

## PHARMACY POLICY STATEMENT North Carolina Marketplace

RUG NAME Hyaluronic Acid Viscosupplements	
BILLING CODE	See table in appendix for list of products and codes
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient hospital
STATUS	Prior Authorization Required

Osteoarthritis is a common chronic joint disorder involving cartilage degradation, bone remodeling, osteophyte formation, and synovial inflammation. These changes lead to pain, stiffness, swelling, and compromised functional capacity of the affected joint. The goal of treatment is to improve pain and mobility. Viscosupplementation is an intra-articular therapy that leverages the physiology of hyaluronic acid, a major component of normal synovial fluid, to restore viscoelasticity and natural protective properties like shock absorption and lubrication of the joint. A multitude of different hyaluronic acid products are available with a variety of properties. They 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 simple analgesics. They have a slower but more durable response than intra-articular steroid injections. Over the years, treatment guidelines have been incongruent in their recommendations, but overall they are considered a safe and effective option in certain situations. It is important to rule out other causes of joint pain such as rheumatoid arthritis, gout, or malignancy.

Hyaluronic acid viscosupplements will be considered for coverage when the following criteria are met:

### Osteoarthritis (OA) of the Knee

For **initial** authorization:

- 1. Member is at least 18 years of age; AND
- Medication must be prescribed by or in consultation with a physician in one of the following specialties: rheumatology, orthopedic surgery, sports medicine, pain medicine, or PM&R (physiatry); AND
- 3. Member has a diagnosis of osteoarthritis of the <u>knee</u> confirmed by radiographic evidence such as joint space narrowing, subchondral sclerosis, osteophytes and subchondral cysts; AND
- 4. Pain interferes with normal daily activity such as walking, standing, or stair climbing; AND
- 5. Member has tried and failed <u>ALL</u> of the following conservative therapies for at least 3 months:
  - a) Non-pharmacologic strategies such as exercise, physical therapy, bracing, weight loss (if overweight or obese)
  - b) Simple analgesics such as acetaminophen or NSAIDs (oral or topical)
  - c) Intra-articular corticosteroid injection (unless contraindicated); AND
- 6. Chart notes must indicate if the request is for the treatment of one or both knees; AND
- 7. Member has not had a total knee replacement (arthroplasty) and knee replacement is not anticipated for at least the next 6 months; AND
- 8. If the request is for a non-preferred product, trial and failure of at least 1 preferred product is required (see Appendix).
- 9. **Dosage allowed/Quantity limit:** Intra-articular injection to the affected knee(s) at weekly intervals. Euflexxa: 2 mL weekly for 3 weeks

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.



Durolane: 3 mL one time Gel-One: 3 mL one time Gelsyn-3: 2 mL weekly for 3 weeks Gen-Visc: 2.5 mL weekly for 3 to 5 weeks Hyalgan: 2 mL weekly for 3 to 5 weeks Hymovis: 3 mL weekly for 2 weeks Monovisc: 4 mL one time Orthovisc: 2 mL weekly for 3 to 4 weeks Supartz FX: 2.5 mL weekly for 3 to 5 weeks Synvisc: 2 mL weekly for 3 weeks Synvisc-One: 6 mL one time TriVisc: 2.5 mL weekly for 3 weeks TriLuron: 2 mL weekly for 3 weeks Visco-3: 2.5 mL weekly for 3 weeks

#### If all the above requirements are met, the medication will be approved for 6 months.

#### For reauthorization:

- 1. Chart notes must show clinically significant improvement of signs and symptoms such as documentation of improved pain scores, improved functional abilities, and/or reduced use of analgesic medications as a result of the treatment to the affected knee; AND
- 2. Symptoms have recurred and at least 6 months have elapsed since completion of the previous course of viscosupplementation; AND
- 3. Member has not had a total knee replacement (arthroplasty) and knee replacement is not anticipated for at least the next 6 months.

If all the above requirements are met, the medication will be approved for an additional 6 months.

# CareSource considers hyaluronic acid viscosupplements not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION	
04/20/2022	New policy for hyaluronic acid viscosupplements created; combination and comprehensive update of past individual policies.	

