INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced. The terms of the federal, state or contractual requirements for benefit plan coverage may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the contractual requirements for benefit plan 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.

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BENEFIT CONSIDERATIONS

Before using this policy, please check the federal, state or contractual requirements for 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. Published data do not permit strong conclusions regarding the efficacy of thermal shrinkage and impact on improving health outcomes.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state or contractual requirements 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 claim payment. Other Policies and Coverage Determination Guidelines may apply.
DESCRIPTION OF SERVICES

Thermal capsulorrhaphy uses thermal energy to restructure collagen in the capsule or ligaments to reduce the capsule size. Thermal shrinkage of joint capsules, ligaments, and tendons has been proposed as a stand-alone technique or as an adjunct to arthroscopic or open surgery for tightening the structures of the ankles, hips, knees, shoulders, or wrists.

The electrothermal shrinkage technique involves the application of heat using a specialized radiofrequency probe to shrink and tighten tissues. Tendons and ligaments are primarily composed of collagen, a type of protein. When collagen is heated to the appropriate temperature, it contracts and shrinks. The body perceives this as an injury and the tissues rebuild around shorter collagen fibers, resulting in a tighter and theoretically improved joint stability.

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. Additional studies are needed to demonstrate the short- and long-term safety and effectiveness of thermal shrinkage for shoulder conditions, and that the procedure demonstrates equal or superior results in improving health outcomes when compared to the currently available treatment modalities.

Chen et al (2016) conducted a meta-analysis to assess the effectiveness of arthroscopic and open surgical techniques on the treatment of shoulder multidirectional instability (MDI). Original articles on the surgical management of multidirectional instability were retrieved against selection criteria. Data were extracted and divided into three groups by surgical technique. Proportion and mean meta-analyses were performed for comparison. The available evidence was from 35 level IV and 1 level II studies. The recurrent instability rate was 9.9% in open capsular shift (OCS) group and 6.0% in arthroscopic capsular plication (ACP) group, between which no difference was observed. However, thermal capsular shrinkage (TCS) group resulted in a recurrent instability rate of 23.9%, significantly higher than the above two groups. OCS and ACP groups revealed low reoperation rates of approximately 5.2% and 4.8% respectively, which are lower than that in TCS group of 16.9%. The results of this review showed ACP and OCS techniques have similar primary outcomes, but the former causes less post-operative stiffness, and it is suggested to avoid TCS in the treatment of MDI.

Mohtadi and colleagues (2014) performed a multicenter, randomized clinical trial with industry support that evaluated the safety and efficacy of electrothermal arthroscopic capsulorrhaphy (ETCA), compared with open inferior capsular shift (ICS) in individuals diagnosed with multidirectional instability or multidirectional laxity with anteroinferior instability of the shoulder. Participants failed nonoperative treatment and the study excluded individuals with bone lesions, labral, biceps anchor, or full-thickness rotator cuff tears. Outcome measures included function and recurrent instability at 2 years postoperatively, surgical times, and Western Ontario Shoulder Instability Index. A total of 54 subjects were randomized to ETCA or open ICS. The groups were comparable at baseline, except for external rotation. At 2 years postoperatively, there were no statistically or clinically significant differences between groups for the Western Ontario Shoulder Instability Index, American Shoulder and Elbow Surgeons score and active range of motion. Recurrent instability was not statistically different. At 2 years postoperatively, quality of life and functional outcomes between groups were not clinically different. ETCA had fewer complications and episodes of recurrence compared with open surgery. Limitations of this study include the small size of the sample population due to application of strict exclusion criteria (which resulted in a 45% intraoperative exclusion rate) and lack of long-term outcomes beyond 2 years.

In 2012, Jansen and colleagues studied the long-term results of thermal capsulorrhaphy (TC) in 12 athletes. Patients were evaluated at 1, 2 and 7 years postoperatively and although significant improvement was observed after the second year, only 25% of patients were able to perform sports at a preoperative level. This study is severely limited by sample size, however it does suggest the efficacy of TC in patients with internal shoulder impingement is not sustained over time.
Johnson and Robinson (2010) reported that although initial results using thermal capsulorrhaphy in the treatment of shoulder instability in individuals with joint hyperlaxity 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.

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 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 (Bohsnack, 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 glenohumeral 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.

Miniacci 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, 2013). 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.

**Hand/Wrist**
There is a small body of literature documenting outcomes for thermal shrinkage procedures for the treatment of hand or wrist instability.

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.

**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.

**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
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).

Other small case series and nonrandomized studies suggest that ACL laxity can recur within several months after thermal capsulorrhaphy, especially in individuals who have chronic laxity or have undergone ACL reconstruction. There is insufficient evidence from these studies to make a definitive conclusion regarding appropriate participant selection criteria or the safety and efficacy of the procedure. In addition, there is a lack of data regarding long-term durability or relative efficacy of thermal capsulorrhaphy compared with established therapies.

**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.

**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.

**Professional Organizations**

**American Academy of Orthopaedic Surgeons (AAOS)**

An advisory statement by the AAOS regarding the use of thermal modalities state 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 and medium-term results have been less favorable than the short-term results (AAOS, 2010).

There are no published clinical practice guidelines from U.S. professional societies which address the use of thermal capsulorrhaphy, either alone or in combination with other procedures, for the treatment of instability of any joint.
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 January 2017)

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for thermal capsulorrhaphy or thermal shrinkage therapy for joint capsules, ligaments and tendons. Local Coverage Determinations (LCDs) do not exist at this time. However, Local Coverage Articles (LCAs) exist; see the LCAs for Thermal Capsulorrhaphy. (Accessed January 12, 2017)

References


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 January 2017)


**POLICY HISTORY/REVISION INFORMATION**

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