Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

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Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for osteochondral autografts and allografts when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Osteochondral allografting may be considered medically necessary as a technique to repair large (e.g., 10 cm²) full thickness chondral defects of the knee caused by acute or repetitive trauma.

Osteochondral autografting, using one or more cores of osteochondral tissue, may be considered medically necessary for the treatment of symptomatic full thickness cartilage defects of the knee caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met:

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years)
- Focal, full thickness (grade III or IV) unipolar lesions on the weight bearing surface of the femoral condyles or trochlea that are between 1 and 2.5 cm² in size
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less), and normal appearing hyaline cartilage surrounding the border of the defect
- Normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting

When Policy Topic is not covered
Osteochondral allografting for all other joints is considered investigational.

Osteochondral autografting for all other joints, including patellar and talar, and any indications other than those listed above, is considered investigational.

Treatment of focal articular cartilage lesions with autologous minced cartilage is considered investigational.

Treatment of focal articular cartilage lesions with allogeneic minced cartilage is considered investigational.

Considerations
In some situations, the chondral defect may be an incidental finding at the time of arthroscopy and therefore, the decision to undergo osteochondral autografting may be made at that time.
If debridement is the only prior surgical treatment, consideration should be given to marrow stimulating techniques before osteochondral grafting is performed.

Severe obesity, e.g., body mass index (BMI) greater than 35 kg/m², may affect outcomes due to the increased stress on weight bearing surfaces of the joint.

Misalignment and instability of the joint are contraindications. Therefore additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with osteochondral allografting or osteochondral autografting.

**Description of Procedure or Service**

Chondral and osteochondral grafts are used in repair of full-thickness chondral defects involving the joint. In the case of osteochondral autografts, one or more small osteochondral plugs are harvested from non-weight-bearing sites in the knee and press fit into a prepared site in the lesion. Osteochondral allografts are typically used for larger lesions to reduce donor site morbidity. Autologous or allogeneic minced cartilage is also being evaluated as a treatment of articular cartilage lesions.

**Background**

Focal chondral defects of the knee, either due to trauma or other conditions such as osteochondritis dissecans, often fail to heal on their own and may be associated with pain, loss of function, disability, and the long-term complication of osteoarthritis. The ideal resurfacing technique would eliminate symptoms, restore normal biomechanics of the knee joint, and prevent the long-term emergence of osteoarthritis and the necessity for total knee arthroplasty. Various methods of cartilage resurfacing have been investigated including marrow-stimulation techniques such as subchondral drilling, microfracture, and abrasion arthroplasty, all of which are considered standard therapies and all of which attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. However, fibrocartilage does not share the same biomechanical properties as hyaline cartilage, and thus various strategies for chondral resurfacing with hyaline cartilage have been investigated.

Both fresh and cryopreserved allogeneic osteochondral grafts have been used with some success, although cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. As a result, autologous osteochondral grafts have been investigated as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission. Autologous grafts are limited by the small number of donor sites; thus allografts are typically used for larger lesions. In an effort to extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from non-weight-bearing sites in the knee for treatment of full-thickness chondral defects. Several systems are available for performing this procedure, the Mosaicplasty System (Smith and Nephew), the Osteochondral Autograft Transfer System (OATS, Arthrex, Inc.), and the COR and COR2 systems (DePuy-Mitek). Although mosaicplasty and OATS may use different instrumentation, the underlying principle is similar; i.e., the use of multiple osteochondral cores harvested from a non-weight-bearing region of the femoral condyle and autografted into the chondral defect. These terms have been used interchangeably to describe the procedure.

Preparation of the chondral lesion involves debridement and preparation of recipient tunnels. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weight-bearing area of the femoral condyle. Donor plugs range from 6-10 mm in diameter. The grafts are press fit into the lesion in a mosaic-like fashion into the same-sized tunnels. The resultant surface consists of transplanted hyaline articular cartilage and fibrocartilage, which is thought to provide “grouting” between the individual autografts. Mosaicplasty may be performed with either an open approach or arthroscopically. Osteochondral autografting has also been investigated as a treatment of unstable osteochondritis dissecans lesions using multiple dowel grafts to secure the fragment. While osteochondral autografting is primarily performed on the femoral condyles of the knee, osteochondral
grafts have also been used to repair chondral defects of the patella, tibia, and ankle. With osteochondral autografting, the harvesting and transplantation can be performed during the same surgical procedure. Technical limitations of osteochondral autografting are difficulty in restoring concave or convex articular surfaces, incongruity of articular surfaces that can alter joint contact pressures, short-term fixation strength and load-bearing capacity, donor site morbidity, and lack of peripheral integration with peripheral chondrocyte death associated with graft harvesting and insertion.

Recently, a minimally processed osteochondral allograft (Chondrofix®, Zimmer) has become available for use. Chondrofix® is composed of decellularized hyaline cartilage and cancellous bone and can be used “off the shelf” with precut cylinders (7-15 mm). Multiple cylinders may be used to fill a larger defect in a manner similar to OATS or mosaicplasty.

Filling defects with minced articular cartilage (autologous or allogeneic), is another single-stage procedure that is being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS, Johnson and Johnson, Phase III trial) harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment. BioCartilage® (Arthrex) consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture. DeNovo NT Graft (Natural Tissue Graft) and DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) are produced by ISTO Technologies with exclusive distribution rights by Zimmer. DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. The tissue fragments are mixed intra-operatively with fibrin glue before implantation in the prepared lesion. It is thought that mincing the tissue helps both with cell migration from the extracellular matrix and with fixation. As there is no use of chemicals and minimal manipulation, the allograft tissue does not require U.S. Food and Drug Administration (FDA) approval for marketing. DeNovo® ET graft (Neocartilage) uses juvenile allogeneic cartilage cells engineered by ISTO Technologies. The FDA approved ISTO’s Investigational New Drug (IND) application for Neocartilage in 2006, which allowed them to pursue Phase III clinical trials of the product in humans.

