

Corporate Medical Policy

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

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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, 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. 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 osteoarthritis over time. These manifestations can severely impair an individual's activities of daily living and quality of life. The vast majority of osteochondral lesions occur in the knee with the talar dome and capitulum being the next most frequent sites. The most common locations of lesions are the medial femoral condyle (69%), followed by the weight-bearing portion of the lateral femoral condyle (15%), the patella (5%), and trochlear fossa. Talar lesions are reported to be about 4% of osteochondral lesions.

There are two main goals 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 primarily to achieve symptomatic relief: débridement (removal of debris and diseased cartilage), 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 marrow stimulation procedures 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.

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 graft's 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

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joint surface and promote long-term tissue repair, thereby improving function and delaying or preventing further deterioration.

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 autologous osteochondral transplantation (AOT) 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 AOT 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 or particulated 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. The Reveille Cartilage Processor (Exactech Biologics) has a high-speed blade and sieve to cut autologous cartilage into small particles for implantation. 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 and distributed 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 AOT or mosaicplasty.

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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.

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 Focal Articular Cartilage Lesions are covered

Fresh 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 (e.g., microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to the size, location, or depth of the lesion.
- Large (area>1.5cm²) or cystic (volume>3.0 cm³) osteochondral lesions of the talus when autografting would be inadequate due to the size, depth, or location of the lesion.
- Revision surgery after failed prior marrow stimulation for large (area>1.5 cm²) or cystic (volume>3.0 cm³) osteochondral lesions of the talus when autografting would be inadequate due to size, depth, or location of the lesion.

Osteochondral autografting, using one or more cores of osteochondral tissue, may be considered medically necessary:

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- 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.
- Large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesions of the talus.
- Revision surgery after failed marrow stimulation for osteochondral lesions of the talus.

When Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions are not covered

Osteochondral allografting or autografting for all other joints, and any indications other than those listed above, is considered investigational.

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

Treatment of focal articular cartilage lesions with allogeneic minced or particulated 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, particularly for lesions less than 1.5 cm² in area or 3.0 cm³ in volume.

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

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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 (e.g., microfracture, drilling), there is evidence that osteochondral autografting decreases failure rates and improves outcomes in patients with medium-size lesions (e.g., 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 when autografting would be inadequate due to lesion size, location, or depth who receive fresh 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 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 (e.g., 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 primary full-thickness articular cartilage lesions of the ankle less than 1.5 cm² who receive an osteochondral autograft, the evidence includes observational studies, and a systematic review of these studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review found similar improvements in outcomes after microfracture or autologous osteochondral transplantation. Given the success of marrow stimulation procedures for smaller lesions (<1.5 cm²) and the increase in donor-site morbidity with graft harvest from the knee, current evidence does not support the use of autologous osteochondral transplantation as a primary treatment for smaller articular cartilage lesions of the ankle. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area >1.5 cm²) or cystic (volume >3.0 cm³) full-thickness articular cartilage lesions of the ankle who receive an osteochondral autograft, the evidence includes an RCT and several observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. An RCT in patients with large lesions found similar efficacy for AOT, marrow stimulation, and arthroplasty at 2-year follow-up. Longer term results were not reported in the RCT. However, observational studies with longer term follow-up (four to five years) have shown favorable results for patients with large or cystic lesions receiving osteochondral autograft transplantation. Limitations of the published evidence preclude determining the effects of the technology on health outcomes. Evidence reported through clinical input supports that the use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Studies on the standard treatment for ankle lesions, marrow stimulation, have reported positive outcomes for

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patients with small lesions of the ankle ($<1.5 \text{ cm}^2$) but have generally reported high failure rates for patients with large ($>1.5 \text{ cm}^2$) lesions. Because the standard treatment has been shown to be less effective on larger lesions, there is support in the clinical community for osteochondral autografts in patients with large lesions of the ankle. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have osteochondral lesions of the ankle that have failed primary treatment who receive an osteochondral autograft, the evidence includes two nonrandomized comparative trials and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The best evidence for revision AOT comes from a nonrandomized comparative study that found better outcomes with AOT than with repeat marrow stimulation. This finding is supported by case series that have indicated good-to-excellent results at mid-term and longer term follow-up with revision AOT. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input further supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary full-thickness articular cartilage lesions of the ankle less than 1.5 cm^2 who receive a fresh osteochondral allograft, there is little evidence. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Because microfracture is effective as a primary treatment for lesions less than 1.5 cm^2 and AOT is effective as a revision procedure, use of allograft for small primary cartilage lesions has not been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area $>1.5 \text{ cm}^2$) or cystic (volume $>3.0 \text{ cm}^3$) cartilage lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes a small number of patients in an RCT, case series, and a systematic review of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The majority of patients in the RCT were patients with revision osteochondral lesions, so conclusions about the few patients with primary lesions could not be made. The systematic review of case series reported improvements in ankle scores and decreases in pain scores, though 25% of patients needed additional surgery and 13% experienced either graft nonunion, resorption, or symptom persistence. Limitations of the published evidence preclude determining the effects of the technology on health outcomes. Evidence reported through clinical input supports that the use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. For particularly large lesions, marrow stimulation techniques have been found to be ineffective and obtaining an adequate volume of autograft may cause significant morbidity. For these reasons, osteochondral allografts may be a considered option for large lesions of the ankle. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have revision osteochondral lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Most of the patients in the RCT had failed a prior microfracture. The RCT found that outcomes were statistically similar with osteochondral allografts compared with autografts. However, failure rates due to nonunion were higher in patients in the allograft group compared with patients in the autograft group. Limitations of the published evidence preclude determining the effects of the technology on health outcomes. Evidence reported through clinical input supports that the use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. For particularly large lesions, marrow stimulation techniques have been found to be ineffective and obtaining an adequate volume of autograft may

