SmartHealth Ascension

Hyaluronan or derivative for intra-articular injection

(Durolane®) J7318 (1mg); (Genvisc 850®) J7320 (1mg) ; (Hymovis®) J7322 (1mg); (Orthovisc®) J7324 (1 dose); (Gel-One®) J7326 (1 dose); (Monovisc®) J7327 (1 dose); (Gelsyn-3®) J7327 (0.1mg); (Trivisc®) J7329 (1mg); (Triluron®) J7332 (1mg)

Covered with prior authorization

Hyaluronan or derivative for intra-articular injection may be authorized when the following criteria are met:

Osteoarthritis of the knee
Initial Therapy

- Diagnosis of osteoarthritis (OA) of the knee supported by imaging (e.g., X-ray, MRI)**; AND**
- The individual reports pain which interferes with functional activities (e.g., ambulation, prolonged standing); **AND**
- The pain is attributed to degenerative joint disease/primary osteoarthritis of the knee; **AND**
- Inadequate response to physical therapy as directed by a physical therapist; **AND**
- Failure of a ≥ 4-week trial of one of the following, unless all are contraindicated or clinically significant adverse effects are experienced:
  - Oral NSAID at continuous therapeutic (prescription strength) dosing; **OR**
  - Topical NSAID if member is ≥ 75 years old or unable to take oral NSAIDs;

AND

- Trial of at least **one** intra-articular glucocorticoid injection with a documented positive but inadequate response, unless contraindicated or history of intolerance; **AND**
- If request is for a product other than Euflexxa® Hyalgan®, Supartz-FX®, Synojoynt®, Synvisc®, Synvisc-One®, Visco-3®:
  - History of trial of adequate dose and duration, resulting in minimal clinical response; **OR**
  - History of failure, contraindication, or intolerance; to **two** of the following agents:
    - Euflexxa®
    - Hyalgan® or Visco-3®
    - Supartz-FX®
    - Synojoynt®
    - Synvisc® or Synvisc-One®

AND

- Prescribed by or in consultation with a rheumatologist, orthopedist, or sports medicine physician; **AND**

- Dose is in accordance with FDA limits.

Continued Therapy

- Individual met initial approval criteria; **AND**
- Individual is responding positively to therapy as evidenced by the following, including but not limited to:
    - Decrease in pain symptoms as evidenced by improvement in the Visual Analog Scale for pain;
    - Improvement in ambulation or range of motion;
    - Improvement in stiffness;
    - Decrease in rescue pain medication use;

AND

- Member has not had total knee arthroplasty in the targeted knee;
- If request is for a product other than Euflexxa®, Hyalgan®, Supartz-FX®, Synojoynt®, Synvisc®, Synvisc-One®, Visco-3®:
    - History of trial of adequate dose and duration, resulting in minimal clinical response; **OR**
    - History of failure, contraindication, or intolerance; to **two** of the following agents:
        - Euflexxa®
        - Hyalgan or Visco-3®
        - Supartz-FX®
        - Synojoynt®
        - Synvisc® or Synvisc-One®

AND

- Six or more months have elapsed since the last treatment cycle; **AND**
- Dose does not exceed one treatment cycle per knee.**; AND**
- Prescribed by or in consultation with a rheumatologist, orthopedist, or sports medicine physician; **AND**
- Dose and treatment cycle is in accordance with FDA limits (listed in table below).

Dosage and Administration: Hyaluronan or derivative for intra-articular injection			
Drug Name	**Dose of Active Ingredient per Injection**	**Injections per Treatment Cycle** Total number of injections per cycle per knee For both knees, double the number of injections	**MSPA Status**
Durolane®	60 mg (3 mL)	1 injection	PA Required
Euflexxa®	20 mg (2 mL)	3 injections	Preferred (No PA)
Gel-One®	30 mg (3 mL)	1 injection	PA Required
Gelsyn-3®	16.8 mg (2 mL)	3 injections	PA Required
GenVisc 850®	25 mg (2.5 mL)	3-5 injections	PA Required
Hyalgan®	20 mg (2 mL)	3-5 injections	Preferred (No PA)
Hymovis®	24 mg (3 mL)	2 injections	PA Required
Monovisc®	88 mg (4 mL)	1 injection	PA Required
Orthovisc®	30 mg (2 mL)	3-4 injections	PA Required
Supartz FX®	25 mg (2.5 mL)	3-5 injections	Preferred (No PA)