APPENDIX: List of products, codes, and status (Y = preferred; N = non-preferred)

Euflexxa	sodium hyaluronate	J7323	Ν
			Y
Durolane	hyaluronic acid	J7318	ř
Gel-One	cross-linked hyaluronate	J7326	N
Gelsyn-3	sodium hyaluronate	J7328	Y
GenVisc 850	sodium hyaluronate	J7320	Ν
Hyalgan	sodium hyaluronate	J7321	N
Hymovis	high molecular weight	J7322	N
	viscoelastic hyaluronan		
Monovisc	high molecular weight	J7327	Ν
	hyaluronan		
Orthovisc	high molecular weight	J7324	N
	hyaluronan		
Supartz FX	sodium hyaluronate	J7321	Y
Synvisc	hylan G-F 20	J7325	Ν

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.

CareSource

Synvisc-One	hylan G-F 20	J7325	Ν
TriVisc	sodium hyaluronate	J7329	Ν
TriLuron	sodium hyaluronate	J7332	N
Visco-3	sodium hyaluronate	J7321	Ν

#### References:

- 1. Euflexxa [package insert]. Ferring Pharmaceuticals, Inc.; 2016.
- 2. Durolane [package insert]. Bioventus LLC; 2017.
- 3. Gel-One [package insert]. Zimmer, Inc.; 2011.
- 4. Gelsyn-3 [package insert]. Bioventus; 2017.
- 5. GenVisc 850 [package insert]. OrthogenRx. N.D.
- 6. Hyalgan [package insert]. Fidia Pharma USA Inc.; 2014.
- 7. Hymovis [package insert]. Fidia Pharma USA Inc.; 2017.
- 8. Monovisc [package insert]. Anika Therapuetics Inc.; 2013.
- 9. Orthovisc [package insert]. Anika Therapeutics. N.d.
- 10. Supartz FX [package insert]. Bioventus LLC; 2015
- 11. Synvisc [package insert]. Genzyme Biosurgery; 2014.
- 12. Synvisc-One [package insert]. Genzyme Biosurgery; 2014.
- 13. TriVisc. [package insert]. OrthogenRx, Inc.
- 14. TriLuron. [package insert]. Fidia Pharma USA Inc.; 2019.
- 15. Visco-3. [package insert]. Bioventus LLC.
- 16. 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
- 17. Uson J, Rodriguez-García SC, Castellanos-Moreira R, et al. EULAR recommendations for intra-articular therapies. *Ann Rheum Dis.* 2021;80(10):1299-1305. doi:10.1136/annrheumdis-2021-220266
- Jordan, K M et al. "EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT)." Annals of the rheumatic diseases vol. 62,12 (2003): 1145-55. doi:10.1136/ard.2003.011742
- 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 [published correction appears in Arthritis Care Res (Hoboken). 2021 May;73(5):764]. *Arthritis Care Res (Hoboken)*. 2020;72(2):149-162. doi:10.1002/acr.24131
- Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. *Cochrane Database Syst Rev.* 2006;2006(2):CD005321. Published 2006 Apr 19. doi:10.1002/14651858.CD005321.pub2
- 21. Evaniew N, Simunovic N, Karlsson J. Cochrane in CORR®: Viscosupplementation for the treatment of osteoarthritis of the knee. *Clin Orthop Relat Res*. 2014;472(7):2028-2034. doi:10.1007/s11999-013-3378-8
- 22. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage*. 2019;27(11):1578-1589. doi:10.1016/j.joca.2019.06.011
- National Institute for Health and Care Excellence (NICE). Osteoarthritis: care and management. Clinical guideline [CG177]. Published: 12 February 2014 Last updated: 11 December 2020. https://www.nice.org.uk/guidance/cg177
- 24. Local Coverage Determination (LCD): Hyaluronan Acid Therapies for Osteoarthritis of the Knee (L35427). Centers for Medicare and Medicaid Services. Available at: <u>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35427</u>. Accessed April 26, 2022.
- 25. Katz JN, Arant KR, Loeser RF. Diagnosis and Treatment of Hip and Knee Osteoarthritis: A Review. *JAMA*. 2021;325(6):568-578. doi:10.1001/jama.2020.22171
- Trojian TH, Concoff AL, Joy SM, Hatzenbuehler JR, Saulsberry WJ, Coleman CI. AMSSM Scientific Statement Concerning Viscosupplementation Injections for Knee Osteoarthritis: Importance for Individual Patient Outcomes. *Clin J Sport Med.* 2016;26(1):1-11. doi:10.1097/JSM.00000000000274
- 27. Bruyère O, Honvo G, Veronese N, et al. An updated algorithm recommendation for the management of knee osteoarthritis from the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.



Effective date: 01/01/2023 Revised date: 04/20/2022