Autologous Chondrocyte Transplant

Policy

Autologous chondrocyte implantation (ACI) involves harvesting chondrocytes from healthy tissue, expanding the cells in vitro, and implanting the expanded cells into the chondral defect under a periosteal or fibrin patch. Second- and third-generation techniques include combinations of autologous or allogeneic chondrocytes, minced cartilage, scaffolds, and growth factors. Carticel is currently the only FDA-approved autologous chondrocyte implantation (ACI) therapy. The entire autologous chondrocyte implantation (ACI) procedure consists of four steps:

1) The initial arthroscopy and biopsy of normal cartilage, (CPT 29868)
2) Culturing of chondrocytes, (HCPCS J7330)
3) A separate arthrotomy to create a periosteal flap and implant the chondrocytes (CPT 27412)
4) Post-surgical rehabilitation. The initial arthroscopy may be scheduled as a diagnostic procedure; as part of this procedure, a cartilage defect may be identified, prompting biopsy of normal cartilage in anticipation of a possible chondrocyte transplant. The biopsied material is then sent for culturing and returned to the hospital when the implantation procedure is scheduled

GEHA considers Autologous Chondrocyte Implantation (ACI) medically necessary for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma and there are symptoms of disabling knee pain related to a full thickness, focal chondral defect and all of the following criteria are met:

- Body mass index (BMI) less than or equal to 35
- Failure of conservative therapy (minimum of 2 months of physical therapy) as well as established surgical interventions (i.e., microfraction, drilling, abrasion, or osteochondral autograft) (diagnostic arthroscopy, lavage, or debridement is not considered adequate to meet this criterion); and
- Focal articular cartilage defect down to but not through the subchondral bone on a load bearing surface of the femoral condyle (medial, lateral, trochlear) (not in the patella); and
- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years)
- Focal, full-thickness (grade III or IV) unipolar lesions of the patella or the weight bearing surface of the femoral condyles or trochlea at least 1.5 cm2 in size
• 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
• Normal knee biomechanics, or alignment and stability achieved concurrently with autologous chondrocyte implantation

GEHA considers the following experimental and investigations because effectiveness has not been established:

• Matrix-induced chondrocyte implantation including the use of Bio-Gide (resorbable bilayer membrane made of porcine collagen)
• Combined meniscal allograft and autologous chondrocyte implantation of the knee
• Combined autologous chondrocyte implantation and osteochondral autograft transfer system for surgical repair of cartilage defects of the knee

RATIONALE

Articular cartilage damaged through acute or chronic trauma or osteochondritis dessecans, has limited ability to regenerate, leading to the symptoms of pain, restricted mobility and locking. Articular surfaces that are damaged by trauma or degenerative processes fill in primarily or completely with fibrocartilage, but only when the subchondral plate is penetrated. Fibrocartilage does not have the biomechanical properties of hyaline cartilage, and degrades over time. Although natural repair with fibrocartilage can produce good short- and medium-term results, biological and epidemiological data suggest that it does not prevent long-term development of osteoarthritis. Current treatment methods to stimulate repair of the cartilage include shaving the margins of the damaged cartilage to remove mechanical obstructions or irritants (abrasion or debridement) or drilling through the cartilage through the underlying bone into the vascular marrow in order to permit the ingrowth of fibrocartilage from the marrow. Long-standing severe damage to the articular cartilage can lead to debilitating osteoarthritis, which ultimately may require a total knee arthroplasty.

