APPENDIX to Thermal Shrinkage/Thermal Capsulorrhaphy Policy

Prior Authorization Requirements

Clinical Evidence is required to determine **medical necessity**.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Over the past decade, thermal shrinkage has been introduced as a less invasive alternative to conventional surgical treatment of ligamentous laxity and instability in joints including the shoulder, knee, hip, hand and wrist joints. Thermal shrinkage combined with other repair procedures (i.e., arthroscopy or open surgery) has been proposed as a technically simpler technique to tighten the capsule and ligaments of a joint.

The efficacy of thermal shrinkage is based on the theory that non-ablative radiofrequency thermal energy (heat) at the right temperature alters collagen in the ligaments and/or capsule, resulting in shrinkage and decreased capsular volume. The body recognizes this alteration as an injury and the tissues rebuild and shorten the collagen fibers in response. Theoretically this restores capsular tension (tightness) and results in a more stable joint. The effect of thermal energy is dependent upon the level of energy, application duration, nature of the tissue, and the type of device utilized. The most thoroughly studied indications for thermal shrinkage have been treatment of shoulder instability (thermal capsulorrhaphy) and anterior cruciate ligament (ACL) laxity.

Thermal shrinkage was initially investigated using laser energy; however, radiofrequency probes are now more commonly used. Thermal probe devices, as part of electrosurgical or electrothermal systems, were granted 510(k) approval by the United States Food and Drug Administration (FDA). These include, but are not limited to, the Oratec ORA-50 Electrothermal System and Accessories (Oratec Interventions, Menlo Park, CA), the Arthrocare System 2000

CAPS® X ArthroWand® (Arthrocare Corporation, Sunnyvale, CA), the VULCAN® EAS® Electrothermal Arthroscopy System and Accessories (Smith and Nephew, Memphis, TN) and VAPR™ TC Electrode (Mitek Products, Norwood, MA).

The benefits of thermal shrinkage have been short-term, and predominantly consisted of decreased tissue trauma. The success of this technique remains controversial.

Shoulder

The shoulder is the most frequently dislocated joint in the body. Shoulder instability is a relatively common occurrence in the general population. Shoulder instability 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. In many cases, trauma results in a Bankart lesion, which is a tear of the labral-ligamentous complex off the glenoid that removes the ligment's anchor. 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. Patients have symptoms of aching, heaviness, pain and decreased range of motion. This occurs most often in athletes or young adults. Initial treatment of shoulder subluxation or dislocation is conservative in nature (i.e., ice, rest and anti-inflammatories) followed by range-of-motion strengthening exercises. Activity modification may be appropriate for patients who can identify a single motion that aggravates instability, such as an overhead throwing motion. 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.

Traditional surgery consists of inspection of the shoulder joint with repair, reattachment, or tightening of the labrum, ligaments, or capsule performed either with sutures attached to absorbable tacks or anchors. While arthroscopic approaches have been investigated over the past decade, their success has been debated due to higher rates of recurrent instability compared with open surgical techniques. Thermal capsulorrhaphy has been proposed as an adjunct to arthroscopic or open surgical repair of torn ligaments or other structures (i.e., repair of Bankart or superior labrum anterior and posterior (SLAP) lesion or glenohumeral laxity). It has also been investigated as a sole arthroscopic treatment in patients with chronic shoulder pain without recognized instability, based on the theory 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's syndrome.

While thermal capsulorrhaphy is considered less difficult than standard arthroscopic techniques, adverse events have been reported including biceps tendon rupture, capsular attenuation, adhesive capsulitis, transient deltoid weakness, and axillary neuropathy (American Academy of Orthopaedic Surgeons (AAOS), 2010; Johnson & Robinson, 2010) and glenohumeral chondrolysis (Good et al., 2007; AAOS, 2010).

There is limited data in the peer reviewed literature regarding the use of thermal capsulorrhaphy, either as a sole arthroscopic procedure, or as an adjunct to other arthroscopic repair of shoulder lesions, to permit strong conclusions regarding its efficacy and impact on health outcomes.

Thermal Capsulorrhaphy as a Sole Arthroscopic Procedure

Levy and colleagues (2001) reported on a case series of 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. Selection criteria included all of the following: 1) a history of either repetitive microtrauma or a minimal traumatic event leading to recurrent symptoms; 2) clinical examination revealing generalized laxity; and 3) arthroscopic finding of a voluminous capsule with increased joint volume. Following diagnostic arthroscopy, thermal capsulorrhaphy was the only arthroscopic treatment performed. Outcomes included assessment of pain, stability, mobility, and return to sport or daily activities. 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. The authors reported these results matched those of some reported case series of open repair of multidirectional instability and suggested due to the minimal morbidity of the arthroscopic approach, thermal shrinkage was a viable alternative to open surgery. Additional studies included review articles (Wolf & Lemak, 2002; Gerber & Warner, 2002; Sekiya et al., 2003) and case series of thermal capsulorrhaphy of the shoulder (Hovis et al., 2002; Gieringer, 2003).

