DRAFT Medical Coverage Policy | Radiofrequency Coblation Tenotomy for Musculoskeletal Conditions

EFFECTIVE DATE: 00|00|2000
POLICY LAST UPDATED: 02|06|2020

OVERVIEW

Radiofrequency (RF) coblation is being evaluated for the treatment of plantar fasciitis, lateral epicondylitis, and various musculoskeletal tendinopathies. When utilized for tenotomy, bipolar RF energy is directed into the tendon to generate a controlled, low-temperature field of ionizing particles that break organic bonds, ablating or debriding target tissue with the goal of relieving pain and restoring function.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Radiofrequency coblation tenotomy is not covered as a treatment for musculoskeletal conditions, including but not limited to plantar fasciitis, lateral epicondylitis, shoulder or rotator cuff tendinopathy, Achilles tendinopathy, patellar tendinopathy and wrist tendinopathy as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Radiofrequency coblation tenotomy is not medically necessary as a treatment for musculoskeletal conditions, including but not limited to plantar fasciitis, lateral epicondylitis, shoulder or rotator cuff tendinopathy, Achilles tendinopathy, patellar tendinopathy and wrist tendinopathy as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Radiofrequency Coblation

RF coblation uses bipolar low-frequency energy in an electrically conductive fluid (eg, saline) to generate a high-density plasma field around the energy source. This creates a low-temperature field of ionizing particles that break organic bonds within the target tissue. Coblation technology is used in a variety of surgical procedures, particularly related to otolaryngology and orthopedics. The proposed advantage of coblation is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue. RF coblation was also found to exhibit several properties that may make it an attractive option for addressing the underlying pathophysiology of chronic tendinopathies, namely increased angiogenesis, reduction of inflammatory responses, and increased expression of growth factors. RF coblation surgical wands are utilized by orthopedic surgeons in minimally invasive arthroscopic procedures to facilitate soft tissue debridement, subacromial decompression, meniscal removal and sculpting, or tendon debridement.

Tendinopathy
Tendinopathy is a clinical pain syndrome characterized by tendon thickening due to proliferation and chronic irritation of neovascular repair tissue with a history of repetitive tendon loading. This condition commonly results from overuse and has a high incidence rate in athletes and laborers. Clinical history should clarify predisposing training or activity and assess the level of functioning. Biomechanical abnormalities during activity should be identified and corrected. Standard treatment may, therefore, consist of biomechanical modification, activity modification, physical therapy (eg, heavy load resistance training), and nonsteroidal anti-inflammatory medication. For chronic tendinopathies, glucocorticoids should only be used in select cases (eg, rotator cuff tendinopathy). Surgical consultation following six months of a well-designed physical therapy program with adjunct medical treatments can be considered if there is no improvement in pain or function. Validated and reliable functional assessment scores should be utilized by the clinician to grade symptoms and assess patient function. Examples of suitable scales include the Victoria Institute of Sport Assessment for Achilles tendinopathy. Surgical approaches may involve incisions to the paratendon and removal of adhesions and degenerate tissue. Longitudinal incisions may be made in the tendon to promote a repair response. This latter strategy has also been delivered via minimally invasive arthroscopic approaches. These approaches may also address the debridement of the neovascular supply to the tendon surface. Collectively, a prolonged recovery duration to accommodate tendon healing may be required with these interventions.

Plantar Fasciitis
Plantar fasciitis is a musculoskeletal condition characterized by pain in the plantar region of the foot that worsens upon initiation of walking and with local point tenderness elicited during a clinical examination. Radiographic and ultrasonographic studies are not typically indicated for primary diagnosis but may be useful in ruling out alternative causes and visualizing the thickening of the plantar fascia. Initial standard therapy may consist of stretching exercises, orthotics, activity and lifestyle modification, nonsteroidal anti-inflammatory drugs, splints or casts, and glucocorticoid injections. The vast majority of patients improve without surgery. Surgery is generally considered a last line of therapy and is reserved for individuals who do not respond to at least 6 to 12 months of initial, nonsurgical therapy. Surgical approaches include variations of open or endoscopic, partial or complete, plantar fascia release which may or may not include calcaneal spur resection, excision of abnormal tissue, and nerve decompression. The use of RF microtenotomy during open or percutaneous surgery has been explored alone or in combination with plantar fasciotomy.

Plantar fasciitis is one of the most common causes of foot and heel pain in adults. It is estimated to be responsible for approximately one million patient medical visits per year in the U. S. The peak incidence of the condition in the general population occurs between ages 40 and 60. There is a higher incidence rate among runners with a younger age of onset. The etiology of plantar fasciitis is poorly understood and may be multifactorial in nature. Contributing risk factors may include obesity, prolonged standing or activity, flat feet, and reduced ankle dorsiflexion. Plantar fasciitis has been reported in association with fluoride use for the treatment of osteoporosis. Differential sources of foot and heel pain may include Achilles tendinopathy, stress fractures due to osteoporosis, rheumatoid arthritis, peripheral neuropathies associated with diabetes, extrinsic factors (eg, inappropriate footwear), aging, and structural disorders.

