Medical Coverage Policy | Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

EFFECTIVE DATE: 10|01|2016
POLICY LAST UPDATED: 10|05|2022

OVERVIEW

A variety of procedures are being developed to resurface articular cartilage defects. Autologous chondrocyte implantation (ACI) involves harvesting chondrocytes from healthy tissue, expanding the cells in vitro, and implanting the expanded cells into the chondral defect. Second- and third-generation techniques include combinations of autologous chondrocytes, scaffolds, and growth factors. This policy addresses autologous chondrocyte implantation (ACI).

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Autologous chondrocyte implantation may be considered **medically necessary** for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma, when all of the following criteria are met:

- 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 weight bearing surface of the femoral condyles, trochlea or patella at least 1.5 cm^2 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

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial products and obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Autologous chondrocyte transplantation for the treatment of cartilage defects of the knee is considered medically necessary when medical criteria are met.

Medicare Advantage Plans

Autologous chondrocyte implantation for all other joints, including the talar, and any indications other than those listed above is not covered, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome**.**

Commercial Products

Autologous chondrocyte implantation for all other joints, including the talar, and any indications other than those listed above is considered not medically necessary, as the evidence is insufficient to that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefits/coverage.

BACKGROUND

Articular Cartilage Lesions

Bamaged articular cartilage typically fails to heal on its own and can be associated with pain, loss of function, and disability and may lead to debilitating osteoarthritis over time. These manifestations can severely impair a patient's activities of daily living and adversely affect quality of life.

Treatment

Conventional treatment options include debridement, subchondral drilling, microfracture, and abrasion arthroplasty. Debridement involves the removal of synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral drilling, microfracture, and abrasion arthroplasty attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Compared with the original hyaline cartilage, fibrocartilage has less capability to withstand shock or shearing force and can degenerate over time, often resulting in the return of clinical symptoms. Osteochondral grafts and autologous chondrocyte implantation (ACI) attempt to regenerate hyaline-like cartilage and thereby restore durable function. Osteochondral grafts for the treatment of articular cartilage defects are not discussed in this policy.

With ACI, a region of healthy articular cartilage is identified and biopsied through arthroscopy. The tissue is sent to a facility licensed by the U.S. Food and Drug Administration (FDA) where it is minced and enzymatically digested, and the chondrocytes are separated by filtration. The isolated chondrocytes are cultured for 11 to 21 days to expand the cell population, tested, and then shipped back for implantation. With the patient under general anesthesia, an arthrotomy is performed, and the chondral lesion is excised up to the normal surrounding cartilage. Methods to improve the first-generation ACI procedure have been developed, including the use of a scaffold or matrix-induced autologous chondrocyte implantation (MACI) composed of biocompatible carbohydrates, protein polymers, or synthetics. The only FDA-approved MACI product to date is supplied in a sheet, which is cut to size and fixed with fibrin glue. This procedure is considered technically easier and less time-consuming than the first-generation technique, which required suturing of a periosteal or collagen patch and injection of chondrocytes under the patch.

Desired features of articular cartilage repair procedures are the ability (1) to be implanted easily, (2) to reduce surgical morbidity, (3) not to require harvesting of other tissues, (4) to enhance cell proliferation and maturation, (5) to maintain the phenotype, and (6) to integrate with the surrounding articular tissue. In addition to the potential to improve the formation and distribution of hyaline cartilage, use of a scaffold with matrix-induced ACI eliminates the need for harvesting and suture of a periosteal or collagen patch. A scaffold without cells may also support chondrocyte growth.

The culturing of chondrocytes is considered by FDA to fall into the category of manipulated autologous structural cells, which are subject to a biologic licensing requirement. In 1997, Carticel® (Genzyme; now Vericel) received FDA approval for the repair of clinically significant, "...symptomatic cartilaginous defects of the femoral condyle (medial lateral or trochlear) caused by acute or repetitive trauma.…"

In December 2016, MACI® (Vericel), received FDA approved for "the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults." MACI® consists of autologous chondrocytes which are cultured onto a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel® was phased out and MACI® is the only ACI product available in the United States.

A number of other second-generation methods for implanting autologous chondrocytes in a biodegradable matrix arecurrently in development or testing or are available outside of the United States. They include Atelocollagen (Koken), acollagen gel; Bioseed® C (BioTissue Technologies), a polymer scaffold; CaReS (Ars

Arthro), collagen gel; Cartilix(Biomet), a polymer hydrogel; Chondron (Sewon Cellontech), a fibrin gel; Hyalograft C (Fidia Advanced Polymers), ahyaluronic acid-based scaffold; NeoCart (Histogenics), an autologous chondrocyte implantation with a 3-dimensionalchondromatrix in a phase 3 trial; and Novocart®3D (Aesculap Biologics), a collagen-chondroitin sulfate scaffold in aphase 3 trial. ChondroCelect® (TiGenix), characterized as a chondrocyte implantation with a completed phase 3 trial,uses a gene marker profile to determine in vivo cartilage-forming potential and thereby optimizes the phenotype (eg,hyaline cartilage vs. fibrocartilage) of the tissue produced with each autologous chondrocyte implantation cell batch. Eachbatch of chondrocytes is graded based on the quantitative gene expression of a selection of positive and negativemarkers for hyaline cartilage formation. Both Hyalograft C and ChondroCelect have been withdrawn from the market inEurope. In 2020, the FDA granted breakthrough status to Agili-C (CartiHeal, Ltd.), a proprietary biocompatible andbiodegradable tapered-shape implant for the treatment of cartilage lesions in arthritic and non-arthritic joints that, whenimplanted into a pre-prepared osteochondral hole, acts as a 3-dimensional scaffold that potentially supports and promotesthe regeneration of the articular cartilage and its underlying subchondral bone.

For individuals who have focal articular cartilage lesions of joints other than the knee who receive autologous chondrocyteimplantation, the evidence includes systematic reviews of case series. Relevant outcomes are symptoms, change indisease status, morbid events, functional outcomes, and quality of life. The greatest amount of literature is for autologouschondrocyte implantation of the talus. Comparative trials are needed to determine whether autologous chondrocyteimplantation improves outcomes for lesions in joints other than the knee. The evidence is insufficient to determine that thetechnology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products
The following codes are covered when the medical criteria above have been met:

There is a specific CPT code for ACI of the knee:
27412 Autologous chondrocyte implantation, knee

HCPCS supply code for the autologous cultured chondrocyte implant:
J7330 Autologous cultured chondrocytes, implant

RELATED POLICIES

Prior Authorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, December 2022
Provider Update, July 2021
Provider Update, July 2020
Provider Update, November 2019
Provider Update, August 2018

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