MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Autologous chondrocyte implantation (ACI) replaces damaged or destroyed articular cartilage with chondrocyte cells that multiply into healthy cartilage. During an arthroscopy, healthy articular cartilage is retrieved. Chondrocyte cells are isolated from the cartilage and cultured for 11 – 21 days to expand the cell population. The damaged cartilage is subsequently removed and the new chondrocyte cells are implanted where they will continue to multiply.

Matrix-induced autologous chondrocyte implantation (MACI) uses a scaffold composed of biocompatible carbohydrates, protein polymers or synthetics. The scaffold is used to attach the healthy new chondrocyte cells. A scaffold without cell may also support chondrocyte growth. No products are currently approved for use in the United States.

AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Criteria:

All requests for autologous chondrocyte implantation will be reviewed by the medical director(s) and/or clinical advisor(s).

- Autologous chondrocyte implantation for the repair of symptomatic, cartilaginous defects of the femoral condyle at the knee (medial, lateral or trochlear) caused by acute or repetitive trauma is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual is between 15 and 55 years of age
  2. **ONE** of the following significant symptoms:

     - Pain
     - Swelling
     - Locking or "catching"
     - Limitation of daily or recreational activities that have lasted greater than 1 year

  3. Other treatments have failed, including surgical repair procedures
  4. Knee is stable with normal alignment
  5. Cartilage defect is 1.5 cm or greater (arthroscopic photograph of defect must be submitted)
  6. Minimal or no evidence of osteoarthritis, degenerative joint disease or inflammatory joint disease (Defined as grade II degeneration or less)
  7. Other parts of the knee, including the patellofemoral joint and tibial articular cartilage are diagnosed as normal

- Autologous chondrocyte implantation for the treatment of osteochondritis dissecans of the knee is considered ***medically necessary*** with documentation that lesion is 7mm or less in depth.

- Autologous chondrocyte implantation for all other joints (e.g., patellar, talar, ankle, hip) is considered ***experimental or investigational*** based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.

- Matrix-induced autologous chondrocyte implantation is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR FOCAL ARTICULAR CARTILAGE LESIONS (cont.)

Resources:

Resources prior to 07/10/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.48 BCBS Association Medical Policy Reference Manual. Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions. Re-issue date 06/12/2014, issue date 07/31/1996.