Autologous chondrocyte implantation (ACI) is another method of cartilage repair involving the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces, which are then cultured and expanded in vitro and implanted back into the chondral defect. ACI techniques are discussed in a separate policy.

Rationale
This policy was created in 2001 and updated periodically with searches of the MEDLINE database. The most recent update was performed for the period of April 2012 through May 8, 2013. Following is a summary of key references to date.

A 2008 systematic review by Magnussen et al. assessed whether “advanced” cartilage repair techniques (osteochondral transplantation or autologous chondrocyte transplantation) showed superior outcomes in comparison with traditional abrasive techniques for the treatment of isolated articular cartilage defects. (1) Finding a total of 5 randomized controlled trials (RCTs) and 1 prospective comparative trial that met their selection criteria, Magnussen and colleagues concluded that no one technique had been shown to produce superior clinical results for treatment of articular cartilage defects. They stated that, “any differences in outcome based on the formation of articular rather than fibrocartilage in the defect may be quite subtle and only reveal themselves after many years of follow-up. Similarly, complications such as donor site morbidity in OAT [osteochondral autograft transfer] may be late in their presentation and thus not be detected at short follow-up.”

Harris and colleagues published a systematic review of combined meniscal allograft transplantation and cartilage repair/restoration in 2010. (2) Six level IV studies (case series) with a total of 110 patients were included in the review. Patients underwent meniscal allograft transplantation with either autologous chondrocyte implantation (ACI, n=73), osteochondral allograft (n=20), osteochondral autograft (n=17), or microfracture (n=3). All studies showed improvement in clinical outcomes at final follow-up compared to the preoperative condition. Outcomes were also compared with historical
outcomes of each individual procedure performed in isolation. Four of the 6 studies found outcomes equivalent to procedures performed in isolation, while 2 studies found that outcomes with combined surgery were not as good as the historical controls. Across the 6 studies, 13 failures (12%) were reported; these included 11 isolated meniscal allograft transplantation failures, 1 combined meniscal allograft and ACI failure, and 1 isolated ACI failure. Three knees with failed meniscal allograft transplantation were converted to total knee arthroplasty. Nearly 50% of the patients underwent one or more subsequent surgeries after combined meniscal allograft transplantation and cartilage repair/restoration procedures.

Hangody, who first reported use of the mosaicplasty technique in humans in 1992, has authored a number of summaries and case series. (3-5) It is likely that these reports contain overlapping populations of patients, and few details are reported. In a 1997 article, Hangody and colleagues refer to a 1992–1994 comparison study of mosaicplasty and abrasion arthroplasty. No details of this study are provided, except to note that the mosaicplasty patients had significantly improved Hospital for Special Surgery (HSS) knee scores, compared to those undergoing abrasion arthroplasty. (1) A 2008 summary paper includes descriptions of a prospective multicenter comparison of 413 resurfacing procedures and follow-up from 1,097 mosaicplasties at the authors’ institution. (5) Although the authors report that the comparative study found hyaline-like resurfacing to result in a better clinical outcome than other techniques, the cited study is not available as a publicly available peer-reviewed publication. For the retrospective analysis, Hangody and colleagues reported 789 implantations on the femoral condyles, 147 in the patellofemoral joint, 31 on the tibia condyles, 98 on talar domes, 8 on the capitulum humeric, 3 on humeral heads, and 11 on femoral heads. About two thirds of the patients were reported to have had a localized cartilage lesion, and the remainder underwent surgery because of osteochondral defects. In 81% of patients, concomitant surgical interventions were performed; these included reconstruction of the anterior cruciate ligament (ACL) realignment osteotomies, meniscus surgery, and patellofemoral realignment procedures. Clinical scores found good to excellent results in 92% of patients with femoral condylar implantations, 87% of tibial resurfacings, 74% of patellar and/or trochlear mosaicplasties, and in 93% of talar procedures. Moderate and severe donor-site disturbances were reported in 3% of patients. Ninety-eight second-look arthroscopies were done for persistent or recurrent pain, swelling, or postoperative intra-articular bleeding (31 patients at 2 months to 11 years); second trauma (26 patients at 1–9 years); or to evaluate recovery in professional athletes (41 patients at 4–7 months). Although at least 57 (58%) second-look arthroscopies were associated with clinical symptoms, the report indicates that 81 (83%) of the evaluations indicated good gliding surfaces, histologically proven survival of the transplanted hyaline cartilage, and acceptable fibrocartilage covering of the donor sites. Slight or severe degenerative changes were seen at the recipient and/or donor sites in 17 cases (17%). The association between clinical symptoms and histological results was not discussed. Painful hemarthroses were observed in 56 (5%) patients. The authors note that although these results are encouraging for use of autologous osteochondral mosaicplasty as an alternative treatment for small- and medium-sized focal defects, postoperative bleeding from the empty donor tunnels represents a possible postoperative complication, and donor-site morbidity remains an open question. Based on their extensive experience with this procedure, Hangody and colleagues consider the optimal indications to be a lesion size of 1–4 cm2, patient age of 50 years or younger (due to decreased repair capacity with aging), and correction of instability, malalignment, and meniscal or ligamental tears. (5)

Osteochondral Autografts and Allografts for Focal Articular Cartilage Lesions of the Knee

Comparative Trials

Osteochondral Autografts in Comparison with Microfracture: Three randomized controlled trials from the same group of investigators and 1 retrospective comparative trial have been identified that compared outcomes following osteochondral autografting or microfracture.

