

Viscosupplementation for Osteoarthritis

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

Clinical guidelines are applicable to certain plans. Clinical guidelines are applicable to members enrolled in Medicare Advantage plans only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of a prior authorization request. Services are subject to the terms, conditions, limitations of a member's policy and applicable state and federal law. Please reference the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Oscar members with certain types of knee pain may be eligible for treatment with hyaluronic acid injections to improve function and decrease pain. Osteoarthritis is an inflammatory-mediated joint condition that often affects one or both knee joints, with increasing prevalence in older adults. It can present as tenderness, stiffness, swelling, and/or instability. Many patients will improve with conservative measures such as physical therapy, exercise, weight loss, oral/topical medications, and/or intra-articular corticosteroid injections. Some patients with more severe symptoms or those who do not improve with conservative therapy may require further treatment. Surgery with total knee replacement is the standard of care for refractory osteoarthritis of the knee. However, some patients may benefit from a non-surgical treatment called viscosupplementation, which is an injection of a lubricating agent called hyaluronic acid to improve function and decrease pain. This guideline will provide coverage criteria and exclusions for viscosupplementation with hyaluronic acid derivatives.

Note: Oscar may require that preferred medications be used first. Please review Oscar Clinical Guideline CG052: Preferred Physician-Administered Specialty Drugs for a full list of our preferred and non-preferred drugs.

Definitions

“Hyaluronan” or **“Sodium hyaluronate”** or **“Hyaluronic acid”** is a thick fluid similar to the fluid naturally inside the joint. When injected into the knee joint in a process known as “viscosupplementation”, it can act as a lubricant and shock absorber in an effort to decrease symptoms and improve function.

“**Osteoarthritis**” is a joint disease caused by inflammation, where the protective cartilage of the joint wears down over time resulting in bone-on-bone contact. This can cause pain, swelling, decreased mobility, and stiffness. Osteoarthritis can be graded using x-ray imaging with the Kellgren-Lawrence System (Table 2).

“**Viscosupplementation**” is a procedure where hyaluronic acid is injected into the joint space. Examples of viscosupplements, or hyaluronic acid injections, are listed below (Table 1).

Table 1. Dosing Guidelines / Injection Series (per 6-month period)	
Sources: Prescribing Information (See References)	
Brand	Dosing Guideline
Durolane® (hyaluronic acid)	60 mg (3 mL) x 1 dose
Euflexxa® (1% sodium hyaluronate)	20 mg once weekly x 3 doses
Gel-One® (cross-linked hyaluronate)	30 mg (3 mL) x 1 dose
Gelsyn-3™ (sodium hyaluronate 0.84%)	16.8 mg (2 mL) once weekly x 3 doses
GenVisc® 850 (sodium hyaluronate)	25 mg once weekly x 3-5 doses
Hyalgan® (sodium hyaluronate)	20 mg once weekly x 5 doses
Hymovis® (high molecular weight viscoelastic hyaluronan)	24 mg (3 mL) once weekly x 2 doses
Monovisc® (high molecular weight hyaluronan)	88 mg (4 mL) x 1 dose
Orthovisc® (high molecular weight hyaluronan)	30 mg once weekly x 3-4 doses
Supartz™ (sodium hyaluronate)	10 mg once weekly x 3-5 doses
Supartz FX™ (sodium hyaluronate)	25 mg once weekly x 5 doses
Synjoynt™ (1% sodium hyaluronate)	3 weekly injections per knee
Synvisc® (hylan G-F 20)	16 mg once weekly x 3 doses
Synvisc-One® (hylan G-F 20)	48 mg x 1 dose
TriVisc™ (sodium hyaluronate)	25 mg (2.5 mL) once weekly x 3 doses
Visco-3™ (sodium hyaluronate)	2.5 mL once weekly x 3 doses

“**Kellgren-Lawrence System**” is a five-grade classification system describing radiographic findings for osteoarthritis (Table 2).

Table 2. Kellgren-Lawrence System for classifying osteoarthritis of the knee ¹⁴	
Grade	Radiographic Findings
0	No radiographic features of osteoarthritis are present
I	Doubtful joint space narrowing and possible osteophytic lipping
II	Definite osteophytes and possible joint space narrowing
III	Moderate multiple osteophytes, definite joint space narrowing, some sclerosis, and possible deformity of bone contour
IV	Large osteophytes, marked joint space narrowing, severe sclerosis, and definite deformity of bone contour

Covered Services and Clinical Indications

Initial Requests

Oscar considers initial requests for viscosupplement injections medically necessary when **ALL** of the following criteria are met:

1. Mild-to-moderate knee osteoarthritis confirmed by imaging performed within the last 12 months (Kellgren-Lawrence Grade II-III, as defined above in Table 2); **and**
2. Pain in the affected knee interferes with functional activities (e.g., ambulation, prolonged standing, ability to sleep); **and**
3. Other forms of joint disease to which the pain may be attributed have been ruled out; **and**
4. There has been a failure to decrease pain or improve function after at least a 3-month trial of conservative treatment which has included at **ALL** of the following:
 - a. Active and ongoing participation in a physical therapy, exercise (e.g., lower extremity flexibility and strengthening program), and/or weight loss program; **and**
 - b. Oral/topical medications (e.g., NSAIDs, acetaminophen, duloxetine, tramadol, capsaicin cream), unless poorly tolerated or contraindicated; **and**
 - c. Intra-articular corticosteroid injection, unless contraindicated; **and**
5. No contraindications to injection, such as any systemic infection, infection of the proposed leg/joint, or any significant bleeding disorder that may predispose to hemarthrosis; **and**
6. **ONE** of the following:
 - a. Not a candidate for surgery (e.g., high risk, contraindication); **or**
 - b. Surgery is not expected within 6 months of the injection series.

Subsequent Requests

Oscar considers subsequent requests for viscosupplement injections medically necessary when **ALL** of the following criteria are met:

1. The above “Initial Requests” criteria continue to be met; **and**

2. At least 6 months have lapsed since the prior injection series (i.e., no more than one injection series may be performed in a 6-month period); **and**
3. The patient demonstrated improvement in overall pain and function from the prior injection series, as demonstrated by **ALL** of the following:
 - a. Documented reduction in pain as evidenced by objective measures (e.g., increased range of motion, decreased tenderness on examination, decrease in the amount and/or frequency of medication use); **and**
 - b. Documented improvement in ability to perform functional activities (e.g., ambulation, prolonged standing, ability to sleep).

Note: Authorization periods are for one injection series only to confirm demonstrated improvement.

The use of viscosupplementation for knee osteoarthritis where the above criteria are not met is considered *not medically necessary* (e.g., severe knee osteoarthritis, defined as Kellgren-Lawrence Grade IV).

Coverage Exclusions

Viscosupplements for any other indication is *not covered* by Oscar, as it is considered experimental investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Acute injury (e.g., sprain, fracture)
- Adhesive capsulitis of shoulder (frozen shoulder)
- Infectious arthritis
- Osteoarthritis for any joints other than the knee (e.g., shoulder, elbow, carpometacarpal, thumb, hip, ankle, metatarsophalangeal)
- Psoriatic arthritis for any joints including the knee
- Rheumatoid arthritis for any joints including the knee
- Temporomandibular joint disorders
- Tendinopathy
- Trigger finger
- Viscosupplementation with mesenchymal stem cells or platelet rich plasma

Applicable Billing Codes (HCPCS/CPT Codes, ICD-10 Codes)

CPT/HCPCS codes covered if criteria are met:	
Code	Description
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, Supartz or Visco-3, 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, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
ICD-10 codes covered if criteria are met:	
<i>Code</i>	<i>Description</i>
M13.0	Polyarthrititis, unspecified
M17.0 - M17.9	Knee osteoarthritis

References

1. American Academy of Orthopaedic Surgeons (AAOS). Treatment of osteoarthritis of the knee. 2nd ed. Summary of Recommendations. Rosemount, IL: AAOS; 2013. Available at: https://www.aaos.org/cc_files/aaosorg/research/guidelines/oaksummaryofrecommendations.pdf.
2. Bert J, Kinney J, Sgaglione NA, et al. Viscosupplementation for Osteoarthritis of the Knee: A Key Opinion Leader Panel Discussion. Journal of Managed Care & Specialty Pharmacy 2018 24:6-a Suppl, S2-S8. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2018.24.6-a.s2>.
3. Bhadra AK, Altman R, Dasa V, et al. Appropriate use criteria for hyaluronic acid in the treatment of knee osteoarthritis in the United States. Cartilage. 2016 Aug 10.
4. Bioventus LLC. Durolane (sodium hyaluronate). Prescribing Information. Durham, NC: Bioventus; October 2017.
5. Bioventus LLC. Gel-syn (sodium hyaluronate). Product Information. Durham, NC: Bioventus; 2016.
6. Bioventus LLC. Visco-3TM (sodium hyaluronate). Prescribing Information. Durham, NC: Bioventus; 2018.
7. Committee on Rheumatologic Care. American College of Rheumatology Position Statement: Intraarticular hyaluronic acid injection in osteoarthritis of the knee. February 2014. Available at: <https://www.rheumatology.org/Portals/0/Files/Viscosupplementation.pdf>. Accessed on: July 15, 2019.
8. Ferring Pharmaceuticals Inc. Euflexxa (1% sodium hyaluronate). Prescribing Information. 6122-09. Parsippany, NJ; 2009.
9. Fidia Pharma USA Inc. Hymovis (hyaluronic acid) Prescribing Information. Parsippany, NJ; Fida Pharma USA; last update August 2017.

10. Genzyme Biosurgery. Synvisc-One (Hylan G-F 20). Information for Prescribers. 70240103. Ridgefield, NJ; revised September 2014.
11. Hayes, Inc. Comparative Effectiveness Review. Hyaluronic Acid for Knee Osteoarthritis: A Review of Reviews. Published: October 31, 2017. Last reviewed: November 8, 2018.
12. Hunter DJ. Viscosupplementation for osteoarthritis of the knee. *N Engl J Med* 2015; 372:1040.
13. Jevsevar D, Donnelly P, Brown GA, Cummins DS. Viscosupplementation for Osteoarthritis of the Knee: A Systematic Review of the Evidence. *J Bone Joint Surg Am* 2015; 97:2047.
14. Kohn MD, Sassoon AA, Fernando ND. Classifications in Brief: Kellgren-Lawrence Classification of Osteoarthritis. *Clin Orthop Relat Res.* 2016;474(8):1886–1893. doi:10.1007/s11999-016-4732-4
15. Miller LE, Altman RD, McIntyre LF. Unraveling the confusion behind hyaluronic acid efficacy in the treatment of symptomatic knee osteoarthritis. *J Pain Res.* 2016;9:421–423. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4918943/>.
16. OrthogenRx, Inc. GenVisc 850 (sodium hyaluronate) [product information]. Doylestown, PA: OrthogenRx; September 2015.
17. Rutjes AW, Jüni P, da Costa BR, et al. Viscosupplementation for osteoarthritis of the knee: a systematic review and meta-analysis. *Ann Intern Med* 2012; 157:180.
18. Trojian TH, Concoff AL, Joy SM, et al. AMSSM Scientific Statement Concerning Viscosupplementation Injections for Knee Osteoarthritis: Importance for Individual Patient Outcomes. *Br J Sports Med* 2016;50:84-92. Available at: <https://bjsm.bmj.com/content/50/2/84>.
19. Seikagaku Corporation. Supartz (sodium hyaluronate). Prescribing information. 6CH40402. Tokyo, Japan; Seikagaku; revised January 30, 2007.
20. Zimmer. Gel-One Cross-linked Hyaluronate. Prescribing Information. 6LA40200. Warsaw, IN: Zimmer; issued May 20, 2011.
21. OrthogenRx, Inc. TriVisc™ (sodium hyaluronate). Full Prescribing Information. Doylestown, PA: OrthogenRx; 2018.

Clinical Guideline Revision / History Information

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