Cigna Medical Coverage Policy

Subject **Osteochondral Grafts for Articular Cartilage Repair (Autografts, Allografts, and Synthetic Grafts)**

Effective Date 10/15/2014
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Allograft Transplantation of the Knee
Chondrocyte Implantation of the Knee

Coverage Policy

Cigna covers EITHER of the following procedures as medically necessary for the repair of a single, focal, full-thickness articular cartilage defect involving the weight-bearing surface of the distal femur:

- osteochondral autograft transplant (e.g., Osteochondral Autograft Transplantation System [OATS], mosaicplasty
- osteochondral allograft transplant

When ALL of the following criteria are met:

- disabling localized knee pain unresponsive to conservative treatment (e.g., medication, physical therapy) and/or prior arthroscopic or other surgical repair
- magnetic resonance imaging (MRI) or arthroscopy demonstrating chondral defect on the weight-bearing portion of the lateral or medial femoral condyle, or trochlear region of the knee
- normal knee alignment
- knee is stable with functionally intact menisci and ligaments
- no evidence of arthritis on the corresponding tibial surface
- normal appearing hyaline cartilage surrounding the borders of the defect
- the individual is not currently a candidate for total or partial (i.e., medial or lateral unicompartmental) knee replacement.

Cigna does not cover osteochondral autograft or allograft transplant for the treatment of articular cartilage defects on ANY other joint surfaces, including the patella, because it is considered experimental, investigational or unproven.

Cigna does not cover synthetic resorbable polymers (e.g., PolyGraft™ BGS, TruFit® [cylindrical plug], TruGraft™ [granules]) for osteochondral articular cartilage defects because each is considered experimental, investigational and unproven.

General Background

Damage to cartilage may result from either traumatic injury or from degenerative conditions (e.g., osteochondritis dissecans, osteonecrosis or osteoarthritis). It is well established that lesions involving cartilage interfere with smooth gliding motion and typically lead to severe pain, instability and joint stiffness.

Cartilage healing and repair are affected by factors such as age, the degree and depth of damage, associated joint instability, the underlying cause, previous meniscectomy, misalignment and genetic factors. Only in limited situations can the damaged articular cartilage remodel and rebuild itself. Undisplaced lesions in skeletally immature individuals generally heal with immobilization; however, in skeletally mature individuals, surgery is often indicated as it is widely accepted that a symptomatic cartilage lesion is likely to persist or worsen without treatment.

Osteochondral grafting is one of a variety of treatments for cartilage defects. According to the American Academy of Orthopaedic Surgeons (AAOS), the most common procedures for restoring articular cartilage include microfracture, drilling, abrasion arthroplasty, autologous chondrocyte implantation, osteochondral autograft transplantation and osteochondral allograft transplantation (AAOS, 2009).

The goal of osteochondral grafting procedures is to re-establish the cartilage matrix with chondrocytes and supporting bone to improve joint function and decrease pain. Both fresh and cryopreserved allogenic (i.e., obtained from cadaveric bone stock) osteochondral grafts have been used with some success. Cryopreservation however may decrease the viability of the cartilage cells and fresh allografts may be difficult to obtain (due to scarcity) and entail a concern of disease transmission. The use of synthetic grafts has been reported in the literature and it has been proposed that synthetic grafts may provide a substrate, encouraging bony in-growth and surface repair. The synthetic implant can be used to backfill harvest sites and is considered an alternative to allografts and autografts by some authors. Consequently, a variety of synthetic substitutes is available and currently undergoing clinical trials. Additionally, there has been ongoing interest in the use of autologous osteochondral grafts (i.e., obtained from the patient) as an option to increase the survival rate of the cartilage while decreasing the possibility of infection.

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®) 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.

The potential value of osteochondral autograft procedures is considered debatable by some authors. Concerns have been raised regarding the viability of the osteochondral plug, degeneration and graft failure (Huntley, et al., 2005; Redman, et al., 2005), although some clinical studies suggest joint function and symptoms improve as a result of osteochondral autografting (Jakob, et al., 2002; Bobic, 1996; Outerbridge, et al., 1995). Comparing clinical outcomes across studies has also been challenging as several scoring and grading systems appear in the literature; few authors report on the histological outcomes. Moreover, patient selection criteria are not clearly defined and vary according to source. Previously, cartilage repair procedures were limited to younger patients. However, patients who remain active longer are generally less willing to accept the limitations of joint replacements. Additionally, data evaluating whether or not tissues derived from non load-bearing sources can withstand the stress of a load-bearing area are limited (Redman, et al., 2005).

