

Sodium hyaluronate: (Durolane<sup>®</sup>, Euflexxa<sup>®</sup>, GelSyn-3<sup>®</sup>, GenVisc 850<sup>®</sup>, Hyalgan<sup>®</sup>, Synjoynt<sup>™</sup>, Supartz FX<sup>®</sup>, Triluron<sup>™</sup>, Trivisc<sup>™</sup>, Visco-3<sup>™</sup>)

Hyaluronan and derivatives: (Hymovis<sup>®</sup>, Monovisc<sup>®</sup>, Orthovisc<sup>®</sup>)

Hylan polymers: (Synvisc<sup>®</sup>, Synvisc One<sup>®</sup>, Gel One<sup>®</sup>)

#### Place of Service

Office Administration

Outpatient Facility Infusion Administration

Infusion Center Administration

#### HCPCS

- J7318 - Durolane per 1 mg
- J7320 - GenVisc 850 per 1 mg
- J7321 - Hyalgan per dose
- J7321 - Supartz FX per dose
- J7321 - Visco -3 per dose
- J7322 - Hymovis per 1 mg
- J7323 - Euflexxa per dose
- J7324 - Orthovisc per dose
- J7325 - Synvisc per 1 mg
- J7325 - Synvisc ONE per 1 mg
- J7326 - Gel-One per dose
- J7327 - Monovisc per dose
- J7328 - GelSyn-3 per 0.1 mg
- J7329 - Trivisc per 1 mg
- J7331 - Synjoynt per 1 mg
- J7332 - Triluron per 1 mg

#### Condition listed in policy (see criteria for details):

- [Treatment of pain in osteoarthritis of the knee in patients who have failed to respond to adequate conservative non-pharmacologic therapy and simple analgesics.](#)

Only FDA approved viscosupplements in manufacturer-approved, United States packaging may be covered. Non-FDA approved viscosupplements cannot be used and billed to Blue Shield by providers.

**AHFS therapeutic class:** Antirheumatic, miscellaneous

**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 improving the elasticity and viscosity of synovial fluid

#### (1) Special Instructions and pertinent Information

**Covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax. All requests for hyaluronic acid must be sent for clinical review and receive authorization prior to the drug administration or claim payment

#### (2) Prior Authorization/Medical Review is required for the following condition(s)

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All requests for hyaluronic acid must be sent for clinical review and receive authorization prior to drug administration or claim payment.

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	<ul style="list-style-type: none"><li>• Cannot recommend use of hyaluronic acid for knee osteoarthritis</li><li>• Strength of recommendation: <b>Moderate*</b></li><li>• Rationale: There is lack of efficacy regarding its use.</li><li>• The effect size is small and statistically significant, but clinically irrelevant.</li></ul>
American College of Rheumatology/Arthritis Foundation (ACR/AF), 2019	<ul style="list-style-type: none"><li>• Conditionally recommend against for use in knee osteoarthritis</li><li>• Strength of recommendation: <b>Conditionally against*</b></li><li>• Rationale: After review that the best evidence fails to establish a benefit and that harm may be associated with these injections.</li></ul>

*\* 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*

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for hyaluronic acid must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s)**

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Synvisc One®, Trilon™, Trivisc™, Visco-3™)

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Blue Shield’s research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Osteoarthritis of all other joints
- Arthritic conditions other than osteoarthritis of the knee.

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code §1367.21, including objective evidence of efficacy and safety are met for the proposed indication

Please refer to the Provider Manual and User Guide for more information.

