

## THERMAL CAPSULORRHAPHY/THERMAL SHRINKAGE THERAPY

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### INSTRUCTIONS FOR USE

*This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.*

*UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.*

### BENEFIT CONSIDERATIONS

#### Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

## COVERAGE RATIONALE

### **Thermal shrinkage therapy of joint capsules, ligaments, and tendons is unproven and not medically necessary.**

Clinical evidence does not support the use of thermal capsulorrhaphy or thermal shrinkage for the treatment of joint instability or ligamentous laxity in any joint. Well designed randomized trials are needed to compare thermal capsulorrhaphy/thermal shrinkage with surgical or other treatment options.

## APPLICABLE CODES

The Current Procedural Terminology (CPT<sup>®</sup>) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT <sup>®</sup> Code	Description
23929	Unlisted procedure, shoulder
29999	Unlisted procedure, arthroscopy

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HCPCS Code	Description
S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy

## DESCRIPTION OF SERVICES

Thermal capsulorrhaphy (also known as thermal arthroscopy or thermal capsular shrinkage) involves the use of a specialized thermal probe that delivers nonablative heat to the joint capsule or stretched ligaments, with the goal of causing the stretched collagen fibers to shrink and shorten, and thereby stabilize the joint (Carter, 2002). This procedure is carried out by percutaneous or arthroscopic placement of a thermal catheter into the joint and can be accomplished by radiofrequency or laser energy. A thermal coagulation generator is utilized to provide the required temperature for collagen shrinkage (Fantom, 2001; Clark, 2001). Thermal shrinkage has been proposed for use in arthroscopic surgery involving various joints including, but not limited to, the shoulder, knee, hip, thumb, wrist and ankle.

## CLINICAL EVIDENCE

### **Shoulder**

The clinical evidence evaluating thermal shrinkage for treatment of shoulder instability consists of few randomized trials, both retrospective and prospective case series (many which lack controls), cohort comparative studies and systematic reviews.

A nonrandomized prospective study conducted by D'Alessandro et al. (2004) included 81 patients (84 shoulders) who had undergone unsuccessful non-operative rehabilitation. Patients were divided into 3 groups based on type of or reason for instability: traumatic anterior dislocation, recurrent subluxation, and multidirectional defect. The average age was 23.2 years (range 12 to 48); 84% of the patients participated in recreational or organized athletics. Based on a clinical grading scale that assessed the patients' ability to return to work or sport, recurrent instability, satisfaction, and the overall American Shoulder and Elbow Surgeons (ASES) shoulder score, successful outcomes were attained in 63% of shoulders. There were 12 patients (15%) who

required revision surgery and the complication rate was 14% (resolved spontaneously). The study was limited by the heterogeneous patient population which limits the generalization of the results to a larger population. Additional limitations of this study include the small number of patients per group and an inconsistent protocol.

In a prospective study, 22 patients received laser-assisted capsular shrinkage with capsulolabral refixation compared with 20 patients who received the same procedure without capsular shrinkage (Bohnsack, 2002). Capsular shrinkage reduced the redislocation rate from 25% to 5% during an average follow-up of 59 months.

A prospective case series by Hawkins et al. (2007), 100 individuals with glenohumoral instability and treated with thermal capsulorrhaphy were reported. A total of 85 subjects were available for follow-up at 2-year minimum; 45 of 85 procedures were successful while 37 were considered a failure. Failure was defined as shoulders requiring revision stabilization or those with recurrent instability, recalcitrant pain or stiffness. The authors concluded that failure rates for thermal capsulorrhaphy, even with labral repairs, are high especially for shoulders with multidirectional instability and posterior instability.