Knee
Patient selection criteria for osteochondral autograft transplant of the knee vary. In general, individuals 45 years of age or younger who have chondral defects and sharp, definite borders surrounded by normal-appearing hyaline cartilage and a unipolar defect from 2–2.5 cm in extent are ideal candidates. Other ideal indications include a symptomatic distal femoral condyle lesion with intact menisci and tibial cartilage in a nondegenerative joint with proper mechanical alignment (Alford and Cole; 2005). Some authors report the ideal lesion size is 1–2 cm in diameter; lesions 3–4cm in diameter may be treated, but is not optimal due to graft size limitations. For best long-term results, normal mechanical alignment, a stable knee, no evidence of ligamentous instability, no evidence of arthritis on the corresponding tibial surface, and radiographically normal or near normal knee joints are necessary (Carlson, 2002). Relative contraindications to the procedure include age over 45 years and chondromalacia of the articular cartilage surrounding the joint (Phillips, 2003). For grade III or IV defects less than 2 cm square, (size limit due to concerns about donor site morbidity), mosaicplasty is generally recommended (Carlson, 2002).

Literature Review: Osteochondral autologous transplantation and autologous chondrocyte implantation have both shown improved knee function in two- to five-year follow-up studies in carefully selected patients for lesions of the femoral condyles and trochlear groove (Carlson, 2002). There is a large body of evidence including both retrospective and prospective case series, randomized controlled trials, nonrandomized controlled/comparative trials, and published reviews (Outerbridge, et al., 1995; Bobeck, 1996; Jakob, et al., 2002; Horas, et al., 2003; Kotani, et al., 2003; Karataglis, et al., 2005; Gudas, et al., 2005; Marcacci, et al., 2005; Miniaci and Tytherleigh-Strong, 2007; Hangody, et al., 2008; ECRI, 2008; Mullen, et al., 2010) supporting the efficacy of osteochondral autograft transplantation. In general, the follow-up periods for reporting clinical outcomes extend several years, with one review evaluating data over a period of 15 years (Hangody, et al., 2008). Many of the studies demonstrate a measurable improvement of function and reduction of pain. The grafts have been documented as being stable, well-incorporated and with satisfactory chondrocyte survival when evaluated postoperatively. Good gliding surfaces and histologically proven survival of the transplanted hyaline cartilage has also been reported. Overall, the evidence in the peer-reviewed published scientific literature, textbook sources and professional societies support short- to intermediate-term efficacy of osteochondral autograft transplant for treatment of articular cartilage defects of the knee.

Patella
Osteoarthritis conditions may also affect the patella. Osteoarthritis dissecans may occur on the medial or lateral facet and the central ridge or the medial or lateral aspect of the trochlea. Treatments for osteoarthritis of the patella typically include patellectomy, realignment procedures, arthroplasty, and resurfacing methods, all of which have varying degrees of success. When mechanical symptoms persist with pain and swelling despite

conservative treatment or microfracture, some authors recommend autologous osteochondral transplant. Nevertheless, patella cartilage is thicker than cartilage in other areas of the knee, and the differences between the donor cartilage and patella cartilage may lead to suboptimal clinical outcomes (Nho, et al., 2008).

Literature Review: There are few studies that specifically report on autologous osteochondral transplantation of the patella and much of the evidence is in the form of case reports or case series lacking control groups and statistical evaluation (Nho, et al., 2008; Visona, et al., 2010; Astur, et al., 2014). The reported clinical outcomes have not been as encouraging compared to those of the femoral condyles although some studies do support improvement in knee function scores following surgery. One group of authors reported that the results of patellar and trochlear osteochondral plug transfers had 79% good to excellent results compared to 92% good to excellent results in a femoral condyle group (Hangody and Fules, 2003). Another group of authors compared autologous chondrocyte implantation to mosaicplasty for treatment of femoral chondyle lesions or patellar lesions. They reported that patients who underwent patellar mosaicplasty had fair to poor arthroscopic appearance in addition to 60% good to excellent results. This group of authors indicated the primary reason for failure may have been due to differences in articular cartilage thickness and concluded that the procedure was contraindicated for chondral lesions of the patella (Bentley, et al., 2003). Evidence in the published scientific literature evaluating patella osteochondral autografts is limited, the reported clinical outcomes are mixed, sample populations are small and patient selection criteria have not been clearly defined. At present, there is insufficient data to support the clinical efficacy of osteochondral autograft transplant for the patella.

