

Hyaluronic Acid Derivatives:

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% (Intra-articular)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

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
sodium hyaluronate 20 mg/2 mL injection	3	6	180
Supartz 25 mg/2.5 mL injection	5	10	180
Supartz FX 25 mg/2.5 mL injection	5	10	180
Synojoynt 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
sodium hyaluronate	J7331	1 mg	20	3	120
Synjoynt	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:

- Patient must try and have an inadequate response, contraindication, or intolerance to Euflexxa

Universal Criteria ^{1-16,24-26}

- 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 †

- Patient has a radiographically* confirmed diagnosis of osteoarthritis of the knee; **AND**
- Trial and failure of conservative therapy (including physical therapy AND pharmacotherapy [e.g., non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen (up to 1 g 4 times/day) and/or topical capsaicin cream]) has been attempted and has not resulted in functional improvement after at least 3 months; **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 ^{1-16,24-26}

Coverage can be renewed based upon the following criteria:

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| <ul style="list-style-type: none"> • Patient must try and have an inadequate response, contraindication, or intolerance to Euflexxa |
|--|
- 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 the following: 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
sodium hyaluronate	20 mg intra-articularly once weekly x 3 administrations
Synojynt	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
sodium hyaluronate	J7331	1 mg	20 mg/2 mL	3	57844-0181-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
Synojynt	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
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VII. References

1. Sodium Hyaluronate 1% [package insert]. North Wales, PA; Teva Pharmaceuticals; March 2019. Accessed September 2022.
2. Supartz/Supartz FX [package insert]. Durham, NC; Bioventus LLC; April 2015. Accessed September 2022.
3. Hyalgan [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; August 2017. Accessed September 2022.
4. Euflexxa [package insert]. Parsippany, NJ; Ferring Pharmaceuticals; July 2016. Accessed September 2022.
5. Synvisc/Synvisc-One [package insert]. Ridgefield, NJ; Genzyme Biosurgery; September 2014. Accessed September 2022.
6. Orthovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; September 2016. Accessed September 2022.
7. Gel-One [package insert]. Warsaw, IN; Zimmer; May 2011. Accessed September 2022.
8. Monovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; February 2014. Accessed September 2022.
9. GelSyn-3 [package insert]. Durham, NC; Bioventus LLC; December 2017; Accessed September 2022.
10. GenVisc 850 [package insert]. Doylestown, PA; OrthogenRx, Inc; November 2019; Accessed September 2022.
11. Hymovis [package insert]. Florham Park, NJ; Fidia Pharma USA Inc.; September 2017. Accessed September 2022.
12. VISCO-3 [package insert]. Durham, NC; Bioventus LLC; December 2015. Accessed September 2022.
13. Durolane [package insert]. Durham, NC; Bioventus LLC; September 2017. Accessed September 2022.
14. Trivisc [package insert]. Doylestown, PA; OrthogenRx, Inc; December 2017. Accessed September 2022.
15. Triluron [package insert]. Florham Park, NJ; Fidia Pharma USA Inc.; July 2019. Accessed September 2022.
16. Synojoynt [package insert]. Naples, FL; Arthrex, Inc.; January 2022. Accessed September 2022.
17. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res (Hoboken)*. 2012 Apr;64(4):465-74.
18. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014 Mar;22(3):363-88. doi: 10.1016/j.joca.2014.01.003. Epub 2014 Jan 24.

19. Brown GA. AAOS clinical practice guideline: treatment of osteoarthritis of the knee: evidence-based guideline, 2nd edition. *J Am Acad Orthop Surg*. 2013 Sep;21(9):577-9. doi: 10.5435/JAAOS-21-09-577.
20. Cooper C, Rannou F, Richette P, et al. Use of intra-articular hyaluronic acid in the management of knee osteoarthritis in clinical practice. *Arthritis Care Res (Hoboken)*. 2017 Jan 24.
21. Bhadra AK, Altman R, Dasa V, et al. Appropriate use criteria for hyaluronic acid in the treatment of knee osteoarthritis in the United States. *Cartilage*. 2016 Aug 10.
22. National Institute for Health and Care Excellence. NICE 2014. Osteoarthritis-Care and management in adults. Published Feb 2014. Clinical guideline CG177. <https://www.nice.org.uk/guidance/cg177/evidence/full-guideline-pdf-191761309>. Accessed August 2018.
23. Strand V, Baraf H, Lavin P, et. al. Effectiveness and Safety of a Multicenter Extension and Retreatment Trial of Gel-200 in Patients with Knee Osteoarthritis. *Cartilage*. 2012 Oct; 3(4): 297–304.
24. American College of Rheumatology. Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC). *Rheumatology.org*. <https://www.rheumatology.org/i-am-a-rheumatologist/research/clinician-researchers/western-ontario-mcmaster-universities-osteoarthritis-index-womac>. Published 2015.
25. Bannaru RR, Osani MC, Vaysbrot EE, et al. 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>.
26. 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.
27. Sakellariou G, Conaghan PG, Zhang W, et al. EULAR recommendations for the use of imaging in the clinical management of peripheral joint osteoarthritis. *Annals of the Rheumatic Diseases* 2017;76:1484-1494.
28. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Viscosupplementation Therapy For Knee (A57256). Centers for Medicare & Medicaid Services, Inc. Updated on 04/16/2021 with effective date 04/01/2021. Accessed September 2022.
29. National Government Services, Inc. Local Coverage Article: Billing and Coding: Hyaluronans Intra-articular Injections of (A52420). Centers for Medicare & Medicaid Services, Inc. Updated on 07/23/2021 with effective date 08/01/2021. Accessed September 2022.
30. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Hyaluronan Acid Therapies for Osteoarthritis of the Knee (A55036). Centers for Medicare & Medicaid Services, Inc. Updated on 04/16/2021 with effective date 04/01/2021. Accessed September 2022.

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): N	NCD/LCA/LCD Document (s): A57256 https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57256&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%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%2CMD%2C6%2C3%2C5%2C1%2CF%2CP
Jurisdiction(s): H, L	NCD/LCA/LCD Document (s): A55036 https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a55036&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%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