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Horizon BCBSNJ
Uniform Medical Policy Manual

Section:	Surgery
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Subject:
Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Description:

IMPORTANT NOTE:

The purpose of this policy is to provide general information applicable to the administration of health benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. If the member's contract benefits differ from the medical policy, the contract prevails. Although a service, supply or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply or procedure is not covered and the member proceeds to obtain the service, supply or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.

Horizon BCBSNJ medical policies do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

Osteochondral grafts are used to repair 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, usually from 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.

Populations	Interventions	Comparators	Outcomes
Individuals: · With full-thickness articular cartilage lesions of the knee	Interventions of interest are: · Osteochondral autograft	Comparators of interest are: · Marrow stimulation · Autologous chondrocyte implantation	Relevant outcomes include: · Symptoms · Functional outcomes

			· Quality of life · Treatment-related morbidity
Individuals: · With full-thickness articular cartilage lesions of the knee when autografting would be inadequate	Interventions of interest are: · Fresh osteochondral allograft	Comparators of interest are: · Osteochondral autograft	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With primary full-thickness articular cartilage lesions of the ankle <1.5 cm^2	Interventions of interest are: · Osteochondral autograft	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With large (>1.5 cm^2) or cystic (>3.0 cm^3) full-thickness articular cartilage lesions of the ankle	Interventions of interest are: · Osteochondral autograft	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With osteochondral lesions of the ankle that have failed primary treatment	Interventions of interest are: · Osteochondral autograft	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With primary full-thickness articular cartilage lesions of the ankle <1.5 cm^2	Interventions of interest are: · Fresh osteochondral allograft	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With large (>1.5 cm^2) or cystic (>3.0 cm^3) cartilage lesions of the ankle when autografting would be inadequate	Interventions of interest are: · Fresh osteochondral allograft	Comparators of interest are: · Osteochondral autograft	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With revision osteochondral lesions of the ankle when autografting would be inadequate	Interventions of interest are: · Fresh osteochondral allograft	Comparators of interest are: · Osteochondral autograft	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity

Individuals: · With full-thickness articular cartilage lesions of the elbow	Interventions of interest are: · Fresh osteochondral autograft	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With full-thickness articular cartilage lesions of the shoulder	Interventions of interest are: · Osteochondral autograft	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder	Interventions of interest are: · Autologous or allogeneic minced or particulated articular cartilage	Comparators of interest are: · Marrow stimulation · Autologous chondrocyte implantation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder	Interventions of interest are: · Decellularized osteochondral allograft plugs	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity
Individuals: · With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder	Interventions of interest are: · Reduced osteochondral allograft discs	Comparators of interest are: · Marrow stimulation	Relevant outcomes include: · Symptoms · Functional outcomes · Quality of life · Treatment-related morbidity

Background

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. 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.[1] Talar lesions are reported to be about 4% of osteochondral lesions.[2]

Treatment

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 microfracture, abrasion arthroplasty, and drilling, all of which are considered standard therapies.

Microfracture

Efficacy of the microfracture technique for articular cartilage lesions of the knee was examined by Mithoefer et al (2009) in a systematic review.[3] Twenty-eight studies (total N=3122 patients) were selected; 6 studies were randomized controlled trials. Microfracture was found to improve knee function in all studies during the first 24 months after the procedure, but the reports on durability were conflicting. A prospective longitudinal study of 110 patients by Solheim et al (2016) found that, at a mean of 12 years (range, 10-14 years) after microfracture, 45.5% of patients had poor outcomes, including 43 patients who required additional surgery.[4] The size of the lesion has also been shown to affect outcomes following marrow stimulation procedures.

Abrasion

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.

Osteochondral Grafting

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 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 & Nephew), the OATS (Osteochondral Autograft Transfer System; Arthrex), 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 (ie, 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 débridement 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 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 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, the 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.

Reddy et al (2007) evaluated donor-site morbidity in 11 of 15 patients who had undergone graft harvest from the knee (mean, 2.9 plugs) for treatment of osteochondral lesions of the talus.[5] At an average 47-month follow-up (range, 7-77 months), 5 patients were rated as having an excellent Lysholm Knee Scale score (95-100 points), 2 as good (84-94 points), and 4 as poor (≤64 points). The reported knee problems were instability in daily activities, pain after walking 1 mile or more, slight limp, and difficulty squatting. Hangody et al (2001) reported that some patients had slight or moderate complaints with physical activity during the first postoperative year, but there was no long-term donor-site pain in a series of 36 patients evaluated 2 to 7 years after AOT.[6]

Filling defects with minced or particulated articular cartilage (autologous or allogeneic) is another single-stage procedure being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS; Johnson & 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 intraoperatively 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. 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.

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 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. Autologous chondrocyte implantation techniques are discussed in 'Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions' (Policy #013 in the Surgery Section).

Regulatory Status

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271. Osteochondral grafts are included in these regulations.

DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) is marketed by ISTO Technologies outside of the United States. FDA approved ISTO's investigational new drug application for Neocartilage in 2006, which allowed ISTO to pursue phase 3 clinical trials of the product in human subjects. However, ISTO's clinical trial for Neocartilage was terminated due to poor enrollment as of August 31, 2017.

