



# Medical Coverage Policy

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## Miscellaneous Musculoskeletal Procedures

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### Related Coverage Resources

- [Bone, Cartilage and Ligament Graft Substitutes](#)
- [CMM 312 Knee Surgery: Arthroscopic and Open Procedures](#)
- [Tissue-Engineered Skin Substitutes](#)

#### INSTRUCTIONS FOR USE

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### Coverage Policy

#### Articular Cartilage Repair

Each of the following procedures\* is considered experimental, investigational or unproven 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 Policy - Musculoskeletal "CMM 312 Knee Surgery: Arthroscopic and Open Procedures" for medical necessity criteria for defects within the knee.

#### Healing Response Technique

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

#### Ankle Subchondroplasty

Ankle subchondroplasty for the treatment of a subchondral bone defect 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.

#### Miscellaneous Knee Procedures

Focal resurfacing of a single knee joint defect (e.g., HemiCAP™, UniCAP™) is considered experimental, investigational, or unproven:

## Overview

This Coverage Policy addresses miscellaneous musculoskeletal procedures, including but not limited to articular cartilage repair (other than the knee joint), healing response microfracture technique, focal resurfacing of a knee joint and ankle procedures.

## General Background

### Articular Cartilage Repair

Autologous chondrocyte implantation (ACI), also referred to as autologous chondrocyte transplantation (ACT), utilizes a patient'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, 2009).

### **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 (Brown, et al., 2005; Washington State Department of Labor and Industries, 2004, updated 2012).

**Use Outside of the US:** MACI is available for use in Europe and Australia.

### **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 nonweight-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<sup>®</sup>) 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. Authors claim that mosaicplasty reduces the possibility of donor-site morbidity and produces a more even surface (Scapinelli, et al., 2002).

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 (Hangody, et al., 2001; Mendicino, et al., 2001; Al Shaihk, et al., 2002). 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 in ankles is limited to retrospective and prospective case series and few randomized controlled trials, nonrandomized controlled trials involving small patient populations and published reviews (Kolker, et al., 2004; Giannini, et al., 2005; Kruez, et al., 2005; Balzer and Arnold, 2005; Scranton, et al., 2006; Gobbi, et al., 2006; Reddi, et al., 2006; Saxena and Elkin, 2007, Zengerink, et al., 2010; Berlet, et al., 2011;

Imhoff, et al., 2011; Emre, et al., 2012; Paul, et al., 2012; Hayes, 2014; Yoon, et al., 2014; Giorgiannos, Bisbinas, 2014). 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. In 2004 Kolker et al. reported their concern as to the overall efficacy of the procedure when used in the treatment of full-thickness, advanced, osteochondral defects of the talar dome. Open bone grafting did not predictably improve symptoms and yielded poor results in the patient population studied. Authors have acknowledged further well-designed studies with larger sample size are needed to assess improved long-term outcomes (Balzer and Arnold, 2005; Scranton, et al., 2006). More recent literature continues to support clinical outcomes that are mixed (Zengerink, et al., 2010; Yoon et al., 2014).

**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 (Shimada, et al., 2005; Tsuda, et al., 2005; Yamamoto, et al., 2006; Iwasaki, et al., 2006; Ansah, et al., 2007; Oveson, et al., 2011; Shimada, et al., 2012). 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). 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 (Schiebel, et al., 2004; Park, et al., 2006). 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<sup>2</sup>, although many experts suggest lesion size of 2–3 cm<sup>2</sup> or greater (Alford and Cole, 2005).

To ensure cellular viability, osteochondral allografts are generally implanted fresh (Brautigan, et al., 2003). 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 (Gomoll, 2016; Farr, et al., 2016). 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 in particular, 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 is inconsistent. 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 (Gross, et al., 2001; Kim, et al., 2002; Tontz, et al., 2003; Rodriguez, et al., 2003; Meehan, et al., 2005; Jeng, et al., 2008; Valderrabano, et al., 2009; Hahn, et al, 2010;Gortz, et al., 2010; Adams, et al., 2011; Haene, et al., 2011, Galli, et al., 2014). Some authors have reported clinical outcomes extending as long as 12 years, (Gross, et al., 2001; Kim, et al., 2002) 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 (Kim, et al., 2002; Jeng, et al., 2008; Haene, et al., 2011, Haene, et al, 2012; Bugbee, et al 2013). Few studies reporting long term clinical outcomes are available.

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 followup 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 (Gross, et al., 2001; Jeng, et al., 2008). 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:** In 2013 the American Orthopaedic Foot and Ankle Society (AOFAS, 2013, updated 2018) published a position statement supporting osteochondral transplantation for the treatment of osteochondral lesions of the talus when the individual has failed non-operative management, particularly for large diameter lesions (>15 mm in diameter) and cystic lesions (i.e., cyst in subchondral bone).

