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Medical Policy

Autologous Chondrocyte Implantation

Policy Number: 1063

Policy History			
Approve Date:	06/01/2018	Effective Date:	06/01/2018
Reviewed/Revised Dates:	07/15/2019, 12/07/2020, 12/20/2021		

Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details.

Policy

Indications of Coverage

I. Health Tradition considers autologous chondrocyte implants medically necessary for repairing cartilage effects of the knee when the following selection criteria are met.
   A. Member has symptoms of disabling knee pain related to a full thickness, focal chondral defect with all of the following:
      i. Age of 15 years or older with documented growth plate closure, or adults less than 55 years of age AND
      ii. Body mass index (BMI) less than or equal to 35 AND
      iii. Failure of conservative therapy (minimum of two 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
      iv. Focal articular cartilage defect is down to but not through the subchondral bone on a load bearing surface of the femoral condyle (medial, lateral, trochlear – but not in the patella AND
      v. Has no active inflammatory or other arthritis, including degenerative arthritis (osteoarthritis) clinically and by x-ray AND
      vi. Has disabling pain and/or knee locking which limits activities of daily living AND
      vii. The size of defect measures less than 7 mm in depth, less than 6.0 cm in length, and area ranging from 1.6 to 10 square centimeters (cm) AND
      viii. There is stable and aligned knee with intact meniscus and normal joint space on x-ray (a corrective procedure in combination with, or prior to, chondrocyte implantation may be necessary to ensure stability, alignment and normal weight distribution within the joint).

II. Health Tradition considers autologous chondrocyte implants experimental and investigational for all other indications because effectiveness has not been established for any other indication including but not limited to the following:
   A. Individuals with a patellar or talar lesion or lesions of other joints (e.g. hip and shoulder) OR
   B. Individuals who have had a previous total menisectomy OR
   C. Individuals with a cartilanginous defect associated with osteoarthritis, rheumatoid arthritis or inflammatory disease or where an osteoarthritic or inflammatory process significantly and adversely affects the quality of the peri lesional cartilage OR

D. Individuals with a known history of anaphylaxis to gentamicin or sensitivities to materials of bovine origin OR
E. Individuals with osteochondritis dissecans (OCD) lesions OR
F. Initial or first line of surgical therapy.

III. Health Tradition considers matrix-induced chondrocyte implantation including the use of Bio-Gide (resorbable bilayer membrane made of porcine collagen) experimental and investigational for all indications including autologous chondrocyte implantation of the knee because its efficacy has not been established in peer reviewed literature.

IV. Health Tradition considers combined meniscal allograft and autologous chondrocyte implantation of the knee experimental and investigational as efficacy has not been established in peer reviewed literature.

Health Tradition considers combination of autologous chondrocyte implantation and osteochondral autograft transfer system for surgical repair of cartilage defects of the knee experimental and investigational because efficacy has not been established in peer reviewed literature.

Background

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. 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.

Autologous chondrocyte implants (autologous chondrocyte transplant) (Carticel, Genzyme Inc., Cambridge, MA) has been investigated as a means of a 3-step treatment for repairing cartilage defects in the knee. First, normal cartilage is harvested from a joint margin during an arthroscopic biopsy procedure. This biopsy of an articular surface serves as the source of cultured chondrocytes. This specimen of live articular cartilage is placed into a culture medium. Under a strictly controlled environment the cells are separated from the cartilage. These cells are then multiplied using a cell-culture technique. They are stored in the frozen state and are thawed and have a final culturing process before they are shipped to the operating room on the day of the implantation. It takes about six weeks to culture chondrocytes for implantation. Approximately 12 million cartilage cells are present in the 0.4ml medium that is ultimately implanted into the defect. The cultured chondrocytes are implanted into the cartilage defect in a second open arthrotomy procedure.

Patients are referred for autologous chondrocyte implantation after already having had surgery for an articular cartilage problem. If the patient remains symptomatic, and the patient and the surgeon decide that autologous chondrocyte implant is the best option, then an arthroscopic biopsy is planned.

Ideally, candidates for autologous chondrocyte implant should be between 15 and 60 years of age, have full thickness localized defects of the femoral condyles, have intact menisci, have no generalized chondromalacia, have no limb mis-alignment and are willing and able to undergo vigorous rehabilitation. This procedure is not recommended for patients who have an unstable knee and for patients sensitive to materials of bovine origins. It is also not recommended for use in children, and not yet in any joint other than the knee.

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