Medical Coverage Policy

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Miscellaneous Musculoskeletal Procedures

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Overview

This Coverage Policy addresses miscellaneous musculoskeletal procedures, including but not limited to articular cartilage repair (other than the knee joint), ligament/meniscus reconstruction, and intra-articular joint injections.

Coverage Policy

Articular Cartilage Repair

Each of the following procedures* is considered not medically necessary for treatment of articular cartilage defects involving joints other than the distal femur and patellar articular cartilage within the knee (e.g., ankle, elbow, shoulder):

- autologous chondrocyte implantation (e.g., Carticel®, MACI® [Vericel Corporation, Cambridge, MA])
- osteochondral allograft transplantation
- osteochondral autograft transplantation

  ***Note**: Please reference the Cigna Medical Coverage Policy - "Knee Surgery: Arthroscopic and Open Procedures" for medical necessity criteria for treatment of articular cartilage defects within the knee.

Articular cartilage repair using ANY of the following, for any joint, is considered experimental, investigational or unproven:

- cartilage regeneration membrane (e.g., Chondro Gide®)
- xenograft implantation into the articular surface
- synthetic resorbable polymers (e.g., PolyGraft™ BGS, TruFit® [cylindrical plug], TruGraft™ [granules])
- juvenile cartilage allograft tissue implantation, including minced cartilage (e.g., DeNovo® NT Natural Tissue Graft, DeNovo® ET™ Engineered Tissue Graft [ISTO Technologies, Inc., St. Louis, MO / Zimmer, Inc., Warsaw IN]; BioCartilage® [Arthrex, Naples, Florida])
- decellularized osteochondral allograft implant (e.g., Chondrofix® Osteochondral Allograft [Zimmer Biomet, Warsaw, IN])

Ligament/Meniscus Reconstruction

Ligament allograft (e.g., anterior cruciate ligament allograft) materials are considered medically necessary when medical necessity has been met for the associated primary procedure*.

  ***Note:** Please reference the Cigna Medical Coverage Policy – "Knee Surgery: Arthroscopic and Open Procedures" for conditions of coverage for primary procedures.

The following are each considered experimental, investigational or unproven when used alone or as part of a ligament or meniscus reconstruction, regeneration, or transplantation:

- bioactive scaffolds (e.g., collagen meniscal implants)
- bioresorbable porous polyurethane scaffold (e.g., meniscus implant)
- meniscal prosthesis
- tissue-engineered menisci
- xenografts

Intra-articular Joint Injections
Intra-articular corticosteroid injections for the treatment of chronic, osteoarthritic joint pain are not covered or reimbursable when administered at an interval more frequent than EITHER of the following:

- four injections during a rolling 12 month year
- two injections on the same day

Healing Response Technique
Healing response microfracture technique for treatment of intra-articular ligament injury is considered experimental, investigational, or unproven.

Subchondroplasty
Subchondroplasty for the treatment of a subchondral bone defect (e.g., ankle, shoulder, hip, knee, toe) is considered experimental investigational or unproven.

Subacromial Balloon Spacer
Implantation of a subacromial balloon spacer for treatment of a massive/irreparable rotator cuff tear is considered experimental, investigational or unproven.

In-Office Diagnostic Arthroscopy
In-office diagnostic arthroscopy (e.g., Mi-Eye2™, VisionScope®) of any upper or lower extremity joint for evaluation of joint pain and/or pathology is considered experimental, investigational or unproven.

Percutaneous Ultrasonic Ablation of Soft Tissue
Percutaneous ablation of soft tissue for treatment of any musculoskeletal condition (e.g., tendinosis, tendinopathy) is considered experimental, investigational or unproven.

Miscellaneous Procedures

The use of a medial knee implanted shock absorber (e.g., MISHA™ Knee System) for any indication, including the management of osteoarthritis, is considered experimental, investigational or unproven.

General Background

Articular Cartilage Repair
Autologous chondrocyte implantation (ACI), also referred to as autologous chondrocyte transplantation (ACT), utilizes a person's own cells in an effort to repair damage to articular cartilage with the goal of improving joint function and reducing pain. The procedure involves the collection and culture of articular cartilage cells (i.e., chondrocytes) that are then implanted into the cartilage defect with the intent that the cultured cells will contribute to the regeneration and repair of the articular surface.

Normal articular cartilage is a complex tissue composed of matrix, chondrocytes, and water. The chondrocytes are responsible for synthesizing the matrix, which is composed primarily of collagen fibers, hyaluronate, and sulfated proteoglycans. Cartilage has a poor intrinsic ability to heal itself. When a full-thickness cartilage injury occurs, the articular surface does not usually regenerate on its own. Pain, effusion, and mechanical symptoms are associated with cartilaginous defects.

According to the American Academy of Orthopaedic Surgeons (AAOS), two procedures commonly used to restore articular cartilage include autologous chondrocyte implantation and osteochondral autograft/allograft transplantation (AAOS, 2021).

Autologous Chondrocyte Repair
Autologous chondrocyte implantation (ACI), a type of tissue engineering, is proposed as surgical treatment for individuals with deep cartilage defects in the knee and involves replacing the defective cartilage with cultured chondrocytes that will produce articular cartilage similar in composition and properties to the original tissue. Based on the available evidence, guidelines, and FDA indications for use, ACI should be limited to use as a second-line treatment for carefully selected symptomatic individuals with defects of the femoral condyle caused by acute or repetitive trauma who have had an inadequate response to prior arthroscopic or other surgical repair.

U.S. Food and Drug Administration (FDA): Until recently, Carticel® (Vericel Corporation, Cambridge, MA) was the only technology that received FDA approval for the culturing of chondrocytes. In December 2016, MACI® (autologous cultured chondrocytes on porcine collagen membrane) (Vericel Corporation, Cambridge, MA) received approval from the U.S. Food and Drug Administration as an autologous cellularized scaffold indicated for repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults. The safety and effectiveness of MACI Implant in joints other than the knee and in individuals over age 55 has not been established.

Literature Review: Although there is sufficient evidence to support improved clinical outcomes using ACI for a subset of individuals with articular cartilage defects of the knee joint, evidence in the medical literature is insufficient to support the use of ACI for articular cartilage lesions of other joints, including but not limited to the tibia, ankle, hip or shoulder. In addition, the published evidence does not support clinical utility for the treatment of generalized osteoarthritis (Washington State Health Care Authority, 2018).

Cartilage Regeneration Techniques Using Collagen Membrane (Chondro Gide®, Geistlich Pharma, Switzerland)
Chondro Gide® (Geistlich Pharma, Switzerland), is an acellular collagen I/III membrane that may be combined with ACI or used alone as part of autologous matrix-induced chondrocyte (AMIC) implantation for treatment of articular cartilage defects involving the hip, knee, or ankle. AMIC involves curettage and debridement of nonviable tissue, microfracture of the subchondral bone (marrow stimulation), and application of the acellular collagen I/III membrane into the lesion, which is then secured with either a fibrin glue or sutures. It may be performed using an open or arthroscopic approach. In contrast to MACI, autologous matrix induced chondrogenesis does not involve the use of autologous articular chondrocytes and is purported as being an alternative to MACI for medium sized defects. However, according to the manufacturer it may also be used in combination with ACI. In regard to regeneration of cells, theoretically the membrane provides a protective shell which can stimulate the growth of new cells and over time form hyaline-like cartilage. Chondro Gide is available in Europe for use however the U.S. FDA has granted Breakthrough Device Designation (BDD) for Chondro Gide®. According to the FDA, BDD is intended to expedite device development but preserves statutory standards for approval.

Evidence in the medical literature illustrates Chondro Gide is being evaluated for safety and efficacy. However, reported outcomes are mixed. Gao et al. published a systematic review evaluating AMIC for treatment of focal chondral defects (2019). A total of 28 studies met inclusion criteria; 12 studies (n=245) involved knee cartilage defects, 12 studies (n=214) involved ankle defects, and four studies (n=308) involved defects of the acetabulum and femoral head. Thirteen studies evaluated only AMIC, 11 studies evaluated AMIC combined with other materials or procedures, and three compared AMIC with microfracture. Using the Coleman Methodology Score (CMS) (range of 0-100) the authors concluded there is a paucity of high-quality studies comparing AMIC with established microfracture or ACI methods for treatment of chondral defects of the knee (57.8), ankle (55.3) and hip (57.7). One study involving the knee reported significant clinical improvement for a medium sized defect compared with microfracture after five years; no study compared AMIC versus microfracture or ACI in the ankle; one study compared AMIC with microfracture of the hip, and one study found no significant difference between AMIC and ACI at five years. Limitations of the systematic review include lack of comparative and high-quality study design, lack of comparative outcomes and overall effect on cartilage defects. In the authors opinion the evidence was insufficient to recommend joint specific indications for AMIC.