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.

Literature Review: 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, ECRI 2007; Zengerink, et al., 2010; Berlet, et al.,2011; Imhoff, et al., 2011; Emre, et al., 2012; Paul, et al, 2012; Yoon, et al., 2014).The evidence base is not as robust when compared to that evaluating the knee, although reported clinical outcomes extend short-to intermediate-term; on average two 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).

A recent systematic review (Zengerink, et al., 2010) compared the effectiveness of several treatments for osteochondral defects of the talus. A total of 52 studies met the inclusion criteria although only one randomized controlled clinical trial was identified. The studies were grouped as follows: nonoperative treatment (7), excision (4), excision and curettage (13), excision, curettage and bone marrow stimulation (BMS) (18), autogenous bone graft (4), transmalleolar drilling (2), osteochondral transplant (OATS) (9), autologous chondrocyte transplant (ACI) (4), retrograde drilling (3) and fixation (1). After calculating proportion of patient population treated

successfully and weighted success rates, the authors reported the following success percentages: excision 54%, excision and curettage 77%, excision, curettage and BMS 85%, autogenous bone graft 61%, transmalleolar drilling 63%, OATS 87%, ACI 76%, retrograde drilling 88%, and fixation 89%. In the authors opinion BMS was the treatment of choice for primary lesions. Although success rates of BMS were similar to OATS, OATS is associated with knee morbidity.

Yoon et al. (2014) reported the results of a clinical study comparing the outcomes of osteochondral autologous transplant (N=22) with repeat arthroscopy (N=22) for treatment of osteochondral lesions of the talus following failed primary arthroscopic treatment. Subjects were evaluated using the VAS for pain and AOFAS Ankle Hindfoot Scale scores at 6, 12, 24 months postoperatively and then yearly following surgery. Treatment failure was defined as persistent or recurrent symptoms, additional surgical treatment or an AOFAS score lower than 80. At six months both groups demonstrated significant improvement (P<.05) in AOFAS and VAS scores, however the repeat arthroscopy group had lower postoperative AOFAS scores, VAS scores, and a higher cumulative clinical failure rate. Overall, fourteen of the 22 subjects who underwent repeat arthroscopy required further revisions compared to zero in the OATs group. The authors noted that poorer outcomes in the repeat arthroscopy group were associated with larger defects. Although the results of this study favor the OAT treatment group following a failed primary arthroscopy, the study is limited by retrospective design, lack of randomization and small sample size.

Elbow
Literature Review: 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. Larger clinical trials evaluating long-term outcomes compared to conventional methods of treatment are needed to support widespread use of this procedure.

Shoulder
Literature Review: 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.

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 (Brautigan, et al., 2003). Cryopreservation often damages the cartilage matrix and kills the chondrocytes. 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.

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.

Knee
Literature Review: There is evidence from several case series suggesting that osteochondral allografting of the knee is a successful alternative to autograft and provides relief of pain and improved joint function for select patients (Ghazavi, et al., 1997; Aubin, et al., 2001; Shasha, et al., 2003; Gross, et al., 2005; Emmerson, et al., 2007). Improvements in pain, range of motion and function have been reported by several authors; and in many studies the reported clinical outcomes extend on average at least ten years (Aubin, et al., 2001; Shasha, et al., 2003; Gross, et al., 2005). One early study reported survivorship analysis of 95% graft survival at five years, 71% at 10 years, and 66% at 20 years (Ghazavi, et al., 1997) with subsequent studies reporting similar results. The available data supports the use of osteochondral allografting in patients who are physically active, but have failed standard medical and surgical treatments and are too young to be considered suitable candidates for total knee replacement.

Ankle
Literature Review: 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).

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.

Patella
Literature Review: There are few studies evaluating osteochondral resurfacing of the patella (AAOS, 2001; Jamali, et al., 2005; Spak and Teitge, 2006). Much of the evidence consists of case series without controls and small sample populations; as such results can not be generalized to larger groups of patients. While some of the results have been successful with authors reporting good to excellent scores for pain relief, function and range of motion, overall the evidence is insufficient to draw reliable conclusions regarding efficacy. In one study the authors reported additional surgery was performed in 12 of the 14 knees; the most common reason being symptomatic hardware (Spak and Teitge, 2006).

