Clinical Policy: Hyaluronate Derivatives (Viscosupplementation)

Reference Number: TX.CP.MP.505 Coding Implications
Last Review Date: 11/25 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Hyaluronate derivatives are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (e.g., acetaminophen).

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that Hyaluronate Derivative preparations (viscosupplementation) for intra-articular injections of the knee are **medically necessary** when *all the following* criteria documented in the medical record are met:

A. Initial:
   1. Symptomatic OA of the knee. Pain that interferes with functional activities (such as, ambulation and prolonged standing).
   2. The diagnosis is supported by radiographic evidence of OA of the knee, for example, joint space narrowing, subchondral sclerosis, osteophytes, and subchondral cysts.
   3. Trial and failure or contraindication of at least 3 months of conservative therapy:
      a. Non-pharmacologic therapy (e.g., physical therapy, exercise, weight management, self-management programs, knee brace, cane).
      b. Pharmacologic therapy (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (oral, topical), topical capsaicin).
   4. Failure of or contraindication to intra-articular glucocorticoid injections.

B. Repeat Injections:
   1. For patients who have responded to a prior series, a REPEAT* series of viscosupplement therapy is considered reasonable and necessary when ALL the following are met:
      a. Patient continues to meet initial criteria.
      b. Symptoms have recurred.
      c. Patient has experienced improvement in pain and functional capacity following the previous series of injections.
      d. At least 6 months have elapsed since the prior series of injections.

   *Note: *A series is defined as a set of injections for each joint and each treatment as per the FDA prescribing information.*

II. The documentation must include the following:

A. Medical history and physical examination that supports symptomatic OA of the knee, and functional limitations.
B. X-ray report and/or notation in the medical record that confirms the diagnosis of OA of the knee.

C. Trial of conservative therapy, or failure, or contraindication to conservative therapy must be documented in the medical record.
D. Documentation must include whether 1 knee is being treated (which knee is being treated) OR both knees are being treated.
E. The frequency of injections and dosage given must be consistent with the FDA approved labeling and must be clearly documented.
F. Response to treatment must be noted.

Note: *The procedure and related care are within the scope of practice of the physician or appropriately trained provider's licensure.*

III. It is the policy of health plans affiliated with Centene Corporation® that Hyaluronate Derivatives (viscosupplementation) for intra-articular injections of the knee are **not medically necessary for the following indications:**

A. The dose and frequency of administration are *not consistent* with the FDA approved labeling. Doses and frequencies that exceed the FDA recommended dosage/frequency as per the prescribing information.
B. Initiation of a repeat series of treatment when at least 6 months have not elapsed since the prior series of injections.
C. As the initial treatment of OA of the knee.
D. It is contraindicated with infections or skin disease in the area of the injection site or joint.
E. It is contraindicated to administer these products if you are allergic to hyaluronate products.
F. A diagnosis other than OA.
G. When there was no improvement in knee pain and functional improvement from a previous series of injections, a repeat series of.
H. Imaging procedures for the purpose of needle guidance that may be considered reasonable and necessary are ultrasound or fluoroscopy. The documentation must support why imaging is needed for needle guidance and insertion. Other imaging modalities (e.g., computed tomography (CT) scan, magnetic resonance imaging (MRI), arthrography) for the purpose of needle guidance and insertion are not medically necessary.
I. There are no studies that have evaluated the efficacy of hyaluronate derivatives in members with OA and coexistent other inflammatory conditions such as rheumatoid arthritis.
J. Members who have had total knee arthroplasty in the targeted knee.

Background

General Information

In the United States (U.S.), osteoarthritis (OA) is the most common type of arthritis and joint disorder, with the knee being the most frequently involved symptomatic joint.[7]

Degenerative joint disease (usually termed OA) of the knee is a condition characterized by the progressive destruction of the articular cartilage that lines the knee joints, the subchondral bone surfaces, and synovium, accompanied by pain, immobility, and reduction in function and the ability to complete activities of daily living (ADL).[1] Knee OA is a chronic debilitating condition - predominantly occurring among the elderly - that affects a large share of the population worldwide. It is the predominant form of arthritis

and the leading cause of disability in the U.S.[5]