Additional evidence in the medical literature evaluating talus lesions consist mainly of retrospective and prospective case series (Ayyaswamy, et al., 2021; Gotze, et al., 2020; Baumfeld, et al., 2018; Usuelli, et al., 2018; Gottschalk, et al., 2017). Outcomes within these trials were measured using various methods such as American Orthopaedic Foot & Ankle Society (AOFAS) scores, visual analog scale (VAS), Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) for repair of cartilage, and Foot and Ankle Activity scores. Lesion size and depth varied among study groups. In general, results of the studies lend some support to improved function, pain and radiological healing at 12-24 month follow-up with low complication rates, however limitations of these studies include small sample size, lack of comparative groups, and lack of long term outcomes. One group of authors reported the results of a comparative trial evaluating arthroscopic microfracture (n=16) versus AMIC (n=16) as treatment of osteochondral lesions of the talus (Becher, et al., 2019). All subjects had a minimum follow-up of five years or more. Both groups showed statistically significant improvements postoperatively in Hannover Scoring System for ankle, (HSS), VAS scales for pain, function and satisfaction when compared with preoperative baseline scores. However, no significant differences were noted in scores between groups. Additionally, postoperative MRI demonstrated regeneration of tissue in the treated area, also without differences between groups. The authors concluded both groups had good clinical outcomes but added the collagen did not appear worthwhile.

Osteochondral Autograft
Osteochondral autologous transplant involves the placement of viable hyaline cartilage grafts obtained from the individual into a cartilage defect. The grafts are harvested from a non-weight-bearing region of the joint during an open or arthroscopic procedure and then transplanted into a cartilage defect to restore the articular surface of the bone. Osteochondral autologous transfers are performed mainly to treat small and medium-size focal chondral and osteochondral defects of the weight-bearing surfaces of the knee joint (i.e., distal femur) but have also been used in the ankle, patella, elbow and tibia. The most common donor sites, whether the recipient site is in the knee or another joint, are the medial and lateral trochlea and the intercondylar notch.

The advantages of using autograft include graft availability, the absence of possible disease transmission risk, and that the procedure is a single-stage procedure. Disadvantages reported include donor site morbidity and limited available graft volume. In addition, tissue may have to be harvested from two different donor sites in order to provide enough material for a large defect without compromising the donor site.

There are two forms of osteochondral autografting addressed in the medical literature: mosaicplasty and the osteochondral autograft transplantation system (OATS) procedure.

The mosaicplasty procedure consists of harvesting cylindrical bone-cartilage grafts and transplanting them into focal chondral or osteochondral defects in the knee. A recipient tunnel is created and sized with a drill bit slightly larger than the length of the graft. The harvested graft is placed in the tunnel by a press-fit method. All subsequent grafts are inserted in a similar pattern. Donor sites are routinely left open and fill with cancellous bone and fibrocartilage within 4–8 weeks.

The OATS procedure is similar to mosaicplasty, involving the use of a larger, single plug that fills an entire defect. It is often performed to graft chondral defects that are also associated with anterior cruciate ligament (ACL) tears. Increased donor-site morbidity has been reported by some authors with the use of larger, single plugs.

Ankle: Older patients and those with severe arthritis or large lesions of the ankle generally undergo ankle fusion or replacement as standard treatment. Ankle replacement has not been successful in many patients, and ankle fusion, while associated with pain relief, may result in functional limitations. Osteochondral autografting has been proposed as an alternative method of treatment for individuals with lesions of the ankle. Although patient selection criteria are not clearly defined, osteochondral autograft of the talus has been recommended for individuals with advanced disease, continued pain and decreased function despite prior conservative management and/or prior arthroscopic procedures, and who are not considered candidates for ankle arthrodesis. Proponents additionally recommend absence of ankle arthritis, infection, bipolar lesions and/or diffuse osteonecrosis of the talar dome.

Preliminary clinical trials demonstrated encouraging results for patients who underwent osteochondral autograft transplant for treatment of symptomatic osteochondral defects of the talus (Al Shaihk, et al., 2002; Hangody, et al., 2001; Mendicino, et al., 2001). Despite these early results, it has been noted in the medical literature that there are some challenges with this method of treatment. Reported concerns include the differences in the characteristics between knee and ankle cartilage, associated donor site morbidity, and complications which may arise from medial and lateral osteotomies (Easley and Scranton, 2003).

Evidence evaluating use of osteochondral autografting in the ankle is primarily limited to retrospective and prospective case series, few randomized controlled trials, nonrandomized controlled trials and registry data, mainly involving small patient populations and outcomes extending one to two years on average (Migliorini, et al. 2022; Bai, et al., 2020; Sabaghhzadeh, et al., 2020; Georgiannos, et al., 2014; Hayes, 2014; Yoon, et al., 2014; Emre, et al., 2012; Paul, et al., 2012; Berlet, et al., 2011; Imhoff, et al., 2011; Zengerink, et al., 2010; Reddy, et al., 2007; Saxena and Elkin, 2007; Gobbi, et al., 2006; Scranton, et al., 2006; Baltzer and Arnold, 2005; Giannini, et al., 2005; Kolker, et al., 2004; Kruez, et al., 2005). The evidence base is not as robust when compared to that evaluating the knee, although reported clinical outcomes extend short to long-term; range of one to eight years post-operatively. In general, the clinical outcomes have been mixed regarding improvement in postoperative pain and function, with some authors reporting high failure rates and the need for further surgery.

Elbow: There is insufficient evidence in the peer-reviewed, published scientific literature evaluating the use of osteochondral autograft transplantation to treat lesions of the elbow. Many of the trials consist of small patient populations, lack control or comparative groups, and evaluate short-term outcomes (Ayzenberg, et al., 2021; Shimada, et al., 2012; Oveson, et al., 2011; Ansah, et al., 2007; Iwasaki, et al., 2006; Yamamoto, et al., 2006; Shimada, et al., 2005; Tsuda, et al., 2005). Mid to long-term outcomes have been reported (Vogt, et al, 2011), however the

sample population of this trial were small and the study was not designed to be comparative. The results of some studies demonstrate improved pain scores in addition to radiograph confirmation of graft incorporation (Shimada, et al., 2005; Iwasaki, et al., 2006; Ansah, et al., 2007; Iwasaki, et al., 2009, Shimada, et al, 2012; Ayzenberg, et al., 2021). Few studies reported that radiographs showed no signs of degenerative changes or osteoarthritis at follow-up (Ansah, et al., 2007). de Graaf et al. (2011) conducted a systematic review of articles (case series) evaluating osteochondral autograft for treatment for osteochondritis dissecans of the elbow and reported the quality of the evidence was methodologically poor. The outcomes reported regarding pain, return to sports and elbow function were satisfactory however the authors noted further long-term clinical trials supporting efficacy are needed. Bexkens et al. (2017) conducted a systematic review of the literature (n=11 studies, 190 subjects) to evaluate donor site morbidity after OATS for capitellar osteochondritis dissecans. Grafts were harvested from either the femoral condyle or the costal-osteochondral junction. The authors concluded donor site morbidity occurred in a considerable group of subjects, in 7.8% after harvesting from the femoral condyle and 1.6% after harvesting from the costal-osteochondral junction. Larger clinical trials evaluating long-term outcomes compared to conventional methods of treatment are needed to support widespread use of this procedure.

Shoulder: Focal osteochondral lesions of the shoulder are less common than those of the knee or ankle. Although evidence is limited, authors have reported on osteochondral autologous transplant as a method of treatment for full-thickness osteochondral lesions of the shoulder. Evidence consists primarily of case reports and small case series evaluating outcomes that, on average, extend two to four years (Park, et al., 2006; Schiebel, et al., 2004). One group of authors (Kircher, et al., 2009) reported results at a mean follow-up of 8.75 years for a group of seven individuals; (short-term results for this same group were previously reported by Schiebel, et al., 2004). The authors noted that there was no deterioration and no complications. Arthritis of the shoulder developed in all patients although findings were not matched by functional restriction, pain or loss of patient satisfaction. The authors acknowledged further studies are needed evaluating long term outcomes and comparing results of other bone-stimulation techniques. At present, there is insufficient data to support the efficacy of osteochondral autograft transplant for the shoulder.

Osteochondral Allograft
The use of allograft cartilage has the advantage of providing osteochondral segments that are able to survive transplant, having the ability to heal to recipient-site tissue, and no associated donor site morbidity. Small grafts have been used for damaged regions of articular cartilage in young, physically active patients.