Gudas et al. reported a well-controlled and blinded comparison of arthroscopic OAT versus microfracture for lesions of the femoral condyle (1–4 cm2) in 60 athletes between 15 and 40 years of age.
age (mean, 24.3 years). (6) Follow-up on 95% of the athletes for up to 3 years following surgery showed that more athletes returned to sports activities (mean, 6.5 months) following OAT (93% vs. 52%), and fewer required revision (1of 28 vs. 9 of 29 – both respectively). Overall, 96% of patients treated by OAT had an excellent or good result compared with 52% treated by microfracture. At 1-year follow-up, scores on the International Cartilage Repair Society (ICRS) cartilage grading system improved from a baseline of 51 to 86 in the OAT group and 76 in the microfracture group. At 3-year follow-up, scores from HSS questionnaires improved from a baseline of 77 to 91 in the OAT group and 81 in the microfracture group. No donor-site morbidity was observed. Blinded arthroscopic and histological assessment in a subset of patients showed hyaline cartilage of normal appearance following transplantation, whereas microfracture was frequently observed to result in surface fibrillation and soft fibroelastic tissue. At 10-year follow-up, there were 4 failures (14%) in the OAT group and 11 failures (38%) in the microfracture group. (7) The Tegner scores decreased in both groups over time, but remained significantly better following OAT than microfracture. In the subgroup of patients who were younger than 25 years of age at the time of surgery, 15 of 20 patients (75%) in the OAT group and 8 of 22 patients (37%) in the microfracture group maintained the same level of activity (competitive athletes or frequently sporting) as before the injury. The level of sporting activity was reported to decrease in older patients because of age or other reasons not related to their knee.

Another report by Gudas and colleagues was a comparison of mosaicplasty versus microfracture or debridement. One hundred and two patients with lesions associated with anterior cruciate ligament (ACL) injury were randomized to one of the 3 procedures in association with ACL repair. (8) A matched control group of 34 patients with ACL injury but no articular cartilage lesion was included for comparison. The postoperative rehabilitation protocol was the same for the 3 treatment groups. At a mean 36.1-month follow-up, patients were evaluated with the International Knee Documentation Committee (IKDC) score, Tegner activity score, and clinical assessment. All groups showed a significant improvement in the IKDC score compared to before surgery. Patients without cartilage lesions had IKDC subjective scores that were significantly better than patients with cartilage lesions. For the 3 groups of patients with cartilage lesions, the mosaicplasty group’s IKDC subjective knee evaluation was significantly better than the microfracture or debridement groups, although the differences between the groups were modest. Tegner activity scores were similar for the mosaicplasty and microfracture groups (7.1 and 6.9, respectively), and slightly lower for the debridement group (6.2).

Gudas and colleagues also published a randomized trial of osteochondral transplantation (n=25) versus microfracture (n=25) in children 12 to 18 years of age (mean of 14.3 years). (9) Only children with grade 3 or 4 osteochondritis dissecans (OCD) defects of the femoral condyles were included in the study. The OCD defects were between 2 and 4 cm² in area, and the mean duration of symptoms was 24 months. Follow-up was obtained in 94% of patients. After 1 year, the proportion of excellent to good outcomes was similar for the 2 groups (92% for osteochondral transplantation vs. 86% for microfracture). However, after a mean 4.2 years of follow-up (range 3 to 6 years), the microfracture group showed 9 failures (41% of 22). In comparison, there were no failures in the osteochondral transplantation group, and good to excellent outcomes were obtained in 83% of the children. Magnetic resonance imaging (MRI) at a mean 18 months after the operation showed no evidence of graft loosening or migration with excellent or good repair in 19 of 21 children (91%). In comparison, blinded evaluation showed excellent or good repair in 10 of 18 children (56%) after microfracture.

Krych et al. reported a retrospective comparison of 96 patients treated with either mosaicplasty or microfracture for articular cartilage defects of the knee. (10) Outcomes were measured annually at 1, 2, 3, and 5 years. At the latest follow-up, there was no significant difference between the 2 groups in the Short Form (SF)-36 physical component, the Knee Outcome Survey activities of daily living, or IKDC scores. The mosaicplasty group showed a greater improvement in the Marx Activity Rating Scale at the 2-, 3-, and 5-year follow-up.

Osteochondral Autografts in Comparison with Autologous Chondrocyte Implantation: There are several randomized controlled trials that compare outcomes following treatment with osteochondral autografts or ACI.
Bentley and colleagues randomized 100 consecutive patients with symptomatic lesions of the knee (average 4.7 cm², range, 1 to 12 cm²) to ACI or mosaicplasty. Seventy-four percent of lesions were on the femoral condyle, and 25% of lesions were on the patella. Ninety-four patients had undergone previous surgical interventions, and the average duration of symptoms before surgery was 7 years. Clinical assessment at 1 year showed excellent or good results in 98% of the ACI patients and 69% of the mosaicplasty patients. The mosaicplasty plugs showed incomplete healing of the spaces between the grafts, fibrillation of the repair tissue, and disintegration of the grafts in some patients. This finding may be related to both the relatively large lesion size and the unusual prominent placement of the plugs in this study, which was intended to allow contact with the opposite articular surface. With 6 patients lost to follow-up at a minimum 10 years after the index surgery, repair was found to have failed in 17% of patients treated with ACI and 55% of patients treated with mosaicplasty.