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cause significant morbidity. For these reasons, osteochondral allografts may be a considered option for revision of large lesions of the ankle. 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 elbow who receive an osteochondral autograft, 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 an osteochondral autograft, 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 one small RCT. 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 subchondral edema, nonhomogenous surface, 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 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 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. Evidence on reduced osteochondral allograft discs consists only of case reports or very small case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2017 supports that the following indications provide a clinically meaningful improvement in the net health outcome and are consistent with generally accepted medical practice.

- Use of osteochondral autograft for:
 - Primary treatment of large (area >1.50 cm²) or cystic (volume >3.0 cm³) osteochondral lesion of the talus.
 - Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.
- Use of a fresh osteochondral allograft for:

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- Primary treatment of large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesion of the talus when autografting would be inadequate due to lesion size, depth, or location.
- Revision surgery for osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location.

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

However, the clinical input does not support whether the following indication provides a clinically meaningful improvement in the net health outcome or is consistent with generally accepted medical practice.

- Use of osteochondral grafts in the elbow.

Thus, the above indication may be considered investigational.

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

BCBSA Medical Policy Reference Manual, 2/15/2002; 7.01.78

Specialty Matched Consultant Advisory Panel - 8/2002

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

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American Academy of Orthopaedic Surgeons. Clinical practice guideline on the diagnosis and treatment of osteochondritis dissecans. 2010. Retrieved from http://www.aaos.org/research/guidelines/OCD_guideline.pdf

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Bleazey S, Brigido SA. Reconstruction of complex osteochondral lesions of the talus with cylindrical sponge allograft and particulate juvenile cartilage graft: provisional results with a short-term follow-up. *Foot Ankle Spec* 2012; 5(5):300-5.

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Specialty Matched Consultant Advisory Panel review 7/2013

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Medical Director review 7/2013

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Farr J, Tabet SK, Margerrison E, Cole BJ. Clinical, Radiographic, and Histological Outcomes After Cartilage Repair With Particulated Juvenile Articular Cartilage: A 2-Year Prospective Study. *Am J Sports Med* published online April 9, 2014.

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Medical Director review 7/2014

Specialty Matched Consultant Advisory Panel review 6/2015

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Medical Director review 4/2016

Specialty Matched Consultant Advisory Panel 6/2016

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.78, 4/12/2018

Specialty Matched Consultant Advisory Panel 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.78, 4/8/2019

Specialty Matched Consultant Advisory Panel 7/2019

Policy Implementation/Update Information

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

5/2002 Original Policy Issued.

8/2002 Specialty Matched Consultant Advisory Panel meeting 8/14/2002. No changes.

5/04 Benefits Application and Billing/Coding sections updated for consistency.

8/26/04 Specialty Matched Consultant Advisory Panel review on 7/15/2004 with no changes made to policy criteria. Title changed from "Osteochondral Autografts in the Treatment of Articular Cartilage" to "Osteochondral Autografts and Allografts in the Treatment of Articular Cartilage Lesions." CPT code 0013T added. References added. Medical term, allograft and definition added.

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.

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- 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 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 than 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.

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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)
- 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 allogeneic 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.
- 8/12/14 Added patella to the “When Covered” section. Deleted patella from the “When not Covered” section. Policy Guidelines updated. References updated. Specialty Matched Consultant Advisory Panel review 7/2014. Medical Director review 7/2014. (mco)
- 7/28/15 Reference added. Related policies added. Specialty Matched Consultant Advisory Panel review 6/24/2015. (sk)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. Medical Director review. “Large (>2.5 cm²)” removed from Policy Statement and Policy Guidelines related to osteochondral allografting. (sk)
- 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,

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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)

- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. (sk)
- 9/15/17 Reference added. Description section updated. Policy Guidelines updated. When Covered statement updated to include osteochondral autografts and allografts are considered medically necessary for lesions of the talus that meet policy criteria. (sk)
- 7/13/18 Reference added. Description section updated. Policy Guidelines updated. “Or articulated” added to the investigational policy statements on minced cartilage. Specialty Matched Consultant Advisory Panel review 6/27/2018. (sk)
- 9/10/19 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 7/30/2019. (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.