Medicare Medical Policy

Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects of the Knee

MEDICARE MEDICAL POLICY NUMBER: 355

Effective Date: 11/1/2026

Last Review Date: 10/2026

Next Annual Review: 10/2027

MEDICARE COVERAGE CRITERIA 2
POLICY CROSS REFERENCES 3
POLICY GUIDELINES 3
REGULATORY STATUS 4
BILLING GUIDELINES AND CODING 4
REFERENCES 5
POLICY REVISION HISTORY 6

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*) • **Medicare Coverage Manuals:** Medicare does not have criteria for autologous chondrocyte implantation (ACI) to treat cartilaginous defects of the knee in a coverage manual. • **National Coverage Determination (NCD):** Medicare does not have an NCD for ACI of the knee. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for ACI of the knee. • Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects of the Knee	Company medical policy for Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects of the Knee I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members either when the Company medical policy criteria are **not** met ***or*** when a service is deemed "not medically necessary" by the Company policy. See *Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Meniscal Allograft Transplantation and Other Meniscal Implants, MP356
- Osteochondral Allografts and Autografts for Cartilaginous Defects, MP357

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for autologous chondrocyte implantation (ACI) to treat cartilaginous defects of the knee available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

There are a number of nonspecific arthrotomy and arthroscopy codes that are not appropriate for autologous chondrocyte implantation (ACI), including but not limited to 27330, 27331, 27334, and 29879. Of note, 29879 should not be billed in conjunction with ACI unless performed in a different compartment of the knee.

Many of the codes in this policy are not specific to autologous chondrocyte implantation (ACI) and may be used for other restorative procedures for the knee, which are addressed in other medical policies. For example: 27415, 27416, 29866 and/or 29867 may also be requested for osteochondral autografting (mosaicplasty or OATS) or allografting. Please see the Cross References section above for applicable Medicare medical policies.

HCPCS Code S2112

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[1], indicates HCPCS code S2112 has been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, HCPCS code S2112 is not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy *(HCPCS S-Codes and H-Codes,* 22.0*).* Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

CODES*		
CPT	1092T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; into chondral defect, open

	1093T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; into a chondral or osteochondral defect, arthroscopic
	1094T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; each additional acellular scaffold implantation (List separately in addition to code for primary procedure)
	27332	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial OR lateral
	27333	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial AND lateral
	27412	Autologous chondrocyte implantation, knee
	27415	Osteochondral allograft, knee, open
	27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting of autograft[s])
	27599	Unlisted procedure, femur or knee
	29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])
	29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)
	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)
	29999	Unlisted procedure, arthroscopy
HCPCS	J7330	Autologous cultured chondrocytes, implant
	S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells) *(CMS-assigned Status "I" code – See above billing guidelines)*

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Physician Fee Schedule (PFS) Relative Value Files. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
12/2022	New Medicare Advantage medical policy (converted to new format 2/2023)
1/2024	Annual review, no changes to criteria but language revision due to Company policy change from "investigational" to "not medically necessary", update title
11/2024	Annual review, no changes to criteria
11/2025	Annual review, no changes to criteria
10/2026	Q4 2026 code updates
11/2026	Annual review, no changes to criteria