Related Policies

- Meniscal Allografts and Other Meniscal Implants (Policy #023 in the Surgery Section)
- Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions (Policy #013 in the Surgery Section)

Policy:

(NOTE: For services provided on December 3, 2018 and after, Horizon Blue Cross Blue Shield of New Jersey ("Horizon BCBSNJ") has contracted with TurningPoint Healthcare Solutions, LLC to conduct Prior Authorization and Medical Necessity Determination reviews for certain Orthopedic services ("the Program") for members enrolled in Horizon BCBSNJ's fully insured plans.

Beginning December 3, 2018, the criteria and guidelines included in this policy will not apply to Horizon BCBSNJ's fully insured members. This policy will only apply to Horizon BCBSNJ's members enrolled in self-insured plans or plans that DO NOT participate in the Program.

To access the criteria and guidelines that apply to Horizon BCBSNJ's fully insured members in the Program:
· Call TurningPoint at 1-833-436-4083, Monday through Friday between 8 a.m. and 5 p.m., Eastern Time (ET).

For Medicare Advantage, please refer to the Medicare Coverage Section below for coverage guidance.)

1. Osteochondral fresh allografting is considered medically necessary as a technique to repair full-thickness cartilage defects of the weight-bearing surface of the femoral condyle (medial or lateral) or trochlear region caused by acute or repetitive trauma when all of the following criteria are met:

a. member is between ages 15 and 55 years;
b. cartilage defect is confirmed by appropriate diagnostic imaging (e.g., MRI, arthroscopic imaging, weight-bearing x-rays);
c. member has had at least 6 months of knee pain that has failed conservative treatment measures (e.g., medications, physical therapy, activity modification, bracing, ice/heat, injections);
d. other cartilage repair techniques (e.g., microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to size, location, or depth;
e. member does not have any of the following contraindications:

- presence of synovial disease, inflammation, osteoarthritis, or infection
- history of malignancy or current unresected tumor in the limb
- misalignment and instability of the joint
  (NOTE: correction of underlying joint abnormalities should be done before or at the time of osteochondral allografting.)
- severe obesity (BMI >35 kg/m^2).

2. Osteochondral allografting for all other joints including, but not limited to, talar and patellar lesions, is considered investigational.

3. Osteochondral autografting, using one or more cores of osteochondral tissue, is considered medically necessary for the treatment of symptomatic focal full-thickness cartilage defects between 1 and 2.5 cm^2 in size on the weight-bearing surface of the femoral condyle (medial or lateral) or trochlear region caused by acute or repetitive trauma when all of the following criteria are met**:**

a. member is between ages 15 and 55 years;
b. cartilage defect is confirmed by appropriate diagnostic imaging (e.g., MRI, arthroscopic imaging, weight-bearing x-rays);
c. 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;
d. member has had at least 6 months of knee pain that has failed conservative treatment measures (e.g., medications, physical therapy, activity modification, bracing, ice/heat, injections);
e. member has had inadequate response to a prior arthroscopic or surgical repair procedure (e.g., microfracture);
f. member does not have any of the following contraindications:

- presence of synovial disease, inflammation, osteoarthritis, or infection
- history of malignancy or current unresected tumor in the limb
- misalignment and instability of the joint
  (NOTE: correction of underlying joint abnormalities should be done before or at the time of osteochondral autografting.)
- severe obesity (BMI >35 kg/m^2).

4. Osteochondral autografting for all other joints including, but not limited to, talar and patellar lesions, and any indications other than those listed above is considered investigational.

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

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

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

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

Medicare Coverage:
There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL for this service. Therefore, Medicare Advantage will follow the Horizon BCBSNJ Medical Policy.

Policy Guidelines: (Information to guide medical necessity determination based on the criteria contained within the policy statements above.)

The Outerbridge Classification is the most commonly used classification system to objectively assess chondral and osteochondral injuries of the knee:
Grade 0 = normal cartilage;
Grade I = cartilage with softening and swelling;
Grade II = a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter;
Grade III = fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm;
Grade IV = exposed subchondral bone.

If débridement 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 cm^2 in area or 3.0 cm^3 in volume.

Severe obesity (eg, body mass index >35 kg/m^2) 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.

Horizon BCBSNJ Medical Policy Development Process:

This Horizon BCBSNJ Medical Policy (the "Medical Policy") has been developed by Horizon BCBSNJ's Medical Policy Committee (the "Committee") consistent with generally accepted standards of medical practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Medical Policy also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Medical Policy considers whether the subject health care services, supplies or procedures are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the services, supplies or procedures are more costly than an alternative service or sequence of services, supplies or procedures that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical practice, the Committee reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty) and any other relevant factor as determined by applicable State and Federal laws and regulations.

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Codes:

(The list of codes is not intended to be all-inclusive and is included below for informational purposes only. Inclusion or exclusion of a procedure, diagnosis, drug or device code(s) does not constitute or imply authorization, certification, approval, offer of coverage or guarantee of payment.)

CPT*

27415
27416
28446
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HCPCS
