Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Description of Procedure or Service

Osteochondral grafts are used in repair of full thickness chondral defects involving a joint. In the case of osteochondral autografts, 1 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. Autologous or allogeneic minced cartilage, decellularized osteochondral allograft plugs, and reduced osteochondral allograft discs are also being evaluated as a treatment of articular cartilage lesions.

Damaged articular cartilage can be associated with pain, loss of function, and disability, and can lead to debilitating osteoarthrosis over time. These manifestations can severely impair an individual’s activities of daily living and quality of life. Autologous or allogeneic grafts of osteochondral or chondral tissue have been proposed as treatment alternatives for patients who have clinically significant, symptomatic, focal defects of the articular cartilage. It is hypothesized that the implanted grafts chondrocytes retain features of hyaline cartilage that is similar in composition and property to the original articulating surface of the joint. If true, the restoration of a hyaline cartilage surface might restore the integrity of the joint surface and promote long-term tissue repair, thereby improving function and delaying or preventing further deterioration.

There are 2 main categories of conventional therapy for patients who have significant focal defects of the articular cartilage: symptom relief and articular surface restoration.

First, there are procedures intended to primarily achieve symptomatic relief: débridement (removal of debris and diseased cartilage); lavage (saline washout); and rehabilitation.

Second, there are procedures intended to restore the articular surface. Treatments may be targeted to the focal cartilage lesion and most such treatments induce local bleeding, fibrin clot formation, and resultant fibrocartilage growth. These include: abrasion arthroplasty, microfracture, and drilling, all of which are considered standard therapies. Fibrocartilage is generally considered to be less durable and mechanically inferior to the original articular cartilage. Thus various strategies for chondral resurfacing with hyaline cartilage have been investigated. Alternatively, treatments of very extensive and severe cartilage defects may resort to complete replacement of the articular surface either by osteochondral allotransplant or artificial knee replacement.

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.
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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 mode of repair 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 mm to 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 or OATS 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.

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) 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) is 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.

A minimally processed osteochondral allograft (Chondrofix®; Zimmer) is now available for use. Chondrofix is composed of decellularized hyaline cartilage and cancellous bone; it 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.

ProChondrix® (AlloSource) and Cartiform® (Arthrex) are wafer-thin allografts where the bony portion of the allograft is reduced. The discs are laser etched or porated and contain hyaline cartilage with chondrocytes, growth factors, and extracellular matrix proteins. ProChondrix® is available in dimensions from 7 to 20 mm and is stored fresh for a maximum of 28 days. Cartiform® is cut to the desired size and shape and is stored frozen for a maximum of 2 years. The osteochondral discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

DeNovo ET graft (ISTO Technologies) uses juvenile allogeneic cartilage cells.
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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 the BCBSNC Medical Policy titled, “Autologous Chondrocyte Implantation.”

Related Policies
Autologous Chondrocyte Implantation
Meniscal Allografts and Other Meniscal Implants

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for Autografts or Allografts in the Treatment of Focal Articular Cartilage Lesions of the knee when it is determined to be medically necessary because the criteria and guidelines shown below have been met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Autografts and Allografts in the Treatment of Articular Cartilage are covered

Osteochondral allografting may be considered medically necessary as a technique to repair full thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (eg, microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to the size, location, or depth of the lesion.

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:

- The patient is skeletally mature and not considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., age greater than 15 and less than 55),
- Focal, full thickness (grade III or IV) uni-polar lesions on the weight bearing surface of the femoral condyles, trochlea or patella 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.
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When Autografts and Allografts in the Treatment of Articular Cartilage are not covered

Osteochondral allografting or autografting for all other joints, including 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.

Treatment of focal articular cartilage lesions with decellularized osteochondral allograft plugs (eg, Chondrofix) is considered investigational.

Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (eg, ProChondrix, Cartiform) is considered investigational.

Policy Guidelines

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.