Dosage and Administration: Hyaluronan or derivative for intra-articular injection			
Drug Name	**Dose of Active Ingredient per Injection**	**Injections per Treatment Cycle** Total number of injections per cycle per knee For both knees, double the number of injections	**MSPA Status**
Synojoynt®	20 mg (2 mL)	3 injections	Preferred (No PA)
Synvisc®	16 mg (2 mL)	3 injections	Preferred (No PA)
Synvisc One®	48 mg (6 mL)	1 injection	Preferred (No PA)
Triluron®	20 mg (2 mL)	3 injections	PA Required
TriVisc®	25 mg (2.5 mL)	3 injections	PA Required
Visco-3®	25 mg (2.5 mL)	3 injections	Preferred (No PA)

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;
- Coexistent active inflammatory arthritis other than OA (e.g., rheumatoid arthritis, spondylitis, gouty arthritis) in the targeted knee;
- History of total knee arthroplasty in the targeted knee;
- Dose does not exceed one treatment cycle per knee for a 6 month period. Approval duration: 6 months (one treatment cycle per knee)
- Hyaluronic acid gel preparations to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic and are not covered

FDA approved sodium hyaluronate products and their respective FDA labeled dosage per treatment course per joint

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
Euflexxa® J7323	Durolane® J7318
Hyalgan® J7321	Gel-One® J7326
Supartz-FX® J7321	Gelsyn-3® J7328
Synojoynt® J7331	Genvisc 850® J7320
Synvisc® J7325	Hymovis® J7322
Synvisc-One® J7325	Monovisc® J7327
Visco-3® J7321	Orthovisc® J7324
	Triluron® J7332
	Trivisc® J7329

Initial authorization is up to 6 months, one treatment cycle per knee.

Reauthorizations will require medical chart documentation that the patient has been seen within the past 6 months and that markers of disease are improved by therapy and are not approved within 6 months of last treatment.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Hyaluronate derivatives are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (e.g., acetaminophen) or non-steroidal anti-inflammatory drugs (NSAIDs).

References:
American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guideline on the Treatment of Osteoarthritis of the Knee (Non-Arthroplasty). Rosemont (IL). Updated 2013.

American College of Rheumatology 2012 Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care and Research. Vol. 64, No. 4, April 2012, pp465-474.

Bannuru RR, Natov NS, Dasi UR, et al. Therapeutic trajectory following intra-articular hyaluronic acid injection in knee osteoarthritis--meta-analysis. Osteoarthritis and Cartilage 2011; 19 (6):611-9.

Bannuru RR, Natov NS, Obadan I, et al. Therapeutic Trajectory of Hyaluronic Acid Versus Corticosteroids in the Treatment of Knee Osteoarthritis: A Systematic Review and Meta-Analysis. Arthritis Rheum. 2009 Dec 15; 61(12):1704-11.

Hayes, Inc. Hayes Health Technology Directory. Comparative Effectiveness Review of Hyaluronic Acid for Knee Osteoarthritis: A Review of Reviews. Lansdale, PA: Hayes, Inc.; October 31, 2017, updated November 2018.

Institute for Clinical Systems Improvement. Diagnosis and treatment of adult degenerative joint disease (DJD)/osteoarthritis (OA) of the knee. Bloomington (MN): Institute for Clinical Systems Improvement; 2007. 41 p.

Juni P, Reichenbach S, Trelle S, et al. Efficacy and safety of intra-articular hylan or hyaluronic acids for osteoarthritis of the knee: a randomized controlled trial. Arthritis Rheum. 2007; 56 (11):3610-3619.

Richette P, Ravaud P, Conrozier T, et al. Effect of hyaluronic acid in symptomatic hip osteoarthritis: a multicenter, randomized, placebo-controlled trial. Arthritis Rheum. 2009 Mar;60(3):824-30.

Rutjes AW, Juni P, da Costa BR, et al. Viscosupplementation for osteoarthritis of the knee: a systematic review and metaanalysis. Annals of Internal Medicine 2012;157(3):180-91.

Six-month efficacy and safety study – FLEXX Trial. Data on file. Ferring Pharmaceuticals Inc.

U.S. Department of Veterans Affairs; U.S. Department of Defense. VA/DoD Clinical Practice Guideline for the Non-Surgical Management of Hip & Knee Osteoarthritis. Version 1.0 – 2014

Criteria History/ Revision Information:

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.