The Washington State Health Care Authority technology assessment program published a technology assessment evaluating Osteochondral Allograft/Autograft Transplantation (2011). The evidence was re-evaluated in 2018 with no change to the original conclusion— there is insufficient evidence to support osteochondral allograft/autograft for joints other than the knee (Washington State Health Care Authority, 2018).

The American College of Rheumatology (ACR) Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee (ACR, 2000) has noted that significant advances such as autologous chondrocyte transplantation, cartilage repair using mesenchymal stem cells, and autologous osteochondral plugs are being investigated; however, they do not recommend those procedures for the treatment of patients with osteoarthritis. There has been no update to the recommendations since the initial publication in 2000.

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

[Articular Cartilage Repair Coding and Billing Information](#)

#### **Healing Response (Microfracture) Technique**

The Healing Response (Microfracture) Technique is a treatment method employed 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.

**U.S. Food and Drug Administration (FDA):** Healing Response Technique is a procedure and as such is not regulated by the US FDA.

**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.

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

[Healing Response Technique and Billing Information](#)

#### **Ankle 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. There is a paucity of evidence in the peer reviewed scientific literature evaluating subchondroplasty of the ankle. As a result, evidence based conclusions regarding safety, efficacy, and the impact on net health outcomes has yet to be determined.

#### [Ankle Subchondroplasty Procedures](#)

#### [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 MRI and standard arthroscopy. Aside from the elimination of the need for magnetic resonance imaging, 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) approval 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 approved and are available for use, for example VisionScope High Definition Endoscopy Camera System (VisionScope Technologies, LLC; Littleton MA) has also received FDA 510(k) approval. Although evidence is limited, a majority of the publications evaluate use for the knee joint (Deirmengian, et al., 2018; **Level 4** Gill, et al, 2018 **Level 3**) 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.

#### [In Office Diagnostic Arthroscopy](#)

#### [Miscellaneous Knee Procedures](#)

##### **Minimally Invasive Knee Replacement**

Minimally invasive surgical (MIS) approaches to knee surgery have been investigated with the intention of limiting surgical dissection without compromising the surgical procedure or patient outcomes. The MIS TKR incision is 4–6 inches long versus 8-10 inches for a traditional approach (AAOS, 2019). The main difference between a traditional approach and the MIS approach is the method in which the surgeon exposes and gains access to the joint—a minimally invasive approach has a smaller incision and avoids patella eversion and quadriceps muscle splitting. Modifications of the medial parapatellar, subvastus and midvastus approaches applying MIS techniques have been published in the literature (Scuderi, et al., 2004) nonetheless less invasive surgical implants (e.g., unicompartmental knee arthroplasty) use different components and incision methods and are not considered minimally invasive surgery.

Various surgical techniques described as minimally invasive approaches have been facilitated by the use of smaller and more patient-specific instrumentation and computer navigation. There have been some concerns raised in the medical literature regarding the risk of inaccurate implant positioning and possible additional complications due to a restricted operative field. Incorrect positioning or orientation of implants, poor soft tissue balancing, and improper alignment of the limb can lead to accelerated wear, loosening and decreased overall performance of the implant. Moreover, malalignment alone can lead to abnormal patellar tracking, increased polyethylene wear, early loosening, and poor functional outcome (Chin, et al., 2007).

**Professional Societies/Organizations:** General information for knee replacement procedures provided by the American Academy of Orthopaedic Surgeons indicates that not everyone is a candidate for MIS knee replacement. Conditions such as significant deformity of the knee, prior knee surgery and being overweight may lead to increased risk for complications. Furthermore, although not a formal position statement, the AAOS acknowledge the current evidence suggests that the long-term benefits of minimally invasive surgery do not differ from those of knee replacement performed with the traditional approach (AAOS, 2015). Within the

AAOS practice guideline “Surgical Management of Osteoarthritis of the Knee” MIS TKR is not referenced (AAOS, 2015).

Advisory statements regarding minimally invasive and small incision joint replacement surgery by the American Association of Hip and Knee Surgeons (AAHKS, 2004; updated 2008) indicate that same or better long-term outcomes have not been validated with less invasive knee replacement surgery, and there is not a great deal of significant scientific proof to support its use at this time. Scientific evidence and rigorous evaluation of minimally invasive joint arthroplasty techniques are needed before these techniques are recommended for more widespread clinical practice. Nevertheless, there has been no recent update to the advisory statements.