Dozin et al. reported results from a multicenter randomized clinical trial in which ACI was compared to mosaicplasty. Forty-four individuals (61% male, 39% female) age 16–40 years (mean 28.7 ± 7.8), who had a focal, symptomatic chondral injury of Outerbridge grade III or IV with no previous surgical treatment, were randomly assigned to ACI or mosaicplasty 6 months after undergoing arthroscopic debridement. The average lesion size was 1.9 cm. Only 12 of 22 (54%) in the ACI group and 11 of 22 (50%) of the mosaicplasty group actually underwent the assigned procedure. Dropouts comprised 14 patients (32%) who reported spontaneous improvement following arthroscopy and did not undergo subsequent surgery, 5 who did not show up at the presurgery examination and could not be further traced, and 2 who refused surgery for personal reasons. Because of the substantial dropout rate, the original primary outcome measure, the mean Lysholm Knee Scoring Scale (LKSS) assessed 12 months post-surgery was converted into a scale in which improvement was categorized by proportions of responders (LKSS <60, LKSS 60-90, LKSS 90-100). With this scale, and including 10 patients who were cured by debridement (intention-to-treat analysis), the percentages of patients who achieved complete success were 89% (16 of 18 evaluable cases) in the mosaicplasty arm versus 68% (13 of 19 evaluable cases) in the ACI arm (test for trend p=0.093). The high rate of spontaneous improvement after simple debridement raises questions about the appropriateness of additional surgical intervention in patients with small lesions similar to those included in this trial.

Horas and colleagues reported 2-year follow-up on a study of 40 patients (between 18 and 42 years of age) with an articular lesion of the femoral condyle (range of 3.2 to 5.6 cm²) who were randomly assigned to undergo either autologous chondrocyte implantation or osteochondral autografting. Eleven (28%) had received prior surgical treatment. The authors reported that both treatments resulted in an improvement in symptoms (85% of each group), although those in the osteochondral autografting group responded more quickly. Histomorphologic evaluation of 5 biopsy specimens at 2 years or less after transplantation indicated that the osteochondral cylinders had retained their hyaline character, although the investigators noted a persistent interface between the transplant and the surrounding original cartilage. Evaluation of autologous chondrocyte implants indicated a rigid, elastic tissue, with partial roughening and the presence of fibrocartilage.

**Autologous Minced Cartilage:** In 2011, Cole et al. reported a multicenter trial with 29 patients (out of 582 screened) randomized in a 1:2 ratio to microfracture or Cartilage Autograft Implantation System (CAIS). In the single-stage CAIS procedure, autologous hyaline cartilage was harvested, minced, affixed on a synthetic absorbable scaffold, and then fixed on the lesion site with absorbable staples. At baseline, there were no significant differences between groups in the duration of symptoms, International Cartilage Repair Society (ICRS) grade, and area and depth of the chondral defect. There was a difference in the gender and work status of the 2 groups. At 3 weeks and 6 months’ follow-up, there were no significant differences in outcomes between the 2 groups, but at later time points, there were differences reported. The IKDC score was significantly higher in the CAIS group compared to the microfracture group at both 12 (73.9 vs. 57.8) and 24 (83.0 vs. 59.5) months. All subdomains of the KOOS (Knee Injury and Osteoarthritis Outcome Score - Symptoms and Stiffness, Pain, Activities of Daily Living, Sports and Recreation, Knee-related Quality of Life) were significantly increased at 24 months in the CAIS group compared with microfracture patients. Qualitative analysis of magnetic
resonance imaging (MRI) at 3 weeks and 6, 12, and 24 months showed no differences in fill of the graft bed, tissue integration, or presence of subchondral cysts. Adverse events were similar for the 2 groups.

Observational Studies
There are a number of observational studies that provide additional information on outcomes, including longer follow-up, following treatment with osteochondral autografts and allografts.

Osteochondral Autografts: Ollat et al. reported a retrospective multicenter study from the French Society of Arthroscopy that included 142 patients and a mean follow-up of 8 years. (16) (The authors comment that this technique has been used extensively in France due to restrictive legislation on restoration techniques, including chondrocyte transfer.) The mean size of the lesion was 2.29 cm², and the most common etiologies were osteochondral fractures (n=79) and OCD (n=61). The mean number of plugs was 4 (range, 1-14). Postoperative complications occurred in 19 patients (13%). Most patients (81.8%) were satisfied or very satisfied with the functional outcomes. There was a significant improvement in the ICRS, International Knee Documentation Committee (IKDC) function, and Hughston scores at follow-up. The factors for a good prognosis were found to be: male gender, location of the defect in the medial femoral condyle, OCD, deep, small defects, and a short interval before surgery. Obesity, smoking, work-related accidents, the level of sports practiced, the percentage of coverage of the defect, the number of plugs, and associated lesions did not have a statistically significant effect on the functional results in the final follow-up.

Laprell and Petersen reported 6- to 12-year follow-up from 29 of 35 patients (83%) with severe osteochondral defects (77% with OCD) who were treated by autologous osteochondral transplantation. (17) The average age of the patients at the time of surgery was 26 years. Clinical evaluation at an average 8 years after the procedure found 12 patients (41%) to be normal, 14 (48%) as nearly normal, and 3 (10%, all of whom refused correction of malalignment) as abnormal. No patient was assessed as severely abnormal. In contrast, no patients considered their functional status to be normal, 3 (10%) considered function to be nearly normal, 20 (69%) thought their function abnormal, and 6 (21%) considered their functional status to be severely abnormal.

Another report described 7-year follow-up on 30 patients who had been treated with autologous osteochondral transplantation for symptomatic grade III to IV chondral lesions (average 1.9 cm, range of 1.0 to 2.5 cm). (18) Nineteen patients received other procedures (ACL reconstruction, meniscectomy, medial collateral ligament repair) at the same time, and it is therefore not possible to assess the contribution of the osteochondral transplantation to the functional results reported. Magnetic resonance imaging at 7 years showed complete bone integration in 96% of patients, complete integration of the grafted cartilage in 75% of cases, complete filling of the cartilage defect in 63% of the patients, and congruency of the articular surface in “some” patients. Subchondral bone changes (edema or sclerosis) were noted in 71% of patients. The donor sites were filled with a tissue of different density than the surrounding bone, presumed to be fibrous tissue. No patients reported anterior knee pain. Non-painful patellar crepitus was observed in 3 (10%) patients.

