PROVIDER POLICIES & PROCEDURES

AUTOLOGOUS CHONDROCYTE IMPLANTATION

The purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for autologous chondrocyte implantation (ACI) or matrix induced chondrocyte implantation (MACI). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

ACI is a two-stage operative procedure used to treat full-thickness articular cartilage defects of the knee. The first procedure is performed arthroscopically and involves the harvesting of healthy articular cartilage from a non-weight-bearing area of the person's knee. This cartilage biopsy is then sent to a laboratory where the chondrocytes are extracted from the biopsy, expanded and then sent back to the surgeon. The second stage is an open procedure whereby the implant is adhered to the defect to form a hyaline-like cartilage resembling native joint cartilage.

CLINICAL GUIDELINE

Coverage guidelines for ACI are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only.* Coverage determinations are based on an assessment of the individual and their clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

ACI may be considered medically necessary when the following criteria are met:

1. Symptomatic full-thickness cartilage defects of the knee with or without bone involvement; and
2. Individual is an adult younger than 55 years of age or an adolescent with radiologically confirmed closure of their growth plates; and
3. Body mass index (BMI) is $\leq$ 35; and
4. Defect is $\geq$ 3 cm^2; and
5. Individual will follow a physician-prescribed post-surgical rehabilitation program.

ACI is contraindicated or unproven and not medically necessary for treating patients with the following indications due to insufficient evidence of efficacy:

- Cartilage defects in locations other than the femoral condyle of the knee including talar lesions
- Children (growth plates have not closed)
- Partial-thickness defects
- Known history of hypersensitivity to gentamicin, or other aminoglycosides, or products of porcine or bovine origin
- Severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders
- Individuals who have had a previous total meniscectomy

- Individuals who have undergone prior knee surgery in the past 6 months, excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant
- Malignancies in the area of the cartilage biopsy or implant
- Pre-existing conditions, including meniscus tears, joint instability, or malalignment, unless these conditions are assessed and treated prior to or concurrent with autologous chondrocyte implantation
- Individuals with active infection of the knee

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization for ACI is required. Requests for coverage of ACI will be reviewed in accordance with procedures in place for reviewing requests for outpatient surgical procedures. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for ACI:
- Fully completed Outpatient Prior Authorization Request Form
- Clinical documentation addressing all of the clinical criteria listed above
- Other information as requested

EFFECTIVE DATE
This Policy is effective for prior authorization requests for ACI for individuals covered under the HUSKY Health Program beginning May 1, 2020.

LIMITATIONS
N/A

CODES:

Codes	Description
27412	Autologous chondrocyte implantation, knee
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
J7330	Autologous cultured chondrocytes, implant

DEFINITIONS
1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for

HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.

3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

RESOURCES AND REFERENCES:

- American Academy of Orthopaedic Surgeons. Clinical practice guideline on the diagnosis and treatment of osteochondritis dissecans 2010. Available at: https://www.aaos.org/research/guidelines/OCD_guideline.pdf. Accessed on January 30, 2020.
- Behery O, Sistona, RA, Harris JD, Flanigan DC. Treatment of cartilage defects of the knee: expanding an existing algorithm. Clin J Sport Med. 2014; 24(1):21-30.
- Brittberg M, Recker D, llgenfritz J, Saris D. Matrix-applied characterized autologous cultured chondrocytes versus microfracture: five-year follow-up of a prospective randomized trial. Am J Sports Med. 2018 May; 46(6):1343-1351.
- Ebert J R, Smith A, Fallon M, Wood DJ, Ackland, T. Correlation between clinical and radiological outcomes after matrix-induced autologous chondrocyte implantation in the femoral condyles. Am J Sports Med 2014 Jun; 42(8): 1857-1864.
- FDA Full Prescribing Information MACI. Available at: https://www.fda.gov/media/101914/download. Accessed on January 30, 2020.

- Mandle L, Martin G. Overview of surgical therapy of knee and hip osteoarthritis. UpToDate. Topic last updated December 2, 2019. Available at: https://www.uptodate.com/contents/search. Accessed on January 30, 2020.
- National Institute for Clinical Excellence (NICE). Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee. Technology Appraisal Guidance No. TA477. London, UK: NICE; 2017. Available at: https://www.nice.org.uk/guidance/ta477/chapter/1-Recommendations. Accessed on January 30, 2020.
- Niemeyer P, Albrecht D, Andereya S, et al. Autologous chondrocyte implantation (ACI) for cartilage defects of the knee: A guideline by the working group "Clinical Tissue Regeneration" of the German Society of Orthopaedics and Trauma (DGOU). Knee. 2016 Jun; 23(3):426-35.

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	April 2020	Approved at the February 26, 2020 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 16, 2020. Approved by DSS on April 16, 2020.
Updated	March 2021	Updated Policy section. Added “talar lesions” and “individuals with previous total meniscectomy” to list of contraindications and unproven Indications. Changes approved at the February 10, 2021 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 15, 2021. Approved by DSS on March 22, 2021.
Reviewed	March 2022	Reviewed without changes at the January 12, 2022 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 21, 2022. Approved by DSS on March 24, 2022.
Updated	June 2023	Updated Clinical Guideline section. Added to criteria, “or an adolescent with radiologically confirmed closure of their growth plates.” Change approved at the April 12, 2023, CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on June 19, 2023. Approved by DSS on June 28, 2023.