

## Autologous Chondrocyte Implantation of the Knee

Policy Number: **M020411319**  
Effective Date: **4/11/2002**  
Sponsoring Department: **Health Care Services**  
Impacted Department(s): **Health Care Services**

**Type of Policy:**  Internal  External

**Data Classification:**  Confidential  Restricted  Public

### Applies to (Line of Business):

- Corporate (All)
- State Products, if yes which plan(s):  MediSource;  MediSource Connect;  Child Health Plus  Essential Plan
- Medicare, if yes, which plan(s):  MAPD;  PDP;  ISNP;  CSNP
- Commercial, if yes, which type:  Large Group;  Small Group;  Individual
- Self-Funded Services (*Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.*)

### Excluded Products within the Selected Lines of Business (LOB)

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N/A

**Applicable to Vendors?** Yes  No

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### Purpose and Applicability:

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To set forth the medical necessity criteria for an **autologous chondrocyte implantation** of the knee.

## Policy:

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### **Commercial, Self-Funded and Medicare Advantage:**

Autologous chondrocyte implantation (ACI) may be considered medically necessary and a covered benefit when **all** the following criteria are met:

- Age 15-55 (or younger if growth plates have fully closed); and
- Body Mass Index <35; and
- Presence of disabling pain and/or knee locking; and
- 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; and
- The defect size is greater than 2 cm squared; and
- Failure of conservative therapy, such as physical therapy, (minimum of three months) as well as established surgical interventions (i.e., micro-fracture, drilling, abrasion, or osteochondral autograft); and
- No active inflammatory or other arthritis, clinically (e.g., Kellgren-Lawrence Grade 2 or less) and by diagnostic studies; and
- Stable knee with intact meniscus and normal joint space on X-Ray; and
- Cooperative member for post-operative weight bearing restriction and activity restrictions together with a potential for completion of post-operative rehabilitation

Based upon our criteria and assessment of peer-reviewed literature, the following techniques for autologous chondrocyte implantation are considered investigational:

1. Allogeneic minced cartilage (e.g., DeNovo® NT Natural Tissue Graft [Zimmer Inc.]])

Based upon our criteria and assessment of peer-reviewed literature ACI is investigational for indications other than the knee.

### **MediSource, MediSource Connect, Child Health Plus and Essential Plan:**

MediSource, MediSource Connect, Child Health Plus and Essential Plan do not cover ACI.

### **Background:**

The literature contains case series in peer-reviewed journals documenting successful use of this procedure in patients where traditional treatments had failed. However, experience is inadequate to determine the long-term durability of the results of this procedure. Therefore, while the outcomes of the procedure appear to be promising, the criteria for authorizing this procedure are currently restricted to those patients for whom the literature suggests the best chance of successful outcomes.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

**Pre-Authorization Required?** Yes  No

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Pre-authorization is required for this service.

## Definitions

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**Autologous chondrocyte implantation (ACI)** is a form of tissue engineering which creates a graft from a patient's own cartilage cells to repair defects in the articular cartilage. The procedure involves the collection and in vitro expansion of articular cartilage cells, which are then implanted into the defect with the goal of improving the quality of cartilage repair.

**Kellgren-Lawrence System** is a method of classifying the severity of osteoarthritis (OA) using five grades:

Numerous variations of the Kellgren and Lawrence classification system have been used in research . Below is the original description:

grade 0 (none): definite absence of x-ray changes of osteoarthritis

grade 1 (doubtful): doubtful joint space narrowing and possible osteophytic lipping

grade 2 (minimal): definite osteophytes and possible joint space narrowing

grade 3 (moderate): moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends

grade 4 (severe): large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends

Osteoarthritis is deemed present at grade 2 although of minimal severity.

**Outerbridge** classification is a grading system for joint cartilage breakdown:

Grade 0 - normal

Grade I - cartilage with softening and swelling

Grade II - a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter

Grade III - fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm

Grade IV - exposed subchondral bone

Subchondral bone is the bone underneath the white joint cartilage.

## References

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### Related Policies, Processes and Other Documents

N/A

### Non-Regulatory references

Anigwe C, Kucirek NK, Feeley BT, et al. Utilization of Autologous Chondrocyte Implantation in the Knee is Increasing While Reoperation Rates Are Decreasing Despite Increasing Preoperative Comorbidities. *Arthroscopy*. 2022 Oct 7:S0749-8063(22)00614-4.

Clar C, Cummins E, McIntyre L, et al. Clinical and cost-effectiveness of autologous chondrocyte implantation for cartilage defects in knee joints: systematic review and economic evaluation. *Health Technol Assess*. 2005;9(47): iii-iv, ix-x, 1-82.

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Hayes, Inc., Search and Summary DeNovo NT Natural Tissue Graft (Zimmer Inc.) for Articular Cartilage Repair. Lansdale PA: November 2013.

Hayes, Inc., Comparative Effectiveness Review of Second- and Third-Generation Autologous Chondrocyte Implantation of the Knee. Lansdale PA: July 2017.

Hayes, Inc. Health Technology Assessment Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure for Repair of Articular Cartilage of the Knee. Lansdale PA: August 2020.

Jungmann PM, Salzmann GM, Schmal H, Pestka JM, Südkamp NP, Niemeyer P. Autologous chondrocyte implantation for treatment of cartilage defects of the knee: what predicts the need for reintervention? *Am J Sports Med*. 2012 Jan;40(1):58-67.

Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthritis. *Ann Rheum Dis*. 1957 Dec;16(4):494-502.

Mandl LA, Martin GM. Overview of surgical therapy of knee and hip osteoarthritis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on November 16, 2022 ).

Washington State Department of Labor and Industries, Office of the Medical Director. Autologous chondrocyte implantation (ACI): 2002 update. Technology Assessment. Olympia, WA: Washington State Department of Labor and Industries; updated June 26, 2002.

### Regulatory References

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest) via email. March 12, 2018.

***This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member’s contract at the time the services are rendered.***

## Version Control

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Signature / Approval on File? Yes  No

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
02/1/2023	Health Care Services	Reviewed
2/1/2022	Health Care Services	Revised
3/1/2021	Health Care Services	Revised
4/1/2020	Medical Management	Revised
5/1/2019	Medical Management	Reviewed
5/1/2018	Medical Management	Reviewed
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7/1/2015	Medical Management	Revised
7/1/2014	Medical Management	Revised
6/1/2013	Medical Management	Revised
7/1/2012	Medical Management	Revised
7/1/2011	Medical Management	Revised
6/1/2010	Medical Management	Revised
5/19/2009	Medical Management	Reviewed
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