
Medical Policy



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***Current Policy Effective Date: 9/1/12**
(See policy history boxes for previous effective dates)

Title: Osteochondral Grafts for Articular Cartilage Lesion Repair (Autografts, Allografts and Synthetic Grafts)

Description/Background

Osteochondral allografting and autografting involve transplantation of a piece of articular cartilage and attached subchondral bone from a donor or donor area to a damaged region of the articular surface of a joint. The goal of this procedure is to provide viable chondrocytes and supporting bone that will be sufficient to maintain the cartilage matrix and thereby relieve pain and reduce further damage to the articular surface of the joint. Damage to the hyaline cartilage may result either from traumatic injury or from degenerative conditions (e.g., osteochondritis dissecans, osteonecrosis or osteoarthritis).

Osteochondritis dissecans is a condition in which a small piece of bone and overlying cartilage cracks loose and becomes avascular with subsequent changes to the overlying articular cartilage. Undisplaced lesions in skeletally immature individuals generally heal with immobilization. However, in skeletally mature individuals, surgery is often indicated. Magnetic resonance imaging is used to determine the size and integrity of the lesions. Arthroscopic evaluation is recommended for patients over the age of 12, and for lesions that are larger than one centimeter (cm) in diameter and located in a weight-bearing area.

Knee:

Focal chondral defects of the knee, 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. 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 different strategies for chondral resurfacing with hyaline cartilage have been investigated. Autologous chondrocyte transplant

involves the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces which are then cultured and expanded in vitro and then transplanted back into the patient.

Both fresh and cryopreserved *allogenic* 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 also create concerns regarding infectious diseases. For these reasons, there has been ongoing interest in *autologous* osteochondral grafts as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission. Autologous grafts have been limited by the small number of donor sites. Single grafts have been harvested from the patella, femoral condyle and proximal part of the fibula. In an effort to extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from various non-weightbearing sites in the knee. Two related procedures, osteochondral mosaicplasty and osteochondral autograft transfer system (OATS) have been described.

In the mosaicplasty procedure, the chondral lesion is excised and abrasion arthroplasty is performed to refresh the bone base of the defect. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weight-bearing area of the femoral condyle. The grafts are press fit into the lesion in a mosaic-like fashion within the same-sized drilled recipient tunnels. The resultant surface consists of transplanted hyaline cartilage and fibrocartilage arising from the abrasion arthroplasty. The fibrocartilage is thought to provide “grouting” between the individual autografts. Mosaicplasty may be performed with either an open approach or arthroscopically if the lesion is small and not more than 4 to 6 grafts are needed.

The OATS procedure focuses on chondral defects that are associated with chronic tears of the anterior cruciate ligament (ACL) using an arthroscopic approach that can provide access to both the ACL for reconstruction and performance of the autograft. 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. In contrast to autologous chondrocyte transplant, in which separate surgical procedures are required to harvest and then transplant the cultured chondrocytes, in osteochondral autografting, the harvesting and transplantation can be performed during the same surgical procedure. While osteochondral autografting has been principally performed on the knee, osteochondral grafts from the femoral condyle have also been used to repair chondral defects of the patella, tibia and ankle.

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 may decrease the viability of the cartilage cells. Fresh allografts may be difficult to obtain (due to scarcity) and may also entail a concern of disease transmission. Additionally, 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.

Ankle:

The talus is the major weight-bearing bone in the ankle, articulating directly with the tibia. Osteochondral lesions of the talus (OLT) occur predominately in younger patients, usually

between the ages of 20 and 35 years, and are thought to result mainly from trauma. These lesions consist of damage to the tough hyaline cartilage overlying the bone with various degrees of damage to the underlying (subchondral) bone. Patients, athletes in particular, may have disabling pain and weakness of the ankle. Initial therapy includes immobilization, physical therapy and medications, but when symptoms persist surgery is the only option. Operations to correct or ameliorate symptoms of OLT include:

- Arthroscopy and debridement
- Drilling
- Microfracture of the bone to promote new blood supply and stimulate new tissue formation and healing, and
- Osteochondral autologous transplant (OAT) or allograft (OAG).

These techniques try to achieve growth of new fibrocartilage on the articular surface. Many patients show improvement after these procedures, even though the resulting fibrocartilage is not as durable as hyaline cartilage. Bone graft procedures are usually reserved for patients who fail to improve after debridement, drilling and/or microfracture treatment. Osteochondral grafts try to achieve healing with a normal or near normal cartilage surface.