Three retrospective studies had relatively strict patient selection criteria resulting in homogeneous populations. In the multidirectional instability group (n=23 patients, 28 shoulders), patients' self-assessment of the thermal capsulorrhaphy (TC) procedure decreased over time (80% satisfied at 1 year to 44% at 2 years or more of follow-up). Recurrent instability was seen in 7 patients and 3 patients required reoperation (Joseph, 2003). Good results were shown in the posterior instability patient population. Of the 13 patients (15 shoulders) who underwent thermal capsulorrhaphy, all had normal shoulder strength, posterior drawer and jerk test results. However, 3 patients had recurrent instability and 1 patient had a sulcus sign of 1 cm and recurrent subluxation (Bisson, 2005). Chen et al. conducted a retrospective comparison study of tissue tacks (n=28) versus tissue tack plus thermal capsulorrhaphy (n=38) and determined that the capsulorrhaphy procedure conferred no additional benefit to anterior instability patients (Chen, 2005). In addition to the homogeneous patient populations, the strength of these studies was the long-term follow-up of patients. However, they did display the following limitations: inconsistent protocol; a subjective measurement tool that had not been validated (Joseph, 2003); small patient populations (Joseph, 2003; Bisson, 2005) and poor study design (Joseph, 2003; Bisson, 2005; Chen, 2005).

Levy et al. (2001) treated multidirectional shoulder instability by laser-assisted capsular shrinkage (n=56 patients, 61 shoulders) or by radiofrequency capsular shrinkage (n=34 patients, 38 shoulders). The two groups of patients were followed for 40 months and 23 months, respectively. There was a failure rate of 36% for the laser-assisted group and 24% for the radiofrequency group.

Levitz et al. (2001) reviewed the charts of 51 patients who underwent non-heat probe surgical shoulder arthroscopy and the charts of 31 patients who had heat-probe surgical shoulder arthroscopy. At 30 months follow-up, 67% of the non-heat probe group and 90% of the heat-probe group were back to sport competition.

Review articles authored by Levine et al. (2001), Khan et al. (2002), and Walton et al. (2002) conclude that further studies are needed before definitive statements can be made.

Two retrospective case series had heterogeneous patient populations, which resulted in very small numbers of patients per group when categorized by type of instability. Noonan et al. (2003) reported a statistically significant improvement in ASES scores postsurgery but did not include patients with treatment failures in their calculations. This creates a bias in favor of the thermal capsulorrhaphy treatment. They did conclude, however, that there was a high failure rate in the multidirectional instability (MDI) patients with the use of laser-assisted thermal capsulorrhaphy. Enad et al. (2004) also reported an unacceptably high failure rate in their anterior and

anteroinferior patient population and stated that overhand athletes may require treatment other than thermal capsulorrhaphy to address instability. The limitations of these studies include the retrospective study design and heterogeneous patient populations.

Miniaci et al. (2003) conducted a comparative study of 19 patients to evaluate thermal capsular shrinkage as a treatment of multidirectional instability of the shoulder. Patients were followed for a minimum of 2 years or until surgical failure and recurrence of symptoms. The results indicate that there were 9 patient surgical failures, defined as a recurrence of the instability, at an average of 9 months (range 7-14 months) postoperatively. Seven of the 9 patients with surgical failure underwent subsequent surgical revision for the recurrent instability. In four patients, the shoulder capsule was thickened, was difficult to mobilize, and generally felt stiffer than usual. Three of the patients had capsular deficiencies, with holes and thin friable tissue. The small sample size significantly limits the generalization of the conclusions of this study to the general population. In addition, the authors state that open or arthroscopic suturing techniques demonstrate more favorable results than the present study.

In a review of the literature on electrothermal arthroscopy, Gerber and Warner (2002) of the Harvard Shoulder Service state, "Currently, however, the indications for thermal capsulorrhaphy are defined poorly, clinical outcome has not been shown to be superior to conventional stabilization procedures, and long-term effects on joint biology and mechanics are not known. Based on a critical review of the literature and personal clinical experience, the authors conclude that additional experimental and clinical investigations are necessary to add this procedure to the accepted modalities applied for the treatment of shoulder instability."

