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Active

**Medical and Behavioral Health Policy**
Section: Surgery
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# OSTEOCHONDRAL ALLOGRAFTS AND AUTOGRAFTS IN THE TREATMENT OF FOCAL ARTICULAR CARTILAGE LESIONS

**Description:**

Osteochondral autografts and allografts are used in repair of full-thickness chondral defects involving the knee joint. In the case of 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. Allografts, which are sterile bones derived from a human donor, are typically used for larger lesions in order to reduce donor site morbidity. The use of osteochondral allografts and autografts has also been investigated for joints outside the knee (e.g., talus).

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

Both fresh and cryopreserved osteochondral allografts have been used for treatment of larger lesions. However, cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and may create concerns regarding infectious

diseases. For these reasons, 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 also limited by the small number of donor sites. 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).

Minced cartilage repair is also being investigated as an alternative treatment for the repair of osteochondral defects. This technique, which is a single-staged surgical procedure, uses minced pieces of hyaline cartilage which are affixed to a bioabsorbable scaffold delivery system. The proposed advantages of minced cartilage repair over conventional treatment are the elimination of the need for in-vitro cell expansion and the elimination of a second surgical procedure. At least two technologies using this principle are being investigated: the cartilage autograft implantation system (CAIS) by DePuy Mitek and the DeNovo NT ("Natural Tissue") and ET ("Extended Tissue") allografts by Zimmer Inc., IN/ISTO Technologies Inc. No autologous minced cartilage (single-staged) product has yet been approved for use in the U.S. The allograft technique does not require FDA approval, since it involves no use of chemicals and minimal tissue manipulation.

**Definitions:**

**Outerbridge Classification:** A grading system for joint cartilage breakdown that includes the following grades:
**Grade 0:** Normal
**Grade I:** Cartilage with softening and swelling
**Grade II:** Partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 centimeters (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 head. Subchondral bone is the bone underneath the joint cartilage.

**Policy:**

**I. Osteochondral Allograft**

A. **Osteochondral allograft** transplantation may be considered **MEDICALLY NECESSARY** for the treatment of symptomatic full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure (e.g., debridement, subchondral drilling, abrasion arthroscopy, microfracture), when all the following criteria are met:

1. Patient is an adult **OR** a skeletally mature adolescent with documented closure of growth plates (e.g., 15

years or older);
2. Total area of the cartilage lesion (i.e. length x width, in centimeters or cm) is greater than 1.5 cm2 (centimeters squared);
3. Focal full-thickness (Outerbridge grade III or IV) cartilage lesions on the weight-bearing surface of the femoral condyles (medial or lateral) or trochlea;
4. 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;
5. Presence of persistent symptoms (e.g., pain, swelling and catching/locking) that significantly limit activities of daily living;
6. Presence of stable ligaments (if ligaments are unstable, documentation should be provided as to how this condition will be addressed);
7. No malalignment present (if malalignment is present, documentation should indicate planned concurrent correction of alignment).

B. **Osteochondral allograft** transplantation for treatment of all other articular cartilage defects of the knee (i.e., defects that do not meet the criteria outlined under I.A.) is considered **INVESTIGATIVE**, due to a lack of evidence demonstrating an impact on improved health outcomes.

C. **Osteochondral allograft** transplantation for all other indications and in all other joints is considered **INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes. Those investigative indications include, but not limited to:
1. Lesions in joints other than the knee (e.g., talus);
2. Lesions of the patella or tibia.

D. **Allograft minced cartilage procedures** are considered **INVESTIGATIVE** for all indications and in all joints, due to a lack of evidence demonstrating an impact on improved health outcomes.

**II. Osteochondral Autografts**

A. **Osteochondral autograft** transplantation (OATS or autologous mosaicplasty), 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 (e.g., debridement, subchondral drilling, abrasion arthroscopy, microfracture), when all the following criteria are met:
1. Patient is an adult **OR** a skeletally mature adolescent with documented closure of growth plates (e.g., 15 years or older);
2. Total area of the cartilage lesion (i.e. length x width, in

centimeters or cm) is ≥ 1.0 cm2 (centimeters squared) and ≤ 2.0 cm2;
3. Focal full-thickness (Outerbridge grade III or IV) cartilage lesions on the weight-bearing surface of the femoral condyles (medial or lateral) or trochlea;
4. 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;
5. Presence of persistent symptoms (e.g., pain, swelling and catching/locking) that significantly limit activities of daily living;
6. Presence of stable ligaments (if ligaments are unstable, documentation should be provided as to how this condition will be addressed);
7. No malalignment present (if malalignment is present, documentation should indicate planned concurrent correction of alignment).

B. **Osteochondral autograft** transplantation for treatment of all other articular cartilage defects of the knee (i.e., defects that do not meet the criteria outlined under II.A.) is considered **INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.
C. **Osteochondral autograft** transplantation for all other indications and in all other joints is considered **INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes. Those investigative indications include, but not limited to:
1. Lesions in joints other than the knee (e.g., talus);
2. Lesions of the patella or tibia.
D. **Autograft minced cartilage procedures** are considered **INVESTIGATIVE** for all indications and in all joints, due to a lack of evidence demonstrating an impact on improved health outcomes.

**Coverage:**

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

**Coding:** *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

**CPT:**

27415 Osteochondral allograft, knee, open

27416 Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting of autograft[s])

28446 Open osteochondral autograft, talus (includes obtaining graft[s])

29866 Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])

29867 Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)

**Policy History:** **Developed November 11, 2009**

**Most recent history:**
Revised November 9, 2011
Reviewed November 14, 2012
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Reviewed October 8, 2014

**Cross Reference:** Autologous Chondrocyte Implantation of Focal Articular Cartilage Lesions, IV-113