Allograft size is not well delineated in the medical literature. Osteochondral allografts can be either dowel grafts (i.e., cylindrical) or shell grafts (i.e., noncylindrical). Dowel grafts are inserted by press fit and are similar to the OATS procedure. Shell grafts are not limited by size or shape, are formed to match the size or contour of the defect and require supplemental fixation. Sizing of allografts can be difficult although some authors recommend using allografts for defects greater than 2.5 cm (Caldwell and Shelton, 2005). Furthermore, while surgeons generally restrict the use of autografts to lesions less than 2 cm, dowel grafts may be applicable to lesions up to 35 mm. Some surgeons have used allografts to treat lesions that are 1 cm^2, although many experts suggest lesion size of 2–3 cm^2 or greater (Alford and Cole, 2005).

To ensure cellular viability, osteochondral allografts are generally implanted fresh. The osteochondral allograft procedure typically involves an arthrotomy incision rather than arthroscopic, with the transplantation of a piece of articular cartilage and attached chondrocytes from a cadaver donor to the damaged region of the articular surface of the joint. Cryopreservation often damages the cartilage matrix and kills the chondrocytes. Chondrofix® (Zimmer Biomet,

Warsaw, IN) is an osteochondral allograft composed of decellularized hyaline cartilage and cancellous bone. Chondrofix is a donated human tissue graft regulated by the FDA which undergoes proprietary processing to remove lipids and decontaminate the tissue, preserving hyaline cartilage (Farr, et al., 2016; Gomoll, 2013). The allograft material can be used off-the-shelf, can be stored up to 24 months at less than 40 degrees C, and is not to be frozen. Purportedly Chondrofix offers structural and osteoconductivity benefits similar to an OATS procedure, removes associated donor site morbidity and eliminates wait time for a fresh allograft (Degen, et al., 2016). Evidence in the peer-reviewed published scientific literature evaluating decellularized cartilage for treatment of osteochondral cartilage defects is limited. Farr et al. (2016) reported the results of a retrospective case series (n=32) evaluating the use of decellularized allograft for treatment of osteochondral cartilage defects. The authors reported failure in 72% of the subjects (n=23) within two years of implantation. Failure was defined as structural damage to the allograft plug using MRI or arthroscopic evaluation demonstrating evidence of subchondral collapse or loss of > 50% of the articular cartilage cap of a plug. Whether or not implantation of decellularized cartilage promotes cell remodeling and repair has not been firmly established in the published scientific literature.

Evidence in the published scientific literature evaluating allograft transplant primarily addresses defects of the knee and ankle, is limited, and evaluates short to intermediate-term outcomes. Authors have reported that treatment of talus lesions is technically challenging but may allow patient's avoidance of other end-stage procedures, similar to indications for osteochondral autografts. Allograft of the talus however is generally reserved for larger extensive lesions and/or when autograft is not available. Evidence regarding defects of other joints (e.g., elbow, shoulder) is also limited and does not allow strong conclusions regarding the efficacy of the procedure.

Ankle: Evidence in the published medical literature evaluating allografts as a method of treatment for osteochondral lesions of the ankle illustrates inconsistent outcomes. Data from well-designed controlled clinical trials that compare osteochondral allografting of the ankle with accepted standards of care (i.e., ankle fusion, ankle arthroplasty) are lacking. Many of the studies are retrospective or prospective case series involving small patient populations and lack controls (Fletcher, et al., 2022; Adams, et al., 2018; Galli, et al., 2014; Haene, et al., 2012; Adams, et al., 2011; Gortz, et al., 2010; Hahn, et al., 2010; Valderrabano, et al., 2009; Jeng, et al., 2008; Meehan, et al., 2005; Tontz, et al., 2003; Kim, et al., 2002; Gross, et al., 2001). Some authors have reported clinical outcomes extending as long as 12 years (Kim, et al., 2002; Gross, et al., 2001) but in general follow-up extends on average to two years. Some studies have demonstrated a trend toward short-term improvement in pain and function, however high failure rates have also been reported (Bugbee, et al., 2013; Haene, et al., 2012; Jeng, et al., 2008; Kim, et al., 2002). Few studies reporting long term clinical outcomes are available.

In 2022 a group of authors published the results of a systematic review and meta-analysis evaluating allograft versus autograft osteochondral transplant of the talus to determine if results were equivalent (Migliorini, et al., 2022). The review included a total of 40 studies evaluating 1174 procedures (219 allograft versus 955 autograft); the main outcomes of interest were visual analog scale (VAS) score for pain, American Orthopaedic Foot and Ankle Society (AOFAS) score, and Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) score. Data concerning the rates of failure and revision surgery were also collected and reported. The average follow-up was 46.5 ± 25 months. The authors reported that at the last follow-up, the MOCART (MD, 10.5; $p=0.04$) and AOFAS (MD, 4.8; $p=0.04$) scores were better in the autograft group, VAS scores were similar between the 2 groups ($p=0.4$), and the autograft group demonstrated a lower rate of revision surgery (OR, 7.2; $p<0.0001$) and failure rate (OR, 5.1; $p<0.0001$). The authors concluded osteochondral allograft of the talus had inferior outcomes when compared to autograft.

Pereira et al. (2021) published results of a systematic review evaluating clinical outcomes following fresh osteochondral allograft transplantation of the talus. Clinical outcomes, according to standardized scoring systems, such as the American Orthopaedics Foot & Ankle Society (AOFAS) Ankle/Hindfoot Scale and the Visual Analog Scale (VAS) were compared across studies. Included in the review were 12 studies with a mean Coleman Methodology Score of 68.1 (57-79; a score used to assess clinical studies for the influence of bias, confounding factors, and chance by use of sub-scores assigned to 10 specific criteria), each study was scored between 0 (lowest quality) and 100 (highest quality). A total of 191 patients were included with an average age of 37.5 (17-74) years and average follow-up of 56.8 (6-240) months. Lesion size was reported in 8 studies with a mean of a 2.0 cm^2 (range 1.2-3.8 cm^2), lesion location was medially in 74.2% of cases. Ten different outcome measures were reported in the 12 studies, six used AOFAS and five used VAS along with others. In six of the studies reviewed, the Ankle/Hindfoot scores were significantly improved ($p<0.05$). A total of 11 studies looked at radiographic results evaluating successful outcomes and postoperative degenerative changes. Seven reported looked at graft incorporation and reported 89.6% of grafts were fully incorporated; eight reported postoperative degenerative changes and noted that signs of degeneration were present in 47.6% of subjects. No complications were reported. The graft failure rate was 13.4%, and an overall aggregate rate for subsequent surgery of 21.6%, which most commonly was an arthroscopic debridement with hardware removal. Limitations of the review include small number of studies, lack of high quality evidence in the review, use of variable outcome measures obtained at different time-points and heterogenous reporting of data. Additional randomized controlled trials using validated outcomes scores are needed to firmly establish safety and effectiveness.

Clinical failure and reported reoperation rates are high. One group of authors (Valderrabano et al., 2009) reported the results of a case series (n=21) and acknowledged long-term clinical outcomes were moderate. At a mean of 72 months, 12 patients were available for follow-up—radiologically recurrent lesions were noted in 10 of 10 cases and in all 12 there was some degree of cartilage degeneration and discontinuity of the subchondral bone. Short-term subjective outcomes were reported as good to excellent. In 2013 Bugbee et al. published the results of a case series with mean follow-up of 5.3 years. Patients with intact grafts showed improvement in ankle pain and function in addition to high levels of satisfaction with the procedure at average follow-up of 5.3 years. However, 36 of 82 ankles (42%) required further surgical procedures after allograft transplantation. A total of 25 (29%) were defined as clinical failures; 10 underwent revision of the graft, seven underwent arthrodesis and two underwent amputation due to persistent pain. Radiographs categorized 29 (46%) as failures (>50% joint space narrowing) at 3.5 years mean follow-up. At five years and 10 years, survivorship of the graft was 76% and 44% respectively. The authors acknowledged their reoperation and revision rates were higher than those reported for ankle arthrodesis or arthroplasty (Bugbee, et al., 2013). VanTienderen et al. (2017) published the results of a systematic review evaluating functional outcomes, complications and reoperation rates following osteochondral allograft of the talus. Five studies were included involving 91 lesions. At a mean follow-up of 45 months AOFAS scores improved, Pain VAS scores improved, and 25% of subjects required at least one reoperation. Reasons for reoperation included development of moderate to severe osteoarthritis, pain due to hardware, extensive graft collapse, and delayed or nonunion at osteotomy site. Twelve of the cases were considered failures.

In general, reported complications associated with allograft transplant of osteochondral ankle lesions include graft fracture, graft fragmentation, poor graft fit, graft subluxation, and non-union. Patients with unsuccessful outcomes after allografting have required ankle fusion or ankle arthroplasty (Jeng, et al., 2008; Gross, et al., 2001). As a result of these and other limitations of the medical literature, accurate conclusions cannot be made regarding the efficacy of osteochondral allografting for articular disorders of the ankle.

Professional Societies/Organizations: The American Orthopaedic Foot and Ankle Society (AOFAS, 2022) position statement supports osteochondral allograft and autograft transplantation for the treatment of osteochondral lesions of the talus when the individual has failed non-operative management, particularly for large diameter lesions, cystic lesions (i.e., cyst in subchondral bone), and lesions that have failed previous surgical treatment.