For individuals who have full-thickness articular cartilage lesions of the knee who receive osteochondral autografts, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and longer term observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several systematic reviews have evaluated osteochondral autografting for cartilage repair at short and mid term. Compared to abrasion techniques (eg, microfracture, drilling), there is evidence that osteochondral autografting decreases failure rates and improves outcomes in patients with medium-size lesions (eg, 2-6 cm²) when measured at longer follow-up. This is believed to be due to the higher durability of hyaline cartilage compared to the fibrocartilage that is formed from abrasion techniques. There appears to be a relatively narrow range of lesion size for which osteochondral autografting is most effective. The best results have also been observed with lesions on the femoral condyles, although treatment of lesions on the trochlea and patella may also improve outcomes. Correction of malalignment is important for success of the procedure. The evidence suggests that osteochondral autografts may be considered an option for moderate-sized symptomatic full-thickness chondral lesions of the femoral condyle, trochlea, or patella. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have full-thickness articular cartilage lesions of the knee who receive osteochondral allografts, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Due to the lack of
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alternatives, this procedure may be considered a salvage operation in younger patients for full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (eg, microfracture, osteochondral autografting, autologous chondrocyte implantation) would be inadequate due to the size, location, or depth of the lesion. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have full-thickness articular cartilage lesions of the ankle who receive osteochondral autografts, the evidence includes 1 small RCT, observational studies, and a systematic review of these studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review and an RCT found similar improvements in outcomes after microfracture or osteochondral autografting. Given the lack of established benefit compared to microfracture and the increase in donor-site morbidity with graft harvest from the knee, evidence does not support the use of osteochondral autografts as a primary treatment for articular cartilage lesions of the ankle. There are some observational studies in patients who have failed a prior surgical procedure. Further study in prospective trials is needed to evaluate outcomes for osteochondral autografting as a secondary procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the ankle who receive osteochondral allografts, the evidence includes 1 case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These series have indicated high failure rates. The largest had a failure rate of nearly 30% with revision to a second allograft, ankle arthroplasty, fusion, or amputation. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the elbow who receive osteochondral autografts, the evidence includes a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Osteochondritis dissecans (OCD) of the elbow typically occurs in patients who play baseball or do gymnastics. The literature on osteochondral autografts for advanced OCD of the elbow consists of small case series, primarily from Europe and Asia, and a systematic review of case series. Although the meta-analysis suggested a benefit of osteochondral autographs compared to débridement or fixation, RCTs are needed to determine the effects of the procedure with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the shoulder who receive osteochondral autografts, the evidence includes a case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence on osteochondral autografting for the shoulder is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive autologous or allogeneic minced articular cartilage, the evidence includes a small RCT and small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on autologous minced cartilage includes 1 small RCT from 2011. The evidence on allogeneic juvenile minced cartilage includes a few small case series. The case series have suggested an improvement in outcomes compared with preoperative measures, but there is also evidence of graft hypertrophy and delamination. For articular cartilage lesions of the knee, further evidence, preferably from RCTs, is needed to evaluate the effect on health outcomes compared with other procedures. There are fewer options for articular cartilage lesions of the ankle. However, further study in a larger number of patients...
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is needed to assess the short- and long-term effectiveness of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive decellularized osteochondral allograft plugs or reduced osteochondral allograft discs, the evidence includes 1 small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single case series on decellularized osteochondral allograft plugs reported delamination of the implants, and high failure rates. No studies have been identified on reduced osteochondral allograft discs. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 27415, 27416, 28446, 29866, 29867*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

For Policy titled Osteochondral Grafting in the Treatment of Articular Cartilage Lesions


ECRI Custom Hotline Response (December 2005). Osteochondral Allograft Transplantation in the Knee.

ECRI Custom Hotline Response (February 2006). Osteochondral Autograft Transplantation in the Knee.


Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions


Specialty Matched Consultant Advisory Panel review 7/2011


Specialty Matched Consultant Advisory Panel review 7/2012

For policy re-titled Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions


Specialty Matched Consultant Advisory Panel review 7/2013

Medical Director review 7/2013


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Specialty Matched Consultant Advisory Panel review 7/2014
Medical Director review 7/2014
Specialty Matched Consultant Advisory Panel review 6/2015
Medical Director review 4/2016
Specialty Matched Consultant Advisory Panel 6/2017

Policy Implementation/Update Information

For Policy titled Osteochondral Grafting in the Treatment of Articular Cartilage Lesions

