

Medical Drug Clinical Criteria

Subject:	Hyaluronan Injections - Step Therapy and Quantity Limit – Medicare ONLY		
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Overview

This document addresses utilization management for hyaluronan injections. Utilization management, including step therapy and quantity limit criteria, may be applied in benefits where coverage of hyaluronan injection is required.

Hyaluronan injections are indicated for the treatment of pain in osteoarthritis of the knee in individuals who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics. Clinical benefit of varying degrees has been shown in a number of trials and meta-analyses of randomized trials. However, many analyses have not shown a clinical benefit beyond the effect seen with placebo. Evidence from recent large double-blinded high-quality trials suggests the clinical benefit of hyaluronan is of minimal benefit over intra-articular placebo (Bannuru 2015). Intra-articular hyaluronan may be associated with potential side effects including pain flare-ups and joint infection, and the use of hyaluronan remains controversial in clinical practice.

Current guidelines for treatment of osteoarthritis of the knee are conflicting. In 2019, the American College of Rheumatology (ACR) published updated guidelines for the management of osteoarthritis of the hand, hip and knee (Kolasinski 2019). The guidelines conditionally recommend against intraarticular hyaluronic acid injections in individuals with knee osteoarthritis. ACR states hyaluronic acid injection benefit has been primarily found in studies with higher risk of bias. The current guidance is based on a systemic review limited to trials with low risk of bias. This meta-analysis has shown the effect size of hyaluronic acid injections compared to saline injections approaches zero.

The American Academy of Orthopedic Surgeons (AAOS) published their Clinical Practice Guideline for Treatment of Osteoarthritis of the Knee in 2013. In their recommendations, the AAOS states that they “cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.” It was noted that the recommendation was based on lack of efficacy, not on potential harm. In their 2021 Management of Osteoarthritis of the Knee (Non-Arthroplasty) guideline update, AAOS revised their recommendation to state hyaluronic acid intraarticular injection is not recommended for routine use in the treatment of symptomatic osteoarthritis of the knee. The updated review of the evidence found that statistically significant improvements were associated with high-molecular cross-linked hyaluronic acid but when compared to mid-range molecular weight, statistical significance was not maintained. This newer analysis did not demonstrate clinically relevant differences when compared to controls.

In 2019, Osteoarthritis Research Society International (OARSI) published updated guidelines for the non-surgical management of knee, hip and polyarticular osteoarthritis (Bannuru 2019). In the 2014 guidance, intra-articular hyaluronic acid was listed as a treatment of “uncertain appropriateness.” The 2019 guidance updated intra-articular hyaluronic acid to conditionally recommended (low consensus) for knee osteoarthritis for longer-term treatment effect (symptom improvement beyond 12 weeks) and favorable safety profile. Treatment modalities with a strong recommendation for knee osteoarthritis include arthritis education, structured land-based exercise programs and topical NSAIDs.

Sodium hyaluronate was discontinued by the manufacturer. Criteria will remain active until February 2023 as claims can adjudicate several years after agent discontinuation.

Step Therapy

Non-Preferred Hyaluronan Injection Step Therapy

A list of the preferred hyaluronan agent(s) is available [here](#).

Requests for non-preferred hyaluronan agents may be approved based on the following criteria:

- I. Individual has had a trial and inadequate response or intolerance to two preferred¹ hyaluronan agent; **OR**
- II. The preferred agents are not acceptable due to contraindications including hypersensitivity/allergy to the following:
 - A. Avian or avian derived agents (applies to Gel-One, Hyalgan, Orthovisc, Supartz FX, Synvisc agents, Triluron, Visco-3); **OR**
 - B. Gram-positive bacterial proteins (applies to Durolane, Euflexxa, Gel-Syn, GenVisc, Hymovis, Monovisc, Sodium hyaluronate, Synjojoynt, TriVisc).

¹Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Hyaluronan Injection Quantity Limits

Drug	Limit
Durolane (sodium hyaluronate) 60 mg/3 mL prefilled syringe	2 prefilled syringes per 6 months
Euflexxa (sodium hyaluronate) 20 mg/2 mL prefilled syringe	6 prefilled syringes per 6 months
Gel-One (sodium hyaluronate) 30 mg/3 mL prefilled syringe	2 prefilled syringes per 6 months
Gel-Syn (sodium hyaluronate) 16.8 mg/2 mL prefilled syringe	6 prefilled syringes per 6 months
GenVisc (sodium hyaluronate) 25 mg/2.5 mL prefilled syringe	10 prefilled syringes per 6 months
Hyalgan (sodium hyaluronate) 20 mg/2mL prefilled syringe or vial	10 prefilled syringes/vials per 6 months
Hymovis (hyaluronate) 24 mg/3 mL prefilled syringe	4 prefilled syringes per 6 months
Monovisc (sodium hyaluronate) 88 mg/4 mL prefilled syringe	2 prefilled syringes per 6 months
Orthovisc (sodium hyaluronate) 30 mg/2 mL prefilled syringe	8 prefilled syringes per 6 months
Sodium hyaluronate 20 mg/2 mL prefilled syringe	6 prefilled syringes per 6 months
Supartz FX (sodium hyaluronate) 25 mg/2.5 mL prefilled syringe	10 prefilled syringes per 6 months
Synjojoynt (sodium hyaluronate) 20 mg/2 mL prefilled syringe	6 prefilled syringes per 6 months
Synvisc-One (hylan G-F 20) 48 mg/6 mL prefilled syringe	2 prefilled syringes per 6 months
Synvisc (hylan G-F 20) 16 mg/2 mL prefilled syringe	6 prefilled syringes per 6 months
Triluron (sodium hyaluronate) 20 mg/2 mL prefilled syringe or vial	6 prefilled syringes/vials per 6 months
TriVisc (sodium hyaluronate) 25 mg/2.5 mL prefilled syringe	6 prefilled syringes per 6 months
Visco-3 (sodium hyaluronate) 25 mg/2.5 mL prefilled syringe	6 prefilled syringes per 6 months

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan or 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, Gel-Syn, for intra-articular injection, 0.1 mg
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

ICD-10 Diagnosis

All diagnoses pend

Document History

Revised: 11/18/2022

Document History:

- 11/18/2022 – Annual Review: Add Synojoynt into the step therapy. Add quantity limits Synojoynt. Step therapy table updates. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Removed outdated information from step table. Coding reviewed: No changes.
- 09/20/2021 – Update step therapy and step therapy table.
- 5/21/2021 – Select Review: Update Non-Preferred Hyaluronan Injection Step Therapy by increasing trial of preferreds. Coding Reviewed: Removed HCPCS J7333. All diagnoses pend.
- 11/20/2020 – Annual Review: Update Synojoynt product name to Sodium hyaluronate. Coding Reviewed: Added HCPCS J7331, Removed HCPCS J7317. Effective 4/1/2021 removed HCPCS J7333.
- 11/15/2019 – Annual Review: Add Synojoynt and Triluron to the Non-Preferred Hyaluronan Injection Step Therapy. Add quantity limits for Synojoynt and Triluron. Remove Supartz as obsolete. Coding Review: Added HCPCS codes J7331 and J7332. Added J7333 (Effective 7/1/2020)
- 11/16/2018 – Annual Review: Add new agents Durolane, TriVisc and Visco-3 into the step therapy. Add quantity limits for Durolane, TriVisc and Visco-3 to allow one treatment course. Add limit of one treatment course per 6 months for all agents. HCPCS Coding review: Durolane code change (C9465 to J7318). Add J7329 for TriVisc and updated wording of J7321 to include Visco-3. No ICD-10 changes.

References

1. American Academy of Orthopaedic Surgeons (AAOS). Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. <https://www.aaos.org/oak3cpg>. Published: August 31, 2021. Accessed: October 11, 2022.
2. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage*. 2019 Nov;27(11):1578-1589. Accessed: October 11, 2022.
3. Bannuru RR, Schmid CH, Kent DM, et al. Comparative effectiveness of pharmacologic interventions for knee osteoarthritis: a systematic review and network meta-analysis. *Ann Intern Med*. 2015; 162(1):46-54. Accessed: October 11, 2022.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
5. Deveza LA, Bennell K. Management of knee osteoarthritis. Updated: May 27, 2021. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. Kolasinski SL, Neogi T, Hochberg MC et al; American College of Rheumatology (ACR). 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis Care Res (Hoboken)*. 2020 Feb;72(2):149-62. Available at: <https://www.rheumatology.org/Portals/0/Files/Osteoarthritis-Guideline-Early-View-2019.pdf>. Accessed: October 11, 2022.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

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CC-0005 Hyaluronan Injections Step Therapy and Quantity Limit – Medicare ONLY

Medicare Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
1/17/2020	Euflexxa Supartz FX Durolane Gelsyn-3	Gel-One GenVisc 850 Hymovis Monovisc Orthovisc Synvisc/Synvisc One TriVisc Hyalgan/Visco-3 Sodium hyaluronate (Synojoynt) Triluron