Lateral Epicondylitis
Lateral epicondylitis, also known as tennis elbow, represents chronic tendinosis of the myotendinous group of the lateral epicondyle characterized by pain and disability. The incidence in the general population may approach 1 to 3 percent. Risk factors include smoking, obesity, forceful activity, and repetitive activity for at least two hours daily. Lateral epicondylitis is characterized by injury to the extensor carpi radialis brevis or extensor digitorum communis muscles. The condition is diagnosed through findings of localized tenderness and pain with clinical examination. Initial conservative management includes modification of activity and biomechanics, counterforce bracing or splinting, nonsteroidal anti-inflammatory drugs, and physical therapy. Surgical referral is typically reserved for patients with severe symptoms that do not improve despite compliance with an appropriately designed physical therapy program for at least six months.

Regulatory Status
In 2014,the TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch, an electrosurgical cutting and coagulation device (ArthroCare Corporation, K140521), was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, on the basis of an earlier predicate device (ArthroCare Topaz Wand, K080282, 2008). The surgical wands are indicated for debridement, resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures, including fasciotomy, synovectomy, tenotomy, and capsulotomy of the foot and tenotomy of the knee, wrist, elbow, ankle, shoulder, and rotator cuff.

For individuals with plantar fasciitis who receive RF coblation tenotomy, the evidence includes nonrandomized, comparative cohort studies and case series. The relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. The trials reported improved pain and functional scores over 3-12 months, with improved outcomes with open vs percutaneous approaches. However, open RF coblation microtenotomy was associated with a higher incidence of postoperative persistent pain (9.1%) compared to endoscopic plantar fasciotomy (0%) in one study, with a separate study reporting a complication rate of 33% when both interventions were used in combination. A higher number of postoperative pain recurrences at 6 and 12 months were also reported with open RF coblation microtenotomy compared to endoscopic plantar fasciotomy. The durability of this intervention is unknown as no studies have reported long-term outcomes beyond 12 months. Studies are limited by small sample sizes, heterogeneity in surgical technique (open, percutaneous, endoscopic), missing data and/or inappropriate exclusions, lack of randomization, unclear blinding practices for patient outcome assessments, and poor statistical reporting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with lateral epicondylitis who receive RF coblation tenotomy, the evidence includes small randomized controlled trials (RCTs). The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trials compared RF microtenotomy to open or arthroscopic elbow release surgery. Clinically meaningful improvements in pain and functional scores were noted for all treatment arms, with no significant differences between groups through one to seven years of follow-up. For disability assessments in one study, open release surgery met the threshold for a clinically meaningful improvement over RF microtenotomy at one year, though this mean difference was not statistically significant. Studies were generally underpowered or demonstrated inconsistent delivery and unclear blinding of outcome assessments and inappropriate handling of missing or crossover data. No studies featuring RF coblation tenotomy for the treatment of wrist tendinopathy were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Achilles tendinopathy who receive RF coblation tenotomy, the evidence includes a small, single-blinded RCT. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trial did not demonstrate an added benefit for RF microdebridement compared to surgical decompression. Pain and functional outcomes improved in both groups but were not statistically different at a six month follow-up. The study was limited by a control group that showed significantly less severe symptom scores at baseline that did not fully meet the two point threshold for a clinically meaningful difference in pain score reduction. Larger, adequately controlled studies with longer follow-up durations are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with shoulder or rotator cuff tendinopathy who receive RF coblation tenotomy, the evidence includes small RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Trials did not demonstrate an added benefit for RF microdebridement compared to arthroscopic subacromial decompression surgery. Pain and functional outcomes improved in both groups

but were not statistically different through one to two years follow-up. Neither study prespecified a clinically meaningful difference in outcome measures nor were harms assessed throughout their course. The loss to follow-up in 1 study was 18.7%. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with patellar tendinopathy who receive radiofrequency coblation tenotomy, the evidence includes one small RCT. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trial did not demonstrate an added benefit for RF microdebridement compared to mechanical debridement in patients with chondral lesions and patellar tendinopathy. The study lacked reporting with validated pain measures over time and reported a higher incidence of crepitus in patients undergoing RF microdebridement. Furthermore, the study only enrolled female participants, limiting the broader applicability of these findings. Larger studies with validated pain and functional outcome measures are required to adequately assess the technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and Commercial Products

There is not a specific code for this service. Claims must be filed with an unlisted CPT code.

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, April 2020

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