

POLICY Document for Hyaluronates

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product

- Policy information specific to preferred medications

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA

HYALURONATES

PREFERRED PRODUCTS: HYALGAN, HYMOVIS, SYNVISIC AND SYNVISIC ONE

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the hyaluronate products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are initiating a new treatment course with a targeted product. Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Hyaluronate products

	Products
Preferred	<ul style="list-style-type: none"> • Hyalgan (sodium hyaluronate) • Hymovis (high molecular weight viscoelastic hyaluronan) • Synvisic (hylan G-F 20) • Synvisic One (hylan G-F 20)
Targeted	<ul style="list-style-type: none"> • Durolane (hyaluronic acid) • Euflexxa (1% sodium hyaluronate) • Gel-One (cross-linked hyaluronate) • Gelsyn-3 (sodium hyaluronate) • Genvisc 850 (sodium hyaluronate) • Monovisc (high molecular weight hyaluronan) • Orthovisc (high molecular weight hyaluronan) • Supartz FX (sodium hyaluronate) • Visco-3 (sodium hyaluronate)

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member is currently undergoing treatment and coverage is required to complete the current course of treatment.

Number of injections per treatment course

- Durolane: 1 injection (3 mL each, 3 mL total) per course
- Euflexxa: 3 injections (2 mL each; 6 mL total) per course
- Gel-One: 1 injection (3 mL each; 3 mL total) per course
- Gelsyn-3: 3 injections (2 mL each, 6 mL total) per course
- GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total)
- Monovisc: 1 injection (4 mL each, 4 mL total) per course
- Orthovisc: 3 or 4 injections (2 mL each; 8 mL total) per course
- Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per course
- Visco-3 (sodium hyaluronate): 3 injections (2.5 mL each, 7.5 mL total) per course

B. Member has tried and experienced a documented intolerable adverse event to all of the preferred products.

Section 2: Clinical Criteria

HYALURONATES

- DUROLANE (hyaluronic acid)**
- EUFLEXXA (1% sodium hyaluronate)**
- GEL-ONE (cross-linked hyaluronate)**
- GELSYN-3 (sodium hyaluronate 0.84%)**
- GENVISC 850 (sodium hyaluronate)**
- HYALGAN (sodium hyaluronate)**
- HYMOVIS (high molecular weight viscoelastic hyaluronan)**
- MONOVISC (high molecular weight hyaluronan)**
- ORTHOVISC (high molecular weight hyaluronan)**
- SUPARTZ (sodium hyaluronate)**
- SYNVISC (hylan G-F 20)**
- SYNVISC ONE (hylan G-F 20)**
- TRIVISC (sodium hyaluronate)**
- VISCO-3 (sodium hyaluronate)**

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen)

B. Compendial Uses

1. Treatment of pain in osteoarthritis of the shoulder
2. Treatment of pain in osteoarthritis of the hip

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Osteoarthritis (OA) of the Knee, Hip, or Shoulder

Authorization of 12 months may be granted for treatment of osteoarthritis (OA) in the knee, hip or shoulder.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

REFERENCES

SECTION 1

1. Durolane [package insert]. Durham, NC: Bioventus, LLC; 2017.
2. Euflexxa [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; June 2015.
3. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
4. Gelsyn-3 [package insert]. Durham, NC: Bioventus LLC; February 2016.
5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; September 2015.
6. Hyalgan [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; May 2014.
7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; October 2015.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; December 2013.
9. Orthovisc [package insert]. Raynham, MA: DePuy Mitek, Inc.; June 2005.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
12. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
13. Visco-3 [package insert]. Durham, NC: Bioventus LLC; December 2015.

SECTION 2

1. Durolane [package insert]. Durham, NC: Bioventus LLC; 2017.
2. Euflexxa [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
3. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
4. Gelsyn-3 [package insert]. Durham, NC: Bioventus LLC; February 2016.
5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; September 2015.
6. Hyalgan [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; May 2014.
7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; October 2015.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; December 2013.
9. Orthovisc [package insert]. Raynham, MA: DePuy Mitek, Inc.; June 2005.
10. Supartz [package insert]. Durham, NC: Bioventus LLC; April 2015.

11. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
12. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
13. Trivisc [package insert]. Doylestown, PA: OrthogenRX; September 2018.
14. Visco-3 [package insert]. Durham, NC: Bioventus LLC; December 2015.
15. Jordan KM, Arden NK, Doherty 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). *Ann Rheum Dis.* 2003;62:1145-1155.
16. 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.* 2012;64(4):465-474.
17. Brander VA, Gomberawalla A, Chambers M, et al. Efficacy and safety of hylan G-F 20 for symptomatic glenohumeral osteoarthritis: a prospective, pilot study. *PM R.* 2010;2(4):259-267.
18. Brocq O, Tran G, Breuil V, et al. Hip osteoarthritis: short-term efficacy and safety of viscosupplementation by Hylan G-F 20. An open-label study in 22 patients. *Joint Bone Spine.* 2002;69:388-391.
19. Caglar-Yagci H, Unsal S, Yagci I, et al. Safety and efficacy of ultrasound-guided intra-articular hylan G-F injection in osteoarthritis of the hip: a pilot study. *Rheumatol Int.* 2005;25:341-344.
20. Conrozier T, Bertin P, Mathieu P, et al. Intra-articular injections of hylan G-F 20 in patients with symptomatic hip osteoarthritis: an open-label, multicenter, pilot study. *Clin Exp Rheumatol.* 2003;21:605-610.
21. Migliore A, Tormenta S, Massafra U, et al. Intra-articular administration of hylan G-F 20 in patients with symptomatic hip osteoarthritis: tolerability and effectiveness in a large cohort study in clinical practice. *Curr Med Res Opin.* 2008;24(5):1309-1316.
22. Neustadt DH. Intra-articular injections for osteoarthritis of the knee. *Cleve Clin J Med.* 2006;73(10):897-911.
23. Qvistgaard E, Christensen R, Torp-Pedersen S, et al. Intra-articular treatment of hip osteoarthritis: a randomized trial of hyaluronic acid, corticosteroid, and isotonic saline. *Osteoarthritis Cartilage.* 2006;14(2):163-170.
24. Vad VB, Sakalkale D, Sculco TP, et al. Role of hylan G-F 20 in treatment of osteoarthritis of the hip joint. *Arch Phys Med Rehabil.* 2003;84:1224-1226.
25. van den Bekerom MP, Lamme B, Sermon A, et al. What is the evidence for viscosupplementation in the treatment of patients with hip osteoarthritis? Systematic review of the literature. *Arch Orthop Trauma Surg.* 2008;128(8):815-823.
26. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage.* 2008;16(2):137-162.
27. Clinical Consult. CVS Caremark Clinical Programs Review. Focus on Rheumatology Clinical Programs. July 2008.
28. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Rheumatology Clinical Programs. July 2011.
29. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage.* 2014;22(3):363-88.