| PART B DRUG MEDICAL/PHARMACY | ASPIRE HEALTH | Effective Date<br>January 1, 2024 | |
|---|---|---|---|
| | **HYALURONIC ACID, VISCOSUPPLEMENTATION:**<br>DUROLANE®, EUFLEXXA™, GEL-ONE®, GELSYN-3™, GENVISC 850®, HYALGAN™, HYMOVIS®, MONOVISC®, ORTHOVISC™, SUPARTZ / SUPARTZ FX™, SYNOJOYNT, SYNVISC™, SYNVISC-ONE™, TRILURON™, TRIVISC™, VISCO-3™, & SODIUM HYALURONATE 1% | **Policy #**<br>Hyaluronic Acid | |
| | | **Review Date**<br>09/27/2023 | **Applicable to:**<br>☑ Medicare Advantage<br>☐ Commercial<br>☐ Elevance Health HMO<br>☐ Blue Shield Trio |
| | **Approver's Name & Title** QI & UM Drug Subcommittee | | |

Aspire Health Plan applies medical drug clinical criteria as a reference for medical policy information only. Federal and state laws or requirements, contract language, and Plan benefit may take precedence over the application of these clinical criteria. Please consult the applicable certificate or contract for benefit details. This policy is subject to revision at the discretion of the Plan and is therefore subject to change. Refer to the 'Disclaimer' section below for more information.

## POLICY

This policy addresses the coverage of hyaluronan preparations (viscosupplementation) for intra-articular injections of the knee.

Available as: Several HA agents are available, with varying molecular weights and injections per course of treatment (single injection HAs and those requiring 3 to 5 injections per course of treatment). Refer to Table in the 'Dosage and Administration' section of this policy and to the respective prescribing information for each product for additional information.

## APPLICABLE HCPCS

**PREFERRED: Durolane and Visco-3; then Euflexxa, and Gelsyn-3**
J7318 Hyaluronan or derivative, Durolane, for intra-articular injection, per dose
J7321 Hyaluronan or derivative, Visco-3, for intra-articular injection, per dose
*(Hyalgan and Supartz are non-preferred)*
J7323 Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7328 Hyaluronan or derivative, Gelsyn-3 for intra-articular injection, 0.1 mg

**NON-PREFERRED**
J7320 Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321 Hyaluronan or derivative, Hyalgan and Supartz for intra-articular injection, per dose *(Visco-3 is preferred)*
J7322 Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
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

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

## CLINICAL CRITERIA

### A. INITIAL CRITERIA

Intra-articular Hyaluronic Acid products may be authorized when ALL of the following criteria are met with documentation:

1. Diagnosis of osteoarthritis of the knee; **AND**

2. Documentation of member's affected knee(s): Left, right or both knees to be treated.
   NOTE: Bilateral injections may be allowed only if both knees meet criteria; **AND**

3. Member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing); **AND**

4. Trial and failure or contraindication of at least 3 months of conservative therapy:

   a. Non-pharmacologic therapy (e.g., physical therapy, exercise, weight management, self-management programs, knee brace, cane)

   b. Pharmacologic therapy (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral, topical), topical capsaicin).

**AND**

5. Failure of, or contraindication to, intra-articular glucocorticoid injections; **AND**

6. Member has no contraindications to the hyaluronic injections or conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, bleeding disorders, etc.); **AND**

7. Administered by, or under the supervision of, a physician specializing in rheumatology, orthopedic surgery, or physical medicine and rehabilitation (physiatrist) or a physician who has received specific training in the administration and use of viscosupplements; **AND**

8. For non-preferred hyaluronic acid intra-articular injections: Refer to Step Therapy Requirements.

### B. REAUTHORIZATION / CONTINUATION OF THERAPY CRITERIA

Hyaluronic Acid products may be authorized for continuation of therapy when initial criteria have been met AND there is documentation of beneficial response from previous course of treatment:

1. At least six (6) months have lapsed since the completion of the prior HA derivative treatment course.

2. Improvement in signs and symptoms of pain and a stabilization or improvement in functional capacity from the prior series of injections is documented in the medical record; **AND**

3. Absence of unacceptable toxicity from the previous injections. Examples of unacceptable toxicity include severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

## STEP THERAPY

*Step therapy criteria do not apply for members who are currently being treated with the requested medications. Step therapy is only applied for members that are new to therapy (have not received the requested drug in the last 365 days.*

A. **PREFERRED PRODUCT(S): Durolane and Visco-3; then Euflexxa, and Gelsyn-3 (no step therapy required)**

B. NON-PREFERRED hyaluronic products may be authorized when ALL of the clinical criteria above are met **AND** the member meets the following criteria for a non-preferred product:

1. Documented history of intolerance or adverse event(s) to the following PREFERRED products unless contraindicated: **Durolane and Visco-3.**

   NOTE: For members with allergies to avian proteins and products (e.g., eggs, feathers): Preferred products are **Euflexxa, Gel-Syn-3.**

**OR**

2. Member has previously received the requested brand of hyaluronic product within the past 365 days and therefore not subject to step therapy requirements.

