Effective February 26, 2018
Policy Replaced by Article A53435

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Thermal Capsulorrhaphy as a Treatment of Joint Instability

Policy #: 077
Category: Surgery

Latest Review Date: June 2015
Policy Grade: Effective March 16, 2016: Active Policy but no longer scheduled for regular literature reviews and updates.

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

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 but may also be proposed to treat capsular laxity in other joints.

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 micro-trauma, 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 as 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 also 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 Monopolar RF Generator (Oratec Interventions, Menlo Park, CA) and ArthroCare® (Arthrocare Corporation, Sunnyvale, CA).

Policy:
Effective for dates of service on or after February 26, 2018 refer to Article A53435

Effective for dates of service on or after July 1, 2005 and prior to February 26, 2018:
Blue Advantage will treat **thermal capsulorrhaphy** as a **covered** benefit when used as the sole treatment of shoulder instability resulting from repetitive overhead throwing motion **when** the patient has failed conservative therapy and still requires the full range of shoulder motion, which would be compromised by conventional surgical repairs.

Grade D

Blue Advantage will treat **thermal capsulorrhaphy** for all other indications for joints other than the shoulder as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **thermal capsulorrhaphy** for patients with shoulder instability resulting from repetitive throwing motion that have other lesions in the same shoulder which require other surgical repair or stabilization procedures as a **non-covered** benefit and as **investigational**.

Grade B

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

There is limited peer-reviewed literature regarding the use of thermal capsulorrhaphy as a sole arthroscopic procedure or as an adjunct to other arthroscopic repair of shoulder lesions. Multiple unresolved issues regarding this technique include the following:

- Identifying and quantifying the laxity
- Treatment temperature and duration
- Response of collagen for individual factors
- Control of tissue shrinkage

- Standards for rehabilitation post treatment

The most recent update of the literature was performed through May 2015. Following is a summary of the key literature to date.

Thermal Capsulorrhaphy of the Shoulder
The evidence on thermal capsulorrhaphy for the shoulder is derived from one small randomized controlled trial (RCT) several nonrandomized comparative studies, and two large case series with mid-term follow-up. Reports of adverse events are also reviewed.

Randomized Controlled Trial
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 two-year follow-up as of publication. This trial is listed as being completed as of March 2012 with an enrollment of 58 patients; however, no results of this trial are identified in the published literature.

Nonrandomized Comparative Studies
Levitz et al reported a study of 82 baseball players undergoing arthroscopic surgery for internal impingement in 2001. The first 51 patients underwent traditional arthroscopic surgery, consisting of debridement 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.

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) in 2000. Additional arthroscopic procedures were performed in both groups, as needed. Two patients treated with thermal capsulorrhaphy had an unsatisfactory outcome compared with three patients in the suture repair group.

Chen et al reported on 40 patients who underwent combined arthroscopic labral repair and thermal capsulorrhaphy; the results were compared with a historical control group of 32 patients who underwent the same surgery without capsulorrhaphy in 2005. There was no difference in outcomes in the two 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 up for 23 to 40 months. In the laser-treated group, 59% of the patients considered their shoulder to be "better" or "much better," with a 36.1% failure

rate. In the radiofrequency-treated group, 76.9% of patients felt "better" or "much better," with a 23.7% failure rate.

Case Series
D'Alessandro et al published the results of a prospective study of 84 patients who underwent thermal capsulorrhaphy for various indications in 2004. 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 D'Alessandro et al.

Two- to six-year follow-up was reported on 85 of 100 consecutive patients treated with thermal capsulorrhaphy for glenohumeral instability in 2007. 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, and swimming) who presented with internal impingement at an average age of 27 years (range, 23 to 34). At two years after surgery, the modified Rowe score had increased from 45.8 to 90.4; at seven years postoperatively, the Rowe score had decreased to 70.4 and visual analog scale score for pain was 4.8. Twenty-five percent of athletes reported that they had returned to their pre-injury level of competition, 25% played at a lower level, and 50% had stopped because of their shoulder pain.

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 mid-carpal 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 eight patients who had developed glenohumeral chondrolysis after shoulder arthroscopy, five had undergone thermal capsulorrhaphy for shoulder instability, and three 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 eight 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 one and six 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 ten reported cases of glenohumeral chondrolysis following shoulder arthroscopy in the English-language literature. Five of the ten 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

five reported cases, four 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 rates of failure 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 describe thermal capsulorrhaphy as a failed new technology in sports medicine.

Summary
The literature does not support the 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 net harm. Because of the lack of efficacy and potential for harm, this procedure is considered not medically necessary.

Practice Guidelines and Position Statements
In 2010, the American Academy of Orthopaedic Surgeons published patient information on thermal capsular shrinkage. 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 higher failure rate and more complications than were first reported. As a result, the procedure is used less frequently.

U.S. Preventive Services and Task Force Recommendations
Not applicable.

Key Words:
Thermally-induced capsulorrhaphy, thermal capsule shift, LACS, laser-assisted capsule shift, thermal capsulorrhaphy ETAC, electrothermally assisted capsulorrhaphy glenohumeral instability, laser tension-plasty ACL, thermal probe, tension-plasty, low energy laser tension-plasty

Approved by Governing Bodies:
Thermal capsulorrhaphy is a surgical procedure and is not subject to FDA approval. FDA previously granted 510(k) clearance for a number of electrosurgical cutting and coagulation devices.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Coding:

CPT Codes:	**27599**	Not otherwise classified knee procedure
	29999	Unlisted procedure, arthroscopy
HCPC Codes	**S2300**	Arthroscopy shoulder, surgery, with thermally induced capsulorrhaphy

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Policy History:

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