Hyaluronic acid (HA) is a component of synovial fluid, which lubricates the joint and absorbs shock. HA is a glycosaminoglycan molecule within the knee joint where it provides viscoelastic properties to synovial fluid.[3] HA is a glycosaminoglycan that occurs naturally within the synovial fluid of the knee, providing lubrication of the joint and protecting the cartilage from mechanical degradation. HA has been shown to provide anti-inflammatory and chondroprotective effects, increase proteoglycan and HA synthesis, and reduce nerve impulses and nerve sensitivity associated with OA pain.[16] HA production is generally reduced and may be of poorer quality with OA, which may exacerbate inflammation. Intra-articular HA aims to replace depleted or poor-quality HA in the joint. HA is available commercially prepared and ready for injection. HA products differ by molecular weight and cross-linkage.

HA injections reduce cartilage breakdown that results from a loss of cartilage oligomeric matrix protein and also reduces inflammatory cytokines such as interleukin-1.[7!]

HA is also known as Hyaluronan or Hyaluronate. Intra-articular injection of HA is also known as viscosupplementation. Viscosupplementation is the injection of an intra-articular compound made of high molecular weight fluid containing hylan products (derivative of hyaluronan) that essentially functions as a viscoelastic glycosaminoglycan.[8]

Patients with OA of the knee who are not responsive to conservative treatments, may be candidates for intra-articular HA for treatment of knee OA. There are several viscosupplementation products (such as Euflexxa®, Durolane®, Gel-One®, GenVisc® 850, Gelsyn-3®, Hyalgan®, Hymovis®, Monovisc®, Orthovisc®, Supartz FX®, Synvisc®, Synvisc-One®, SynoJoynt™, Visco-3™, TriVisc®, and Triluron®) that have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of pain associated with OA of the knee who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).

Dosage and Administration:

May not be complete list of therapies available.

Drug Name	Active Ingredient	Dose of Active Ingredient per Injection	Treatment Cycle*
Durolane	Hyaluronic acid	60 mg (3 mL)	1 injection
Euflexxa	Sodium hyaluronate	20 mg (2 mL)	3 injections
Gel-One	Cross-linked sodium hyaluronate	30 mg (3 mL)	1 injection
Gelsyn-3	Sodium hyaluronate	16.8 mg (2 mL)	3 injections
GenVisc 850	Sodium hyaluronate	25 mg (2.5 mL)	3-5 injections
Hyalgan	Sodium hyaluronate (Hyalectin®)	20 mg (2 mL)	3-5 injections
Hymovis	Sodium hyaluronate (HYADD®4)	24 mg (3 mL)	2 injections

Monovisc‡	Cross-linked sodium hyaluronate	88 mg (4 mL)	1 injection
Orthovisc‡	Sodium hyaluronate	30 mg (2 mL)	3-4 injections
Supartz FX	Sodium hyaluronate	25 mg (2.5 mL)	3-5 injections
Synojoynt	Sodium hyaluronate	20 mg (2 mL)	3 injections
Synvisc	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	16 mg (2 mL)	3 injections
Synvisc One	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	48 mg (6 mL)	1 injection
Triluron	Sodium hyaluronate	20 mg (2 mL)	3 injections
TriVisc	Sodium hyaluronate	25 mg (2.5 mL)	3 injections
VISCO-3	Sodium hyaluronate	25 mg (2.5 mL)	3 injections

*Treatment cycle: Total number of injections per cycle per knee (if treating both knees, double the number of injections per treatment cycle).
‡Per product label, one injection of Monovisc is equivalent to 3 injections of Orthovisc.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
N/A	N/A

HCPCS Codes	Description
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan, Supartz, or VISCO-3, for intra-articular injection, per dose
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
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, 1 mg
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, Gel-Syn, for intra-articular injection, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
J3470	Injection, hyaluronidase, Wydase, up to 150 units
J3471	Injection, hyaluronidase, Vitrase, ovine, preservative free, per 1 USP unit (up to 999 USP units)
J3472	Injection, hyaluronidase, Vitrase, ovine, preservative free, per 1000 USP units
J3473	Injection, hyaluronidase, Hylenex, recombinant, 1 USP unit

Reviews, Revisions, and Approvals	Date	Approval Date
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Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39260

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence.

Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.