There is no standard approach to the treatment of hyaline cartilage defects in the knee. Non-operative treatment in the form of weight reduction, physical therapy, braces and orthotics, nonsteroidal anti-inflammatory drugs (NSAIDs), and/or intra-articular injection of hyaluronic acid derivatives may provide effective pain relief for some patients. Arthroscopic lavage with saline and/or debridement of loose tissue and unstable cartilage fragments may be performed, although there is debate over how this procedure contributes to long-term functional recovery (Kirkley et al., 20081). Results from these conventional methods can be suboptimal or short-lasting, except in individuals with very low activity demands. If defects progress to severe osteoarthritis, total knee replacement (TKR) may be necessary. The Agency for Healthcare Research and Quality (AHRQ)2 estimated that more than 721,000 TKRs

occurred in 2010, twice as many as in the year 2000 (CDC, 2011b). Due to the expected life of current prostheses, treatment strategies typically try to avoid TKR for patients younger than age 55.

ACI is being performed increasingly throughout the country despite a lack of any definitive studies demonstrating its effectiveness over other surgical procedures in similar populations. Current National Institute for Health and Clinical Evidence (NICE): Current NICE Guidelines recommend against ACI for the treatment of articular cartilage defects of the knee joint, except in the context of ongoing or new clinical studies that are designed to generate robust and relevant outcomes data, including the measurement of health-related quality of life and long-term follow-up. Patients should be fully informed of the uncertainties about the long-term effectiveness and the potential adverse effects of this procedure. Several studies suggested that ACI provides short-term outcomes comparable to those provided by other surgical options for second-line treatment of full-thickness defects in the articular cartilage of the knee, and some studies suggested that improvements in ACI groups were durable over time. Moderate-quality evidence suggests that short-term outcomes of second-line ACI are similar to those of second-line marrow stimulation, but complications were somewhat more frequent following first-generation ACI. There are some small studies regarding the long-term (7-10 years) effectiveness of ACI. Several studies suggested that ACI provides short-term outcomes comparable to those provided by other surgical options for second-line treatment of full-thickness defects in the articular cartilage of the knee, and some studies suggested that improvements in ACI groups were durable over time.

CPT CODES COVERED IF SELECTION CRITERIA ARE MET:

27412 AUTOLOGOUS CHONDROCYTE IMPLANTATION, KNEE

29870 ARTHROSCOPY, KNEE, DIAGNOSTIC; WITH OR WITHOUT SYNOVIAL BIOPSY (SEPARATE PROCEDURE)

27416 OSTEOCHONDRAL AUTOgraFT(S), KNEE, OPEN (EG, MOSAICPLASTY) (INCLUDES HARVESTING OF AUTOgraFT[S]) [NOT COVERED IN COMBINATION WITH AUTOLOGOUS CHONDROCYTE IMPLANTATION]

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27447 ARTHROPLASTY, KNEE, CONDYLE AND PLATEAU; MEDIAL AND LATERAL COMPARTMENTS WITH OR WITHOUT PATELLA RESURFACING (TOTAL KNEE ARTHROPLASTY)

29866 ARTHROSCOPY, KNEE, SURGICAL; IMPLANTATION OF OSTEochondRAl AUTOgrafts (E.G., MOSAICPLASTY) (INCludes HARVESTING OF AUTOgrafts) [NOT COVERED IN COMBINATION WITH AUTOLOGOUS CHONDROCYte IMPLANTATION]

29871 ARTHROSCOPY, KNEE, SURGICAL; FOR INFECTION, LAVAGE AND DRAINAGE

29874 FOR REMOVAL OF LOOSE BODY OR FOREIGN BODY (E.G., OSTEOCHONDritis DISSECANS FRAGMENTATION, CHondRAL FRAGMENTATION)

29877 DEBRIDEMENT/SHAVING OF ARTICULAR CARTILAGE (CHONDROPLASTY)

29879 ABRASION ARTHROPLASTY (INCLUDES CHONDROPLASTY WHERE NECESSARY) OR MULTIPLE DRILLING OR MICROFRACTURE

HCPCS CODES COVERED IF SELECTION CRITERIA ARE MET:

J7330 AUTOLOGOUS CULTURED CHONDROCYTES, IMPLANT

S2112 ARTHROSCOPY, KNEE, SURGICAL, FOR HARVESTING OF CARTILAGE (CHONDROCYTE CELLS)