



Subject: *Autologous Chondrocyte Implant*

Number: **200309-0003**

Effective date: 10/01/2003

Revision date(s): 02/1998; 09/25/2003

Important note

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following Web site: <http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

Overview

Autologous chondrocyte implant (Carticel, Genzyme Inc., Cambridge, Mass.) is part of a three-step treatment for repairing cartilage defects in the knee. First, normal cartilage is harvested during an arthroscopic biopsy. This serves as the source of cultured chondrocytes. This specimen is placed into a culture medium and the cells are separated from the cartilage. These cells are then multiplied – which takes about six weeks – and stored in the frozen state.

After being thawed and a final culture process, the cells are sent to the operating room on the day of the implantation or transplant surgery. The cultured chondrocytes are implanted into the cartilage defect in a second open arthrotomy procedure.

Policy and criteria

NOTE: These services require prior authorization by the plan medical director.

When services are covered:

We cover **autologous chondrocyte implant** (ACI) to repair cartilage defects in the knee when ALL of the following criteria are met:

- age 15 to 45 years; and
- focal articular cartilage defect down to but not through the subchondral bone on a load bearing surface of the medial and/or lateral femoral condyle (not in the patellofemoral area); AND
- size of defect is a minimum of 1 cm²; AND
- body Mass Index (BMI) of < 35; AND
- disabling pain and/or knee locking; AND
- stable knee with intact meniscus and normal joint space on X-ray; AND
- no active inflammatory or other arthritis, clinically and by X-ray; AND
- procedure is not being done for treatment of degenerative arthritis; AND
- failure of conservative therapy, defined as a minimum of two months of physical therapy, and other traditional surgical interventions, such as abrasion, drilling and microfraction.

In addition, the patient must:

- Be cooperative to actively participate in postoperative weight bearing restrictions and activity restrictions together with a potential for completion of postoperative rehabilitation; AND
- Have given informed consent with realistic expectations.

When services are not covered:

We **do not cover** services when the above criteria are not met.

We **do not cover** the following as their effectiveness has not been proven and are considered experimental and investigational:

- autologous chondrocyte transplants for patellar or talar lesions or lesions of other joints
- autologous osteochondral mosaicplasty in the treatment of articular cartilage defects or lesions

Codes:

Codes	Number	Description
CPT	27330-27335, 27403	Code range, arthrotomy of the knee
	29871	Arthroscopy; lavage
	29874	removal of chondral fragments
	29877	debridement of articular cartilage
	29879	Abrasion, drilling or microfracture of cartilage
	0012T	Arthroscopy, knee, surgical, implantation of osteochondral graft(s); autografts
HCPCS	J7330	Autologous cultured chondrocytes, implant
	S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

FCHP products to which this policy applies:

- ⊕ FCHP Direct and FCHP Select Care (HMO)
- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home

Medicare plan – *reminder* to refer to CMS for policy and criteria

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Mandated benefit/Regulatory issues

- Ø Federal
- Ø Commonwealth of Massachusetts
- Ø Medicare – National Policy
- Ø Medicare – Local Medical Review Policy
- Ø Not applicable

Committee review dates:

Benefit Committee: 06/1995; 05/0996; 03/1997; 02/1998

Technology Assessment Committee: 11/2003

Utilization Management Committee: 06/2003

Approved by:	Signature on file	09/30/2003
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