## DRUG INFORMATION

PHARMACOLOGIC CATEGORY: Antirheumatic Miscellaneous

ROUTE OF ADMINISTRATION: Intra-articular injection into the knee joint

FDA-APPROVED INDICATIONS:

Osteoarthritis of the knee: Treatment of pain in osteoarthritis of the knee in patients who have failed nonpharmacologic treatment or simple analgesics (Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Monovisc, OrthoVisc, sodium hyaluronate [Teva], Supartz FX, Synvisc, Synvisc-One, Triluron, TriVisc, Visco-3) or nonsteroidal anti-inflammatory drugs (Gel-One).

COMPENDIAL APPROVED (OFF-LABELED) USES: NONE

CONTRAINDICATIONS: Hypersensitivity to hyaluronate or any component of the formulation; known hypersensitivity to gram-positive bacterial proteins (*Hymovis*, *Monovisc* and *Orthovisc* only); knee joint infections, infections, or skin diseases in the area of the injection site or joint; known systemic bleeding disorders (*Monovisc* only).

## DOSAGE AND AUTHORIZATION TIMEFRAMES

| Drug | HCPCS | Number of Administration (per knee per 180 days) | Max Units (per 180 days)* *Max units are based on administration to both knees | 1 Billable Unit (BU) | BU per Admin |
|---|---|---|---|---|---|
| Durolane | J7318 | 1 injection | 120 | 1 mg | 60 |
| Euflexxa | J7323 | 3 injections | 6 | 1 dose | 1 |
| Gel-One | J7326 | 1 injection | 2 | 1 dose | 1 |
| GelSyn-3 | J7328 | 3 injections | 1008 | 0.1 mg | 168 |
| GenVisc 850 | J7320 | 5 injections | 250 | 1 mg | 25 |
| Hyalgan; Supartz; Supartz FX | J7321 | 5 injections | 10 | 1 dose | 1 |
| Hymovis | J7322 | 2 injections | 96 | 1 mg | 24 |
| Monovisc | J7327 | 1 injection | 2 | 1 dose | 1 |
| Orthovisc | J7324 | 4 injections | 8 | 1 dose | 1 |
| sodium hyaluronate | J7331 | 3 injections | 120 | 1 mg | 20 |
| Synojoynt | J7331 | 3 injections | 120 | 1 mg | 20 |
| Synvisc | J7325 | 3 injections | 96 | 1 mg | 16 |
| Synvisc-One | J7325 | 1 injections | 96 | 1 mg | 48 |
| Triluron | J7332 | 3 injections | 120 | 1 mg | 20 |
| Trivisc | J7329 | 3 injections | 150 | 1 mg | 25 |
| VISCO-3 | J7321 | 3 injections | 6 | 1 dose | 1 |

1. Recommended / Maximum Dose:
   One treatment course per joint every 6 months. Dose and frequency should be in accordance with the FDA label or *CMS-recognized compendia. Refer to Table in the 'Appendix' section for the number of administrations that may be authorized per knee.

   **The CMS approved authoritative compendia are listed in the CMS Internet Only Manual (IOM) Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50.4.5 (in no particular order): American Hospital Formulary Service-Drug Information (AHFS DI®); Clinical Pharmacology©; DRUGDEX®; Lexi-Drugs®; and NCCN Compendium®.*

2. Authorization Period: Re-authorization is required every 12 months to determine effectiveness of therapy and continued need based criteria stated in the 'Continuation of Therapy' section.

## CLINICAL SUMMARY / APPENDIX

The recommendations regarding the use of hyaluronic acid injections vary among professional society guidelines:

- American College of Rheumatology (ACR) notes that when trials with high risk of bias are excluded, hyaluronic acid does not provide a meaningful benefit; the overall quality of the evidence is low and the guideline groups all give conditional or moderate recommendations; shared decision making is appropriate taking into account patient values.
- American Academy of Orthopaedic Surgeons (AAOS) recommends against routine use of hyaluronic acid intra-articular injections in patients with symptomatic knee OA (AAOS 2021).
- American College of Rheumatology (ACR) recommends against intra-articular hyaluronic acid injections in patients with knee OA (ACR 2020)
- Osteoarthritis Research Society International (OARSI) recommends considering the use of intra-articular hyaluronic acid injections in all patients with knee OA (OARSI 2019).
- National Institute for Health and Care Excellence (NICE) recommends against offering intra-articular hyaluronic acid injections in patients with knee OA (NICE 2022 Oct:NG226)

## REFERENCES


**Government Agency**

Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified; no LCDs available for local MAC). Available from CMS.