The Washington State Health Care Authority technology assessment program published a technology assessment evaluating Osteochondral Allograft/Autograft Transplantation and in 2018 re-evaluated the evidence. There was no change to the initial conclusion— there is insufficient evidence to support osteochondral allograft/autograft for joints other than the knee (Washington State Health Care Authority, 2018).

Osteochondral Xenograft
Xenografts for repair of osteochondral cartilage defects is being studied by some investigators as an alternative to osteochondral autografts and allografts. As a xenograft however, methods must be in place to prevent immunologic responses, including host rejection. As such, decellularization processes are in the early stages of investigation in order to remove antigens from the graft, which in theory would reduce rejection. Once decellularization methods are established, additional preclinical studies (e.g., nonhuman trials) will be necessary to establish evidence of safety and efficacy, followed by subsequent human clinical trials. Until such trials are conducted xenograft implantation into articular cartilage remains unproven.

Synthetic Resorbable Polymer for Osteochondral Defects
Synthetic bone void fillers can be categorized into ceramics, polymers and composites. Ceramics are osteoconductive and are composed of calcium; total degradation time depends on the composition. Composite grafts combine osteoconductive matrix with bioactive agents that provide osteoinductive and osteogenic properties. Polymers are osteoconductive and when used with marrow could provide a biodegradable osteoinductive implant for repairing large defects. Synthetic bone void fillers have been proposed by some researchers an alternative to allografting.

U.S. Food and Drug Administration (FDA): PolyGraft BGS (bone graft substitute), a resorbable bone void filler, was granted 510(k) marketing clearance by the FDA in 2003 as it was considered to be substantially equivalent to another device already on the market (i.e., Wright Plaster of Paris Pellets [K963562] and ProOsteon 500R [K980817]). The grafts are Class II devices intended for filling bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of bony structure.

Literature Review: Although synthetic resorbable polymers, such as PolyGraft, are available and have been proposed as bone graft substitute materials, human studies in the published scientific literature are limited and consist mainly of case reports and case series. Although some clinical outcomes are encouraging, poor clinical outcomes such as persistent pain, functional deficits and failure of graft incorporation have been reported and lend support to problems with biocompatibility when using synthetic implants for some individuals. Consequently, evidence in the medical literature is insufficient to support the potential value of synthetic resorbable polymers as an alternative to allograft or autograft for the repair of osteochondral defects.

Minced Juvenile Cartilage Allograft (DeNovo® NT Natural Tissue Graft; DeNovo® ET™ Engineered Tissue Graft [ISTO Technologies, Inc., St. Louis, MO, Zimmer, Inc., Warsaw IN])
Filling defects with minced articular cartilage (autologous or allogeneic), is a single-stage procedure that is being investigated for cartilage repair. DeNovo® NT Natural Tissue Graft is a juvenile cartilage allograft tissue intended for the repair of articular cartilage defects (e.g., knee, ankle, hip, shoulder, elbow, great toe). The DeNovo NT Graft consists of particulated natural

articular cartilage with living cells. Tissues are recovered from juvenile donor joints. The cartilage is manually minced to help with cell migration from the extracellular matrix and facilitate fixation. During implantation, the minced cartilage is mixed in a fibrin glue adhesive. According to the National Institutes of Health, studies are being conducted to evaluate long-term outcomes, including pain relief and improvement of function, for both knee and ankle cartilage repair.

DeNovo® ET™ Engineered Tissue Graft (i.e., RevaFlex™) is a scaffold free tissue-engineered juvenile cartilage graft proposed for the treatment of articular cartilage lesions. DeNovo ET uses juvenile articular cartilage cells applied to defects of the joint surface using a protein-based adhesive. Other cartilage matrices under investigation include the Cartilage Autograft Implantation System (CAIS, Johnson and Johnson, Phase III trial) that purportedly harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment and BioCartilage® (Arthrex, Naples, Florida) which consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture.

U.S. Food and Drug Administration (FDA): DeNovo NT is classified as minimally manipulated allograft tissue and is therefore not subject to the FDA premarket approval process. The FDA requires that the manufacturers of human allograft products be registered. Currently DeNovo NT is registered on the FDA's Human Cell and Tissue-Based Products (HCT/P) list. No listing could be found for DeNovo ET.

Literature Review: Evidence in the peer-reviewed published scientific literature is insufficient to support the safety and efficacy of DeNovo ET or DeNovo NT.

Professional Societies/Organizations: In 2022 the American Orthopaedic Foot and Ankle Society published a position statement regarding osteochondral transplantation for the treatment of osteochondral lesions of the talus. According to this position statement the AOFAS does not consider the procedure, using either autograft or allograft, experimental when the individual has failed non-operative management, particularly for large diameter lesions, cystic lesions (i.e., cyst in subchondral bone), and those that have failed previous surgical treatment.

Ligament/Meniscus Reconstruction

The use of adjunctive treatments such as autologous platelet-derived growth factors (e.g., centrifuged platelet aggregates) have been utilized to assist in healing of tissues, however, there is insufficient evidence in the medical literature at this time, in particular with ACL/PCL reconstruction using allograft tissue or meniscal transplant, to support any improvement in health outcomes with the use of these adjunctive treatments.

Meniscus Regeneration/Transplantation: The meniscus is a crescent-shaped wedge of fibrocartilage located in the knee joint between the femoral condyle and tibial plateau. Small meniscal tears can be sutured, however, management of more severe meniscal injury involves arthroscopic or open surgery, often with meniscal allograft transplant. Other options under investigation for meniscal regeneration and/or transplantation include tissue-engineered menisci, bioactive scaffolds (collagen meniscal implants, bioresorbable porous polyurethane), and synthetic devices (e.g., hydrogel). Collagen meniscal implants have been proposed by some authors for filling defects of partial meniscectomy with functional repair tissue. Authors hypothesize the collagen meniscal implant may help prevent or delay the progression of osteoarthritis, protecting from degenerative joint disease. In addition, xenografts and meniscal prostheses are under investigation for use as an alternative approach to meniscal allograft transplantation.

U.S. Food and Drug Administration (FDA): Menaflex™ (ReGen Biologics, Inc., Hackensack, NJ), was granted 510(k) clearance from the FDA in December 2008. Menaflex is a resorbable collagen matrix regulated by the FDA as a Class II device. The collagen scaffold is used to

reinforce weakened soft tissue and provide a resorbable scaffold that is replaced by the patient's own tissue. According to the FDA, the scaffold was approved for the reinforcement and repair of soft tissue injuries of the medial meniscus (FDA, 2008); the device was not cleared for use in lateral meniscal injuries. However, in 2010 the FDA announced that the Menaflex device should not have been cleared for marketing in the U.S. and implemented a rescission. A rescission is an action by the FDA to revoke a marketing clearance later determined to be erroneous. The FDA concluded that the Menaflex device is intended to be used for different purposes and is technologically different from predicate devices (i.e., devices already on the market); these differences can affect the safety and effectiveness of the device.

A polyurethane meniscus implant (PMI), Actifit®, a biodegradable meniscus polyurethane scaffold (Saratoga Partners, LLC formerly known as Orteq Sports Medicine Ltd.) has received FDA Breakthrough Designation, although an FDA approval was not found on the FDA site. This implant is a cell-free scaffold that is intended to promote regeneration of meniscal fibrocartilage by stimulating stromal cells from adjacent tissues, in articular synovium.

Literature Review: Evidence evaluating the safety and efficacy of collagen meniscal implants generally involve small patient populations. Some of the preliminary results were encouraging, suggesting meniscus regeneration occurs with an associated reduction in patient symptoms (Zaffagnini, et al., 2007). Results of a recent systematic review evaluating the clinical outcomes and failure rates of meniscal scaffolds demonstrated that there is insufficient evidence to suggest improvements in clinical outcomes, failure rates are high, and its use is not recommended (Kohli, et al., 2022). Another group of authors published a systematic review of in-vivo and clinical studies evaluating meniscal implants also concluded additional evidence is needed to support safety and efficacy. The two implants evaluated in the clinical trials of this review included a collagen meniscal implant (11 studies) and ActiFit® (19 studies). Following their review, the authors concluded that the overall quality of the available evidence is modest, that both scaffolds present limited regenerative potential associated to structural flaws, and that additional trials are necessary (Veronesi, et al., 2021).