**Use Outside of the US:** The National Institute for Health and Care Excellence (NICE) issued a procedural guidance regarding mini-incision surgery for total knee replacement (March, 2010). The Institute concluded that current evidence on the safety and efficacy of mini-incision surgery for total knee replacement is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

**Focal Knee Joint Resurfacing**

Focal resurfacing of a knee joint defect is a surgical procedure in which a limited amount of bone is removed from the surface of the joint and then replaced with a metal or metal/plastic implant. It has been proposed as an alternative to unicompartmental or total knee replacement, involving less removal of the patient’s bone and theoretically allowing more normal joint function. Candidates for resurfacing are usually younger in age, physically active, and have focal articular defects (i.e., early stage OA changes that are isolated).

**U.S. Food and Drug Administration(FDA):** Two FDA approved knee resurfacing prosthesis include the HemiCAP™ Femoral Condyle System (Arthrosurface, Inc., Franklin, MA) and the UniCAP™ Unicompartmental Knee Resurfacing Implant (Arthrosurface, Inc., Franklin, MA). These devices are approved through the FDA 510(k) approval process as Class II devices and are intended to be used with bone cement.

**Literature Review:** Evidence in the peer-reviewed published scientific literature evaluating safety and efficacy of focal knee joint resurfacing using these or other similar devices is limited. Becher et al. (2011) published the results of a case series involving 21 patients who received a HemiCap device with average follow-up of 5.3 years. Boller et al. reported the results of a case series involving 19 subjects treated with a HemiCap device with an average follow-up of 34 months. Although there was improvement in pain and function scores, the studies were limited by small populations, lack of a control group and short to mid-term outcomes. Published data regarding the safety, efficacy and improved health outcomes with the use of this technology as an alternative to TKR or UKR is insufficient and precludes the ability to draw conclusions as this time.

[Miscellaneous Knee Procedures Coding and Billing Information](#)

**Centers for Medicare & Medicaid Services (CMS)**

- National Coverage Determination (NCD): NCD not found.
- Local Coverage Determination (LCD): Total Knee Arthroplasty (L36575) (2016). The LCD is less broad in scope than the Coverage Policy. Refer to the CMS LCD table of contents link in the reference section.

**Appendix 1 – Procedure to Coding Crosswalk**

Musculoskeletal Procedure/Orthobiologic	Intended Use (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
Healing Response Technique	Knee ligament repair	29999	
Matrix-induced autologous chondrocyte implantation: <ul style="list-style-type: none"> <li>• MACI® (Vericel Corporation, Cambridge, MA)</li> </ul>	Treatment of articular cartilage defects, other than knee	23929 24999 27299 27899 29999	J7330 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, 29999	J7330 L8699
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 <u>other</u> 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 <u>other</u> 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: <ul style="list-style-type: none"> <li>• TruFit® cylindrical plug</li> <li>• TruGraft™ granules</li> </ul>	Treatment of osteochondral articular cartilage defects	23929, 24999, 27299, 27599, 27899, 29999	L8699
Ankle Subchondroplasty	Treatment of an ankle subchondral bone defect	27899, 29999	L8699
Focal resurfacing of a single knee joint: <ul style="list-style-type: none"> <li>• HemiCAP™</li> <li>• UniCAP™</li> </ul>	Knee arthroscopy	27438, 27440, 27442	C1776, L8699

## Coding/Billing Information

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

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

### Articular Cartilage Repair

**Experimental/Investigational/Unproven when autologous chondrocyte (e.g., Carticel®, MACI®), osteochondral autograft or allograft transplant is used for the treatment of articular cartilage defects in locations other than the distal femur or patella within the knee:**

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

### **Healing Response Technique**

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

CPT®* Codes	Description
29999	Unlisted procedure, arthroscopy

### **Ankle Subchondroplasty**

**Experimental, investigational, unproven when used to report ankle subchondroplasty:**

CPT®* Codes	Description
27899	Unlisted procedure, leg or ankle
29999	Unlisted procedure, arthroscopy

HCPCS Codes	Description
L8699	Prosthetic implant, not otherwise specified

### **In-Office Diagnostic Arthroscopy**

**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)
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

### **Miscellaneous Knee Procedures**

**Experimental, investigational, unproven when used to report focal resurfacing of a single knee joint defect (e.g. HemiCAP, UniCAP):**

CPT®* Codes	Description
27438	Arthroplasty, patella; with prosthesis
27440	Arthroplasty, knee, tibial plateau
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee;
27599	Unlisted procedure, femur or knee

HCPCS Codes	Description
C1776	Joint device (implantable)
L8699	Prosthetic implant, not otherwise specified

**\*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.**

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