In 2004, D'Alessandro and colleagues published results of a prospective study of 84 patients who underwent thermal capsulorrhaphy for various indications. 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 the high rate of unsatisfactory results was of great concern. Levine and colleagues (2004) reported the initial wave of enthusiasm for thermal capsulorrhaphy had largely subsided, given the negative results reported by D'Alessandro.

A Canadian workgroup reported on an ongoing multicenter randomized controlled trial comparing arthroscopic thermal capsulorrhaphy versus open inferior capsular shift for patients with shoulder instability (Mohtadi et al., 2006). Enrollment was slower than anticipated due to high intra-operative exclusion rates and subsequent adverse reports from other case series which resulted in decreased enthusiasm of the technique in surgeons. Nineteen patients treated with thermal capsulorrhaphy and 15 subjects treated with surgical repair have completed two-year follow-up as of publication, without any serious adverse events.

In 2007, two- to six-year follow-up was reported on 85 of 100 consecutive patients treated with thermal capsulorrhaphy for glenohumeral instability (Hawkins et al., 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. The authors concluded this compared unfavorably with the reported 7.5% failure rate when thermal capsulorrhaphy was used to supplement suture plication, and they now generally used it only in combination with other surgical procedures.

A Medical Technology Directory report by Hayes, Inc., (2006) evaluated the evidence regarding thermal capsulorrhaphy for shoulder instability. The authors concluded there was insufficient evidence thermal capsulorrhaphy provided any clinical benefit when used as a stand-alone

treatment for multidirectional or unidirectional instability. The conclusions of this report were unchanged in an update search conducted in 2010.

A 2010 case series by Engelsma and Willems observed a tendency toward inferior outcomes after thermal capsulorrhaphy (n = 9) in comparison to capsulorrhaphy by suture (n = 3) or labral fixation (n = 7) for treatment of posterior shoulder instability.

Thermal Capsulorrhaphy Combined with Other Arthroscopic Procedures

A 2003 technology assessment by the Washington State Department of Labor and Industries evaluated histological studies, as well as retrospective and prospective case series of patients who underwent thermal capsulorrhaphy. Regarding shoulder instability, the summary concluded "Findings do not substantially show thermal shrinkage's efficacy or effectiveness for the treatment of shoulder instability... "

In 2005, Chen and colleagues reported on a case series of 40 patients who underwent combined arthroscopic labral repair and thermal capsulorrhaphy. The results were compared to a historical control group of 32 patients who underwent the same surgery without capsulorrhaphy. They found no differences in outcomes between the two groups, which lead the authors to conclude capsulorrhaphy neither improved nor compromised the results of conventional arthroscopic treatment.

The authors of the same report by Hayes, Inc., (2006) discussed earlier also concluded there was insufficient evidence to suggest thermal capsulorrhaphy was an effective and durable treatment for patients with multidirectional or unidirectional instability of the shoulder, as an adjunct to surgical repair. The authors cited weak study design, small sample size, inconsistent treatment protocols, and confounding results due to concurrent surgical repair. Additionally, there were variable success rates, and high failure or recurrence rates. The subsequent Hayes, Inc., update search in 2010 did not change any of the above conclusions.

Recent reviews have indicated while initial results of thermal capsulorrhaphy seemed promising, subsequent studies with longer follow-up showed "unacceptable high failure rates and postoperative complications" (Johnson & Robinson, 2010). Therefore, thermal capsulorrhaphy could not be recommended as a treatment of shoulder instability (Greiwi & Ahmad, 2010; Johnson & Robinson, 2010; Engelsma & Williams, 2010). Additionally, an informational report by the AAOS (2010), stated:

> Long-term results of thermal capsular shrinkage are not known at this time. 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.

In a 2011 review, Virk and Kocher described thermal capsulorrhaphy as a failed new technology in sports medicine.

Knee

The knee has four major stabilizing ligaments, the anterior and posterior cruciate ligaments (PCL) and the medial and lateral collateral ligaments. One of the most common knee injuries is an ACL sprain or tear and about half of all ACL injuries occur along with damage to other

structures in the knee, such as articular cartilage, meniscus, or other ligaments. The PCL is located in the back of the knee and injuries are commonly from falls and hyperextension. Ligament injuries result in pain, decreased range of motion, and some degree of functional impairment. Conservative treatment for partial tears of the ACL or PCL includes rest, anti-inflammatory medications, compression, strengthening exercises and cortisone injections. For patients with complete tears, surgical reconstruction may be the only option. Thermal shrinkage has been suggested as a treatment option for patients with partial ACL or PCL ligament tears, however, published peer reviewed literature remains controversial.

