MEDICAL POLICY

Excellus

SUBJECT: AUTOLOGOUS CHONDROCYTE IMPLANTATION	EFFECTIVE DATE: 07/02/99 REVISED DATE: 02/01/01, 01/17/02, 03/20/03, 01/15/04, 01/20/05, 11/17/05, 07/20/06, 06/21/07, 05/14/08, 04/16/09, 05/27/10, 05/19/11, 05/24/12, 04/18/13, 03/20/14
POLICY NUMBER: 7.01.38 CATEGORY: Technology Assessment	PAGE: 1 OF: 9

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, autologous chondrocyte implantation (ACI) is **medically appropriate** for treatment of symptomatic isolated cartilage defects of the femoral condyle in a stable knee when all of the following are present:
   A. Patient's age is between 15 and 55 years;
   B. There is symptomatic cartilaginous defect in the medial, lateral or trochlear area of the femoral condyle. If the defect extends deep into subchondral bone, repair of the subchondral base must be addressed first;
   C. There are clinically significant symptoms, cartilage injury (acute or chronic), that are unresponsive to physical therapy, conservative treatment, prior arthroscopic or other surgical repair procedure (e.g. debridement, drilling, microfracture);
   D. The defect size greater than 2 cm^2;
   E. The knee must be stable and aligned; an osteotomy may be required to achieve this; and
   F. There is no evidence of osteoarthritis or inflammatory disease (e.g., rheumatoid arthritis, gout, Bechterew syndrome, chondrocalcinosis).

II. Based upon our criteria and assessment of peer-reviewed literature, autologous chondrocyte implantation (ACI) is **investigational** for use in sites other than the femoral condyle (e.g. patella, talus).

III. Based upon our criteria and assessment of peer-reviewed literature, the following techniques for autologous chondrocyte implantation are considered **investigational**:
   A. Matrix induced or scaffold associated ACI;
   B. Allogeneic minced cartilage (e.g., DeNovo NT Graft).

Refer to Corporate Medical Policy # 7.01.59 regarding Osteochondral Grafting.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Destruction of the articulating surface of the synovial joint of the knee results in increased pain and loss of function to the joint. Damaged articular cartilage fails to heal on its own making repair of articular surfaces difficult. Autologous chondrocyte implantation (ACI) is a surgical treatment for patients with deep cartilage defects in the knee. The procedure involves replacing defective articular cartilage with cultured chondrocytes that will produce articular cartilage that is similar in composition and properties to the original tissue. Cells are harvested from the patient's own knee, grown in a laboratory and then implanted into the knee to improve knee function and reduce pain. A periosteum patch covers the implanted cells. The procedure is performed via arthroscopy.

Only Carticel® has received has received FDA approval through a biologics license for the culturing of chondrocytes. The approval restricts Carticel® to use for the repair of symptomatic cartilaginous defects of the femoral condyle (medial, lateral, or trochlear), caused by acute or repetitive trauma in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure.

Methods to improve the ACI procedure are being investigated, including the use of a scaffold or matrix-induced ACI (MACI) composed of biocompatible carbohydrates, protein polymers or synthetics (e.g., matrix based ACI, Hyalograft C, Cartipatch). The use of minced cartilage techniques are also in the early stages of development. The tissue fragments are mixed intra-operatively with fibrin glue before implantation. It is thought that mincing the tissue helps with cell migration.

RATIONALE:

Genzyme Tissue Repair's Carticel autologous chondrocytes received approval by the FDA of its biologics license for repair of symptomatic cartilaginous defects of the femoral condyle (medial, lateral, or trochlear), caused by acute or repetitive trauma in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. There is sufficient data published in the peer-reviewed literature to conclude that autologous chondrocyte transplantation results in relief of symptoms and improved function in patients who had failed conservative management and arthroscopic or other surgical treatments. Several studies include reports of histological examinations of the graft site showing stable hyaline cartilage after surgery. Studies in the United States enrolled patients between the ages of 15 and 45 years.

