Clinical Policy: Hyaluronate Derivatives

Reference Number: CP.PHAR.05
Effective Date: 10.01.08
Last Review Date: 11.24
Line of Business: Commercial, HIM-Medical Benefit*, Medicaid

Coding Implications
Revision Log

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

Description

The following are hyaluronate derivatives requiring prior authorization: sodium hyaluronate (Euflexxa®, Gelsyn-3™, GenVisc®850, Hyalgan®, Supartz FX™, Synojoynt™, Triluron™, TriVisc™, VISCO-3™), hyaluronic acid (Durolane®), cross-linked hyaluronate (Gel-One®), hyaluronan (Hymovis®, Orthovisc®, Monovisc®), and hylan polymers A and B (Synvisc®, Synvisc One®).

***For Health Insurance Marketplace (HIM),** coverage of hyaluronate derivatives is excluded for the pharmacy benefit and should not be approved using these criteria; these criteria may be used for medical benefit review.*

FDA Approved Indication(s)

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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that hyaluronate derivatives are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoarthritis of the Knee (must meet all)**:**

1. Diagnosis of OA of the knee supported by imaging (e.g., X-ray, MRI);
2. Prescribed by or in consultation with a rheumatologist, orthopedist, or sports medicine physician;
3. Inadequate response to physical therapy as directed by a physical therapist;
4. Failure of a ≥ 4-week trial of one of the following (a or b), as evidenced by claims history, unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Oral non-steroidal anti-inflammatory drug (NSAID) at continuous therapeutic (prescription strength) dosing;
   b. Topical NSAID* if member is ≥ 75 years old or unable to take oral NSAIDs;
   **Prior authorization may be required for topical NSAIDs*
5. Trial of at least one intra-articular glucocorticoid injection with a documented positive but inadequate response *(see Appendix D for examples)* unless contraindicated or history of intolerance;

**Prior authorization may be required for intra-articular glucocorticoids*

6. If request is for a product other than Euflexxa, Monovisc, Orthovisc, Synvisc, and Synvisc One: Failure of two of the following (a, b, or c), unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Euflexxa;
   b. Monovisc or Orthovisc;
   c. Synvisc or Synvisc One;
7. Member does not have any of the following:
   a. Coexistent active inflammatory arthritis other than OA (e.g., rheumatoid arthritis, spondylitis, gouty arthritis) in the targeted knee;
   b. History of total knee arthroplasty in the targeted knee;
8. Dose does not exceed one treatment cycle per knee for a 6 month period.

Approval duration: 6 months (one treatment cycle per knee) (*refer to section V*)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, HIM-Medical Benefit) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for HIM-Medical Benefit, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for HIM-Medical Benefit, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Osteoarthritis of the Knee (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy as evidenced by the following, including but not limited to:
   a. Decrease in pain symptoms as evidenced by improvement in the Visual Analog Scale for pain;
   b. Improvement in ambulation or range of motion;
   c. Improvement in stiffness;
   d. Decrease in rescue pain medication use;

3. Member has not had total knee arthroplasty in the targeted knee;
4. If request is for a product other than Euflexxa, Monovisc, Orthovisc, Synvisc, and Synvisc One: Failure of two of the following (a, b, or c), unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Euflexxa;
   b. Monovisc or Orthovisc;
   c. Synvisc or Synvisc One;
5. Six or more months have elapsed since the last treatment cycle;
6. Dose does not exceed one treatment cycle per knee.

Approval duration: 6 months (one treatment cycle per knee) *(refer to section V)*

