



# Cigna Medical Coverage Policy

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Subject Thermal Shrinkage

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## Hyperlink to Related Coverage Policies

### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

## Coverage Policy

**Cigna does not cover thermal shrinkage for ANY indication, including treatment of a joint capsule, ligament, or tendon because it is considered experimental, investigational or unproven.**

## General Background

Thermal shrinkage of the joint capsule (e.g., thermal capsulorrhaphy, thermal capsular shrinkage, arthroscopic thermal capsulorrhaphy, electrothermal arthroscopic capsulorrhaphy [ETAC]), and ligaments or tendons (e.g., electrothermal therapy, radiofrequency thermal shrinkage, thermal shrinkage), utilizes a radiofrequency probe or laser to deliver nonablative heat to a targeted area. It is hypothesized that heat from the thermal catheter will cause the collagen fibers of the tissue to shrink through collagen denaturation, resulting in a tightening and improved stabilization of the joint capsule or ligaments and tendons. 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.

Monopolar radiofrequency probes (single electrode tip and grounding plate) and bipolar radiofrequency probes (two points on the tip of a probe) are used to apply heat to soft tissue. The heat ultimately causes the ligament to shrink and shorten by altering the collagen, in turn tightening it and improving the stability of the joint. The thermal effect of the energy is dependent on the level of energy, the duration of the application, the nature of the tissues and the type of device used.

Overall, the reported outcomes of thermal shrinkage have been short-term and consist mainly of decreased tissue trauma at the time of surgery. Published data do not permit strong conclusions regarding the efficacy of thermal shrinkage and impact on improving health outcomes. Complications and failure that may be related to

inadequate shrinking or overheating of tissue have been reported in the medical literature. Reported complications have included capsular necrosis, loss of capsular and glenohumeral ligament integrity, nerve damage, and failure leading to recurrent instability.

### **U.S. Food and Drug Administration (FDA)**

Several thermal probe devices used as part of electrosurgical or electrothermal systems have been granted 510(k) approval by the U.S. Food and Drug Administration (FDA) and include: Oratec ORA-50 Electrothermal System and Accessories (Oratec Interventions, Menlo Park, CA), Arthrocare System 2000 CAPS<sup>®</sup> X ArthroWand<sup>®</sup> (Arthrocare Corporation, Sunnyvale, CA), VULCAN<sup>®</sup> EAS<sup>®</sup> Electrothermal Arthroscopy System and Accessories (Smith and Nephew, Memphis, TN) and VAPR<sup>™</sup> TC Electrode (Mitek Products, Norwood, MA). These devices are regulated as electrosurgical cutting and coagulation devices and accessories and are considered Class II devices.

### **Anterior/Posterior Cruciate Ligament (ACL/PCL) Injury**

Injuries of the ACL or PCL often result in complete rupture, although in some cases injuries result only in a partial tear or stretching. Depending on the severity of the injury, a person may experience pain, decreased range of motion, and/or some degree of functional impairment. Nonsurgical treatment options may include rest, anti-inflammatory medications, compression, strengthening exercises, and/or physical therapy and cortisone injections. These conservative treatments are frequently used for individuals where there is an incomplete tear or when reconstruction is not desired. For those individuals with complete tears, surgical reconstruction may be the only option.

The standard surgical approach involves the use of allograft or autograft tissue in reconstructing the ligament by way of open arthrotomy or arthroscopy. Thermal shrinkage has been suggested as a treatment modality for individuals with partially intact ACL/PCL ligaments.

**Literature Review:** Evidence evaluating thermal shrinkage for the treatment of ACL/PCL instability consists of both retrospective and prospective case series (Farng, et al., 2005; Halbrecht, 2005; Indelli, et al., 2003; Carter, et al., 2002) and case reports (Oakes and McAllister, 2003). The published case series involve small patient populations, evaluate short-term outcomes and lack controls. While some of the studies support improved knee function during the initial post-operative period (Farng, et al., 2005; Halbrecht, 2005; Indelli, et al., 2003), laxity can recur and some of the studies (Halbrecht, 2005; Carter, et al., 2002) have demonstrated greater than 50% failure rates at final follow-up. A recent prospective multicenter clinical trial (n=64) with mid-term follow-up (at least two years for 61 subjects) showed a failure rate for lax grafts of 78.9% and a failure rate for lax native ligaments of 38.1% when subjects underwent thermal shrinkage of the ACL (Smith, et al, 2008). Evidence in the peer-reviewed published scientific literature is insufficient to support safety and efficacy, and long-term durability of the procedure has not been demonstrated.

### **Shoulder Instability**

Disruption of the glenohumeral ligament (laxity or elongation) may result from trauma or from congenital or developmental weakness and may lead to joint instability. Individuals experience symptoms of aching, heaviness, pain and decreased range of motion. This condition often occurs in individuals who are athletic and in young adults.

Standard treatment consists of conservative therapy, using activity modification, exercises and patient education. For cases that do not respond to treatment, surgical repair may be necessary. The goal of surgery is to re-stabilize the shoulder and maintain full, pain-free range of motion. Surgery consists of inspecting the shoulder joint and repairing, reattaching, or tightening the labrum, ligaments or capsule, with either sutures alone or sutures attached to absorbable tacks or anchors. Although arthroscopic approaches have frequently been performed, there is more concern about the instability recurring after arthroscopic surgery than after open procedures. In some cases, authors posit that the recurrence of instability results from lack of tightening in the stretched-out capsule despite the operative repair. Arthroscopic thermal shrinkage, also referred to as electrothermal arthroscopic capsulorrhaphy (ETAC), has been suggested as a treatment for shoulder instability in cases requiring both tightening of the ligament and reattachment procedures. Reported complications associated with thermal shrinkage of the shoulder include biceps tendon rupture, capsular attenuation, adhesive capsulitis, and axillary neuropathy.

