

TITLE:	VISCOSUPPLEMENTATION POLICY		
POLICY #:	MM-PNP-022		
VERSION #:	01		
DEPARTMENT:	UTILIZATION REVIEW		
ORIGINAL EFFECTIVE DATE:	12/01/2023		
CURRENT REVISION DATE:	N/A		

1. PURPOSE

Brand Selection for Medically Necessary Indications

Health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Synojoynt, Synvisc, Synvisc One, Triluron, and Trivisc viscosupplement products are more costly to Curative than other viscosupplement products for medically necessary indications. There is a lack of reliable evidence that Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Synojoynt, Synvisc, Synvisc One, Triluron, Trivisc, and are superior to the lower cost viscosupplement products: Durolane, Supartz FX, and Visco-3.

Preferred viscosupplements:

• Durolane, Supartz FX, and Visco-3.

All other viscosupplements are considered Non-Preferred.

2. SCOPE

Medical and Pharmacy UM Departments.

3. **DEFINITIONS**

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Note: Requires Prior Approval:

• Prior Approval of viscosupplementation products are required of all Curative participating providers and members in applicable plan designs.

Criteria for Initial Approval

- Curative considers viscosupplementation (hyaluronates) medically necessary for the 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., as 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
- o 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); and
- The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing); *and*
- 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); and
- 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; and
- 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; and
- The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.
- Curative considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

Continuation of Therapy

- Curative considers continuation of viscosupplement therapy medically necessary for treatment of osteoarthritis in knee when *all* of the following criteria are met:
- Member meets all initial medical necessity criteria; and
- Member has experienced improvement in pain and functional capacity following the previous injections; and
- At least 6 months have elapsed since the last injection in the prior completed series of injections.

Experimental and Investigational

- Curative considers intra-articular polynucleotides in the treatment of knee osteoarthritis experimental and investigational because the effectiveness of this approach has not been established.
- Ultrasound guidance, fluoroscopic guidance, and knee arthrography for viscosupplement injections is considered experimental and investigational because it has not been established that this approach will improve health outcomes.

- Curative considers viscosupplementation in combination with anesthetics, corticosteroids, mannitol/sorbitol, mesenchymal stem cells, or platelet rich plasma experimental and investigational because the effectiveness of these combinations has not been established. Note: Administration of local anesthetic to anesthetize the injection site for viscosupplementation is considered medically necessary.
- Curative considers amobarbital / hyaluronic acid hydrogel experimental and investigational for post-traumatic osteoarthritis (OA) prevention because the effectiveness for this indication has not been established.
- Curative considers intra-articular injection of an hexadecylamide derivative of hyaluronic acid experimental and investigational for the treatment of femoro-acetabular impingement because the effectiveness for this indication has not been established.
- Curative considers viscoelastic hydrogel Hymovis MO.RE experimental and investigational for the treatment of knee OA because the effectiveness for this indication has not been established.
- Curative considers viscosupplementation experimental and investigational for the following indications (not an all-inclusive list) because the effectiveness of viscosupplementation for these indications has not been established:
 - Chondromalacia patellae
 - Facet joint arthropathy
 - Following anterior cruciate ligament reconstruction
 - Following arthroscopic knee surgery/partial meniscectomy
 - For use in joints other than the knee (e.g., ankle, carpo-metacarpal joint, elbow, hip, metatarso-phalangeal joint, shoulder, thumb, and temporomandibular joint)
 - Hemophilic arthropathy
 - Meniscectomy
 - Muscle stiffness
 - Osteochondritis dissecans
 - Palendromic rheumatism
 - Partial or total knee arthroplasty
 - Patellofemoral arthritis
 - Patellofemoral syndrome (patellar knee pain)
 - Peripheral nerve pain
 - Plantar nerve entrapment syndrome
 - Psoriatic arthritis
 - Spastic hemiparesis
 - Treatment of first metatarsophalangeal osteoarthritis (hallux rigidus).

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Curative Medical and Pharmacy UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

- 11. COLLABORATING DEPARTMENTS
 - 11.1. Medical and Pharmacy UM Departments
- 12. DOCUMENT CONTROL

APPROVED BY:				
(Printed Name)	(Date)	(Signature)		

REVISION HISTORY					
Date	Author	Version	Comments		
			Initial Version		

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: