Medicare Medical Policy

Viscosupplementation

MEDICARE MEDICAL POLICY NUMBER: 202

Effective Date: 10/1/2024

Last Review Date: 9/2024

Next Annual Review: 9/2025

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." • **Medicare Coverage Manuals:** Medicare does not have criteria for intraarticular hyaluronan injections or viscosupplementation, for any indication, in a coverage manual. • **National Coverage Determination (NCD):** Medicare does not have an NCD for viscosupplementation, for any indication. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, the Medicare Administrative Contractor (MAC) for the plan service area (Noridian J-F) does **not** have an LCD or LCA for viscosupplementation. • In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6)(i)(C) as there is no Medicare coverage criteria available, including no LCD or LCA by the plan's service area MAC. ***According to a CMS FAQ dated February 6, 2024, internal coverage criteria used by an MAO may include the use of LCD criteria from a geographic area that is not the MA plan's service area, as long as all requirements of § 422.101(b)(6) are satisfied.*** • For viscosupplementation, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, **the plan is adopting published LCD criteria from the MAC, Wisconsin Physician Services (WPS).** • See **Policy Guidelines** below for more information about CMS requirements for § 422.101(b)(6).
Intraarticular Hyaluronan Injections (Viscosupplementation)	**Wisconsin Physician Services (WPS) LCD:** Intraarticular Knee Injections of Hyaluronan (L39529) **NOTES:** • "Limitation" #3 within the LCD addresses viscosupplementation of ***joints other than*** the knee.

	• "Limitation" #10 within the LCD addresses ***knee diagnoses other than osteoarthritis***. • See below for the Summary of Evidence and the sources (citations) used in the development of this LCD.

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

None

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

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

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))*

According to Medicare:

> "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." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

When Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(b)(6), including the absence of an LCD or LCA by the plan's service area MAC, then according to a *CMS FAQ dated February 6, 2024*, ***internal coverage criteria used by an MAO may include the use of LCD criteria from a geographic area that is not the MA plan's service area, as long as all requirements of § 422.101(b)(6) are satisfied.***

The requirements of § 422.101(b)(6) are:

- Coverage criteria must be based on current evidence in widely used treatment guidelines or clinical literature.
- The coverage criteria can be used **only** when Medicare coverage criteria are not fully established for our service area (as described by § 422.101(b)(6)(i)(A)-(C)).
- The MAOs use of this criteria must be publicly accessible (as described by § 422.101(b)(6)(ii)(A)-(C)). This includes:
    - Publicly publish the internal coverage criteria used by the plan, accessible via a website (not behind a paywall or require a subscription for access) **and** must be available to **all** of the public (not just enrollees or contracted providers).
    - A summary of evidence.
    - Citations or sources of the evidence.
    - An explanation of the rationale for using the criteria that is in our policy.

According to the *Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.1.1 - Local Coverage Determinations (LCD) Definition & Statutory Authority for LCDs,* these same elements are also required in LCDs. CMS states (bold added for emphasis):

> "The 2016 21st Century Cures Act included changes to the LCD process, adding language to 1862(l)(5)(D) of the SSA to describe the LCD process. Section 1862(l)(5)(D), of the SSA requires each MAC that develops an LCD to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:
>
> (i) Such determination in its entirety.
> (ii) Where and when the proposed determination was first **made public**.
> (iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.
> (iv) A **summary of evidence** that was considered by the contractor during the development of such determination **and a list of the sources of such evidence**.
> (v) **An explanation of the rationale that supports such determination**."