**Prescribing Information**

1. Durolane (sodium hyaluronate) [prescribing information]. Durham, NC: Bioventus LLC; September 2019.
2. Euflexxa [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc; July 2016.
3. Hyalgan (hyaluronic acid derivative) [prescribing information]. Parsippany, NJ: Fidia Pharma; May 2014.
4. Hymovis (hyaluronic acid derivative) [prescribing information]. Parsippany, NJ: Fidia Pharma; September 2017.
5. Gelsyn-3 (sodium hyaluronate) [prescribing information]. Durham, NC: Bioventus; September 2019.
6. Gel-One (cross-linked hyaluronate) [prescribing information]. Warsaw, IN; Zimmer; August 2018.
7. GenVisc 850 (sodium hyaluronate) [prescribing information]. Doylestown, PA: OrthogenRx Inc; November 2019.
8. Monovisc [prescribing information]. Bedford, MA: Anika Therapeutics; July 2020.
9. Sodium hyaluronate [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; March 2019.
10. Supartz FX (sodium hyaluronate) [prescribing information]. Durham, NC: Bioventus; April 2015.
11. Synojoynt [package insert]. Naples, FL; Arthrex, Inc.; January 2022.
12. Synvisc (hylan G-F 20) [prescribing information]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
13. Synvisc One (hylan G-F 20) [prescribing information]. Ridgefield, NJ: Genzyme Biosurgery a division of Genzyme Corporation; September 2014.
14. TriVisc (sodium hyaluronate) [prescribing information]. Doylestown, Pennsylvania: OrthogenRx Inc; November 2019
15. Triluron (sodium hyaluronate) [prescribing information]. Florham Park, NJ: Fidia Pharma USA Inc; July 2019.
16. Visco-3 (sodium hyaluronate) [prescribing information]. Warsaw, IN: Zimmer; received April 2017.

**Peer-reviewed Literature, Guidelines, Consensus**

1. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (NonArthroplasty) Evidence-Based Clinical Practice Guideline. https://www.aaos.org/oak3cpg Published 08/31/2021.
2. Brophy RH, Fillingham YA. AAOS Clinical Practice Guideline Summary: Management of

Osteoarthritis of the Knee (Nonarthroplasty), Third Edition. AAOS 2021 Aug 31 PDF
3. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage. 2019 Jun;27(11):1578-1589. DOI:https://doi.org/10.1016/j.joca.2019.06.011.
4. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee Arthritis Rheumatol. 2020 Feb;72(2):220-233. doi: 10.1002/art.41142. Epub 2020 Jan 6.
5. National Institute for Health and Care Excellence (NICE) NICE guideline (NG226) Osteoarthritis in over 16s: diagnosis and management. Published: 19 October 2022 https://www.nice.org.uk/guidance/ng226.

## IMPORTANT REMINDER

This Medicare Part B Step Therapy Medical Necessity Guideline is provided for informational purposes only and neither constitutes nor replaces professional medical advice. Physicians, hospitals, and other providers are expected to administer or use drugs/biologicals in the most effective and clinically appropriate manner. Treating physicians and other health care providers are solely responsible for all medical care decisions. In accordance with the member's Evidence of Coverage (EOC), every benefit plan has its own coverage provisions, limitations, and exclusions. In the event of a conflict between this policy and the member's EOC, the member's EOC provisions will take precedence.

Aspire Health Plan (AHP) adheres to Medicare guidelines, including National Coverage Determination (NCD), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other relevant Medicare manuals established by CMS. Compliance with these guidelines is required when applicable. Refer to the CMS website at http://www.cms.hhs.gov. For the most up-to-date Medicare policies and coverage, please search the Medicare Coverage Database. All LCDS are the same for each state within a Jurisdiction. Medicare Part B Administrative Contractor (MAC) for CA [Jurisdiction E (1)]: Active LCDs - JE Part B – Noridian (noridianmedicare.com). In the event of a discrepancy between this policy and the Medicare NCD or LCD, the Medicare NCD/LCD will govern.

This policy is utilized by AHP to determine coverage in the absence of applicable CMS Medicare guidelines. Please refer to the links provided in the References section below to access the Medicare source materials that were used for developing this resource document. This document does not serve as a substitute for the official Medicare source materials that provide detailed information on Medicare coverage requirements. In the event of a conflict between this document and Medicare source materials, the Medicare source materials will take precedence.

The inclusion of a code in this policy does not imply that the health service it describes is covered or not covered. Benefit coverage for health services is determined by the member-specific plan document and applicable laws that may mandate coverage for a particular service. Inclusion of a code does not imply or guarantee reimbursement or payment of a claim. Other Policies and Standards may also apply. Providers are expected to retain or have access to the necessary documentation when requested in order to support coverage.

## POLICY HISTORY

| Version | Approval Date | Summary of Changes |
|---|---|---|
| 1 | 9/27/2023 | New Policy |