



# Louisiana

## Thermal Capsulorrhaphy as a Treatment of Joint Instability

Policy # 00033

Original Effective Date: 05/12/2003

Current Effective Date: 04/13/2020

*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.

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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<sup>®</sup>† ORA-50 Monopolar RF Generator (Oratec Interventions, Menlo Park, CA) and ArthroCare<sup>®</sup>‡ (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 electro-surgical cutting and coagulation devices were cleared for marketing by FDA through the 510(k) process. FDA product code: GEI.

## **Rationale/Source**

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.

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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.

## **Supplemental Information**

### **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 much higher failure rate and more complications than were first reported. As a result, the procedure is used less frequently.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

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

## **References**

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### **Policy History**

Original Effective Date: 05/12/2003

Current Effective Date: 04/13/2020

- |            |  |
|------------|--|
| 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  |

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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.
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2020	Medical Policy Committee review
03/11/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2021

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### **Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	29999
HCPCS	S2300
ICD-10 Diagnosis	All related diagnoses

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

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would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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