

Origination Date: 3/05	Revision Date(s): 2/06, 8/06, 8/07, 8/08
Developed By: Medical Criteria Committee	

*Csaba Mera M.D.*

Approved: Csaba Mera, MD

Date: 8/18/08

**Description:**

***Allograft transplants*** of the knee are a type of procedure used in the treatment of individuals with symptomatic disabling cartilage injury or disease. This surgical technique can restore knee function in patients with focal articular cartilage defects due to trauma or other conditions such as osteochondritis dissecans. The procedure involves the transplantation of a piece of articular cartilage from a cadaver donor to the damaged surface of the knee.

***Osteochondral autografting*** is a surgical procedure used in an attempt to repair damaged articular cartilage. This type of procedure involves the placement of viable hyaline cartilage grafts into a cartilage defect. The grafts are harvested from a non-weight bearing region of the joint during an open or arthroscopic procedure and then transplanted into a cartilage defect to restore the articular surface of the bone. Osteochondral autografts are performed mainly to treat small and medium-size focal chondral and osteochondral defects of the weight-bearing surfaces of the knee joint. Two forms of osteochondral autografting are mosaicplasty and the osteochondral autograft transplantation system (OATS®) procedure. Although different instrumentation is used in mosaicplasty and OATS® procedures, the underlying principle is similar. These procedures use either multiple osteochondral cores or a single graft, harvested from a nonweight-bearing region of the joint that are autografted into the chondral defect.

***Autologous Chondrocyte Transplantation (ACT)*** or Autologous Chondrocyte Implantation (ACI) is a surgical treatment for patients who have clinically significant, symptomatic defects or damage to the cartilage of the knee that fails to heal on its own. The damage is usually caused by acute or repetitive trauma. Through arthroscopy, the patient's own healthy cartilage cells are removed and cultured in a laboratory with Carticel®, which is used to stimulate the growth of the patient's own cartilage cells. After 11-21 days an arthrotomy is performed and the chondral lesion is excised up to the normal surrounding cartilage. The cultured chondrocytes are then injected beneath a periosteal flap that has been created. The injected chondrocytes are proposed to create new cartilage development in the knee joint.

**Criteria:**

**Allograft** transplants of the knee (anterior cruciate ligament, meniscus, and osteochondral) will be covered to plan limitations when the following criteria are met:

**Anterior Cruciate Ligament (ACL):**

1. The patient is physically active; **and**
2. Patient has failed standard medical and surgical treatments; **and**
3. No evidence of advanced degenerative or inflammatory disease of the knee; **and**
4. Patient has a Body Mass Index of less than 35

**AND** the presence of ONE of the following:

5. Patient is not a candidate for autogenous transplantation due to autogenous tissues have been compromised by previous surgery or injury; **or**
6. Other contra-indications to using patient's own tissue such as collagen disease or generalized ligamentous laxity; **or**
7. Pathology such as chronic patellar tendonitis and hamstring injury exist

**Meniscus:**

Origination Date: 3/05	Revision Date(s): 2/06, 8/06, 8/07, 8/08
Developed By: Medical Criteria Committee	

1. Patient is physically active and under the age of 55; **and**
2. The patient has knee pain that has not responded to conservative treatment; **and**
3. MRI or previous arthroscopy reveal absence or near absence of the meniscus; **and**
4. Degenerative changes are absent or minimal; **and**
5. Knee is stable with an intact or reconstructed ACL; **and**
6. Patient has a Body Mass Index of less than 35

Osteochondral:

1. Patient has a Body Mass Index of less than 35

**AND** the presence of ONE of the following:

2. Treatment of an isolated, traumatic injury that is a full-thickness (grade 4) lesion, surrounded by healthy cartilage. The opposing articular surface should be free of disease or injury; **or**
3. Non-repairable stage 3 or 4 osteochondritis dissecans; **or**
4. Avascular necrosis lesions of the femoral condyle; **or**
5. Patient is otherwise healthy, active and non-elderly who has either failed earlier arthroscopic procedures or is not a candidate for such procedures due to the size, shape, or location of the lesion.