K Zaslav and colleagues (2009) conducted a prospective, cohort study (STAR) to assess the effectiveness of autologous chondrocyte implantation in patients who failed prior treatments for articular cartilage defects of the knee. STAR was a prospective, open-label 4-year study in 154 patients (mean age: 35 years; 69% male) from 29 clinical centers. Each patient served as his or her own control, undergoing ACI after having failed or experienced an inadequate response to a prior cartilage repair procedure. Outcomes included change from baseline in knee function, knee pain, quality of life, and overall health. Duration of benefit after autologous chondrocyte implantation was compared with the failed prior non-autologous chondrocyte implantation procedure. One hundred twenty-six patients (82%) completed the protocol. Seventy-six percent of patients were treatment successes at study end, while 24% were deemed treatment failures. Preoperative mean knee pain score was 3.0 (SD, 1.8; 0 = severe, 10 = normal). Mean improvements were observed from baseline to all time points ($P < .001$) for all outcome measures. Preoperative to 48-month values, respectively, were as follows: On the Knee injury and Osteoarthritis Outcome Score subscales of pain: 48.7 to 72.2; other symptoms: 51.8 to 70.8; sports/recreation: 25.8 to 55.8; knee quality of life: 20.9 to 52.2; and activities of daily living: 58.6 to 81.0; on the Modified Cincinnati Overall Knee score: 3.3 to 6.3; on the visual analog scale: 28.8 to 69.9; and on the SF-36 Overall Physical Health: 33.0 to 44.4. Seventy-six patients (49%) had subsequent surgical procedure(s), predominantly arthroscopic. The authors concluded that patients with moderate to large chondral lesions with failed prior cartilage treatments can expect sustained and clinically meaningful improvement in pain and function after autologous chondrocyte implantation.

There is insufficient evidence in the literature to support the use of chondrocyte implantation other than the femoral condyle of the knee.

The literature describing the use of a porcine collagen rather than a periosteum cover and matrix induced autologous chondrocyte implantation, using for example, Hyalgraft C or the MACI technique is limited, and use of these products in the autologous chondrocyte implantation procedure has not been approved by the FDA. The use of minced cartilage techniques are also in the early stages of development. DeNovo NT (natural tissue) Graft and DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) are produced by ISTO Technologies (exclusively distributed by Zimmer, Inc.). DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. As there are no chemicals used and minimal manipulation, it is regulated as an allograft tissue rather than a biological implant. Therefore, the allograft tissue does not require FDA approval for marketing. DeNovo NT is currently available in the USA. Neocartilage uses juvenile allogeneic cartilage cells that are isolated and expanded in vitro, similar

to other ACI techniques. Neocartilage is currently being studied in human clinical trials in the USA under an FDA approved investigational new drug (IND) application.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	27412	Autologous chondrocyte implantation, knee

HCPCS:	J7330	Autologous cultured chondrocytes, implant
	S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)
ICD9:	715.16	Osteoarthrosis, localized, primary, lower leg
	715.26	Osteoarthrosis, localized, secondary, lower leg
	715.36	Osteoarthrosis, localized, not specified whether primary or secondary, lower leg
	715.96	Osteoarthrosis, unspecified whether generalized or localized, lower leg
	716.16	Traumatic arthropathy, lower leg
	717.9	Unspecified internal derangement, knee
	718.86	Other joint derangement, lower leg
	719.86	Other specified disorders of joint, lower leg
	732.7	Osteochondritis dissecans
	733.90	Other unspecified disorder of bone and cartilage
ICD10:	M12.561-M12.569	Traumatic arthropathy (code range)
	M17.0- M17.9	Osteoarthritis of knee (code range)
	M23.50-M23.52	Chronic instability of knee (code range)
	M23.90-M23.92	Unspecified, internal derangement of knee (code range)
	M25.261-M25.269	Flail joint, knee (code range)
	M25.361-M25.369	Other instability, knee (code range)
	M25.861-M25.869	Other specified joint disorder, knee (code range)
	M85.9	Disorder of bone density and structure, unspecified
	M89.9	Disorder of bone, unspecified
	M93.20	Osteochondritis dissecans of unspecified site
	M93.261-M93.269	Osteochondritis dissecans knee (code range)
	M94	Disorder of cartilage, unspecified

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*key article

KEY WORDS:

Carticel, De Novo ET, DeNovo NT, Matrix-induced, MACI, Minced cartilage, Neocartilage, Scaffold-induced

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, autologous chondrocyte implantation is not addressed in National or Regional Medicare coverage determinations or policies.