Solheim and colleagues reported 5- to 9-year follow-up from 69 patients treated for articular cartilage defects of the femoral condyle (n=47), patella (n=18), or trochlea (n=4). (19) Exclusion criteria were joint space narrowing, axial malpositioning, ligament instabilities, or inability to follow the rehabilitation protocol. Four of the 73 patients (5%) who met the study criteria were not available for/or refused to participate in the long-term follow-up. In 23 patients (33%), second-look arthroscopy was performed due to insufficient improvement of symptoms between 1 and 5 years after the index procedure. Of these, 6 patients were found to have lost one or more of the transplanted grafts, while a new lesion surrounding the grafts was observed in another 6 patients; these were treated with microfracture and/or debridement. The study found significant improvement in Lysholm score and visual analogue scale (VAS) score for pain at 5- to 9-year follow-up, with 53 patients (77%) improved over the preoperative condition. Results were not reported by location of the index lesion.
Nho et al. reported average 29-month follow-up following patellar resurfacing with osteochondral autografts in 22 patients. (20) Indications for surgery were patellofemoral malalignment, isolated cartilage lesion, OCD, or patellar dislocation. Concomitant procedures, including patellar realignment, were performed according to surgeon preference. The mean lesion size was 1.6 cm², filled with an average 1.8 plugs per defect. The International Knee Documentation Committee (IKDC) score improved from 47 preoperatively to 74 at follow-up. The activity of daily living score increased from 60 preoperatively to 85 at follow-up. There was a trend toward greater improvements in the 11 patients who did not undergo concomitant distal realignment of the patella than for the 9 patients who had distal realignment along with osteochondral autografting.

Osteochondral Allografts: Long-term outcomes with osteochondral allografting have been reported in case series. Emmerson et al. reported mean 7.7 year follow-up (range 2-22 years) from 66 knees of 64 patients who underwent fresh osteochondral allografting for the treatment of OCD of the femoral condyle. (21) All patients had undergone previous surgery, with an average of 1.7 prior surgeries on each knee. The mean allograft size was 7.5 cm². One knee was lost to follow-up. Of the remaining 65 knees, 10 patients (15%) underwent reoperation, 47 (72%) were rated good to excellent and 8 (13%) were rated fair to poor. Kaplan-Meier survival analysis demonstrated 91% graft survival at 5 years and 76% graft survival at 10 and 15 years. The mean D’Aubigne and Postel score improved from 13.0 (fair) preoperatively to 16.4 (good) at the most recent follow-up. Subjective knee function improved from a mean of 3.4 to 8.4 on a 10-point scale.

Osteochondral Autografts: Zengerink et al. published a systematic review of treatment of osteochondral lesions of the talus in 2010. (23) Fifty-one nonrandomized and 1 randomized trial were included in the review. Success rates averaged 85% for bone marrow stimulation, 87% for osteochondral autografting, and 76% for ACI. Because of the high cost of ACI and the knee morbidity seen with osteochondral autografting, the authors concluded that bone marrow stimulation is the treatment of choice for primary osteochondral talar lesions. A 2009 report examined the association between defect size and outcomes following marrow stimulation techniques in 120 ankles. (24) Eight ankles subsequently underwent osteochondral transplantation and 22 ankles were considered clinical failures (American Orthopaedic Foot and Ankle Society [AOFAS] Ankle-Hindfoot score <80). Linear regression suggested a cutoff defect size of 1.5 cm² for marrow stimulation techniques, with an 80% failure rate compared to a 10.5% failure rate for ankles with a defect size less than 1.5 cm². Three of 58 ankles (5.2%) with a defect area
less than 1 cm² showed clinical failure, while 7 of 37 ankles (18.9%) with a defect area between 1.0 and 1.5 cm² had failed.

The sole controlled trial that has been identified randomized 32 patients with osteochondral lesions of the talus to chondroplasty, microfracture, or OAT. (25) This study found similar improvements (approximately 40 points) for the 3 treatment groups as measured by the AOFAS Ankle-Hindfoot Score (baseline score of 31 to 37) and the Subjective Assessment Numeric Evaluation (baseline score of 35 to 36). Complication rates were also similar, with persistent pain reported by one patient following chondroplasty, by 2 patients following microfracture, and by 2 patients following OAT. Postoperative pain, measured by Numeric Pain Intensity Scores, was greater following OAT (5.25) than chondroplasty (3.3) or microfracture (3.4).

A prospective, uncontrolled study of 32 patients who underwent open osteochondral autografting of the talus for osteochondritis dissecans was reported in 2012. (26) The osteochondral grafts were harvested from the ipsilateral knee and placed in the talus after medial malleolar osteotomy. At baseline, the average AOFAS score was 59.1. At a mean 16.8 months’ follow-up (range, 12 to 24 months), the AOFAS score had improved to 87.9. All patients showed an improvement of at least 20 points. The Lysholm score, used to assess donor site morbidity, was 88 points at 6 weeks postoperatively and 98 points at 6 months. Two patients had persistent knee pain at the last follow-up.

In 2006, Scranton et al. reported a study of 50 consecutive patients with a type-V cystic talar defect who were treated with a single osteochondral graft (15 mm) taken from the ipsilateral knee. (27) Patients with larger lesions in which multiple allograft plugs were used were excluded from analysis. Thirty-two patients (64%) had undergone a previous surgical procedure on the ankle; further surgery was required in 17 patients (34%). When contacted at a mean of 36 months (range, 24 to 83) after the index procedure, 45 patients (90%) had a good to excellent score on the Karlsson-Peterson Ankle Score questionnaire. Two patients had severe degenerative changes and underwent arthrodesis.

