hyaluronate and derivatives

Commercial Medical Benefit Drug Policy

Sodium hyaluronate: Durolane, Euflexxa, GelSyn-3, GenVisc 850, Hyalgan, Synojoynt , Supartz FX, Triluron, Trivisc, Visco-3
Hyaluronan and derivatives: Hymovis, Monovisc, Orthovisc
Hylan polymers: Synvisc, Synvisc One, Gel One

Place of Service
Office Administration
Outpatient Facility Infusion Administration
Infusion Center Administration

Drug Details

USP Category: MISCELLANEOUS THERAPEUTIC AGENTS
Mechanism of Action: Intra-articular viscosupplementation with hyaluronic acid, high molecular weight fractions of purified natural sodium hyaluronate, and cross-linked polymers of hyaluronan known as hylans are aimed at
HCPCS:
J7318:Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg
J7320:Hyaluronan or derivitive, 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
J7331:Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg
J7332:Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg
How Supplied:
Durolane: 60 mg/3 mL, pre-filled syringe
Euflexxa: 20 mg/2 mL, pre-filled syringe
Orthovisc: 30 mg/2 mL, pre-filled syringe
Hyalgan: 20 mg/2 mL, vials and prefilled syringe
Hymovis: 24 mg/3 mL, pre-filled syringe
Gel One: 30 mg/3 mL, pre-filled syringe
Gelsyn-3: 16.8 mg/2 mL, pre-filled syringe
GenVisc 850: 25 mg/3 mL, pre-filled syringe
Monovisc: 88 mg/4 mL, pre-filled syringe
Supartz/Supartz FX: 25 mg/2.5 mL, pre-filled syringe
Synojoynt: 20 mg/2 mL pre-filled syringe
Synvisc: 16 mg/2 mL, pre-filled syringe
Synvisc One: 48 mg/6 mL, pre-filled syringe

Triluron: 20 mg pre-filled syringe and solution
Trivisc: 25 mg/2.5 mL, solution
Visco-3: 25 mg/2.5 mL, pre-filled syringe

Condition(s) listed in policy *(see coverage criteria for details)*

- Treatment of Pain in Osteoarthritis of the Knee

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Treatment of Pain in Osteoarthritis of the Knee
Meets medical necessity if all the following are met:

Hyaluronic acid for the treatment of pain in osteoarthritis of the knee is not considered medically necessary.

There is a lack of definitive treatment benefit despite a large quantity of literature, and given the biases present in the available evidence, it is unlikely there is a treatment benefit that is clinically meaningful.

The evidence for viscosupplements includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Many RCTs have been published over the last two decades. While outcomes of these RCTs have been mixed, the RCT evidence base is characterized by studies showing small treatment effects of IA hyaluronan injections. In many cases, these trials are at risk of bias, and it cannot be determined with certainty whether there is a true treatment effect or whether the reported differences are due to bias. Meta-analyses of RCTs have also had mixed findings. Some meta-analyses estimating the magnitude of treatment benefit have concluded that there is no clinically significant benefit.

The American Academy of Orthopaedic Surgeons (AAOS) strongly recommends against its use, citing lack of efficacy, while the American College of Rheumatology/Arthritis Foundation (ACR/AF) conditionally recommends against its use, due to limited evidence of benefit.

Practice Guideline	Consensus statements on use of hyaluronic acid injections

American Academy of Orthopaedic Surgeons (AAOS), 2021	• Hyaluroinc acid is not recommended for routine use in symptomatic knee osteoarthritis • Strength of recommendation: **Moderate*** • Rationale: There is lack of consistent findings for or against its use.
American College of Rheumatology/Arthritis Foundation (ACR/AF), 2019	• Conditionally recommend against for use in knee osteoarthritis • Strength of recommendation: **Conditionally against*** • Rationale: After review that the best evidence fails to establish a benefit and that harm may be associated with these injections.

** The strength of a recommendation reflects the quality of evidence and the level of certainty that benefit outweighs the harm of an intervention. Graded recommendations from each guideline are as follows: AAOS - strong, moderate, limited, inconclusive, and consensus; ACR/AF – strongly recommended, conditionally recommended, strongly against, conditionally against, no recommendation.*

References

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Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee