

Hyaluronic Acid Derivatives:

Durolane[®], Euflexxa[™], Gel-One[®], GelSyn-3[™], GenVisc 850[®], Hyalgan[™], Hymovis[®], Monovisc[®], Orthovisc[™], Supartz/Supartz FX[™], Synjoynt, Synvisc[™], Synvisc-One[™], Triluron[™], TriVisc[™], & VISCO-3[™]

(Intra-articular)

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I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Drug	Injections per knee	Injections both knees	Days Supply
Durolane 60 mg/3 mL injection	1	2	180
Euflexxa 20 mg/2 mL injection	3	6	180
Gel-One 30 mg/3 mL injection	1	2	180
GelSyn-3 16.8 mg/2 mL injection	3	6	180
GenVisc 850 25mg/3 mL injection	5	10	180
Hyalgan 20 mg/2 mL injection	5	10	180
Hymovis 24 mg/3 mL injection	2	4	180
Monovisc 88 mg/4 mL injection	1	2	180
Orthovisc 30 mg/2 mL injection	4	8	180
Supartz 25 mg/2.5 mL injection	5	10	180
Supartz FX 25 mg/2.5 mL injection	5	10	180
Synjoynt 20 mg/2 mL	3	6	180

Synvisc 16 mg/2 mL injection	3	6	180
Synvisc-One 48 mg/6 mL injection	1	2	180
Triluron 20 mg/2 mL injection	3	6	180
Trivisc 25 mg/2.5mL injection	3	6	180
VISCO-3 25 mg/2.5 mL injection	3	6	180

B. Max Units (per dose and over time) [HCPCS Unit]:*

Drug	HCPCS	1 Billable Unit (BU)	BU per Admin	No. Admins (per knee per 180 days)	Max Units (per 180 days)*
Durolane	J7318	1 mg	60	1	120
Euflexxa	J7323	1 dose	1	3	6
Gel-One	J7326	1 dose	1	1	2
GelSyn-3	J7328	0.1 mg	168	3	1008
GenVisc 850	J7320	1 mg	25	5	250
Hyalgan; Supartz; Supartz FX	J7321	1 dose	1	5	10
Hymovis	J7322	1 mg	24	2	96
Monovisc	J7327	1 dose	1	1	2
Orthovisc	J7324	1 dose	1	4	8
Synojoint	J7331	1 mg	20	3	120
Synvisc	J7325	1 mg	16	3	96
Synvisc-One	J7325	1 mg	48	1	96
Triluron	J7332	1 mg	20	3	120
Trivisc	J7329	1 mg	25	3	150
VISCO-3	J7321	1 dose	1	3	6

*Max units are based on administration to both knees

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- For approval of viscosupplements other than Euflexxa or Synvisc-One, the patient must have tried and failed to have an adequate response to or had an intolerance to both preferred agents (Euflexxa and Synvisc-One); **AND**

Universal Criteria ^{1-15,23-25}

- Patient does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, bleeding disorders, etc.); **AND**
- Patient has not received therapy with intra-articular long-acting corticosteroid type drugs (i.e. Zilretta, etc.) within the previous 6 months of therapy; **AND**

Osteoarthritis of the knee † 1-15,23-25,27-29

- Patient has a radiographically* confirmed diagnosis of osteoarthritis of the knee; **AND**
- The patient has had a trial and failure to BOTH of the following conservative methods which have not resulted in functional improvement after at least three (3) months:
 - Non-Pharmacologic (i.e., physical, psychosocial, or mind-body approach [e.g., exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.]); **AND**
 - Pharmacologic Approach (e.g., topical NSAIDs, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.); **AND**
- The patient has failed to adequately respond to aspiration and injection of intra-articular steroids; **AND**
- The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)

**Note: Imaging is not required to make the diagnosis in patients with a typical presentation of OA²⁷*

† FDA Approved Indication(s)

IV. Renewal Criteria 1-15,23-25,27-29

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by improvement in signs and symptoms of pain and a stabilization or improvement in functional capacity during the 6-month period following the previous series of injections as evidenced by objective measures; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

V. Dosage/Administration (per knee per 180 days)

Drug	Dose
Durolane	60 mg intra-articularly x 1 administration
Euflexxa	20 mg intra-articularly once weekly x 3 administrations
Gel-One	30 mg intra-articularly x 1 administration
GelSyn-3	16.8 mg intra-articularly once weekly x 3 administrations
GenVisc 850	25 mg intra-articularly once weekly x 5 administrations
Hyalgan	20 mg intra-articularly once weekly x 5 administrations

Hymovis	24 mg intra-articularly once weekly x 2 administrations
Monovisc	88 mg intra-articularly x 1 administration
Orthovisc	30 mg intra-articularly once weekly x 4 administrations
Synjoynt	20 mg intra-articularly once weekly x 3 administrations
Supartz/Supartz FX	25 mg intra-articularly once weekly x 5 administrations
Synvisc	16 mg intra-articularly once weekly x 3 administrations
Synvisc-One	48 mg intra-articularly x 1 administration
Triluron	20 mg intra-articularly once weekly x 3 administrations
Trivisc	25 mg intra-articularly once weekly x 3 administrations
VISCO-3	25 mg intra-articularly once weekly x 3 administrations

VI. Billing Code/Availability Information

HCPCS Code & NDC:

Drug	HCPCS Code	1 Billable Unit	Dose per Injection	Injections (per knee per 180 days)	NDC
Durolane	J7318	1 mg	60 mg/3 mL	1	89130-2020-xx
Euflexxa	J7323	1 dose	20 mg/2 mL	3	55566-4100-xx
Gel-One	J7326	1 dose	30 mg/3 mL	1	50016-0957-xx
GelSyn-3	J7328	0.1 mg	16.8 mg/2 mL	3	89130-3111-xx
GenVisc 850	J7320	1 mg	25mg/2.5 ml	5	50653-0006-xx
Hyalgan	J7321	1 dose	20 mg/2 mL	5	89122-0724-xx
Hymovis	J7322	1 mg	24 mg/3 mL	2	89122-0496-xx
Monovisc	J7327	1 dose	88 mg/4 mL	1	59676-0820-xx
Orthovisc	J7324	1 dose	30 mg/2 mL	4	59676-0360-xx
Supartz	J7321	1 dose	25 mg/2.5 mL	5	89130-5555-xx
Supartz FX	J7321	1 dose	25 mg/2.5 mL	5	89130-4444-xx
Synjoynt	J7331	1 mg	20 mg/2 mL	3	82197-0721-xx
Synvisc	J7325	1 mg	16 mg/2 mL	3	58468-0090-xx
Synvisc-One	J7325	1 mg	48 mg/6 mL	1	58468-0090-xx
Triluron	J7332	1 mg	20 mg/2 mL	3	89122-0879-xx
Trivisc	J7329	1 mg	25 mg/2.5 mL	3	50563-0006-xx
Visco-3	J7321	1 dose	25mg/2.5 mL	3	50016-0957-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD):

Jurisdiction(s): J, M	NCD/LCA/LCD Document (s): A59030
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a59030&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	
Jurisdiction(s): 6, K	NCD/LCA/LCD Document (s): A52420
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52420&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	
Jurisdiction(s): 5, 8	NCD/LCA/LCD Document (s): A56157

<https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56157&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP>

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC