

**Medical Policy**

Hyaluronate Injections for Osteoarthritis of the Knee	
<b>MEDICAL POLICY NUMBER</b>	Med_Clin_Ops_082
<b>CURRENT VERSION EFFECTIVE DATE</b>	March 1, 2023
<b>APPLICABLE PRODUCT AND MARKET</b>	<i>Individual Family Plan: All Plans</i> <i>Small Group: All Plans</i> <i>Medicare Advantage: All Plans</i>

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## PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Hyaluronate Injections for Osteoarthritis of the Knee.

## POLICY

### Prior Authorization and Medical Review is required.

Coverage will be provided according to the below quantity limitations.

Coverage Quantity Limitations	
Product	Quantity Limit
Euflexxa	20mg once weekly x 3 doses - <b>Maximum 6 injections per 180 days</b>
Gel-One	30mg x 1 dose - <b>Maximum 2 injection per 180 days</b>
Gelsyn-3	16.8 mg once weekly x 3 doses - <b>Maximum 6 injections per 180 days</b>
GenVisc 850	25mg once weekly x 5 doses - <b>Maximum 10 injections per 180 days</b>

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Hyalgan	20mg once weekly x 5 doses - <b>Maximum 10 injections per 180 days</b>
Hymovis	24mg once weekly x 2 doses - <b>Maximum 4 injections per 180 days</b>
Monovisc	88mg x 1 dose - <b>Maximum 2 injections per 180 days</b>
Orthovisc	30mg once weekly x 3 or 4 doses - <b>Maximum 8 injections per 180 days</b>
Sodium Hyaluronate 1%	20 mg once weekly x 3 doses - <b>Maximum 6 injections per 180 days</b>
Supartz FX	25mg once weekly x 5 doses - <b>Maximum 10 injections per 180 days</b>
Synvisc	16mg once weekly x 3 doses - <b>Maximum 6 injections per 180 days</b>
Synvisc-One	48mg x 1 dose - <b>Maximum 2 injections per 180 days</b>
Trivisc	25mg once weekly x 3 doses - <b>Maximum 3 injections per 180 days</b>
Durolane	60mg (3mL) x 1 dose - <b>Maximum 2 injections per 180 days</b>
Triluron	20 mg once weekly x 3 doses - <b>Maximum 3 injections per 180 days</b>
Synjoynt	1% once weekly x 3 doses - <b>Maximum 3 injections per 180 days</b>
Visco-3	25mg once weekly x 3 doses

### Initial Coverage

- A. Patient has a documented diagnosis of symptomatic osteoarthritis (OA) of the knee;  
**AND**
- B. Patient has had a trial and failure of **at least 3 months** of conservative therapy or the patient is unable to tolerate conservative therapy due to adverse effects
  - a. Conservative therapy includes, but is not limited, to physical therapy, pharmacotherapy (e.g., non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen (up to 1 g 4 times/day) and/or topical capsaicin cream); **AND**
- C. Patient has had a trial and has failed to adequately respond to aspiration and injection of intra-articular steroids; **AND**
- D. Patient reports pain that interferes with functional activities (e.g., ambulation, prolonged standing).

### Renewal Criteria

- A. Documentation demonstrating reduction in dose of NSAIDS (or other analgesics or anti-inflammatory medication) during the 12-month period following the previous series of injections
- B. Objectively documentation of significant improvement in pain and functional capacity as the result of the previous injections

### LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Use to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic and are not a covered benefit.
3. Patients with known hypersensitivity to hyaluronate derivatives or allergies to avian or avian-derived products (including eggs, feathers or poultry). (EXCLUDING Orthovisc)

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4. Do not administer to patients with known hypersensitivity (allergy) to gram positive bacterial proteins (Orthovisc ONLY)

### BACKGROUND

Hyaluronan (HA), also known as hyaluronate or hyaluronic acid, is a naturally occurring macromolecule that is a major component of synovial fluid and is thought to contribute to its viscoelastic properties. Chemical cross-linking of hyaluronan increases its molecular weight; cross-linked HA are referred to as hylans.

In osteoarthritis (OA), the overall length of HA chains present in cartilage and the HA concentration in the synovial fluid are decreased. Intra-articular injection of HA has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in patients with osteoarthritis. This treatment has been referred to as visco-supplementation.

### CODING

Applicable NDC Codes	
89130-2020-01	DUROLANE, hyaluronic acid 20 mg/1 ml, 3 ml
50653-0006-01	GENVISC 850, hyaluronate sodium 10 mg/1 ml, 2.5 ml
89122-072420	HYALGAN, hyaluronate sodium 10 mg/1 ml, 2 ml
89122-072412	HYALGAN, hyaluronate sodium 10 mg/1 ml, 2 ml
89130-4444-01	SUPARTZ FX, hyaluronate sodium 10 mg/1 ml, 2.5 ml
87541-0301-31	VISCO-3, hyaluronate sodium 10 mg/1 ml, 2.5 ml 3s
50016-0957-21	VISCO-3, hyaluronate sodium 10 mg/1 ml, 2.5 ml 3s
89122-0496-63	HYMOVIS, hyaluronic acid 8 mg/1 ml, 3 ml 2s
55566-4100-01	EUFLEXXA, hyaluronate sodium 10 mg/1 ml, 2 ml 3s
59676-0360-01	ORTHOVISC, hyaluronic acid 15 mg/1 ml, 2 ml
58468-0090-01	SYNVISC, hylan polymers a and b 8 mg/1 ml, 2 ml 3s
58468-0090-03	SYNVISC ONE, hylan polymers a and b 8 mg/1 ml, 6 ml
87541-0300-91	GEL-ONE, hyaluronate sodium 30 mg/3 ml, 3 ml
50016-0957-11	GEL-ONE, hyaluronate sodium 30 mg/3 ml, 3 ml
59676-0820-01	MONOVISC, hyaluronic acid 22 mg/1 ml, 4 ml
89130-3111-01	GELSYN-3, hyaluronate sodium 8.4 mg/1 ml, 2 ml
50653-0006-04	TRIVISC, hyaluronate sodium 10 mg/1 ml, 2.5 ml
89122-0879-01	TRILURON, hyaluronate sodium 20 mg/2 ml, 2 ml
57844-0181-21	SODIUM HYALURONATE, hyaluronate sodium 10 mg/1 ml, 2 ml

Applicable Procedure Code	
J3490	Unclassified drugs
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose
J7320	Hyaluronan or derivative, genvisc 850, for intra-articular injection, 1 mg

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J7321	Hyaluronan or derivative, Hyalgan or Supartz, or Visco-3, for intra-articular injection, per dose
J7322	Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg
J7323	Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
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
J7328	Hyaluronan or derivative, Gelsyn-3 for intra-articular injection, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, Synjoynt, for intra-articular injection, 1 mg
J7333	Hyaluronan or derivative, (Visco-3), for intra-articular injection

Applicable ICD-10 Codes	
M13.0	Polyarthritis, unspecified
M16.0	Bilateral primary osteoarthritis of hip
M16.10	Unilateral primary osteoarthritis, unspecified hip
M16.11	Unilateral primary osteoarthritis, right hip
M16.12	Unilateral primary osteoarthritis, left hip
M16.2	Bilateral osteoarthritis resulting from hip dysplasia
M16.30	Unilateral osteoarthritis resulting from hip dysplasia, unspecified hip
M16.31	Unilateral osteoarthritis resulting from hip dysplasia, right hip
M16.32	Unilateral osteoarthritis resulting from hip dysplasia, left hip
M16.4	Bilateral post-traumatic osteoarthritis of hip
M16.50	Unilateral post-traumatic osteoarthritis, unspecified hip
M16.51	Unilateral post-traumatic osteoarthritis, right hip
M16.52	Unilateral post-traumatic osteoarthritis, left hip
M16.6	Other bilateral secondary osteoarthritis of hip
M16.7	Other unilateral secondary osteoarthritis of hip
M16.9	Osteoarthritis of hip, unspecified
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified
M26.69	Other specified disorders of temporomandibular joint
M26.601	Right temporomandibular joint disorder, unspecified
M26.602	Left temporomandibular joint disorder, unspecified
M26.603	Bilateral temporomandibular joint disorder, unspecified

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M26.609	Unspecified temporomandibular joint disorder, unspecified side
M26.611	Adhesions and ankylosis of right temporomandibular joint
M26.612	Adhesions and ankylosis of left temporomandibular joint
M26.613	Adhesions and ankylosis of bilateral temporomandibular joint
M26.619	Adhesions and ankylosis of temporomandibular joint, unspecified side
M26.621	Arthralgia of right temporomandibular joint
M26.622	Arthralgia of left temporomandibular joint
M26.623	Arthralgia of bilateral temporomandibular joint
M26.629	Arthralgia of temporomandibular joint, unspecified side
M26.631	Articular disc disorder of right temporomandibular joint
M26.632	Articular disc disorder of left temporomandibular joint
M26.633	Articular disc disorder of bilateral temporomandibular joint
M26.639	Articular disc disorder of temporomandibular joint, unspecified side
M26.641	Arthritis of right temporomandibular joint
M26.642	Arthritis of left temporomandibular joint
M26.643	Arthritis of bilateral temporomandibular joint
M26.649	Arthritis of unspecified temporomandibular joint
M26.651	Arthropathy of right temporomandibular joint
M26.652	Arthropathy of left temporomandibular joint
M26.653	Arthropathy of bilateral temporomandibular joint
M26.659	Arthropathy of unspecified temporomandibular joint

**EVIDENCE BASED REFERENCES**

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### POLICY HISTORY

Original Effective Date	November 1, 2021
Revised Date	November 8, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UMC (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022