 15722277
8. Levy O, Wilson M, Williams H, et al. Thermal capsular shrinkage for shoulder instability. Mid-term longitudinal outcome study. *J Bone Joint Surg Br*. Jul 2001;83(5):640-645. PMID 11476296
9. D'Alessandro DF, Bradley JP, Fleischli JE, et al. Prospective evaluation of thermal capsulorrhaphy for shoulder instability: indications and results, two- to five-year follow-up. *Am J Sports Med*. Jan-Feb 2004;32(1):21-33. PMID 14754720
10. Levine WN, Bigliani LU, Ahmad CS. Thermal capsulorrhaphy. *Orthopedics*. Aug 2004;27(8):823-826. PMID 15369001
11. Hawkins RJ, Krishnan SG, Karas SG, et al. Electrothermal arthroscopic shoulder capsulorrhaphy: a minimum 2-year follow-up. *Am J Sports Med*. Sep 2007;35(9):1484-1488. PMID 17456642
12. Jansen N, Van Riet RP, Meermans G, et al. Thermal capsulorrhaphy in internal shoulder impingement: a 7-year follow-up study. *Acta Orthop Belg*. Jun 2012;78(3):304-308. PMID 22822568
13. Mason WT, Hargreaves DG. Arthroscopic thermal capsulorrhaphy for palmar midcarpal instability. *J Hand Surg Eur Vol*. Aug 2007;32(4):411-416. PMID 17950196
14. Zheng N, Davis BR, Andrews JR. The effects of thermal capsulorrhaphy of medial parapatellar capsule on patellar lateral displacement. *J Orthop Surg Res*. 2008;3:45. PMID 18826583
15. Good CR, Shindle MK, Kelly BT, et al. Glenohumeral chondrolysis after shoulder arthroscopy with thermal capsulorrhaphy. *Arthroscopy*. Jul 2007;23(7):797 e791-795. PMID 17637423
16. Lubowitz JH, Poehling GG. Glenohumeral thermal capsulorrhaphy is not recommended--shoulder chondrolysis requires additional research [editorial]. *Arthroscopy*. Jul 2007;23(7):687. PMID 17637401
17. Johnson SM, Robinson CM. Shoulder instability in patients with joint hyperlaxity. *J Bone Joint Surg Am*. Jun 2010;92(6):1545-1557. PMID 20516333
18. Virk SS, Kocher MS. Adoption of new technology in sports medicine: case studies of the Gore-Tex prosthetic ligament and of thermal capsulorrhaphy. *Arthroscopy*. Jan 2011;27(1):113-121. PMID 20974526
19. American Academy of Orthopaedic Surgeons (AAOS). *OrthoInfo: Thermal Capsular Shrinkage*. 2010; <http://orthoinfo.aaos.org/topic.cfm?topic=a00034>. Accessed April, 2015.

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04/25/2003 Medical Policy Committee review

05/12/2003 Managed Care Advisory Council approval

05/03/2005 Medical Director review

05/17/2005 Medical Policy Committee review. Format revision. Rationale/ source added. Policy statement expanded from; "electrothermal arthroscopy is investigational" to, "as a treatment of joint instability, including, but not limited to the shoulder, knee and elbow"

05/23/2005 Managed Care Advisory Council approval

07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.

04/04/2007 Medical Director review

04/18/2007 Medical Policy Committee approval. Name changed from Electrothermal Arthroscopy to Thermal Capsulorrhaphy as a Treatment of Joint Instability to match Blue Cross Blue Shield Association. No change to coverage eligibility.

03/04/2009 Medical Director review

03/18/2009 Medical Policy Committee approval. No change to coverage eligibility.

03/05/2010 Medical Director review

03/19/2010 Medical Policy Committee approval. No change to coverage eligibility.

03/03/2011 Medical Policy Committee review

03/16/2011 Medical Policy Implementation Committee approval. Coverage changed from investigational to not medically necessary.

03/01/2012 Medical Policy Committee review

03/21/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/07/2013 Medical Policy Committee review

03/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/06/2014 Medical Policy Committee review

03/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/05/2015 Medical Policy Committee review

03/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

03/03/2016 Medical Policy Committee review

03/16/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

03/02/2017 Medical Policy Committee review

03/15/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/01/2018 Medical Policy Committee review

03/21/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2019

Coding

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HCPCS	S2300
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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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