POLICY Document for

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 FX (sodium hyaluronate)
SYNOJOYNT (1% sodium hyaluronate)
SYNVISC (hylan G-F 20)
SYNVISC ONE (hylan G-F 20)
TRILURON (sodium hyaluronate)
TRIVISC (sodium hyaluronate)
VISCO-3 (sodium hyaluronate)

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

CAREFIRST: EXCEPTIONS CRITERIA
OSTEOARTHRITIS, VISCOSUPPLEMENTS

PREFERRED PRODUCTS: DUROLANE, EUFLEXXA, GELSYN-3

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

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 osteoarthritis viscosupplement products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products 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 all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Osteoarthritis Viscosupplement Products

	Product(s)
Preferred*	• **Durolane** (hyaluronic acid) • **Euflexxa** (1% sodium hyaluronate) • **Gelsyn-3** (sodium hyaluronate)
Targeted	• **Gel-one** (cross-linked hyaluronate) • **Genvisc 850** (sodium hyaluronate) • **Hyalgan** (sodium hyaluronate) • **Hymovis** (high molecular weight viscoelastic hyaluronan) • **Monovisc** (high molecular weight hyaluronan) • **Orthovisc** (high molecular weight hyaluronan) • **Supartz fx** (sodium hyaluronate) • **SynoJoynt** (sodium Hyaluronate) • **Synvisc** (hylan G-F 20) • **Synvisc-one** (hylan G-F 20) • **Triluron** (sodium hyaluronate) • **Trivisc** (sodium hyaluronate) • **Visco-3** (sodium hyaluronate)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

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

A. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products
B. There is documentation that the member is currently undergoing treatment, and coverage is required to complete the current course of treatment.

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

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 FX (sodium hyaluronate)

SYNOJOYNT (1% sodium hyaluronate)
SYNVISC (hylan G-F 20)
SYNVISC ONE (hylan G-F 20)
TRILURON (sodium hyaluronate)
TRIVISC (sodium hyaluronate)
VISCO-3 (sodium hyaluronate)
1% 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.

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).

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Osteoarthritis (OA) of the Knee
Authorization of 12 months may be granted for treatment of osteoarthritis (OA) in the knee when all of the following criteria are met:

A. The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts) or the member has at least 5 of the following signs and symptoms:
   1. Bony enlargement
   2. Bony tenderness
   3. Crepitus (noisy, grating sound) on active motion
   4. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
   5. Less than 30 minutes of morning stiffness
   6. No palpable warmth of synovium
   7. Over 50 years of age
   8. Rheumatoid factor less than 1:40 titer (agglutination method)
   9. Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm^3)
B. The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
C. The member has experienced an inadequate response or adverse effects with non-pharmacologic treatment options (e.g., physical therapy, regular exercise, insoles, knee bracing, weight reduction).
D. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of an analgesic (e.g., acetaminophen up to 3 to 4 grams per day, non-steroidal anti-inflammatory drugs [NSAIDs], topical capsaicin cream) for at least 3 months.
E. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of intraarticular steroid injections for at least 3 months.
F. The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment of osteoarthritis in the knee when all of the following criteria are met:

A. Member meets all criteria for initial approval.
B. Member has experienced improvement in pain and functional capacity following the previous injections.
C. At least 6 months has elapsed since the last injection in the prior completed series of injections.

REFERENCES:

SECTION 1

1. Durolane [package insert]. Durham, NC: Bioventus, LLC; September 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; December 2017.
5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
6. Hyalgan [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; September 2017.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synojoynt [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
12. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
13. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
14. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
15. Trivisc [package insert]. Doylestown, PA: OrthogenRX; September 2018.
16. Visco-3 [package insert]. Warsaw, IN: Zimmer Inc.; May 2017.

SECTION 2

1. Durolane [package insert]. Durham, NC: Bioventus LLC; September 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; December 2017.
5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
6. Hyalgan [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
7. Hymovis [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; June 2021.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synojoynt [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
12. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
13. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
14. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.: July 2019.
15. Trivisc [package insert]. Doylestown, PA: OrthogenRx, Inc.; September 2018.
16. Visco-3 [package insert]. Warsaw, IN: Zimmer; May 2017.
17. 1% Sodium Hyaluronate [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
18. 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.
19. 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.
20. Neustadt DH. Intra-articular injections for osteoarthritis of the knee. *Cleve Clin J Med*. 2006;73(10):897-911.
21. 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.
22. 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.

23. Kolasinski SL, Tuhina N, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guidelines for the management of osteoarthritis of the hand, hip, and knee. *Arthritis Rheumatol.* 2020 Jan 6. doi: 10.1002/art.41142. [Epub ahead of print]
24. 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.
25. Scali JJ. Intra-articular hyaluronic acid in the treatment of osteoarthritis of the knee: a long term study. Eur J Rheumatol Inflamm. 1995;15(1):57-62.