In the shoulder, there are many potential complications of thermal capsulorrhaphy including capsular necrosis, axillary nerve neuritis, and capsulitis (ECRI, 2012). The available evidence is limited by heterogeneous or highly selected patient populations, inconsistent protocols, and the absence of well-designed randomized trials comparing thermal capsulorrhaphy with surgical or other treatment options with sufficient follow-up and identification of complications including re-surgical rates. Therefore, the evidence is insufficient to support definitive conclusions regarding efficacy and appropriate patient selection criteria.

The Washington State Department of Labor and Industries (2003) completed a technology assessment of electrothermal arthroscopy for shoulder and other joints. This evidence based report concluded that the evidence comes from primarily case series and retrospective studies with small sample sizes and heterogeneous populations. They concluded that the findings do not establish the efficacy or effectiveness of this treatment for shoulder instability.

The clinical evidence was reviewed on January 10, 2014 with no additional information identified that would change the unproven conclusion.

## **Hand/Wrist**

A review by DeWal et al. (2002) concluded that initial findings of thermal energy for wrist instability are promising; however, further studies are needed to clarify the potential benefits and long term results of thermal shrinkage.

A case series by Chu et al. (2009) evaluated radiofrequency electrothermal treatment for thumb basal joint instability. Seventeen patients underwent arthroscopic electrothermal shrinkage of the volar ligaments and joint capsule. Patients were followed at a mean of 41 months (range, 24 to 80 months). Pain improved in all thumbs along with thumb pinch strength. The study is limited by small sample size and study design. Further studies are needed to evaluate the efficacy of thermal capsulorrhaphy in the thumb joint.

The clinical evidence was reviewed on January 10, 2014 with no additional information identified that would change the unproven conclusion.

## Hip

Currently only one review article on thermal capsular shrinkage of the hip has been published. Phillipon (2001) concluded that short-term results appear promising however, more studies are required to determine the long-term efficacy of this procedure in the treatment of this challenging disorder.

The clinical evidence was reviewed on February 27, 2013 with no additional information identified that would change the unproven conclusion.

## Knee

### ***Anterior Cruciate Ligament (ACL)***

When conservative methods of treatment are not effective in correcting knee stability (i.e., rest, ice, physical therapy), surgical intervention may be necessary to repair the lax or damaged ACL.

The most thoroughly studied indication for thermal shrinkage, other than shoulder instability, is ACL laxity. Data from the available published studies on ACL instability indicate that, while thermal shrinkage may be initially effective in tightening the ACL, laxity often recurs within several months, especially in patients who have chronic laxity and/or have undergone ACL reconstruction.

A prospective, multicenter study by Smith et al. (2008) of 64 patients evaluated the effectiveness of thermal shrinkage on both lax native anterior cruciate ligament (ACL) and lax reconstructions. Follow-up occurred at 2 years post procedure with 3 patients lost to follow-up. Of the remaining 61 patients, failure occurred in 31 (50.8%). The failure rate for lax grafts alone was 78.9%, and there was a failure rate of 38.1% for lax native ligaments. The authors concluded that electrothermal shrinkage of lax native or reconstructed ACLs is not an effective treatment treatment for ACL repair and lax reconstructions.

A study by Carter et al. (2002) was limited to 18 patients who had ACL injuries with documented joint laxity but ligament continuity. Seven patients had previously undergone ACL reconstruction. Patients were evaluated at 6-month intervals until failure or for a mean of 20 months in the successful cases. Outcome measures included subjective and objective assessments of knee function, including range of motion, Lachman and pivot shift test, and arthrometer testing. In this study, thermal shrinkage produced a decrease in joint laxity in all treated knees within a month after the procedure; however, by 6 months, over half of the joints had functional knee instability. The majority of failures were in patients who had ACL grafts and/or chronic laxity prior to thermal treatment.