Therefore, for viscosupplementation services, because Medicare coverage criteria are "not fully established" in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, **the plan as opted to adopt published LCD criteria from the MAC, Wisconsin Physician Services (WPS).**

SUMMARY AND SOURCES OF EVIDENCE

This LCD is based on current evidence in widely used treatment guidelines or clinical literature, and it includes a systemic review of evidence-based guidelines and published literature, which were considered in the development of the LCD criteria. In addition, the summary of evidence, as well as the list of citations (bibliography list), that were used in the development of the LCD coverage criteria, are provided within the LCD, and are also publicly available. *[CFR § 422.101(b)(6)(ii)(A) and (B)]* As of the date of the most recent policy review, the summary of evidence and the sources of information used in the development of the WPS LCD L39529 are as follows:

SUMMARY OF EVIDENCE

Analysis of Evidence (Rationale for Determination)

Various polymers of hyaluronic acid have been approved and marketed as implanted prosthetic devices. Clinical practice guidelines for the treatment of knee osteoarthritis have conflicting recommendations for intra-articular hyaluronic acid treatment for knee osteoarthritis.12 The systematic review by the technology assessment program4 reported a small, statistically significant effect of HA on function. Clinical studies of sodium hyaluronate and hylan G-F 20 have demonstrated that injection of these agents into the joint space of osteoarthritic knees is sometimes marginally more effective than placebo procedures in reduction of pain and improvement in functional capacity in some patients. These marginal beneficial results are more pronounced with the larger molecular weight compound hylan G-F 20. There is no data indicating that these agents reverse or retard the osteoarthritic process in the injected joints. The long-term effects of repeated injections are unknown.

Literature evaluating pain control and functional recovery of viscosupplementation performed at the end of arthroscopic meniscectomy or in the postoperative period after ACL reconstruction does not demonstrate significant clinical benefits.9-10

Literature suggests that fluoroscopy or ultrasound guidance may improve injection accuracy in the target intra-articular joint space of large joints including the knee. The use of other imaging procedures for viscosupplement injections has not been established as having an improvement on health outcomes.

SOURCES OF EVIDENCE

Sources of Information

Other Contractors Policies

Novitas Solutions, Inc. LCD L35427 Hyaluronan Acid Therapies for Osteoarthritis of the Knee.

UnitedHealthCare Medical Policy Number: CS110.N. Sodium Hyaluronate. Effective Date June 1, 2018.

Bibliography

1. American Academy of Orthopaedic Surgeons. Viscosupplementation Treatment for Knee Arthritis. *OrthoInfo*. Last Reviewed February 2021. https://orthoinfo.aaos.org/en/treatment/viscosupplementation-treatment-for-knee-arthritis/. Accessed January 18, 2023.
2. U.S. Food and Drug Administration (FDA) approval letters and manufacturer's inserts. Devices@FDA.https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=170&showFR=1&subpartNode=21:3.0.1.1.1.5 . Accessed January 5, 2023.
3. Vad VB. Hyaluronic Acid Injections for Knee Osteoarthritis. *Arthritis-Health*. Updated 03/28/2019. https://www.arthritis-health.com/treatment/injections/viscosupplementation-knee-osteoarthritis. Accessed March 7, 2023.

