Viscosupplementation for Osteoarthritis

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Viscosupplementation for Osteoarthritis drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Euflexxa, Synvisc, and Synvisc One are the preferred products. The criteria will require the use of the health plan's preferred products before the use of targeted products (Durolane, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, sodium hyaluronate injection 20mg/2mL, Supartz FX, Synojoynt, Triluron, Trivisc, Visco-3), unless there are clinical circumstances that exclude the use of the preferred products and may be based on previous use of a product. While multiple brands of viscosupplementation are commercially available, there is no evidence, to date, that any have superior efficacy or safety.

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)

Table 1. Hyaluronate products

Medication	Generic Name
Preferred Products:	
Synvisc	hylan G-F 20
Synvisc One	hylan G-F 20
Euflexxa	1% sodium hyaluronate
Targeted Products:	
Durolane	hyaluronic acid
Gel-One	cross-linked hyaluronate
Gelsyn-3	sodium hyaluronate
Genvisc 850	sodium hyaluronate
Hyalgan	sodium hyaluronate
Hymovis	high molecular weight viscoelastic hyaluronan
Monovisc	high molecular weight hyaluronan
Orthovisc	high molecular weight hyaluronan
sodium hyaluronate inj 20mg/2mL (manufactured by Teva)	1% sodium hyaluronate
Supartz FX	sodium hyaluronate
Synojoynt	sodium hyaluronate
Triluron	sodium hyaluronate
TriVisc	sodium hyaluronate
Visco-3	sodium hyaluronate

POLICY

Must meet BOTH the Preferred Drug Plan Design (for the specific drug) and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

I. 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 (60 mg per 3 mL) per 180-day course

- Gel-One: 3-5 injections (30 mg per 3 mL) per 180-day course
- Gelsyn-3: 3 injections (2 mL each, 6 mL total) per 180-day course
- GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180-day course
- Hyalgan: 3 to 5 injections (2 mL each; 10 mL total) per 180-day course
- Hymovis: 2 injections (3 mL each; 6 mL total) per 180-day course
- Monovisc: 1 injection (88 mg per 4 mL) per 180-day course
- Orthovisc: 3 to 4 injections (30 mg per 2 mL) per 180-day course
- sodium hyaluronate inj 20mg/2mL: 3 injections per 180-day course
- Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180-day course
- Synojoynt: 3 injections per 180-day course
- Triluron: 3 injections (2 mL each; 6 mL total) per 180-day course
- TriVisc: 3 injections (2.5 mL each, 7.5 mL total) per 180-day course
- Visco-3: 3 injections (2.5 mL each, 7.5 mL total) per course

B. Member has tried and experienced an intolerable adverse event to at least two of the preferred products: a) Euflexxa, b) Synvisc or Synvisc One.

Criteria for Initial Approval

I. 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.

Continuation of Therapy

I. 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.

Intra-articular hyaluronan injections are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to age and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity limits apply:

Synvisc-One: 1 injection (6 mL each; 6 mL total) per 180 day course
Synvisc: 3 injections (2 mL each; 6 mL total) per 180 day course
Hyalgan: 3 to 5 injections (2 mL each; 10 mL total) per 180 day course
Hymovis: 2 injections (3 mL each; 6 mL total) per 180 day course
Euflexxa: 3 injections (2 mL each; 6 mL total) per 180 day course
Gel-One: 1 injection (3 mL each; 3 mL total) per 180 day course
Gelsyn-3: 3 injections (2 mL each, 6 mL total) per 180 day course
GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
Monovisc: 1 injection (4 mL each, 4 mL total) per 180 day course
Orthovisc: 3 or 4 injections (2 mL each; 8 mL total) per 180 day course
sodium hyaluronate inj 20mg/2mL: 3 injections per 180 day course
Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
Synojoynt: 3 injections per 180 day course
Triluron: 3 injections (2 mL each; 6 mL total) per 180 day course
Durolane: 1 injection (3 mL each, 3 mL total) per course
TriVisc: 3 injections (2.5 mL each, 7.5 mL total) per 180 day course
Visco-3: 3 injections (2.5 mL each, 7.5 mL total) per course

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9465 – Hyaluronan or derivative, Durolane, for intra-articular injection, per dose
- J7318 – Hyaluronan or derivative, Durolane, for intra-articular injection, 1mg
- J7320 – Hyaluronan or derivative, Genvisc 850, for intra-articular injection, 1mg
- J7321 – Hyaluronan or derivative, Hyalgan, Supartz or Visco-3, for intra-articular injection, per dose
- J7322 – Hyaluronan or derivative, Hymovis, for intra-articular injection, 1mg
- J7323 – Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
- J7324 – Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
- J7325 – Hyaluronan or derivative, Synvisc or Synvisc One®, for intra-articular injection, 1mg
- J7326 – Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
- J7327 – Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
- J7328 – Hyaluronan or derivative, Gelsyn-3, for intra-articular injection, 0.1mg
- J7329 – Hyaluronan or derivative, TriVisc, for intra-articular injection, 1mg
- J7331 – Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1 mg
- J7332 – Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
- J7333 – Hyaluronan or derivative, Visco-3, for intra-articular injection, per dose (code deleted effective 3/31/2021, see J7321 starting 4/1/2021)
- J3490 – Unclassified drugs (sodium hyaluronate inj 20mg/2mL)

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POLICY HISTORY

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