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

<table>
<thead>
<tr>
<th>Hyaluronan and derivatives: (Hymovis®, Monovisc®, Orthovisc®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hylan polymers: (Synvisc®, Synvisc One®, Gel One®)</td>
</tr>
</tbody>
</table>

**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
- 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 - Synojoynt per 1 mg
- J7332 - Triluron per 1 mg

- For Visco-3 per dose
  - J7333 (Through 3/31/2021)
  - J7321 (Effective 4/1/2021 and after)

**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

**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)

**Commercial**

Hyaluronic acid, Sodium Hyaluronate (Durolane®, Euflexxa®, Gel One®, GelSyn-3®, GenVisc 850®, Hyalgan®, Hymovisc®, Monovisc®, Orthovisc®, SupartzFX®, Synojoynt™, Synvisc®, Synvisc One®, Triluron™, Trivisc™, Visco-3™)

Effective: 03/31/2021
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.

<table>
<thead>
<tr>
<th>Practice Guideline</th>
<th>Consensus statements on use of hyaluronic acid injections</th>
</tr>
</thead>
</table>
| 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. |
| 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

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

**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
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
- AHFS®. Available by subscription at http://www.lexi.com
- Durolane® Package Insert, Bioventus. 2017
• Hyalgan® Package Insert. Sanofi Aventis, Inc. 2014
• Hymovisc® Package insert Fidia Pharma USA 2015
• Monovisc® Package insert. Anika Therapeutics, Inc. 2014
• Orthovisc® Package Insert. Anika Therapeutics, Inc. 2006
• Supartz FX® Package Insert. Seikagaku, Inc. 4/2015.
• Synvisc® Package Insert. Genzyme, Inc. 2014
• Synvisc One® Package Insert. Genzyme, Inc. 2014

(7) Policy Update
Date of last revision: 1Q2021
Date of next review: 4Q2021
Changes from previous policy version:
• No clinical change to policy following revision.