Sodium hyaluronate: (Durolane®, Euflexxa®, GelSyn-3™, GenVisc 850®, Hyalgan®, Supartz FX™, Trivisc™)

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

HCPCS:

- J7318 - Durolane per dose
- J7320 - GenVisc 850 per 1 mg
- J7321 - Hyalgan per dose
- J7321 - Supartz FX 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 0.1mg
- J7329 - Trivisc 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 are 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)

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 Osteoarthritis Research Society International (OARSI) provides uncertain recommendations for use, due to inconsistency in the evidence.

Practice Guideline	Consensus statements on use of viscosupplementation
American Academy of Orthopaedic Surgeons (AAOS), 2013	• Cannot recommend use of hyaluronic acid for knee osteoarthritis • Strength of recommendation: **Strong*** • Rationale: There is lack of efficacy regarding its use. • The effect size is small and statistically significant, but clinically irrelevant.
Osteoarthritis Research Society International (OARSI), 2014	• No recommendations for use in knee osteoarthritis • Strength of recommendation: **Uncertain*** • Rationale: After review of good quality, high level evidence, there are inconsistent conclusions regarding the magnitude of efficacy and conflicting results regarding safety of its use.

** 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; OARSI - appropriate, not appropriate, and uncertain.*

(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)

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
Synvisc: 16 mg/2 mL, pre-filled syringe
Synvisc One: 48 mg/6 mL, pre-filled syringe
Trivisc 25 mg/2.5 mL, pre-filled syringe

(6) References

- Durolane® Package Insert, Bioventus. 2017
- Euflexxa® Package Insert. Ferring Pharmaceuticals, Inc. 2015
- Hyalgan® Package Insert. Sanofi Aventis, Inc. 2014
- Orthovisc® Package Insert. Anika Therapeutics, Inc. 2006
- Supartz FX® Package Insert. Seikagaku, Inc. 2015
- Synvisc® Package Insert. Genzyme, Inc. 2014
- Synvisc One® Package Insert. Genzyme, Inc. 2014
- Gel One® Package insert. Seikagaku, corp. 2011.
- Monovisc® Package insert. Anika Therapeutics, Inc. 2014
- GelSyn-3™ Package insert. Bioventus, 2016
- GenVisc 850 Package insert. OrthogenRX, 2016
- Hymovis® Package insert Fidia Pharma USA 2016
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- 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.
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- Jevsevar D, et al. Viscosupplementation for osteoarthritis of the knee – a systematic review of evidence. Journal of Bones & Joint Surgery, 2015. 97: 2046-2060.
- 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

- 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_oa_march_2014.pdf
- American Academy of Orthopaedic Surgeons. Treatment of Osteoarthritis of the Knee – Evidence Based Guidelines, 2013. Available at: http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.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

(7) Policy Update

Date of last review: 1Q2019
Date of next review: 1Q2020
Changes from previous policy version:

- Added new Durolane J-code of J7318.
- Added product Trivisc (J7329) to policy.

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