5/04 Benefits Application and Billing/Coding sections updated for consistency.
9/9/04 Title changed from "Osteochondral Autografts and Allografts in the Treatment of Articular Cartilage Lesions" to "Osteochondral Grafting in the Treatment of Articular Cartilage Lesions" for the purpose of reducing characters.
1/6/05 Codes 27415, 29866, 29867 added to Billing/Coding section of policy.
6/16/2005 SUR6493 added as key word. Reference added. CPT 0012T and 0013T removed as deleted codes. Statement added to Policy Guideline section regarding investigational services for consistent policy language. Osteochondral allografting added as a key word. Allografting added to the policy statement as being considered noncovered as investigational. Covered and noncovered section titles changed to indicate when osteochondral grafting is covered or not covered.
8/21/06 Rationale supporting investigational status of policy added to Policy Guidelines section. References updated. Specialty Matched Consultant Advisory Panel review 7/24/06. No changes to policy criteria. (adn)
12/31/07 Coding update. Added CPT codes 27416 and 28446 to Billing/Coding section. (adn)
8/25/08 The following statement was added to the Policy Guidelines section: "An updated literature review (through March 2008) identified a number of small case series
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describing use of osteochondral autografts for cartilage defects of the knee, elbows and ankle. Longer-term controlled studies on larger patient populations are needed. Evidence remains insufficient to determine whether osteochondral transplantation improves the net health outcomes." Definitions of Mosaicplasty and OATS added to Medical Term Definitions. Specialty Matched Consultant Advisory Panel review 7/14/08. No change to policy statement. (adn)

3/30/09 Policy statement changed to read, "BCBSNC will provide coverage for Osteochondral Autografts or Allografts in the Treatment of Articular Cartilage Lesions when it is determined to be medically necessary because the criteria and guidelines shown below have been met." Osteochondral allografting may be considered medically necessary as a technique to repair large (e.g., 10cm2) full thickness chondral defects 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 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: The patient is skeletally mature and not considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., age greater than 15 and less that 55), 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. The following statement added to the When Not Covered section: Osteochondral allografting or autografting for all other joints, including patellar and talar, and any indications other than those listed above, is considered investigational. Rationale for coverage added to the Policy Guidelines section. (adn)

8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Medical Policy number removed. References updated. Description section updated. Policy Guidelines updated to state: “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.”(mco)

8/16/11 Revised Policy Statement as follows: “BCBSNC will provide coverage for Osteochondral Autografts or Allografts in the Treatment of Articular Cartilage Lesions of the knee when it is determined to be medically necessary because the criteria and guidelines shown below have been met.” Revised “When Covered” section to state: “Osteochondral allografting may be considered medically necessary as a technique to repair large (e.g., 10cm2) full thickness chondral defects of the knee caused by acute or repetitive trauma.” Removed the following criterion from the “When Covered” section: “Absence of meniscal pathology.” Added the following statement to the “Policy Guidelines” section: “In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with osteochondral allografting or osteochondral autografting.” References updated. Specialty Matched Consultant Advisory Panel review 7/2011. (mco)
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8/7/12   Description section updated to include new minimally processed osteochondral allograft Chondrofix®. References updated. Specialty Matched Consultant Advisory Panel review 7/2012. Revised the following statement in “When Covered” section: “(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.” New statement: “Osteochondral allografting may be considered medically necessary as a technique to repair large (> 2.5 cm²) full thickness chondral defects of the knee caused by acute or repetitive trauma.” Policy Guidelines updated. Medical Director review. (mco)

For policy re-titled Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

8/13/13   Policy re-titled from “Osteochondral Grafting in the Treatment of Articular Cartilage Lesions” to “Autografts and Allografts in the Treatment of Focal Articular Lesions.” Description section updated. Added the following statements to the “When not Covered” section as follows: “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.” Autologous and allogenic minced cartilage was formerly addressed in the BCBSNC policy titled, “Autologous Chondrocyte Implantation.” Policy Guidelines updated. References updated. Specialty Matched Consultant Advisory Panel review 7/2013.


2/24/17   Reference added. Policy Guidelines and Description sections extensively revised. The following statements were added to the When Not Covered section: “Treatment of focal articular cartilage lesions with decellularized osteochondral allograft plugs (eg, Chondrofix) is considered investigational and treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (eg, ProChondrix, Cartiform) is considered investigational. Notification given 2/24/17 for effective date 4/28/17. (sk)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.