In 2006, Kreuz et al. reported outcomes from a series of 35 patients who underwent osteochondral grafting from the ipsilateral talar articular facet (with or without osteotomy) following failed bone marrow stimulation. (28) Six of the patients had previously undergone osteochondral or cancellous bone grafting of the defect area. The mean lesion size was 6.3 mm. At a mean follow-up of 49 months (range 33 to 77 months), the AOFAS Ankle-Hindfoot score had improved from 54.5 (range 47–60) to 89.9 points (range 80-100).

In 2011, Imhoff and colleagues reported a retrospective review with long-term outcomes following osteochondral autografts of the talus in 28 consecutive patients. (29) The osteochondral grafts were harvested from the femoral condyles and malleolar osteotomies were performed whenever the osteochondral defect could not be reached from the anterior incision. One patient was lost to follow-up, and 2 patients had a revision operation on the ankle. For 16 of the remaining 25 patients (64%), the autograft was the first line of treatment, and in 9 patients (36%), it was a second surgical intervention. Between baseline and average 7 years’ follow-up (range, 53-124 months), the AOFAS score increased from 50 to 78 points, the Tegner score increased from 3.1 to 3.7, and the VAS for pain decreased from 7.8 to 1.5. Patients who had transplant as a second procedure had significantly worse AOFAS (62 vs. 87) and Tegner scores (2.0 vs. 4.6) and higher VAS scores (3 vs. 0.6 – all respectively).

Hangody et al. reported 2- to 7-year follow-up in 36 consecutive patients treated with osteochondral autografting for OCD of the talus. (30) Most of the patients had previous surgical interventions and presented with Stage III or IV lesions (completely detached or displaced fragment). The average size of the defect was 1 cm, and the average number of grafts per patients was 3 (range, 1-6). At mean follow-up of 4.2 years, ankle function measured by the Hannover scoring system showed good to excellent results in 34 cases (94%). Examination by radiograph, computed tomography (CT), and magnetic resonance imaging (MRI) showed incorporation into the recipient bed and congruency of the articular surface.
In 2011, Liu et al. reported osteochondral autografting in 16 patients for acute osteochondral fractures of the talar dome associated with an ankle fracture. (31) Ankle radiographs were taken at 2, 6, and 12 weeks postoperatively and every 3 months after fracture healing. MRI was performed after 12 months and at the latest follow-up. At an average 36-month follow-up (range, 21–48 months), the AOFAS score was 95.4 (range, 86-100). At the latest follow-up, there was no radiographic evidence of post-traumatic arthritis, and MRI showed bony integration and articular congruity of the talar dome in 93.7% of the osteochondral grafts.

Donor Site Morbidity: One study evaluated donor-site morbidity in 11 of 15 patients who had undergone graft harvest from the knee (mean of 2.9 plugs) for treatment of osteochondral lesions of the talus. (32) At an average 47-month follow-up (7–77 month range), 5 patients were rated as having an excellent Lysholm score (95–100 points), 2 as good (84–94), and 4 as poor (64 or less). Reported knee problems were instability in daily activities, pain after walking 1 mile or more, having a slight limp, and difficulty squatting. Hangody et al. reported that some patients had slight or moderate complaints with physical activity during the first postoperative year, but there was no long-term donor site pain in a series of 36 patients evaluated 2-7 years after osteochondral autografting. (30) A 2009 report from Europe described osteochondral autografting for lesions of the talus in 200 patients, 112 of whom had been followed up for a minimum of 2 years. (33) The focus of this study was to determine factors contributing to donor-site morbidity in the knee, rather than outcomes for the talus. The number of grafts, size of the transplanted plugs, and patient age were not related to donor-site morbidity. Body mass index (BMI) was found to be significantly associated with knee scores, with a decrease in Lysholm score by 1 point (1%) for each point increase in BMI. Interpretation of these results is limited by the lack of preoperative assessment of knee pain and function.

Osteochondral Allografts: Use of allografts for large defects of the talus has been reported in case series. Due to the relatively rare occurrence of this condition, most series have fewer than 20 patients.

The largest series is from Bugbee et al., who reviewed outcomes of 86 ankles (82 patients) treated with bipolar fresh osteochondral allografts for arthritis of the tibiotalar joint. (34) All patients had declined arthrodesis. Patients who did not present for follow-up were contacted via telephone and/or mail to obtain subjective outcomes. At a mean follow-up of 5.3 years (range, 2 to 11), 36 ankles (42%) had undergone additional surgery. Twenty-five ankles (29%) were considered clinical failures (i.e., revision allograft, conversion to total ankle arthroplasty, arthrodesis, or amputation) and 11 ankles (13%) had undergone operations that did not involve graft removal. Radiographic evaluation categorized 29 of 63 ankles (46%) as failures, with graft collapse observed in 11 of the 29 (38%). Survivorship of the osteochondral allograft estimated by Kaplan-Meier analysis was 76% at 5 years and 44% at 10 years. For patients who did not undergo additional surgery, 62% were classified as having excellent to good results, 26% as fair, and 12% as poor.

In 2012, Haene et al. reported a prospective study of fresh talar osteochondral allografts in 16 patients (17 ankles) with large osteochondral lesions of the talus. (35) All but one of the ankles had previously undergone single or multiple procedures. Computed tomography (CT) at an average follow-up of 4.1 years (range, 2 to 6 years) identified failure of graft incorporation in 2 ankles, osteolysis in 5, subchondral cysts in 8, and degenerative changes in 7 ankles. Clinically, 5 ankles (29%) were considered failures, and 2 (12%) had poor outcomes requiring additional surgery. Ten ankles (59%) had good to excellent results based on validated outcome scores and clinical history.