Rodkey published results of a prospective randomized trial (n=311) in 2008 and demonstrated the use of a collagen meniscus implant appeared safe, supported new tissue ingrowth and improved clinical outcomes (e.g., pain scores, Lysholm scores and patient assessment scores) in patients with chronic meniscal injury at an average follow-up of 59 months. The authors noted that patients who received the implant regained significantly more of their lost activity when compared to a group of patients who underwent repeat partial meniscectomy (Rodkey, et al., 2008). A technology assessment conducted by the California Technology Assessment Forum (Tice, 2010) concluded that the collagen meniscal implant for irreparable medial meniscus injury did not meet CTAF technology assessment criterion. The published evidence did not support improvement in health outcomes or that clinical improvement was attainable outside of the investigational setting. Although promising, long-term data supporting safety, efficacy and improved clinical outcomes, including prevention of osteoarthritis, are not yet available to support widespread use of this bioactive scaffold for meniscal regeneration.

There is a paucity of evidence in the peer-reviewed published scientific literature evaluating meniscal scaffolds and implants (Veronesi, et al., 2021; Tice, 2010; Rodkey, et al., 2008; Zaffagnini, et al., 2007). For other emerging technologies, much of the evidence is in the form of animal, cadaveric or short-term clinical trials and does not support safety and efficacy. Additionally, there is no consensus opinion with regard to their widespread clinical application.

Intra-articular Joint Injections

Intra-articular joint injections are often indicated for the treatment of pain related to osteoarthritis when other conservative measures have failed. Osteoarthritis (OA) is the most common form of

arthritis, affecting just over 300 million people worldwide (Kolasinski, et al., 2020). A higher prevalence of knee osteoarthritis has been reported in Black individuals in comparison to White individuals, particularly women, although Black individuals and Whites have similar prevalence of hip osteoarthritis (Reyes and Katz, 2021).

Osteoarthritis is a leading cause of disability among older adults. The joints most often affected include the knee, hip, shoulder, hand, and spine. It is often described as involving the entire joint, and includes cartilage degradation, bone remodeling, osteophyte formation, and synovial inflammation, all of which may lead to pain, stiffness, swelling, and loss of normal joint function. Inflammatory arthritis includes conditions such as gout, lupus, psoriatic arthritis, and rheumatoid arthritis.

Management of arthritis includes multiple modalities, including exercise, weight management, braces/splints, thermal modalities and use of assistive devices (i.e., bracing, cane). Pharmacologic therapy includes analgesics, oral and topical nonsteroidal anti-inflammatory agents, opioids and intra-articular injections of steroids or hyaluronates. Although differences in use of exercise, use of nonsteroidal anti-inflammatory medications, and prescribing patterns of opioids by race and/or socioeconomic status has been reported, studies examining the differences in use of intra-articular steroid injection by race or socioeconomic status are limited (Reyes and Katz, 2021).

Intra-articular steroids work by reducing swelling within the joint thereby reducing pain and stiffness. For short term relief intra-articular steroids (with or without local anesthetic) are recommended for relief of pain in the hip or knee, while other injections, such as hyaluronic acid for the knee joint, may be recommended for long-term relief (e.g., > 12 weeks). For osteoarthritis affecting the hand there is less evidence to support use of intra-articular steroid injections, although it may be recommended for some individuals (e.g., painful interphalangeal joints). When considering subsequent injections, one should take into consideration whether there was a clinical benefit from the prior injection, other available treatment options, the type of medication and safety concerns, as well as the presence of comorbidities.

There is some concern that intra-articular steroids may result in joint damage (Charlesworth, et al., 2019, McAlindon, et al., 2017), consisting primarily of cartilage loss although damage can occur to tendons as well. Charlesworth et al. (2019) reported evidence suggesting that cortisone injections into the knee before surgery may increase the risk of subsequent infection in people who undergo total knee arthroplasty. Nevertheless, the long-term effects of intra-articular injections have not been well-studied, including the long-term impact and clinical significance of any potential cartilage loss.

Although commonly used in clinical practice there is little consensus regarding the number of injections that should be administered (Samuels, et al., 2021; Uson, et al., 2021) or any insight into a recommended schedule for repeat injections (Phillips, et al., 2021). It is however well established in the medical literature that relief is primarily short-term, generally lasting no more than 12 weeks (Degen, et al., 2022; National Institute for Health and Care Excellence [NICE], 2022; American Academy of Orthopaedic Surgeons [AAOS], 2021; Uson, et al., 2021). Although not based on robust research, generally accepted clinical practice suggests a steroid should not be injected into the same joint more than every three months. In addition, intra-articular injections are usually performed in a single joint; injecting more than two joints at a time is uncommon. Injecting several large joints simultaneously should be avoided due to the increased risk of hypothalamic-pituitary-adrenal suppression and other adverse effects which may occur.

Professional Societies/Organizations: Several professional society organizations support the use of intra-articular injections using corticosteroids as safe and temporarily efficacious, including the American Academy of Orthopaedic Surgeons (AAOS), the American College of Rheumatology,

the Royal Australia College of General Practitioners, Osteoarthritis Research Society International, and the Arthroscopy Association of Canada.

The Arthroscopy Association of Canada developed a consensus statement for "Intra-articular Injections for Hip Osteoarthritis" (Degen, et al., 2022). Within this consensus statement the authors reported that intra-articular corticosteroid injections are safe and effective at reducing pain and improving function for up to three months in patients with symptomatic hip osteoarthritis, with a low risk of adverse events." This recommendation is graded "Good-A" which is defined as "Good evidence (level 1 studies with consistent findings)".

In 2021 the AAOS published updated guidelines for non-surgical management of osteoarthritis of the knee, within these guidelines the AAOS notes that intra-articular corticosteroids could provide short-term relief for patients with symptomatic osteoarthritis of the knee, using a moderate recommendation. A total of 19 high quality and six moderate quality studies were reviewed that support the use of intra-articular injection; the duration of benefit generally lasted three months in the studies the AAOS reviewed. The "Moderate" strength recommendation is defined as "Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention."

The European Alliance of Associations for Rheumatology (EULAR) published evidence based guidelines for intra-articular therapy in 2021; within this guideline the authors concluded while there is no consensus, a general rule for frequency is for is 3-4 injections per joint per year (Uson, et al., 2021).

The American College of Rheumatology (Kolasinski, et al., 2020) published guidelines for the management of osteoarthritis of the hand, hip, and knee. Within these guidelines the authors reported that intraarticular glucocorticoid injections are strongly recommended for individuals with knee and/or hip osteoarthritis and conditionally recommended for patients with hand osteoarthritis. Trials of intraarticular glucocorticoid injections have demonstrated short-term efficacy in knee osteoarthritis. Intraarticular glucocorticoids injection is conditionally, rather than strongly, recommended for the hand given the lack of evidence specific to this anatomic location.

The Osteoarthritis Research Society International (OARSI) published updated guidelines in 2019 for non-surgical management of knee, hip and polyarticular osteoarthritis (Bannuru, et al., 2019). For knee osteoarthritis, the use of intra-articular corticosteroids was conditionally recommended, and a "Good Clinical Practice Statement" applying to intra-articular treatments for all comorbidity subgroups was added in the update, noting that intra-articular corticosteroids may provide short term pain relief, whereas intra-articular hyaluronic acid may have beneficial effects on pain at and beyond 12 weeks of treatment, and a more favorable long-term safety profile than repeated intra-articular corticosteroid injections.

Within a guideline for the "Management of Knee and Hip Osteoarthritis" published by the Royal Australia College of General Practitioners (RACGP, 2018), the authors provide a conditional recommendation for intra-articular corticosteroid injections and state that "It may be appropriate to offer an intra-articular corticosteroid injection for some people with knee and/or hip OA for short-term pain relief." They further state "clinicians need to be cautious of the potential harms of repeated use."

Healing Response (Microfracture) Technique

The Healing Response (Microfracture) Technique is a treatment method proposed for treatment of intra-articular ligament injuries that theoretically promotes vascularization by stimulating blood clot and subsequent scar formation. The technique has been utilized to assist in healing of tissues, for example with anterior cruciate ligament reconstruction. As part of an arthroscopic procedure

small microfracture holes are made in the bone where the ligament originates. The blood clot that forms theoretically captures the injured portion of the ligament and as it heals attaches it back to the bone.

Literature Review: There is insufficient evidence in the medical literature at this time, in particular with ACL/PCL reconstruction using allograft tissue or meniscal transplant, to support any improvement in health outcomes with the use of this adjunctive treatment.