Indelli et al. (2003) reported their experience with thermal repair on 28 consecutive knees with partial ACL tears. Based on measurements of ACL stability two or more years after surgery, the authors found the results to be comparable to ACL reconstructions with allograft. The authors stated, however, that longer follow-up and the results of other studies will better define the selection, methods, and results of thermal repair of partial ACL tears. Oakes and McAllister (2003) stated that although the use of thermal energy to selectively shrink tissues may ultimately prove to be an invaluable tool, the lack of well-designed, randomized controlled studies to firmly establish its efficacy in the treatment of partial cruciate injuries mandates cautious use of this technique at this time.

Halbrecht (2005) treated 19 patients with partial tears of the ACL or stretched ACL grafts and concluded that thermal shrinkage provides short-term benefit in the treatment of ACL laxity but leads to catastrophic failure in the majority of patients at long-term follow-up. The author no longer recommends this procedure for the treatment of ACL laxity.

Other authors concluded that although the use of thermal energy to selectively shrink tissues may ultimately prove to be an invaluable tool, the lack of well-designed, long-term randomized controlled studies to firmly establish its efficacy in the treatment of partial ACL injuries mandates cautious use of this technique at this time (Lamar, 2005).

### ***Retinaculum and Patellar Tendon***

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated thermal shrinkage of the retinaculum or patellar tendon.

The clinical evidence was reviewed on January 10, 2014 with no additional information identified that would change the unproven conclusion.

### **Ankle**

A prospective, multicenter study by de Vries et al. (2008) evaluated arthroscopic capsular shrinkage for chronic ankle instability with thermal radiofrequency in 39 patients. Follow-up occurred at 9 months for each patient. Primary outcomes were measured by radiologic and manually tested mechanical laxity. Secondary outcome measurements were the number of complications, reoperations and symptoms, range of motion, and functional (ankle) scores. Mechanical stability showed no clinically relevant improvement whereas most secondary outcome measures showed a substantial and statistically significant improvement. The authors conclude that arthroscopic thermal capsular shrinkage of the ankle is a safe procedure, leading to resolution of symptoms in the majority of patients with chronic ankle instability. This study is limited by small patient sample and short-term follow-up. Further well designed clinical trials evaluating long term outcomes are required to support safety and efficacy of the procedure when used to treat ankle instability.

The clinical evidence was reviewed on January 10, 2014 with no additional information identified that would change the unproven conclusion.

### **Professional Organizations**

**American Academy of Orthopaedic Surgeons (AAOS)** An advisory statement by the American Association of Orthopaedic Surgeons® (AAOS) regarding the use of thermal modalities that long-term results of thermal capsular shrinkage are not known at this time. Thermal capsular shrinkage must be undertaken with caution. The role of thermal capsular shrinkage for the treatment of shoulder instability is still being defined. (AAOS, 2010).

### **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Thermal capsulorrhaphy is a procedure, and thus, not regulated by the FDA. However, a thermal probe is used during the surgery. Several probe devices have been approved under the FDA 510(k) criteria, product code GEI and GEX. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> Accessed February 3, 2014.

### **Additional Products**

ArthroCare System 2000 CAPS® X ArthroWand®, ORA-50 ElectroThermal System and Accessories, TOPAZ, VULCAN® EAS® ElectroThermal Arthroscopy System and Accessories, VAPR™ TC Electrode for use with VAPR™ II Electrosurgical System

### **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) for thermal capsulorrhaphy/thermal shrinkage therapy for joint capsules, ligaments and tendons. Local Coverage Determinations (LCDs) do not exist at this time.

(Accessed January 10, 2014)



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#### POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
04/01/2014	<ul style="list-style-type: none"> <li>Reorganized policy content</li> <li>Added benefit considerations language for <i>Essential Health Benefits for Individual and Small Group</i> plans to indicate: <ul style="list-style-type: none"> <li>For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs")</li> </ul> </li> </ul>



Date	Action/Description
	<ul style="list-style-type: none"> <li>○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans</li> <li>○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage</li> <li>● Updated coverage rationale; added language to indicate the unproven service is "not medically necessary"</li> <li>● Archived previous policy version 2013T0426I</li> </ul>