Berlet et al. reported a 2011 prospective study with minimum follow-up of 2 years in 12 patients who had received an osteochondral allograft for talar defects. (36) In another patient, the graft had failed and was not included in the analysis. All patients had failed at least one prior surgical treatment and had a mean lesion size of 1.5 cm2. At follow-up (mean 3.3 years), AOFAS Ankle-Hindfoot scores improved from 61 at baseline to 79. There was a trend toward improvement in the physical or mental health components of the Short-form (SF)-12 Health Survey, although the study was underpowered to detect a significant difference. Radiographs and MRI performed yearly showed radiolucencies in 3 grafts (25%), edema in 4 (33%), and failure to incorporate for 1 graft.
El-Rashidy et al. reported a retrospective review of 38 of 42 total patients who were treated with osteochondral allografts. (37) All patients had failed conservative management and had a mean lesion size of 1.5 cm². Grafts were harvested from a similar anatomic location on the donor talus to match the contour and surface anatomy of the recipient bed. The average duration of follow-up was 38 months. Including scores from 4 patients (10.5%) in whom graft failure occurred, the AOFAS Ankle-Hindfoot score improved from 52 to 79 points and VAS improved from 8.2 to 3.3 points. Patient satisfaction with the outcome was rated as excellent, very good, or good by 28 of the 38 patients (74%) and as fair or poor by 10 patients (26%). Of the 15 patients who had postoperative MRI, 5 (33%) had signs of graft instability.

Raikin published results from a series of 15 patients who underwent fresh matched osteochondral allograft transplantation for talar lesions with a volume greater than 30 cm³. (38) At an average 54 months after surgery (minimum of 2 years), mean VAS for pain had improved from 8.5 to 3.3 and the mean AOFAS Ankle-Hindfoot score had improved from 38 to 83 points. Two ankles had undergone conversion to fusion. Radiographic analysis revealed some evidence of collapse or resorption in 10 of the 15 ankles (67%).

Gortz et al. reported on a series of 11 patients (12 ankles) who underwent fresh osteochondral allografting for unipolar lesions of the talus. (39) Patients had undergone an average of 1.8 prior surgeries (range, 1 to 5). The average graft size was 3.6 cm², which was an average of 40.5% of the talar surface. At a mean 38-month follow-up (range, 24 to 107 months) 2 of the ankles had failed and undergone revision or fusion. For the remaining 10 patients, the mean Olerud-Molander Ankle Score (OMAS) improved from a score of 28 to 71. Outcomes were categorized at good to excellent in 5 ankles (42%), fair in 3 (25%), and poor in 2 (17%). All patients demonstrated radiographic union by 6 months, with an overall graft survival rate of 83%.

Allogeneic Minced Cartilage: Bleazey and Brigado conducted a retrospective review of 7 patients who were treated with juvenile minced cartilage (DeNovo NT) together with sponge allograft. (40) All patients had failed conservative therapy (walking boot and physical therapy) and 4 patients had failed microfracture. Patients were evaluated with VAS for pain and activity at 6-month follow-up. All patients showed clinically significant improvement. Pain during walking decreased from an average of 7.7 at baseline to 1.9 at 6 months. Ability to walk 4 blocks improved from a score of 4.8 to 9.2.

Osteochondritis Dissecans of the Elbow

Osteochondral Autografts: OCD of the elbow is an uncommon condition that in its early stages can be treated nonoperatively or with simple fragment removal. (41) The literature on osteochondral autografts for advanced OCD of the elbow consists of small case series, primarily from Europe and Asia.

Iwasaki et al. reported minimum 2-year follow-up after osteochondral mosaicplasty for OCD of the elbow in 19 teenage athletes (mean age of 14 years) in Japan. (42) Preoperative symptoms consisted of pain with sports activities (n=19) patients, limited range of motion (n=5), and elbow catching (n=3). Indications for surgery included failure of more than 6 months of conservative treatment or evidence on plain radiographs and MRI of unstable lesions, such as displaced (n=7) or detached (n=12) fragments. The mean defect size was 1.5 cm² (range, 0.5 to 3.0 cm²). Two independent observers assessed clinical findings at a mean of 45 months (range, 24–87 months); the radiologist was blinded to the clinical outcomes. Graft incorporation was observed in all patients, with nearly normal surface integrity of the articular cartilage and underlying bone in 18 patients. Eighteen of the 19 patients were classified with good to excellent results and were free from elbow pain. One patient was classified as fair with mild pain. Seventeen of the 19 patients, including all pitchers, returned to a competitive level of baseball. Mild donor site pain in the knee was reported in one patient.

Yamamoto et al. reported minimum 2-year follow-up (range, 24-63 months) from 18 juvenile baseball players with OCD of the elbow who were treated with osteochondral autografts. (43) Most of the patients had failed conservative management at another hospital in Japan. For grade 3 lesions (separated but in situ), 1 or 2 osteochondral plugs from the femoral condyle or patellofemoral joint were
used to restore the articular surface or fix unstable OCD lesions. For grade 4 lesions (displaced fragment), 1 to 3 plugs were used to restore the articular surface. For the 9 patients with a grade 3 lesion, the subjective score was increased (from 75.0 to 95.6), but the objective score (from 88.3 to 88.3) did not change. For the 9 patients with a grade 4 lesion, both subjective (from 65.6 to 88.9) and objective scores (from 72.8 to 88.3) were increased significantly. At 6 months after surgery, all patients but one could throw a ball without pain.