4. Newberry SJ, Fitzgerald JD, Maglione MA, et al. *Systematic Review for Effectiveness of Hyaluronic Acid in the Treatment of Severe Degenerative Joint Disease (DJD) of the Knee*. Rockville (MD): Agency for Healthcare Research and Quality (US); July 23, 2015.
5. VA/DoD Clinical Practice Guideline for Non-Surgical Management of Hip and Knee Osteoarthritis Guideline Summary. Prepared by The Osteoarthritis Working Group. V1.0; 2014. https://www.healthquality.va.gov/. Accessed January 20, 2023.
6. National Institute for Health and Care Excellence (NICE) Clinical Guideline Osteoarthritis: care and management. Updated October 19, 2022. Nice.org.uk/guidance/cg177. Accessed January 17, 2023.
7. American Academy of Orthopaedic Surgeons, Treatment of Osteoarthritis of the Knee Evidence-Based Guideline, 2nd Edition, Adopted by the American Academy of Orthopaedic Surgeons Board of Directors May 18, 2013.
8. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res*. 2012 Apr;64(4):465-74.
9. Filardo G, Di Matteo B, Tentoni F, et al. No Effects of Early Viscosupplementation After Arthroscopic Partial Meniscectomy: A Randomized Controlled Trial. *Am J Sports Med*. 2016 Dec;44(12):3119-3125.
10. Di Martino A, Tentoni F, Di Matteo B, et al. Early Viscosupplementation After Anterior Cruciate Ligament Reconstruction: A Randomized Controlled Trial. *Am J Sports Med*. 2016 Oct;44(10):2572-2578.
11. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. *Clin Interv Aging*. 2012;7:89-95. doi: 10.2147/CIA.S29265.
12. Altman RD, Schemitsch E, Bedi A. Assessment of clinical practice guideline methodology for the treatment of knee osteoarthritis with intra-articular hyaluronic acid. *Semin Arthritis Rheum*. 2015 Oct;45(2):132-9. doi: 10.1016/j.semarthrit.2015.04.013.
13. Aetna Policy Number: 0179. Viscosupplementation. Last Reviewed 04/13/2018.
14. Altman R, Hackel J, Niazi F, Shaw P, Nicholls M. Efficacy and safety of repeated courses of hyaluronic acid injections for knee osteoarthritis: A systematic review. *Semin Arthritis Rheum*. 2018 Oct;48(2):168-175. doi: 10.1016/j.semarthrit.2018.01.009.
15. American Medical Association (AMA) CPT Assistant. Coding Clarification: Hip Arthrography. June 2012, Volume 22, Issue 6, page 14.
16. Bert JM and Waddell DD. Viscosupplementation with Hylan G-F 20 in Patients with Osteoarthrosis of the Knee. *Ther Adv Musculoskelet Dis*. 2010 Jun; 2(3): 127–132. doi: 10.1177/1759720X10370930.
17. Florida Blue Medical Coverage Guideline 09-J10000-22 Viscosupplementation, Hyaluronan Injections (e.g. Synvisc®). Revised 04/01/2021.
18. Maricar N, Parkes MJ, Callaghan MJ, Felson DT, O'Neill TW. Where and how to inject the knee a systematic review. *Semin Arthritis Rheum*. 2013 Oct;43(2):195-203. doi: 10.1016/j.semarthrit.2013.04.010.
19. Telikicherla M, Kamath SU. Accuracy of Needle Placement into the Intra-Articular Space of the Knee in Osteoarthritis Patients for Viscosupplementation. *J Clin Diagn Res*. 2016 Feb;10(2):RC15-7. doi: 10.7860/JCDR/2016/17127.7275.
20. U.S. Food and Drug Administration (FDA) approval letters and manufacturer's inserts. Devices@FDA. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170016D.pdf. Accessed January 17, 2023.
21. U.S. Food and Drug Administration (FDA) approval letters and manufacturer's inserts. Devices@FDA. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180040C.pdf. Accessed January 18, 2023.

Details regarding the review of this literature can be found in the LCD directly.

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

Codes J7318-J7332 are medically necessary when billed with the following diagnosis codes (based on WPS LCA A56157, which is the billing and coding companion to the WPS LCD noted above):

- M17.0
- M17.11
- M17.12
- M17.2
- M17.31
- M17.32
- M17.4
- M17.5

CODES*		
CPT	20600	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); without ultrasound guidance
	20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting
	20605	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance
	20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting
	20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance
	20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting
HCPCS	J3490	Unclassified drugs
	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg
	J7320	Hyaluronan or derivative, genvisc 850, for intra-articular injection, 1 mg
	J7321	Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose
	J7322	Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg

	J7323	Hyaluronan or derivative, euflexxa, for intra-articular injection, per dose
	J7324	Hyaluronan or derivative, orthovisc, for intra-articular injection, per dose
	J7325	Hyaluronan or derivative, synvisc or synvisc-one, for intra-articular injection, 1 mg
	J7326	Hyaluronan or derivative, gel-one, for intra-articular injection, per dose
	J7327	Hyaluronan or derivative, monovisc, for intra-articular injection, per dose
	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1mg
	J7329	Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg
	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg
	J7332	Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg

***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

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
8/2022	Annual review (converted to new format 2/2023)
4/2023	Interim update.
8/2023	Annual review; removed use of Wisconsin Physician Services (WPS) reference as criteria source; language revision due to Company policy change from "investigational" to "not medically necessary"
10/2024	Annual review; removed use of Company policy criteria due to archival, replaced with Wisconsin Physician Services (WPS) LCD, along with supporting CMS documentation