Synthetic Resorbable Polymers
An alternative to allografting that has been proposed by some researchers is the synthetic graft. 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.

U.S. Food and Drug Administration (FDA): PolyGraft BGS (bone graft substitute), a resorbable bone void filler, was granted 510(k) marketing approval by the FDA in 2003 because 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 device is a Class II device intended for filling bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of bony structure.

Literature review: Synthetic resorbable polymers, such as PolyGraft, are available and have been proposed as bone graft substitute materials (Gardiner and Weitzel, 2007; Niederauer, et al., 2006). However, the available evidence for their use consists mainly of studies performed on animals; human studies are limited and consist mainly of a few 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 patients. Consequently, the 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.

Professional Societies/Organizations
In 2013 the American Orthopaedic Foot and Ankle Society (AOFAS, 2013) 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 (>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). Regarding the evidence for the effectiveness of autograft OAT/mosaicplasty in the knee and ankle, there were substantial differences in patient populations, comparators, and outcome measures across all studies and given the high potential for bias, it was noted no firm conclusions could be drawn.

The Washington State Department of Labor and Industries (2004) developed and published recommendations for review criteria of knee surgery based on evidence in the medical literature combined with expert opinion and community-based practicing physicians. Their patient selection criterion for consideration of osteochondral autograft knee surgery includes all of the following:
- the presence of joint pain and swelling
- previous conservative therapy, including medication or physical therapy
- failure of previous subchondral drilling or microfracture

- large, full-thickness chondral defect measuring less than 3 cm in diameter and 1 cm in bone depth on the weight-bearing portion of the medial or lateral femoral condyle
- stable knee with intact, fully functional menisci and ligaments
- normal knee alignment and normal joint space
- body mass index of less than 35
- MRI or arthroscopy demonstrating chondral defect on the weight-bearing portion of the lateral or medial femoral condyle

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.

There are no formal position statements, recommendations or guidelines available from either the American Academy of Orthopedics or the International Cartilage Repair Society regarding osteochondral grafting procedures.

Use Outside of the US
In 2006 the National Institute for Health and Clinical Excellence issued guidance for mosaicplasty for knee cartilage defects (NICE, 2006). According to the guidance the evidence suggests there are no major safety concerns and there is some evidence of short-term efficacy. Due to uncertainties about the benefits of mosaicplasty for knee cartilage defects NICE recommends special arrangements for consent and audit or research and that patients understand the uncertainty about the procedure's efficacy and the options for alternative treatments.

Summary
Evidence from the peer-reviewed published scientific literature, textbook and some professional societies support short to intermediate-term efficacy of osteochondral autograft transplant of the knee in specific patient subgroups. In general, the larger the defect, the higher the complication rate; osteochondral autografts are limited to treating smaller lesions. Evidence evaluating treatment for other articular cartilage defects (e.g., shoulder, elbow, ankle or hip) consists mainly of case reports, case series, and nonrandomized trials; evaluate short to mid-term outcomes, and involve small sample populations. The evidence is insufficient to support clinical utility of osteochondral autograft transplant for treatment of other articular cartilage defects.

There is sufficient evidence to support the use of osteochondral allograft of the knee in patients who are physically active, have failed standard medical and surgical treatments, and are considered too young for total knee arthroplasty. Similar to autografts of other articular cartilage defects, evidence in the medical literature is insufficient to support efficacy for osteochondral allograft of other joints, including but not limited to the ankle and patella.

In addition, the evidence in the medical literature is insufficient to support the safety and effectiveness of synthetic resorbable polymers as an alternative to allograft or autograft for the repair of osteochondral defects.

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.

Knee

Covered when medically necessary:

CPT®* Codes	Description
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting

	of autograft[s])
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)

Any other joint surface

Experimental/Investigational/Unproven/Not Covered when osteochondral autograft or allograft transplant is used for the treatment of articular cartilage defects involving ANY other joint surface:

CPT* Codes	Description
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal
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])

Synthetic Resorbable Polymers

Experimental/Investigational/Unproven/Not covered when used to report synthetic resorbable polymers for the treatment of articular cartilage defects:

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

 *Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.

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