Policy: MP115

Section: Medical Benefit Policy

Subject: Autologous Chondrocyte Implantation

I. Policy: Autologous Chondrocyte Implantation

II. Purpose/Objective:

To provide a policy of coverage regarding Autologous Chondrocyte Implantation

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Autologous chondrocyte implantation (ACI) of the knee utilizes the patient’s own cartilage cells to repair damage to articular cartilage, with the intended goal of improving joint function and reducing pain. The process involves collecting and producing an ex vivo FDA-approved matrix-induced chondrocyte culture of articular cartilage, which is implanted into the cartilage defect, where they contribute to the regeneration and repair of the articular surface.

INDICATIONS:
Autologous Chondrocyte Implantation (ACI) for the treatment of full thickness articular cartilage defects of the knee may be considered medically necessary when all of the following criteria are met:

- The presence of disabling pain, swelling and/or locking or catching of the knee that remains unresponsive to physical therapy and at least one prior arthroscopic or open surgical repair procedure (e.g., micro-fracture, debridement, drilling, abrasion, etc.); and
- Skeletal maturity has been reached. Adolescents must have documented closure of growth plates. Adults should be too young to be considered an appropriate candidate for total knee replacement (e.g., less than 55 years of age) or other reconstructive knee surgery; and
- Focal, symptomatic, full thickness uni-polar lesions on the weight bearing surface (medial, lateral or trochlear) of the femoral condyles or trochlea at least 2 cm² or greater in size; and
- Documented minimal to absent degenerative changes in the surrounding articular cartilage, and normal appearing cartilage surrounding at least 75% of the border of the defect; and
- Normal knee mechanics, or alignment and stability to be achieved concurrently with the ACI procedure; and
- Absence of meniscal pathology (including, but not limited to infection, inflammatory disease, osteoarthritis, or malignancy); and
- Body mass index less than or equal to 35; and
- The insured individual has the ability to comply with the postoperative rehabilitation protocol.

EXCLUSIONS: The Plan does NOT provide coverage for Autologous Chondrocyte Implantation for joint articular surfaces other than the knee because it is considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this procedure on health outcomes in joints other than the knee when compared to established tests or technologies.

Autologous chondrocyte implantation performed in combination with osteochondral autograft transfer system (hybrid ACI/OATS) is considered to be experimental, investigational or unproven for the treatment of osteochondral defects. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this procedure on health outcomes in joints other than the knee when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Autologous Chondrocyte Implantation

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

27599 Unlisted procedure, femur or knee
27412 Autologous chondrocyte Implantation, knee
27416 Osteochondral autograft(s), knee, open (e.g., mosaicplasty)(includes harvesting of autograft[s])
29866  Arthroscopy, knee, surgical, implantation of osteochondral graft(s) for treatment of articular surface defect; autografts

29867  Arthroscopy, knee, surgical, implantation of osteochondral graft(s) for treatment of articular surface

J7330  Autologous cultured chondrocytes, implant

S2112  Arthroscopy, knee, surgical harvest of cartilage (chondrocyte cells)


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Technology Assessment, Department of Labor and Industries, Autologous Chondrocyte Implantation. June 2002


This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 7/03

**Revised:** 12/06, 08/10, 8/19 (add hybrid ACI/OATS exclusion)

**Reviewed:** 1/08, 7/11, 8/12, 8/13, 8/14, 8/15, 8/16, 7/17, 8/18