

POLICY Document for GEL-ONE (cross-linked 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*	<ul style="list-style-type: none"> • Durolane (hyaluronic acid) • Euflexxa (1% sodium hyaluronate) • Gelsyn-3 (sodium hyaluronate)

Targeted	<ul style="list-style-type: none"> • 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)
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*: 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:

- Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products
- 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 Hyaluronates

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Durolane	hyaluronic acid
Euflexxa	1% sodium hyaluronate
Gel-One	cross-linked hyaluronate

Brand Name	Generic Name
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
Synojynt	1% sodium hyaluronate
Synvisc	hylan G-F 20
Synvisc One	hylan G-F 20
Triluron	sodium hyaluronate
Trivisc	sodium hyaluronate
Visco-3	sodium hyaluronate

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 Indications¹⁻¹⁷

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.

Coverage Criteria

Osteoarthritis (OA) of the Knee¹⁻²⁴

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

- 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:
 - Bony enlargement
 - Bony tenderness
 - Crepitus (noisy, grating sound) on active motion

- Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
- Less than 30 minutes of morning stiffness
- No palpable warmth of synovium
- Over 50 years of age
- Rheumatoid factor less than 1:40 titer (agglutination method)
- Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm³)
- The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
- 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).
- 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.
- 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.
- The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

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:

- Member meets all requirements in the coverage criteria.
- Member has experienced improvement in pain and functional capacity following the previous injections.
- At least 6 months has elapsed since the last injection in the prior completed series of injections.

REFERENCES:

SECTION 1

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