Osteochondral autograft transplant (OAT) involves the transplantation into the talus of small cores of healthy bone and hyaline cartilage, usually taken from the side of the femoral head at the knee. The Osteochondral Autograft Transfer System (OATS) is a specific device used for the transplantation of a single plug, whereas “mosaicplasty” refers to the transplantation of multiple smaller plugs. Surgical access is through an open incision or via arthroscopy. The injured tissue is removed and replaced by the osteochondral graft.

Osteochondral allografting (OAG) uses a graft of fresh or frozen cadaver tissue and is usually reserved for very large articular surface defects. The allografts are size-matched to the recipient by x-rays and a precise area of the damaged ankle is removed surgically and replaced with an exact-fit graft shaped from the donor tissue. Tissue matching is not necessary since bone grafts do not stimulate the host’s immune system. The results of OAG are not as good as with other procedures and more long-term studies are needed. One additional concern with fresh allografts is the possibility of transmission of disease.

Osteochondral graft procedures to the ankle are usually limited to patients under age 50, with stable joints and no associated arthritis. A newer procedure for repairing large articular defects, called autologous chondrocyte implantation (AIC), which uses cultured chondrocytes implanted under a periosteal barrier, is more complex. There is only limited information at this time regarding the safety and advisability of this procedure.

Other Joints:

Osteochondral *auto*- and *allografts* have been attempted for repair of other joints, including the shoulder and elbow and hip. There have been few studies with limited numbers of patients. Randomized, controlled studies are needed to determine long-term effectiveness for these procedures.

Synthetic Grafts:

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 bone graft substitute implant can be used to back-fill harvest sites and may be considered an

alternative to allografts and autografts by some authors. Consequently, a variety of synthetic substitutes is available and currently undergoing clinical trials.

Medical Policy Statement

- The safety and effectiveness of osteochondral allografting and autografting in the **knee** have been established. It may be considered a useful therapeutic option as a technique to repair large (e.g., 10 cm²) full-thickness chondral defects caused by acute or repetitive trauma to the knee.
 - Osteochondral autografts in the treatment of articular cartilage lesions of the **ankle** are considered established. The safety and effectiveness of these procedures have been proven.
 - Osteochondral allografts of articular cartilage lesions of the **ankle** are considered experimental and investigational. The safety and effectiveness of this procedure have not been proven.
 - Osteochondral allografting and autografting of **all other joints**, including but not limited to the shoulder, elbow and hip are experimental and investigational.
 - The use of synthetic grafting material for any articular cartilage repair is experimental and investigational. The safety and effectiveness of these devices have not been proven.
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Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Knee:

Inclusions:

Allograft transplant: It may be used as a technique to repair large (e.g., 10 cm²) full-thickness chondral defects caused by acute or repetitive trauma to the knee.

Autograft transplant: The safety and effectiveness of osteochondral autografting in the knee, using 1 or more cores of osteochondral tissue, have been established. It may be considered a useful therapeutic option as a technique to repair symptomatic full-thickness cartilage defects 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.
- Absence of meniscal pathology.

Exclusions:

Patients not meeting all the above selection criteria.

Ankle:

Inclusions:

- Autografting is used when all other forms of treatment either have failed or are not indicated for the diagnosis.

Exclusions:

- Autografts are not covered as a first-line treatment
- Osteochondral *allograft* to the ankle.

Other joints:

Neither osteochondral *autografts* nor *allografts* are covered for use in joints other than the knee or ankle.

CPT/HCPCS Level II Codes (*Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure*)

Established codes:

27415	27416	28446	29866	29867	29891
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Other codes (investigational, not medically necessary, etc.):

27899	29999
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Rationale

Knee:

The reviewed information provides evidence that osteochondral autografting and allografting may provide pain relief and improved joint function in patients with focal cartilage defects on the knee. Short term studies have shown success with these procedures. At the *Arthroscopy Association* Fall Meeting of 2004, good to excellent results were reported with a five to ten year follow up.

Osteochondral autologous transplantation in the knee appears to offer good short- to intermediate-term results for full-thickness osteochondral lesions of the femoral condyle. There is a large body of evidence including both retrospective and prospective case series, randomized controlled trials, nonrandomized controlled/comparative trials, and published reviews 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). In addition to demonstrating improvement of function and decrease in 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

Ankle:

Ankle fusion or replacement is normally the treatment of choice for older patients and patients with severe arthritis or large lesions of the ankle. Ankle replacement has not been successful in many patients. Ankle fusion results in significant functional limitations. Osteochondral autografting has been proposed as an alternative method of treatment for individuals with lesions of the ankle.

Preliminary clinical trials demonstrated encouraging results for patients who underwent osteochondral autograft transplant for treatment of symptomatic osteochondral defects of the talus. 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. 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.