**Osteochondral autograft** of the knee (i.e. mosaicplasty, OATS®) will be covered to plan limitations when ALL of the following criteria are met:

1. Small to medium focal chondral defects (less than or equal to 2 cm<sup>2</sup>) of articulating cartilage; **and**
2. Patient has significant symptoms that are not relieved by conservative treatment or non-surgical therapy; **and**
3. Patient has a Body Mass Index of less than 35

**Autologous Chondrocyte Transplantation (ACT)** will be covered to plan limitations when ALL of the following criteria are met:

1. Patient is between the age of 15 and 65 years old; **and**
2. Full-thickness (grade III or IV) isolated cartilaginous defect of the knee involving the femoral condyle (medial, lateral or trochlear; not in the patellofemoral area); **and**
3. Size of the defect measures from 1cm<sup>2</sup> to 10cm<sup>2</sup>; **and**
4. Patient has failed conservative treatment, including physical therapy and arthroscopic or surgical repair; **and**
5. Symptoms of lesion pain, swelling, catching, locking, etc. limit activities of daily living; **and**
6. Knee is stable with an intact meniscus and in good alignment (corrective procedure in combination with or prior to ACT may be necessary); **and**
7. No active arthritis seen clinically and by x-ray; **and**
8. Patient has no known history of an allergy to the antibiotic gentamicin or sensitivity to materials of a bovine origin; **and**
9. Patient has a Body Mass Index of less than 35

ODS considers ACT experimental and investigational for patellar or talar lesions or lesions of other joints because the effectiveness of ACT for these lesions has not been established.

**Information to be Submitted with Pre-Authorization Request:**

- Clinical records from treating physician, including history and physical
- Documentation of conservative treatment tried and failed
- Appropriate x-rays, MRI, CT or other diagnostic imaging study report

Origination Date: 3/05	Revision Date(s): 2/06, 8/06, 8/07, 8/08
Developed By: Medical Criteria Committee	

**References:**

- American Academy of Orthopaedic Surgeons. Advisory Statement: Use of musculoskeletal tissue allografts. February 2001; Document No. 1011.
- National Guideline Clearinghouse. Review criteria for knee surgery. [www.guidelines.gov](http://www.guidelines.gov) accessed on 03/07/05.
- Tins BJ, McCall IW, Takahashi T, et al. Autologous chondrocyte implantation in knee joint: MR imaging and histologic features at 1-year follow-up. Radiology. 2005 Feb; 234(2):501-8.
- Gross AE. Repair of cartilage defects in the knee. Journal of Knee Surgery. Summer 2002; 15(3):167-9.
- Bugbee WD. Fresh osteochondral allografts. Journal of Knee Surgery. Summer 2002; 15(3):191-5.
- Shasha N, Aubin PP, Cheah HK, et al. Long-term clinical experience with fresh osteochondral allografts for articular knee defects in high demand patients. Cell Tissue Bank. 2002; 3(3):175-82.
- Noyes FR, Barber-Westin SD, Rankin M. Meniscal transplantation in symptomatic patients less than fifty years old. J. Bone Joint Surg Am. 2004 July; 86-A(7):1392-404.
- Ma HL, Hung SC, Wang ST, et al. Osteochondral autografts transfer for post-traumatic osteochondral defect of the knee-2 to 5 years follow-up. Injury. 2004 Dec; 35(12):1286-92.
- Hangody L, Fules P. Autologous osteochondral mosaicplasty for the treatment of full-thickness defects of weight-bearing joints. The Journal of bone and Joint Surgery. 2003; 85:25-32
- Rose T, Craatz S, Hepp P, et al. The autologous osteochondral transplantation of the knee: clinical results, radiographic findings and histological aspects. Arch Orthop Trauma Surg. 2005 Nov; 125(9):628-37.
- Detterline AJ, Goldberg S, Bach BR Jr, Cole BJ. Treatment options for articular cartilage defects of the knee. Orthop Nurs. 2005 Sep-Oct; 24(5):361-6.
- Caldwell PE 3<sup>rd</sup>, Sherton WR. Indications for allografts. Orthop Clin North Am. 2005 Oct; 36(4):459-67.
- Sekiya JK, West RV, Groff YJ, et al. Clinical outcomes following isolated lateral meniscal allograft transplantation. Arthroscopy. 2006 Jul; 22(7):771-80.
- Physician Advisors