Subchondroplasty

Subchondral bone refers to the epiphyseal bone directly below the articular cartilage. In general, treatment of a subchondral bone defect, such as a bone marrow lesion or edema, includes analgesics, unloader bracing, reduction in weight bearing, activity modification, and appropriate nutrition including additional calcium and vitamin D, if appropriate. Subchondroplasty is a procedure currently under investigation for treatment of nonhealing subchondral bone defects. Under fluoroscopic guidance, a bone void filler is injected into the region of the bone marrow lesion defect with the goal of improving the structural integrity of the damaged bone, until it is replaced by bone. The overall goal is to prevent bone collapse and osteoarthritic progression. There is a paucity of high quality evidence in the peer reviewed scientific literature; studies consist primarily of case reports and case series with an average follow-up of 12 months and involve small sample populations (Nairn, et al., 2021; Pasqualotto, et al., 2021; Krebs, et al., 2020; Astur, et al., 2019). Most of the evidence evaluates subchondroplasty for treatment of bone defects involving the knee; the evidence base is more limited for hip, shoulder, or ankle defects. Authors of a systematic review (Nairn, et al., 2021) concluded the evidence evaluating subchondroplasty for treatment of bone marrow lesions was low quality and lend some support to improvements in pain and function, however the results are short to medium term. The authors acknowledged high quality studies with long term outcomes are required to firmly establish efficacy. The current evidence is insufficient to support safety and efficacy of subchondroplasty, and the impact on net health outcomes has yet to be determined.

Percutaneous Ultrasonic Ablation

Percutaneous ultrasonic ablation is a minimally invasive surgical procedure proposed for the fragmentation, emulsification, and aspiration of soft tissue associated with various conditions, including chronic or degenerative conditions of the musculoskeletal system involving fascia or tendons of the ankle, foot, elbow, hip, knee, shoulder, or wrist. It is also referred to as percutaneous ultrasonic fasciotomy, or percutaneous ultrasonic tenotomy and combines the use of ultrasound and a minimally invasive needle-like probe that uses ultrasonic energy to visualize, cut and remove diseased or damaged tissue in individuals with tendinopathies. The procedure involves ultrasound to determine the location of degenerative tissue, insertion of a probe under guidance, which produces ultrasonic energy, and that theoretically breaks down the damaged tissue. At the same time, a built-in inflow-outflow fluid system simultaneously irrigates and sucks up the broken down/emulsified tissue. Once the tissue is cleared away, the probe is removed.

U.S. Food and Drug Administration (FDA): One system currently available is the Tenex Health TX System® (Tenex Health, Inc., Lake Forest, CA) which was granted marketing clearance by the FDA via the 510(k) process on March 3, 2016. This device is considered to be substantially equivalent to another device already on the market – the TX1 Tissue Removal System. Under the FDA 510(k) process, the manufacturer is not required to supply to the FDA evidence of the effectiveness prior to marketing the device. The system consists of a console that houses user functions (e.g., irrigation and aspiration pumps), ultrasonic hand piece, inflation cuff, and foot pedal which controls the device functions. The FDA states that the Tenex Health TX System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including general surgery, orthopedic surgery, laparoscopic surgery and plastic and reconstructive surgery (FDA, 2016).

Literature Review: There is a paucity of evidence evaluating safety and efficacy of percutaneous ultrasonic ablation for musculoskeletal conditions and is primarily in the form of case reports, case series and a systematic review. Vajapey et al. (2021) examined data published on percutaneous ultrasonic tenotomy for treatment of tendinosis. Included in their review were seven studies, five evaluating elbow tendinopathy, and one study each evaluating Achilles tendinopathy and plantar fasciitis. Three studies were retrospective, four were prospective, all were case series with no control, average follow-up ranged from 12 to 36 months and sample populations ranged from seven to 34. Regarding treatment of chronic epicondylosis of the elbow, VAS and DASH scores improved at one year post treatment when compared with baseline, and subjects with refractory tendinopathies also experienced improved functional scores one year post treatment. The authors of the study evaluating Achilles reported that of the 34 subjects, four were pain free at follow-up (11-36 months), 13 had mild pain, two had moderate pain, one had severe pain, and the rest were lost to follow-up. Authors of the study group evaluating treatment for plantar fasciitis reported that 11/12 subjects had complete pain relief three months post treatment. The review is limited by small number of studies, short-term follow-up across all studies, and some with high loss to follow-up. As a result of insufficient high quality evidence strong conclusions regarding safety and efficacy cannot be made and additional research is needed.

Subacromial Balloon Spacer Implantation
Surgical repair of a massive or irreparable rotator cuff tear is a technically challenging procedure and associated with high rates of failure, and there is no consensus regarding optimal management. Conventional treatment options, some less complex, include arthroscopic debridement, subacromial decompression, partial cuff repair, tendon transfers, superior capsular reconstruction, biceps tenotomy, and reverse shoulder arthroplasty (Wright, et al, 2020; Stewart, et al., 2019). An emerging treatment modality is the use of a biodegradable balloon system arthroscopically inserted through a lateral portal. The device acts as a physical barrier to decrease subacromial friction and theoretically restore proper shoulder biomechanics by lowering the humeral head closer to its anatomic position against the glenoid cavity during dynamic movements (Stewart, et al., 2019).

One device that is currently available is the InSpace™ Subacromial Tissue Spacer System (Stryker Corp., Kalamazoo, MI). This device is indicated for the treatment of patients with massive, irreparable full-thickness torn rotator cuff tendons due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age whose clinical conditions would benefit from a treatment with a shorter surgical time compared to partial rotator cuff repair. The FDA granted a DeNovo request in 2020; the device is currently assigned a Class II classification with special controls.

InSpace is designed to restore shoulder function and reduce pain and is a biodegradable implantable balloon (spacer) used to reduce friction between the acromion and the humeral head or rotator cuff to allow smooth gliding of the humeral head against the acromion. The balloon may be inserted arthroscopically or by using a mini-open procedure. Implantation of the biodegradable subacromial spacer insertion is performed with the individual under general or regional anesthesia. The subacromial space is visualized using either arthroscopy or minimal access open surgery. A surgical clearance of the damaged area is carried out. Measurements are made to determine the required size of the biodegradable spacer. The balloon-like spacer is then inserted into the subacromial space and inflated with saline solution. Once sufficient volume is reached, the balloon is sealed and left in situ. According to the manufacturer the balloon spacer is made from a biodegradable polymer and resorbs over a period of about one year.

Literature Review: Evidence in the peer reviewed scientific literature remains insufficient to support the safety and efficacy of a subacromial balloon spacer such as the Stryker's InSpace™

Subacromial Tissue Spacer System for the treatment of rotator cuff tears. There is a lack of well-designed studies reporting long term follow-up for this implant and much of the evidence involves small sample populations, lack controls, and are primarily in the form of case reports and case series, with few randomized controlled trials (RCTs) and meta-analyses (Berk, et al., 2023; Bilsel, et al., 2022; Metcalfe, et al., 2022; Moreno, et al., 2022; Verma, et al., 2022; Familiari, et al., 2021; Kucirek, et al., 2021; Liu, et al., 2021; Piekaar, et al., 2020; Wright, et al., 2020; Stewart, et al., 2019; Maman, et al., 2017; Senokovic, et al., 2017). Outcomes on average extend one to three years; one study reported outcomes to five years although it was a small sample population (Senokovic, et al., 2017). Within this study, which was a prospective pilot trial involving 24 subjects who underwent subacromial implantation with the InSpace™ biodegradable spacer, the overall dropout rate was 37.5%. Of the participating subjects who reached a five year follow-up, 84.6% showed a clinically significant improvement of at least 15 points using the Total Constant Score (TCS) for shoulder function, 61.54% showed at least 25 point improvement, and only 10% showed no improvement or worsening in the shoulder score compared to baseline. Limitations of the trial include small sample population and lack of control group.

Verma et al. (2022) published the results of an industry sponsored, single-blinded, multicenter RCT to evaluate the safety and efficacy of the InSpace™ implant compared with arthroscopic partial repair of irreparable posterosuperior massive rotator cuff tears. The study group included 184 subjects who were randomized intraoperatively to either the InSpace™ group (n=93) or the partial repair group (n=91). Subjects were followed for 24 months using American Shoulder and Elbow scores (ASES), Western Ontario Rotator Cuff score (WORC), visual analogue (VAS), Constant Murley Shoulder score (CMS), and Euro Qual-5 Dimensions 5-level (EQ-5D-5L) scores. A total of 10 subjects in the InSpace™ group and 12 subjects in the partial repair were lost to follow-up. There was no significant difference in VAS, EQ-5D-5L or CMS score at any postoperative timepoint between groups. At 24 months functional and patient reported outcomes were comparable in both groups. At day 10, week 6, month 12 and month 24 forward elevation was significantly greater in the InSpace group compared with the repair group. There was a total of four reoperations in the InSpace group compared with three in the partial repair group and no device related complications. The authors concluded use of the balloon spacer was noninferior when compared to partial repair. Although the study presented results on intermediate-term follow-up at two years, longer-term follow-up is needed to examine the duration of benefit. Limitations noted by the authors include lack of standardization of concomitant procedures and repair techniques, and lack of blinding of physical examiners which may introduce bias.