The 2003 technology assessment by the Washington State Department of Labor and Industries discussed earlier also concluded findings did not demonstrate efficacy or the effectiveness of thermal shrinkage for the treatment of ACL laxity.

Lamar et al., (2005) evaluated the effectiveness of thermal modification for the treatment of partial tears of the ACL in a prospective non-randomized consecutive case series. The authors concluded thermal modification may be a viable treatment option for partial ACL tears, however further investigation was necessary to determine the long-term effectiveness of this procedure.

In another case series, Halbrecht (2005) evaluated 19 patients at one and five years after thermal shrinkage for laxity of their ACL. Fourteen of these patients had partial tears of the ACL while the remaining five had stretched ACL grafts. According to Halbrecht, thermal shrinkage could no longer be recommended for the treatment of ACL laxity.

A 2008 publication by Zheng and colleagues stated "no immediate difference was found after thermal capsulorrhaphy of the medial parapatellar capsule. Open surgery immediately improved the lateral stiffness of the knee capsule."

Smith et al., (2008) conducted a prospective multicenter clinical trial of 62 patients who underwent electrothermal shrinkage of the ACL. At mid-term follow-up (at least two years for 61 patients), failure occurred in 31 (50.8%) of patients. Lax graft failure rates were 78.9%, and lax native ligament failure rates were 38.1%. The authors concluded electrothermal shrinkage of lax native or reconstructed ACLs was "not an appropriate treatment."

Ankle

Chronic lateral ankle instability occurs in 10% to 20% of people after an acute ankle sprain (deVries et al., 2011). Initial treatment is conservative (i.e., rest, ice, compression, elevation, and ankle support, physical therapy) however, if treatment fails and ligament laxity is present, surgical intervention (i.e., ligament repair or reconstruction) may be considered.

Literature on the use of athroscopic thermal shrinkage for ankle instability is limited. Maiotti et al., (2005) reviewed 22 male soccer players (average age, 18 years) with chronic lateral ankle instability who underwent arthroscopic thermal capsulorrhaphy between 1997 and 1998. Results showed 18 of the 22 patients presented with no evidence of ankle instability during physical examination or on stress radiographs. Only one patient was not able to return to his previous level of sports activity. These authors suggested arthroscopic thermal shrinkage was a valid and safe procedure for treatment of chronic lateral ankle instability. However, they also pointed out longer follow-up was needed. In addition, this study involved a small group of patients and lacked a control group.

In a prospective study, de Vries and colleagues (2008) examined chronic ankle instability treated with arthroscopic capsular shrinkage. Thirty-nine adult patients were included. Mechanical stability showed no clinically relevant improvement whereas most secondary outcomes measures showed a statistically significant improvement. The authors concluded arthroscopic thermal capsular shrinkage of the ankle was a safe procedure with resolution of symptoms. However, as pointed out, efficacy was not established and the small group lacked a control.

Hip

Philippon (2001) proposed that arthroscopic thermal modification of hip capsular collagen appeared to be a treatment option for patients with hip instability. This author concluded short-term results appeared promising, however, more studies were required to establish efficacy for this indication.

This was the only review found regarding hip thermal shrinkage in a search of MEDLINE through September 2011. Further study is required to determine the long-term efficacy of thermal shrinkage for the treatment of hip instability.

Hand and Wrist

Thermal shrinkage has also been proposed as a treatment for unstable or partial ligament injuries of the wrist, but its use remains controversial. DeWal and colleagues (2002) wrote thermal energy in arthroscopic surgery needed further evaluation to clarify the potential benefits and long-term results needed to be compared with other accepted standards of management.

Darlis and associates (2005) reported on 16 patients (range 18 to 54 years of age) with partial (Geissler grade I and II) scapholunate (SL) interosseous ligament injuries of the wrist. These patients presented with chronic dorsoradial wrist pain unresponsive to initial conservative therapy and no radiologic signs of static dissociation (SL interval, <3.5 millimeters (mm); mean SL angle, 49 degrees). After debridement and thermal shrinkage, 14 patients experienced substantial pain relief whereas in two patients the pain remained unchanged. Static or dynamic instability remained unchanged (SL interval, <3.5 mm; mean SL angle, 53 degrees). The authors cautioned longer follow-up studies were necessary to determine the ultimate efficacy of this procedure.