## **(5) Additional Information**

### **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

## **(6) References**

- Agency for Healthcare Research and Quality. Systematic Review for Effectiveness of Hyaluronic Acid in the Treatment of Severe Degenerative Joint Disease of the Knee. July 23, 2015. Available at: <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/id101TA.pdf>
- AHFS®. Available by subscription at <http://www.lexi.com>
- American College of Rheumatology/Arthritis Foundation. Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee, 2019. Available at: <https://www.rheumatology.org/Portals/0/Files/Osteoarthritis-Guideline-Early-View-2019.pdf>
- American Academy of Orthopaedic Surgeons. Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline (2021). Available at: [oak3cpg.pdf \(aaos.org\)](https://www.aaos.org/aaos.org/oak3cpg.pdf)
- American College of Rheumatology. Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee, 2012. Available at: <http://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Osteoarthritis>
- Buel A, Narducci DM. Osteoarthritis Management: Updated Guidelines from the American College of Rheumatology and Arthritis Foundation (2021); Am Fam Physician; 103(2): 120-121

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- Colen S, et al. Hyaluronic acid in the treatment of knee osteoarthritis – a systematic review and meta-analysis with emphasis on the efficacy of difference products. *Biodrugs*, 2012. 26(4): 257-268.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Durolane® (sodium hyaluronate) [Prescribing information]. Durham, NC: Bioventus LLC; 2017.
- Euflexxa® (sodium hyaluronate) [Prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc; 7/2016.
- Gel-One® (cross-linked hyaluronate) [Prescribing information]. Tokyo, Japan: Seikagaku Corporation; 5/2011.
- Gelsyn-3™ (sodium hyaluronate) [Prescribing information]. Durham, NC: Bioventus; 9/2019.
- GenVisc 850 (sodium hyaluronate) [prescribing information]. Doylestown, PA: OrthogenRx Inc; 11/2019.
- Hyalgan® (hyaluronic acid derivative) [prescribing information]. Parsippany, NJ: Fidia Pharma; 8/2017.
- Hymovis® (hyaluronic acid derivative) [prescribing information]. Parsippany, NJ: Fidia Pharma; 6/2021.
- Jevsevar D, et al. Viscosupplementation for osteoarthritis of the knee – a systematic review of evidence. *Journal of Bones & Joint Surgery*, 2015. 97: 2046-2060.
- Monovisc® (hyaluronan) [Prescribing information]. Bedford, MA: Anika Therapeutics Inc; 7/2020.
- Orthovisc® (hyaluronan) [Prescribing information]. Bedford, MA: Anika Therapeutics Inc; 10/2020.
- Osteoarthritis Research Society International. Guidelines for the Non-Surgical Management of knee, hip, and polyarticular osteoarthritis, 2019. Available at: [https://www.oarsijournal.com/article/S1063-4584\(19\)31116-1/pdf](https://www.oarsijournal.com/article/S1063-4584(19)31116-1/pdf)
- Osteoarthritis Research Society International. Guidelines for the Non-Surgical Management of Knee Osteoarthritis, 2014. Available at: [https://www.oarsi.org/sites/default/files/docs/2014/non\\_surgical\\_treatment\\_of\\_knee\\_oo\\_marc\\_h\\_2014.pdf](https://www.oarsi.org/sites/default/files/docs/2014/non_surgical_treatment_of_knee_oo_marc_h_2014.pdf)
- Rutjes AS, et al. Viscosupplementation for osteoarthritis of the knee – a systematic review and meta-analysis. *Annals of Internal Medicine* 2012; 157(3): 180- 192.
- Supartz FX (sodium hyaluronate) [Prescribing information]. Durham, NC: Bioventus; 4/2015.
- Synjoynt™ (sodium hyaluronate) [Prescribing information]. North Wales, PA : Teva Pharmaceuticals USA, Inc. 5/2018.
- Synvisc One (hylan G-F 20) [Prescribing information]. Ridgefield, NJ: Genzyme Biosurgery a division of Genzyme Corporation; 5/2023.
- Triluron (sodium hyaluronate) [prescribing information]. Florham Park, NJ: Fidia Pharma USA Inc; 7/2019.
- TriVisc™ (sodium hyaluronate) [Prescribing information]. Doylestown, PA: OrthogenRx Inc; 11/2019.
- Visco-3™ (sodium hyaluronate) [Prescribing information]. Warsaw, IN: Zimmer; received 4/2017.

## (7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

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*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*

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