Metcalfe and associates (2022) reported the results of a double blind, multicenter RCT (STARTS: REACT trial) comparing arthroscopic debridement with biceps tenotomy with the same procedure but including the InSpace implant as treatment of irreparable massive rotator cuff tear. Inclusion criteria consisted of a rotator cuff tear with intrusive symptoms, failed conservative management, and a tear that was irreparable. Exclusion criteria were based on current clinical use and manufacturer’s recommendations (advance shoulder osteoarthritis, subscapularis deficiency, pseudoparalysis, an unrelated ipsilateral shoulder disorder, interfering neurological or neuromuscular conditions). Subjects were randomized intraoperatively in 24 hospitals within the United Kingdom. The primary outcome was the Oxford Shoulder Score at 12 months. A total of 117 subjects were included in the study, 61 were randomized to the debridement group and 56 to the debridement and device group. Primary outcome data was available for 114 subjects (97%). The mean Oxford Shoulder Score at 12 months was 34.3 in the debridement only group and 30.3 in the debridement and device group, favoring the control group. The authors concluded results favored the debridement only group and did not recommend use of the InSpace balloon. Limitations noted by the authors include lack of power for subgroup analysis and inability to complete objective data collections due to COVID 19 restrictions.

Bilsel and colleagues (2022) compared the clinical and radiographic outcomes of partial rotator cuff repair (RCR) (n=20) with (PRS group) and without (PR group) implantation of a biodegradable subacromial spacer (n=12) in the treatment of symptomatic massive rotator cuff tears. Patient-reported outcomes, including VAS, ASES, and Constant scores in addition to ROM were collected pre-operatively and at the final follow-up. The authors determined the percentages of all subjects that achieved the minimal clinical important difference (MCID), substantial clinical benefit (SCB), and patient-acceptable symptomatic state (PASS) for the VAS, ASES, and Constant scores. Median follow-up occurred at 28 months in the partial repair group and 17 months in the device group. At the final follow-up, the ASES, VAS, and Constant scores were significantly higher in the PRS group (75.5 [55 to 88.3], 1.0 [0 to 3], and 70.0 [43 to 79], respectively, compared to the PR group (55.0 [37.5 to 65], 2.0 [0 to 4], and 55.0 [31 to 79], respectively; $p<0.05$). The only statistically significant differences were found between the PR and PRS groups in terms of the proportions of the patients who achieved MCID for the ASES (70 % versus 100 %; $p=0.04$) and in terms of the proportions of the patients who achieved SCB for the ASES (60 % versus 100 %; $p=0.01$). Statistically significant differences between the PR and PRS groups, in terms of the proportions of the patients who achieved PASS for the VAS and ASES ([30 % versus 66.7 %; $p=0.04$] and [0 % versus 50 %; $p=0.001$], respectively) were also noted. Acromiohumeral distance improved, and range of motion was greater in the device group. There was no difference in terms of external rotation between groups (3° [2° to 5°] versus 3.0° (2° to 4°); $p=0.4$). The authors concluded that arthroscopic partial repair with implantation of a subacromial spacer resulted in satisfactory clinical and radiographic outcomes in patients with symptomatic irreparable MRCT compared with patients treated with partial repair alone. Limitations of the study include retrospective design, no treatment group with subacromial spacer implantation alone, and varying duration of follow-up between groups.

Liu and colleagues (2021) conducted a meta-analysis to evaluate the efficacy of subacromial balloon spacers for patients with massive, irreparable rotator cuff tears. Electronic databases, including Medline/PubMed, Embase and Cochrane Library, were systematically searched to identify studies evaluating the efficacy of subacromial spacers for patients with irreparable or massive rotator cuff tears. Ten case series with a total of 261 patients involving 270 shoulders were deemed viable for inclusion in the meta-analysis. The results demonstrated that at final follow-up there was significant improvement in the TCS (pooled mean difference = 26.4, 95% CI: 23.2-29.5) as well as significant improvements in the forward flexion and external rotation, rather than in abduction and external rotation variables. The authors concluded that although the short- and middle- term effect (between three months and thre years of follow-ups), is significant, the long-term effect needs to be confirmed by large-sample randomized controlled trials.

Systematic reviews evaluating the subacromial balloon spacer have been published (Viswanath and Drew, 2021; Johns, et al., 2020; Moon, et al., 2019; Stewart, et al., 2019). These reviews included non-randomized controlled trials but did have a tendency to show consistent improvement in the TCS, Oxford Shoulder Scores, American Elbow and Shoulder Scores, and shoulder range of motion. However long-term results are lacking as the average follow-up within these reviews ranged from 19 to 33 months. Reported complication rates were generally low; some individuals required reoperation, including at least five for InSpace migration, one for synovitis, and another six who underwent reverse total shoulder arthroplasty due to worsening of symptoms (Johns, et al., 2020). The author group Viswanath and Drew (2021) reviewed a total of 20 studies (n=513 subjects) noting that four did not recommend the device while the other study groups did support use. The authors acknowledged there was much heterogeneity in study design and inclusion criteria, there was notable bias present in the studies, and lack of randomized controlled trials (RCTs).

Professional Societies/Organizations: Guidance provided by the National Institute for Health and Care Excellence (NICE, 2023) for biodegradable subacromial spacer insertion for rotator cuff

tears indicates that when debridement is a suitable option, the spacer should not be used. Evidence has indicated that symptoms including shoulder dysfunction and pain may be worse after spacer insertion, compared with after debridement. Per NICE, when debridement is not a suitable option, spacer insertion for rotator cuff tears should only be used in a research context. The guidance document noted that although evidence does not suggest any major safety concerns, evidence on long-term safety and benefit is limited.

In-Office Diagnostic Arthroscopy
Surgical arthroscopy is the standard of care for diagnosis of intra-articular joint pathology. Recently in-office arthroscopy, using a small-bore needle/endoscopic camera probe, has been under investigation as a minimally invasive office procedure for diagnosing intra-articular joint pathology as an alternative to magnetic resonance imaging (MRI) and standard arthroscopy. Aside from the elimination of the need for MRI, proposed advantages include reduced recovery time compared to that of standard surgical arthroscopy, improved diagnostic accuracy as compared to MRI, and potential avoidance of more invasive surgery. The procedure is performed under local anesthesia in an office setting. One system currently available, Mi-Eye2™ (Trice Medical, Malvern, PA), received FDA 510(k) clearance for use in diagnostic and operative arthroscopic and endoscopic procedures. The device purportedly provides illumination and visualization of an interior cavity of the body through either a natural or surgical opening, according to the manufacturer. Images are captured on a tablet or monitor via an interface using a hand-held sheath that is inserted into the joint for the arthroscopic procedure. Other systems have been FDA-cleared and are available for use, for example VisionScope High-Definition Endoscopy Camera System (VisionScope Technologies, LLC; Littleton MA). Although evidence is limited, a majority of the publications evaluate use for the knee joint (Deirmengian, et al., 2018) with little to no evidence evaluating other joints. While authors claim in-office diagnostic arthroscopy improves the accuracy of diagnostic findings for some conditions, overall there is a paucity of evidence in the peer-reviewed published scientific literature evaluating safety and/or impact on health outcomes and patient selection criteria have not yet been clearly established. Additional well-designed comparative studies involving large populations are needed to firmly support improved health outcomes resulting from in-office needle arthroscopy procedures.

Miscellaneous Procedures

Medial Knee Implanted Shock Absorber (MISHA™ Knee System)
A medial knee implanted shock absorber is a device implanted subcutaneously, but outside of the joint capsule and superficial to the medial collateral ligament, extending from the distal femur to the proximal tibia. The device employs a shock absorbing mechanical system and is biomechanically stabilized by plates and screws. It is intended to reduce loads on the intra-articular medial joint surface to improve symptoms of osteoarthritis. Specifically, the device is proposed for individuals with osteoarthritic knee pain which interferes with activities of daily living, who are unable or unwilling to undergo total knee replacement surgery.

U.S. Food and Drug Administration (FDA): In April 2023, the FDA granted marketing approval to Moximed, Inc. (Fremont, CA) for the MISHA™ Knee System under the De Novo classification pathway (DEN220033). Per the approval, the MISHA Knee System is indicated for patients with medial compartment knee osteoarthritis that have failed to find relief in surgical and/or non-surgical treatment modalities and are still experiencing pain that interferes with activities of daily living and are also unwilling to undergo or ineligible for total knee replacement due to age or absence of advanced osteoarthritis.

Literature Review: Evidence in the peer-reviewed published scientific literature evaluating the safety and efficacy of a medial knee implanted shock absorber for any indication, including the management of osteoarthritis, is limited. Literature is primarily in the form of retrospective case-

control studies with small patient populations and short to midterm follow-ups (Pareek, et al., 2024; Diduch, et al., 2023; Gomoll, et al., 2023; Pareek, et al., 2023). Published data regarding the safety, efficacy and improved health outcomes with the use of this technology as an alternative to conservative or standard operative treatments is insufficient, and precludes the ability to draw conclusions at this time.

Professional Societies/Organizations: In 2015, the National Institute for Health and Care Excellence (NICE) published guidance on the implantation of a shock absorber to treat mild to moderate symptomatic medial knee osteoarthritis. An evaluation of one case series and three case reports was undertaken. NICE concluded that evidence on the safety and efficacy of this treatment was inadequate in quantity and quality, and thus the procedure should only be performed in a research context.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found	
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination).

Appendix: Procedure to Coding Crosswalk

Musculoskeletal Procedure/Orthobiologic	Intended Use (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
Bioresorbable porous polyurethane (bioactive/tissue engineered scaffold)	Meniscal regeneration/transplantation	29999	L8699
Collagen meniscal implant (bioactive/tissue engineered scaffold)	Meniscal regeneration/transplantation	29999 G0428	L8699
Healing Response Technique	Knee ligament repair	29999	
Juvenile cartilage allograft: • DeNovo® NT Natural Tissue Graft Graft • DeNovo® ET™ Engineered Tissue Graft • Graft BioCartilage	Treatment of articular cartilage defects	23929, 24999, 27299, 27599, 28899, 29999	L8699
Matrix-induced autologous chondrocyte implantation: • MACI® (Vericel Corporation, Cambridge, MA)	Treatment of articular cartilage defects, other than knee	23929 24999 27299 27899 29999	J7330 L8699
Meniscal prosthesis/total meniscus replacement	Meniscal regeneration/transplantation	29999	L8699
Autologous chondrocyte transplantation (e.g., Carticel®, MACI®) for lesions other than the femoral condyle	Treatment of lesions in any joint other than the femoral condyle or patella (e.g., tibia, ankle, hip, shoulder)	23929, 24999, 27299, 27899,	J7330 L8699

Musculoskeletal Procedure/Orthobiologic	Intended Use (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
		29999	
Autologous chondrocyte transplantation (e.g., Carticel®, MACI®)	Treatment of cartilage damage associated with generalized osteoarthritis	23929, 24999, 27299, 27899	J7330 L8699
Osteochondral autograft transplantation	Treatment of articular cartilage defects involving joint surfaces other than the femoral condyle or patella (e.g., ankle)	20962, 23929 24999 27299 27899 28103 28446 29999	L8699
Osteochondral allograft transplantation	Treatment of articular cartilage defects involving joint surfaces other than the femoral condyle or patella	20962, 23929 24999 27299 27899 28103 28446 29999	L8699
Osteochondral allograft using decellularized cartilage (e.g., Chondrofix)	Treatment of articular cartilage defects using allograft		L8699
Osteochondral synthetic resorbable polymers: • TruFit® cylindrical plug • TruGraft™ granules	Treatment of osteochondral articular cartilage defects	23929 24999 27299 27599 27899 29999	L8699
Subchondroplasty	Treatment of an ankle subchondral bone defect	27899 29999 0707T	L8699
Xenograft	Meniscal regeneration/transplantation	29999	L8699

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Articular Cartilage Repair

Considered Not Medically Necessary when used to report treatment of articular cartilage defects involving joints other than the distal femur and patellar articular cartilage within the knee (e.g., ankle, elbow, shoulder):

CPT®* Codes	Description
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal
23929	Unlisted procedure, shoulder
24999	Unlisted procedure, humerus or elbow
27299	Unlisted procedure, pelvis or hip joint
27899	Unlisted procedure, leg or ankle
28103	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with allograft
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
29999	Unlisted procedure, arthroscopy

HCPCS Codes	Description
J7330	Autologous cultured chondrocytes, implant
L8699†	Prosthetic implant, not otherwise specified

†**Note: Considered Experimental/Investigational/Unproven when used to report xenograft implant and cartilage regeneration membrane (e.g., Chondro Gide®) products for articular cartilage repair.**

Considered Experimental/Investigational/Unproven when used to report articular cartilage repair of any joint:

CPT®* Codes	Description
0737T	Xenograft implantation into the articular surface

Bone Filler Materials

Considered Experimental/Investigational/Unproven when synthetic resorbable polymers (e.g., PolyGraft™ BGS, TruFit® [cylindrical plug], TruGraft™ [granules]); juvenile cartilage allograft tissue implantation (e.g., DeNovo® NT Natural Tissue Graft, DeNovo® ET™ Engineered Tissue Graft); or decellularized osteochondral allograft implant (e.g., Chondrofix® Osteochoncral Allograft) are used to report the treatment of articular cartilage defects:

CPT®* Codes	Description
23929	Unlisted procedure, shoulder
24999	Unlisted procedure, humerus or elbow
27299	Unlisted procedure, pelvis or hip joint
27599	Unlisted procedure, femur or knee
27899	Unlisted procedure, leg or ankle
28899	Unlisted procedure, foot or toes
29999	Unlisted procedure, arthroscopy

HCPCS Codes	Description
C1762	Connective tissue, human (includes fascia lata)
C1889	Implantable/insertable device, not otherwise classified
L8699	Prosthetic implant, not otherwise specified

Ligament/Meniscus Reconstruction

Considered Experimental/Investigational/Unproven when used alone or as part of a ligament or meniscus reconstruction, regeneration, or transplantation are used to report bioactive scaffolds (e.g., collagen meniscal implants), bioresorbable porous polyurethane, meniscal prosthesis, tissue engineered menisci, or xenograft:

CPT®* Codes	Description
29999	Unlisted procedure, arthroscopy

HCPCS Codes	Description
C1762	Connective tissue, human (includes fascia lata)
C1781	Mesh (implantable)
C1889	Implantable/insertable device, not otherwise classified
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, menaflex)
L8699	Prosthetic implant, not otherwise specified

Intra-articular Joint Injections

Intra-articular corticosteroid injections for the treatment of chronic, osteoarthritic joint pain, are not covered or reimbursable when administered at an interval more frequent than EITHER four injections during a rolling 12 month year and/or two injections on the same day:

HCPCS Codes	Description
20600	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); without ultrasound guidance
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting
20605	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting
20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

Healing Response Technique

Considered Experimental/Investigational/Unproven when used to report healing response technique:

CPT®* Codes	Description
29999	Unlisted procedure, arthroscopy

Subchondroplasty

Considered Experimental/Investigational/Unproven when used to report subchondroplasty of any bone defect:

CPT®* Codes	Description
23929	Unlisted procedure, shoulder
27299	Unlisted procedure, pelvis or hip joint
27599	Unlisted procedure, femur or knee
27899	Unlisted procedure, leg or ankle
28899	Unlisted procedure, foot or toes
0707T	Injection(s), bone-substitute material (eg, calcium phosphate) into subchondral bone defect (ie, bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization

HCPCS Codes	Description
L8699	Prosthetic implant, not otherwise specified

Subacromial Balloon Spacer

Considered Experimental/Investigational/Unproven when used to report implantation of a subacromial balloon spacer for treatment of a massive/irreparable rotator cuff tear:

HCPCS Codes	Description
C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed

In-Office Diagnostic Arthroscopy

Considered Experimental/Investigational/Unproven when used to report an in-office diagnostic arthroscopy (e.g., Mi-Eye2™, VisionScope®) of any upper or lower extremity joint for evaluation of joint pain and/or pathology:

CPT®* Codes	Description
29805	Arthroscopy, shoulder, diagnostic, with or without synovial biopsy (separate procedure)

CPT®* Codes	Description
29830	Arthroscopy, elbow, diagnostic with or without synovial biopsy (separate procedure)
29840	Arthroscopy, wrist, diagnostic, with or without synovial biopsy (separate procedure)
29860	Arthroscopy, hip, diagnostic, with or without synovial biopsy (separate procedure)
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
29999	Unlisted procedure, arthroscopy

Percutaneous Ultrasonic Ablation of Soft Tissue

Considered Experimental/Investigational/Unproven when used to report percutaneous ablation of soft tissue for treatment of any musculoskeletal condition (e.g., tendinosis, tendinopathy):

CPT®* Codes	Description
20999	Unlisted procedure, musculoskeletal system, general
23929	Unlisted procedure, shoulder
24999	Unlisted procedure, humerus or elbow
25999	Unlisted procedure, forearm or wrist
26989	Unlisted procedure, hands or fingers
27599	Unlisted procedure, femur or knee
27899	Unlisted procedure, leg or ankle
28899	Unlisted procedure, foot or toes

Miscellaneous Procedures

Considered Experimental/Investigational/Unproven when used to report a medial knee implanted shock absorber (e.g., MISHA™ Knee System):

HCPCS Codes	Description
C1889	Implantable/insertable device, not otherwise classified

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Added policy statement for medial knee implanted shock absorber. • Remove statements for focal resurfacing of knee joint and allograft bone substitutes for isolated facet fusion.	4/15/2024
Focused review	• Added policy statement for frequency of intra-articular joint injections.	5/15/2023