BlueCross BlueShield of Minnesota Medical Policy

Medical Policy:	IV-115-006
Topic:	Osteochondral Allografts and Autografts in the Treatment of Focal Articular Cartilage Lesions
Section:	Surgery
Effective Date:	October 29, 2018
Issue Date:	October 29, 2018
Last Reviewed:	October 2018

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. Osteochondral autografts and allografts are used in repair of full-thickness chondral defects involving the knee joint.

Autografts involve harvesting one or more small osteochondral plugs from non-weight-bearing sites in the knee or other joints and press fit into a prepared site in the lesion. These grafts are limited by the small number of donor sites. Investigators have used multiple, small osteochondral cores harvested from non-weight-bearing sites in the knee to extend the amount of available donor tissue. Several systems are available for performing this procedure including the Mosaicplasty System, the Osteochondral Autograft Transfer System (OATS), and the COR and COR2 systems.

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). 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.

Minced cartilage repair is also being investigated as an alternative treatment for the repair of osteochondral defects. This 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. Technologies using this principle are being investigated include the Cartilage Autograft Implantation System (CAIS), BioCartilage and DeNovo NT® (Natural Tissue Graft). The DeNovo® ET Live Chondral Engineered Tissue Graft is marketed outside the United States. 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.

A minimally processed osteochondral allograft, 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. ProChondrix® and Cartiform® 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.

Definitions

The Modified Outerbridge Classification is a method of determining the extent of cartilage damage, based on magnetic resonance imaging (MRI) or arthroscopy.

- Grade 0: Normal
- Grade I: Cartilage with softening and swelling by arthroscopy OR signal intensity alterations with an intact surface of the articular cartilage compared with the surrounding normal cartilage by MRI
- 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.

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

Policy Position Coverage is subject to the specific terms of the member's benefit plan.

I. Osteochondral Allografting

- Osteochondral allografting may be considered **MEDICALLY NECESSARY AND APPROPRIATE** 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) or are not candidates for such procedures, when **ALL** the following criteria are met:
  - Patient is an adult **OR** a skeletally mature adolescent with documented closure of growth plates (e.g., 15 years or older);
  - Total area of the cartilage lesion (i.e., length x width, in centimeters or cm) is greater than 1.5 cm2 (centimeters squared);
  - Focal full-thickness (modified Outerbridge grade III or IV) cartilage lesions on the weight-bearing surface of the femoral condyles (medial or lateral) or trochlea;
  - Documented minimal to absent degenerative changes in the surrounding articular cartilage (modified Outerbridge grade II or less) and normal appearing hyaline cartilage surrounding the border of the defect;
  - Presence of persistent symptoms (e.g., pain, swelling and catching/locking) that significantly limit activities of daily living;
  - Presence of stable ligaments (if ligaments are unstable, documentation should be provided as to how this condition will be addressed);
  - No malalignment present (if malalignment is present, documentation should indicate planned concurrent correction of alignment).
- The following are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes:
  - Osteochondral allografting for articular cartilage defects of the knee that do not meet medical necessity criteria above
  - Osteochondral allografting for all other indications and in all other joints including but not limited to the talus, patella or tibia
  - Allograft minced cartilage for all indications and in all joints
  - Decellularized osteochondral graft plugs (eg., Chondrofix) for all indications and in all joints
  - Allograft discs (e.g., ProChondrix, Cartiform) for all indications and in all joints

II. Osteochondral Autografting

- **Osteochondral autografting** (OATS or autologous mosaicplasty), using one or more cores of osteochondral tissue, may be considered **MEDICALLY NECESSARY AND APPROPRIATE** 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) or are not candidates for such procedures, when **ALL** the following criteria are met:
  - Patient is an adult OR a skeletally mature adolescent with documented closure of growth plates (e.g., 15 years or older);
  - Total area of the cartilage lesion (i.e., length x width, in centimeters or cm) is ≥ 1.0 cm2 (centimeters squared) and ≤ 4.0 cm2;
  - Focal full-thickness (modified Outerbridge grade III or IV) cartilage lesions on the weight-bearing surface of the femoral condyles (medial or lateral) or trochlea;
  - Documented minimal to absent degenerative changes in the surrounding articular cartilage (modified Outerbridge grade II or less) and normal appearing hyaline cartilage surrounding the border of the defect;
  - Presence of persistent symptoms (e.g., pain, swelling and catching/locking) that significantly limit activities of daily living;
  - Presence of stable ligaments (if ligaments are unstable, documentation should be provided as to how this condition will be addressed);
  - No malalignment present (if malalignment is present, documentation should indicate planned concurrent correction of alignment).
- The following are considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes:
  - Osteochondral autografting for articular cartilage defects of the knee that do not meet medical necessity criteria above
  - Osteochondral autografting for all other indications and in all other joints including but not limited to the talus, patella or tibia
  - Autograft minced cartilage procedures for all indications and in all joints

Procedure Codes
27415, 27416, 28446, 29866, 29867

Denial Statements

No additional statements.

Links