**Literature Review:** The 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 (Engelsma and Williams, 2010; Hawkins, et al., 2008; Massoud, et al., 2007; Miniaci, Codsì, 2006; Park, et al., 2005; Bisson, et al., 2005; Chen, et al., 2005; D'Alessandro, et al., 2004; Miniaci and McBirnie, 2003; Mishra and Fanton, 2001). Several of the studies involve small sample populations evaluating short- to mid-term outcomes. When utilized to treat shoulder ligaments, reported failure rates are generally high and are often related to recurrent instability (Hawkins, et al., 2008; Massoud, et al., 2007; Park, et al., 2005; D'Alessandro, et al., 2004; Miniaci, McBirnie, 2003). When used to treat internal shoulder impingement (n=12) Jansen et al. (2012) reported that at seven year follow-up only 25% of athletes were able to perform at a preoperative sports level. Although short term results in this same group were promising at one and two years, there was significant deterioration at seven years (p<0.001). Additionally, Some published reviews indicate that due to unacceptable high failure rates and complications thermal capsulorrhaphy is no longer recommended as a treatment for shoulder instability (Bell, 2010; Bradley and Tejqani, 2010; Johnson and Robinson, 2010; Greiwi and Ahmad, 2009).

### **Ankle Instability**

Arthroscopic shrinkage has also been proposed for treatment of ankle instability, although the medical literature is limited and consists mainly of case series and case reports (de Vries, et al., 2008; Maiottie, et al., 2005; Hyer and Vancourt; 2004). Despite some improvement in mechanical stability and function, these studies evaluate short term outcomes in small patient populations, and the results cannot be generalized. 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.

### **Hip Instability**

Thermal modification of the hip capsular tissue has been suggested as a treatment for hip instability. The hip joint capsule consists of collagen tissue, and shrinkage may help stabilize the joint (Phillipon, 2001). While limited short-term results appear promising, further long-term, controlled studies are required to support the safety and efficacy of thermal shrinkage for this use.

### **Hand and Wrist Instability**

Thermal energy has been used to treat unstable or loose partial-thickness cartilage defects, meniscal lesions and ligamentous tears of the wrist. Thermal energy has also been proposed for the treatment of scapholunate instability which describes a wide variety of clinical conditions affecting the scapholunate interosseous ligament of the wrist, including laxity or stretch (Manuel and Moran, 2007). While some authors have reported improvement in pain after thermal shrinkage (Lee et al., 2012; Garcia-Lopez, et al., 2012; Darlis, et al., 2005) other authors have reported injury to subchondral bone as a result of heat application to the chondral surface (Lu, et al., 2001). Moreover, authors have acknowledged that the potential benefits of thermal shrinkage for wrist instability need to be clarified (DeWal, et al., 2002).

Chu and colleagues (2009) studied electrothermal treatment of thumb basal joint instability (n=17) over a minimum two year period. All patients underwent arthroscopic electrothermal treatment of the volar ligaments and joint capsule. At an average follow-up of 41 months pain was improved in all thumbs and the authors reported a significant improvement in thumb pinch strength (P<.01).

The evidence in the peer-reviewed scientific literature is insufficient to demonstrate safety and efficacy and further, long-term clinical studies are required to support improved patient outcomes when thermal energy is used to treat hand or wrist instability.

### **Professional Societies/Organizations**

An advisory statement by the American Association of Orthopaedic Surgeons® (AAOS) regarding the use of thermal modalities indicates the AAOS endorses a scientific approach toward the use of thermal modalities in orthopaedic surgery and encourages further clinical and biological study on the potential benefits and hazards of thermal technology (AAOS, 2003). Within this statement the AAOS notes that although research is ongoing, the use of thermal modalities for "shrinkage," or tissue modification in the shoulder, in the treatment of instability is still controversial as is the use of the thermal modification of articular cartilage in the knee. The AAOS concluded the use of thermal energy for tissue modification in any joint required further study to determine the indications for future use. In 2010, the AAOS provided additional information noting, "Long-term results of thermal capsular shrinkage are not known at this time and that medium-term results have been less favorable than the short-term

results. 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).

The Washington State Department of Labor and Industries (2003) conducted a technology assessment evaluating histologic studies as well as retrospective and prospective case series of patients who underwent thermal capsulorrhaphy. In summary of their assessment, the committee concluded, “Findings do not substantially show thermal shrinkage’s efficacy or effectiveness for the treatment of shoulder instability or anterior cruciate ligament laxity.”

**Use Outside of the US:** No relevant information.

### Summary

Evidence in the peer-reviewed published scientific literature evaluating thermal shrinkage consists of case series, case reports and nonrandomized controlled trials. Reported clinical outcomes are short- to mid-term and do not lead to strong conclusions. Evidence supporting improvement of long-term clinical outcomes is lacking. Reported complication rates and failure rates are generally high with some authors no longer recommending/performing the procedure. Overall the medical literature does not support clinical utility when compared to standard treatment. Further studies are needed to demonstrate term safety and effectiveness in addition to improved net health outcomes when compared to other conventional treatment modalities.

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### Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Experimental, investigational or unproven and not covered when used to report arthroscopy with thermally-induced capsulorrhaphy for any joint capsule, ligament or tendon:**

CPT®* Codes	Description
29999	Unlisted procedure, arthroscopy

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

\*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.

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