Mason and Hargreaves (2007) published one small case series (13 patients) reporting the use of arthroscopic thermal capsulorrhaphy for palmar midcarpal instability. It was concluded early results showed thermal capsulorrhaphy as effective in reducing the instability symptoms of palmar midcarpal instability.

Chloros et al., (2008) reviewed the literature regarding arthroscopic treatment of radial fractures, including the use of electrothermal devices. The authors reported the preliminary results of electrothermal devices were encouraging; however complications have been reported and their use is controversial.

Chu et al., (2009), in a therapeutic case series, evaluated radiofrequency electrothermal treatment of thumb basal joint instability (n = 17) over a two year period. The authors concluded most patients had good subjective results (n = 16) and pinch strength improved significantly ($p < .01$) in most patients. The authors reported study limitations including small participant sample size,

lack of control/comparison group, lack of functional testing parameter, and a short-term follow-up period. Well-designed studies are needed to verify findings.

An on-line expert consult by Battistella and colleagues (2009) evaluated the use of arthroscopic thermal shrinkage with radiofrequency for the treatment of SL ligament injuries. The authors reported while this recent technique was an attractive alternative to the use of a mechanized resector for debridement of SL ligament tears and stabilization of the SL joint; the real effectiveness of the technique was undetermined. Additionally, there continued to be uncertainty about the effectiveness of thermal shrinkage in the wrist, and technology, rather than scientific clinical evidence, was likely the driving force for its use in orthopedic surgery.

In summary there is insufficient evidence in the currently available literature to permit scientific conclusions regarding the use of thermal shrinkage, alone or in combination with other arthroscopic procedures, in comparison to standard treatment modalities. Study populations were small, non-randomized, and non-controlled, with insufficient follow-up periods to determine long-term outcomes. There continues to be unresolved issues regarding this technique including, but not limited to, identifying and quantifying joint laxity, determining optimal temperature and length of thermal exposure, and the variable response of collagen to heat based on the patient's age and other factors.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy

Type	Number	Description
CPT	None	

Type	Number	Description
HCPC	S2300	Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

American Shoulder and Elbow Surgeons Score - Scoring system has two parts, one for the patient and one for the physician. The patient subjective section contains visual analog scales for pain and a series of questions relating to function of the extremity. The responses to the questions are scored on a 4-point ordinal scale. The physician objective assessment section has four parts: motion, stability, strength, and physical findings.

Bankart lesion - Specific type of shoulder labral tear. Over 95% of all shoulder dislocations have an accompanying Bankart lesion and often contributes to shoulder instability. As the shoulder pops out of joint, it often tears the labrum, especially in younger patients.

Capsule - Membrane sac enclosing the articulating ends of the bones in a joint. In the shoulder, the capsule is thicker above and below than elsewhere, and is remarkably loose and lax, so that it has no action in keeping the bones in contact, but allows them to be separated from each other more than 2.5 centimeters. This allows for extreme freedom of movement which is peculiar to this articulation. This also allows for the ease of subluxation.

Chondrolysis - The disappearance of articular cartilage as the result of lysis or dissolution of the cartilage matrix and cells.

Glenohumeral - Joint, commonly known as the shoulder joint, is a multiaxial synovial ball and socket joint which involves articulation between the glenoid fossa of the scapula (shoulder blade) and the head of the humerus (upper arm bone).

International Knee Documentation Committee - Committee of international knee experts created the International Knee Documentation Committee Subjective Knee Form. This knee-specific test measures change in symptoms, function, and sports activity in patients treated for a variety of knee conditions.

Labrum - The shoulder joint is a ball and socket joint, similar to the hip; however, the socket of the shoulder joint is extremely shallow, and therefore inherently unstable. To compensate for the shallow socket, the shoulder joint has a cuff of cartilage called a labrum that forms a cup for the end of the arm bone (humerus) to move within. This cuff of cartilage makes the shoulder joint much more stable, yet allows for a very wide range of movements. In fact, the range of movements the shoulder can make far exceeds any other joint in the body.

Scapholunate - Intra-articular ligament binding the scaphoid and lunate bones of the wrist together. It is divided into three areas, dorsal, proximal and palmar, with the dorsal segment being the strongest part. It is the main stabilizer of the scaphoid.

Subluxation - Shoulder subluxation is a temporary, partial dislocation of the shoulder joint. The shoulder is a ball-and-socket joint. The ball of the upper arm bone is normally held in the socket of the shoulder blade by a group of ligaments. (Ligaments are strong bands of tissue that connect the bones). In subluxation, the ball of the upper arm bone slips partially out of the shoulder socket.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

N/A

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
9/25/2009	New Policy Adoption	Medical Policy Committee
10/7/2011	Policy title change from Thermal Capsulorrhaphy with position change	Medical Policy Committee

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