Medical Policy

Autologous Chondrocyte Implantation	
MEDICAL POLICY NUMBER	MED_Clin_Ops-117
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to establish the clinical review criteria for determination of medical necessity of Autologous Chondrocyte Implantation (ACI).

POLICY

Clinical Review Criteria

Autologous Chondrocyte Implantation (ACI) may be considered medically necessary for the treatment of full-thickness articular cartilage defects of the knee in patients who had inadequate improvement from conservative and/or previous surgical treatments when **ALL** of the following criteria are met:

1. **ONE** or more of the following criteria is met:
    a. Member is 15 years or older with a documented growth plate closure
    b. Member is an adult less than 55 years of age.
2. Member has **ONE** or more of the following
    a. Disabling pain that impairs activities of daily living
    b. Range of motion limitation that impairs activities of daily living

c. Locking that impairs activities of daily living.

3. Member has focal and full thickness (Grade III or IV chondral defect) unipolar lesion(s) on the weight bearing surface of the femoral condyle, trochlea or patella.
4. Defect size is less than 7 mm deep, less than 6 cm wide and area from 1.6 to 10 cm^2
5. Body mass index (BMI) is less than or equal to 35.
6. Failure to improve with conservative therapy, including a minimum of 2 months of physical therapy.
7. Knee is stable and aligned with normal joint space on x-ray and meniscus intact.
8. Authorization is **NOT** for treatment of osteoarthritis, other arthritis, or inflammation.
9. Member is informed and able to participate in post operative rehabilitation including activity restrictions and limitations to weight bearing.

Refer to MED-Clin-Ops-021 Arthroscopic Knee Surgery for more information regarding coverage of knee surgery.

BACKGROUND

Articular cartilage is composed of chondrons within a territorial matrix surrounded by a highly organized extracellular matrix comprising collagen II fibrils, proteoglycans, glycosaminoglycans, and non-collagenous proteins. Damaged articular cartilage has a limited potential for healing and untreated defects often progress to osteoarthritis. One such strategy, autologous chondrocyte implantation (ACI), was first reported in 1994 as a treatment for deep focal articular cartilage defects. ACI has since evolved to become a worldwide well-established surgical technique. For ACI, chondrocytes are harvested from the lesser weight bearing edge of the joint by arthroscopy, their numbers expanded in monolayer culture for at least four weeks, and then re-implanted in the damaged region under a natural or synthetic membrane via an open joint procedure.[2] MCG ACG: A-0415 (AC) 23rd edition accessed 6/10/2022 indicates inconclusive or Non-Supportive Evidence for the procedure.

Review of recent published articles indicate growing evidence of long-term effectiveness including a 2017 review funded by the English National Institute for Health Research Health Technology Assessment program. Their conclusions were*: The evidence base for ACI has improved since the last appraisal by the National Institute for Health and Care Excellence. In most analyses, the incremental cost-effectiveness ratios for ACI compared with MF appear to be within a range usually considered acceptable. Research is needed into long-term results of new forms of ACI.* Finally, other payers have evaluated and consider the procedure to be medically necessary with the indications above.

DEFINITIONS

1. **Arthroscopic knee surgery** is a procedure that allows physicians to view the knee joint without making a large incision through the skin and other soft tissues. Arthroscopic knee surgery is used to diagnose and treat a wide range of knee problems.

Medical Policy

2. **Authorization:** A decision by Brand New Day/Central Health Medicare Plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary or meets other member contract terms. Sometimes called prior authorization, prior approval or precertification. Brand New Day/Central Health Medicare Plan requires preauthorization for certain services before a member receives them, except in an emergency. Authorization is not a promise that Brand New Day/Central Health Medicare Plan will cover the cost.

3. **Autologous Chondrocyte Implantation (ACI)** was developed for the treatment of traumatic cartilage defects in an attempt to prevent or delay total knee replacement. The first step of the procedure is an arthroscopic examination of the chondral lesion followed by harvesting of cartilage from a lesser weight-bearing portion of the knee joint. The cartilage specimen is then sent for chondrocyte isolation and culture in the laboratory. The second stage of the procedure, which includes defect preparation and implantation of chondrocytes, takes place 5 to 9 weeks later. The chondrocytes are injected into the defect and covered with a periosteal patch which is sutured to the edge of the defect.

CODING

The codes listed below are for reference purposes. This list does not imply whether the code is covered or not covered. The benefit document should be referenced for coverage determination. This list of applicable codes may not be all-inclusive.

CPT CODE	DESCRIPTION
27412	Autologous chondrocyte implantation, knee
27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting of autograft[s])
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
29871	Arthroscopy, knee, surgical; for infection, lavage and drainage
29874	Arthroscopy, knee, surgical; for removal of loose body or foreign body (eg, osteochondritis dissecans fragmentation, chondral fragmentation)
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture

HCPCS CODE	DESCRIPTION
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

EVIDENCE BASED REFERENCES

- Autologous Chondrocyte Implantation Versus Matrix-Induced Autologous Chondrocyte Implantation. W. Bartlett, J. A. Skinner, C. R. Gooding, R. W. J. Carrington, A. M. Flanagan, T. W. R. Briggs, G. Bentley. The Journal Of Bone And Joint Surgery, Vol. 87-B, No. 5, May 2005
- Regenerative Medicine: A Review of the Evolution of Autologous Chondrocyte Implantation (ACI) Therapy Rebecca L Davies 1,2 and Nicola J Kuiper 1,2, Bioengineering 2019, 6, 22; doi:10.3390/bioengineering 6010022
- Autologous Chondrocyte Implantation: Past, Present, and Future; Welch, Tyler 1 ; Mandelbaum, Bert 2 ; Tom, Minas 3 ; Sports Medicine and Arthroscopy Review, Volume 24, Number 2, June 2016, pp. 85-91(7)
- Autologous Chondrocyte Implantation (ACI) for Knee Cartilage Defects: A Review of Indications, Technique, and Outcomes. Krill, Michael MD1; Early, Nicholas MD2; Everhart, Joshua S. MD, MPH2; Flanigan, David C. MD1,2,a JBJS Reviews: February 2018 - Volume 6 - Issue 2 - p e5

- Autologous chondrocyte implantation in the knee: systematic review and economic evaluation. Mistry H1, Connock M1, Pink J1, Shyangdan D1, Clar C1, Royle P1, Court R1, Biant LC2, Metcalfe A3, Waugh N1. Health Technology Assessment (Winchester, England), 01 Feb 2017, 21(6):1-294 DOI: 10.3310/hta21060 PMID: 28244303

POLICY HISTORY

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan policies on clinical criteria and policy development.

Approval Body	Utilization Management Committee		
Version History	**Approval Date**	**Effective Date**	**Action**
V1	07-14-2022	07-14-2022	New Policy
V2	10-12-2022	10-12-2022	Codes confirmed, criteria confirmed and reorganized for clarity
V3	10-12-2022	03-01-2023 01-01-2024	Adopted by MA UMC Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)