The published evidence on the effectiveness and safety of osteochondral autografts for patients with osteochondral lesions of the talus (OLT) comparing outcomes for osteochondral autologous transplant (OAT), chondroplasty and microfracture indicates that pain reduction and functional improvement are better in osteochondral autograft transplant patients with small OLTs. In the case series, good to excellent results were obtained in 90% or more of patients undergoing OAT with few complications. One randomized study showed similar results for OAT, drilling and microfracture techniques.

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. 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. Osteochondral grafting to the talus should be reserved for surgeons skilled in the procedure, for patients who are not suitable candidates for ankle fusion or replacement.

Other joints:

Elbow:

Evidence in the peer-reviewed, published scientific literature regarding the use of osteochondral autograft transplantation to treat lesions of the elbow is limited. The study samples are small, and additional long-term studies are limited.

Shimada and associates (2005) conducted a retrospective case series and reviewed the results of osteochondral autografts in ten young athletes with advanced osteochondritis dissecans of the elbow. While the results of the study were encouraging, the study is limited by small sample size and short-term follow-up, in addition to lack of controls or comparison groups.

Tsuda, et al. (2005) published the results of a case report evaluating three patients (non-throwing athletes) who underwent osteochondral autograft transplantation for treatment of osteochondritis dissecans of the capitellum. The authors reported that all three patients

returned to their sports activities within six months of surgery and the results of their study suggest OAT should be considered a surgical option for patients with end-stage osteochondral lesion defects of the capitellum. This study is limited by small population and evaluation of short-term outcomes.

Iwasaki, et al. (2006) reported the results from a case series of teenage patients with osteochondral lesions of the capitellum who underwent OAT. The authors concluded that their results were encouraging; however, long-term follow-up with a larger patient population will confirm the surgical efficacy for mosaicplasty in the treatment of advanced lesions of capitellum OCD.

Ansah, et al. (2007) reported overall good to excellent results in a small case series of seven patients who were treated with osteochondral autograft transplant for lesions of the capitellum humeri. All patients received a single graft using the OATS system. In the authors opinion success of the procedure depends on an exact fit of the graft with anatomical alignment of the cartilage surface. Larger studies with longer follow-up are warranted.

Shoulder:

Focal osteochondral lesions of the shoulder are less common than those of the knee. Although evidence is limited, authors have reported on osteochondral autologous transplant as a method of treatment for full-thickness osteochondral lesions of the shoulder. Scheibel, et al. (2004) conducted a retrospective study assessing the clinical and radiological results of eight patients who underwent osteochondral autologous transplant from the knee to the shoulder. Four patients had additional capsular shift with labral augmentation. Postoperatively, all but two patients were able to achieve full work and sporting activity levels. Excellent graft viability and osseointegration of the osteochondral plugs was noted on magnetic resonance imaging in all but one patient. Gleno-humoral osteoarthritic changes were present at the latest follow-up in all patients. The authors concluded that osteochondral autograft of the shoulder appears to offer good clinical results in terms of pain relief and functional recovery. The analysis of this study is limited by small sample size, and some patients had correction of associated underlying pathology; therefore, results cannot be generalized to larger populations, and further studies are warranted.

Park et al. (2006) published a case report evaluating osteochondral autograft transplant for a defect of the humeral head. Arthroscopy at five months post-surgery revealed both recipient and donor sites were healed.

Other joints:

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. 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.

Government Regulations

National:

There is no Medicare NCD on osteochondral *allografting* or *autografting*. 27415, 27416, 28446, 29866, 29867 and 29891 are all payable for Medicare. NOC codes would be reviewed on an individual consideration basis. NOC codes require manual review.

Local:

There is no Medicare LCD on osteochondral *allografting* or *autografting*.

27415, 27416, 28446, 29866, 29867 and 29891 are all payable for Medicare. NOC codes would be reviewed on an individual consideration basis. NOC codes require manual review.

Michigan Department of Community Health:

There is no medical policy in the Medicaid manual on this topic. All codes are payable. NOC codes require manual review.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Meniscal Allograft Transplants and Collagen Meniscus Implants

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/16/12, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/09	8/18/09	8/18/09	Joint policy established; combined two previous policies on osteochondral grafts for the knee and for the ankle. Added additional information regarding grafting for other joints.
9/1/12	6/12/12	6/19/12	Updated references and rationale. No change in policy statement.

Next Review Date: 2nd Qtr, 2013

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OSTEOCHONDRAL GRAFTS FOR ARTICULAR CARTILAGE REPAIR
(AUTOGRAFTS, ALLOGRAFTS AND SYNTHETIC GRAFTS)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	Covered; criteria apply.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	Covered; criteria apply.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.