In 2011, Ovesen et al. reported mean 30-month follow-up from 10 patients (age, 13-27 years) treated with osteochondral autografts from the lateral patellofemoral joint for advanced OCD of the elbow. (44) Eight of the patients (80%) were pain-free postoperatively. The Mayo Elbow Performance Score improved from a preoperative mean of 71 points to 93.5 points postoperatively. This compared to a score of 100 points for the nonoperated elbows. The Constant functional elbow score averaged 92.5 points for the operated elbow and 100 for nonoperated elbows. Postoperative radiographs and MRI/computed tomography showed incorporation and a normal contour of the subchondral cortex in all patients. No problems were observed regarding donor site pain.

Donor Site Morbidity: Nishimura et al. evaluated recovery of the donor knee after osteochondral autograft harvesting for capitellar OCD in 12 young athletes (age range, 12 to 17 years). (45) Pain and function were assessed at 1, 2, 3, 6, 12, and 24 months after the surgery. Knee joint effusion persisted in 7 of the 12 patients at 1 month, but none of the patients had effusion at 3 months. At 3 months, muscle power of the knee extensor was reduced in 8 patients compared to the preoperative level. At 12 months, 11 patients had reached preoperative knee extensor muscle strength. All patients were pain-free at the donor site by 6 months (mean Lysholm score of 100) and returned to the previous competitive level of their sport.

Shoulder
Osteochondral Autografts: A European study reported 9-year follow-up after osteochondral autografting for cartilage defects of the shoulder in 7 patients. (46) One additional patient was reported to have had donor-site morbidity at the knee and chose not to return for follow-up. All of the plugs showed full integration with the surrounding bone, and 6 of 7 patients showed a congruent joint surface. The Constant score improved from 76 preoperatively to 90 points at 33 months and remained at 91 points at the 9-year follow-up. Subscores for pain and activities of daily living showed significant improvement at 33-month follow-up, with a very slight non-significant decline at 9-year follow-up. None of the patients required additional shoulder surgery.

Ongoing Clinical Trials
A search of the online site www.clinicaltrials.gov in May 2013 identified an industry-sponsored Phase IV (post-marketing) trial with Chondrofix® (NCT01410136). The study has an estimated enrollment of 50 patients who may have up to 2 cartilage lesions, each measuring less than 8 cm², of the femoral condyle or trochlea. The study will follow patients through 60 months and has an estimated completion date of September 2017.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2008
In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2008. All reviewers agreed that osteochondral autografts and allografts are considered reasonable for patients with full-thickness chondral defects who meet specific criteria.

2011
In response to requests, input was received from 3 academic medical centers while this policy was under review in 2011. The clinical input was generally in agreement with the stated criteria for osteochondral grafting with the exception of the following: input was mixed regarding the requirement for an inadequate response to a prior surgical procedure, the size of the lesion, and the requirement for an absence of meniscal pathology. Input was also mixed regarding the investigational status of osteochondral grafts in other joints, including the patellar and talar joints, and for the use of autologous minced cartilage.

Summary
Evidence is sufficient to consider osteochondral allografting medically necessary as a technique to repair large (e.g., 10 cm²) full-thickness chondral defects of the knee caused by acute or repetitive trauma. Use of allografts for large defects of the talus has been reported in small case series. Evidence is insufficient to evaluate the effect of osteochondral allografting of the talus, or other joints, on health outcomes. Therefore, osteochondral allografts for joints other than the knee are considered investigational.

For osteochondral autografting, only 3 relatively small randomized controlled trials from the same investigators in Europe have demonstrated improved clinical outcomes with osteochondral autografting of the knee when compared with microfracture. Data regarding the long-term viability of the transplanted osteochondral hyaline cartilage is also limited. However, controlled studies demonstrate similar benefit to other cartilage resurfacing procedures in appropriately selected patients, and a number of uncontrolled studies indicate that osteochondral autografts can improve symptoms in some patients with lesions of the femoral condyle who have failed prior surgical treatment. These patients have limited options. Therefore, based on the clinical input received and additional literature reviewed, it is concluded that osteochondral autografts may be considered an option for symptomatic full-thickness chondral lesions of the femoral condyle or trochlea caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. Recent evidence indicates that osteochondral grafting combined with meniscal allograft results in outcomes similar to either procedure performed alone; therefore combined procedures may be considered medically necessary.

Evidence is currently insufficient to evaluate the efficacy of osteochondral autografts for joints other than the knee, or to evaluate the efficacy of osteochondral autografts in comparison with other surgical repair procedures as a primary treatment of small lesions. Questions also remain about the natural history of asymptomatic lesions found incidentally during other surgical procedures. Controlled trials with longer follow-up are needed to demonstrate that use of osteochondral autografts as a primary treatment results in improved clinical outcomes in comparison with traditional marrow-stimulating procedures.

Minced cartilage techniques are in the early stages of development and testing and/or not approved in the U.S.; these are considered investigational.

Practice Guidelines and Position Statements
In 2010 and 2012 clinical practice guidelines on the diagnosis and treatment of osteochondritis dissecans (OCD), the American Academy of Orthopaedic Surgeons (AAOS) was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable osteochondritis dissecans lesion. (47, 48)

The Interventional Procedures Advisory Committee of the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) conducted a 2005 review of mosaicplasty for knee cartilage defects. (49) The corresponding NICE Guidance on mosaicplasty, released in 2006, (50) stated that “There is some evidence of short-term efficacy, but data on long-term efficacy are inadequate.”

Medicare National Coverage
There is no national coverage determination.
References

Billing Coding/Physician Documentation Information

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<td>27415</td>
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Additional Policy Key Words

N/A

Policy Implementation/Update Information

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removed from policy statement per separate policy.

2/1/13 No policy statement changes.
8/1/13 Coding updated.
2/1/14 Investigational statements added on autologous and allogeneic minced cartilage.
Removed "Osteochondral" from title.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.