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, HIM-Medical Benefit) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for HIM-Medical Benefit, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for HIM-Medical Benefit, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for HIM-Medical Benefit, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drug
OA: osteoarthritis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Oral NSAIDs		
diclofenac (Voltaren®)	50 mg PO TID	150 mg/day
etodolac (Lodine®)	400-500 mg PO BID	1,200 mg/day
fenoprofen (Nalfon®)	400 mg PO TID to QID	3,200 mg/day
ibuprofen (Motrin®)	400-800 mg PO TID to QID	3,200 mg/day
indomethacin (Indocin®)	25-50 mg PO BID to TID	200 mg/day
indomethacin SR (Indocin SR®)	75 mg PO QD to BID	150 mg/day
ketoprofen (Orudis®)	25-75 mg PO TID to QID	300 mg/day
meloxicam (Mobic®)	7.5-15 mg PO QD	15 mg/day
naproxen (Naprosyn®)	250-500 mg PO BID	1,500 mg/day
naproxen sodium (Anaprox®, Anaprox DS®)	275-550 mg PO BID	1,650 mg/day
oxaprozin (Daypro®)	600-1,200 mg PO BID	1,800 mg/day
piroxicam (Feldene®)	10-20 mg PO QD	20 mg/day
salsalate (Disalcid®)	500-750 mg PO TID, titrated up to 30,00 mg QD	3,000 mg/day
sulindac (Clinoril®)	150 mg-200 mg PO BID	400 mg/day
tolmetin DS (Tolectin DS®)	400 mg PO TID, titrated up to 1,800 mg QD	1,800 mg/day
Topical NSAIDs		
diclofenac 1.5% (Pennsaid®)	40 drops QID on each painful knee	320 drops/day
Voltaren® Gel 1% (diclofenac)	2-4 g applied to affected area QID	32 g/day
Intra-articular glucocorticoids		
Kenalog® (triamcinolone acetonide)	40 mg (1 mL) for large joints	80 mg/treatment
Hexatrione® (triamcinolone hexacetonide)	10-40 mg for large joints	40 mg/treatment
methylprednisolone acetate (Depo-Medrol®)	20-80 mg for large joints	80 mg/treatment
hydrocortisone acetate	25-50 mg for large joints	75 mg/treatment
Zilretta® (triamcinolone acetonide)	32 mg (5 mL) for large joints	32 mg/treatment

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Durolane, Euflexxa, Gelsyn-3, GenVisc 850, Hyalgan, Supartz FX, Synojoynt, Triluron, TriVisc, VISCO-3, Gel-One, Hymovis, Orthovisc, Monovisc, Synvisc, Synvisc One:
    - Known hypersensitivity to hyaluronan preparations
    - Patients with knee joint infections, infections, or skin disease in the area of the injection site
  - Hymovis, Monovisc, Orthovisc: do not administer to patients with known hypersensitivity to gram positive bacterial proteins
  - Monovisc: do not administer to patients with known systemic bleeding disorders
- Boxed warning(s): none reported

Appendix D: General Information

- Examples of documented positive but inadequate response to intra-articular glucocorticoid injections include but are not limited to the following: inadequate pain relief, frequent need of rescue medications such as NSAIDs or opioids, need to decrease or inability to increase activity levels, adequate pain relief but with steroid-induced hyperglycemia.
- Per the 2014 and 2019 Osteoarthritis Research Society International guidelines, hyaluronate derivatives are not appropriate for multiple joint OA subtypes or joint OA other than the knee.
  - In DeGroot et al., single hyaluronic acid was compared to saline injection in a small RCT (N=64). At 6 and 12 weeks, there were no significant differences in improvement between the two groups on the American Orthopedic Foot and Ankle Society clinical rating score, the Ankle Osteoarthritis Scale score, or the patient-reported visual analog pain scale. Migliore et al., conducted a review of seven studies for ankle OA that showed mixed results, but were unable to complete a meta-analysis due to use of study design limitations (e.g., inconsistent use of primary endpoints, varying comparators, small sample size) leading to study heterogeneity.
  - Richette et al. conducted a multicenter, randomized, placebo-controlled trial in hip OA. At 3 months, hyaluronic acid was not more effective than placebo with a treatment difference in pain score of −0.15 (95% CI −11.04, 10.74). Responder rates were 33.3% for hyaluronic acid and 32.6% for placebo (p = 0.94). Additionally, analgesics were taken by 81% of study days by patients on placebo, and 88% of patients in the hyaluronic acid group.
- There are no studies that have evaluated the efficacy of hyaluronate derivatives in patients with OA and coexistent other inflammatory conditions such as rheumatoid arthritis.
- There is no data to suggest efficacy of hyaluronate derivatives in patients who have had total knee arthroplasty in the targeted knee.

V. Dosage and Administration

Drug Name	Active Ingredient	Dose of Active Ingredient per Injection	Treatment Cycle*
Durolane	Hyaluronic acid	60 mg (3 mL)	1 injection

Drug Name	Active Ingredient	Dose of Active Ingredient per Injection	Treatment Cycle*
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.

VI. Product Availability

Drug Name	Active Ingredient	Availability**
Durolane	Hyaluronic acid	3 mL syringe
Euflexxa	Sodium hyaluronate	2.25 mL syringe
Gel-One	Cross-linked sodium hyaluronate	3 mL syringe
GenVisc 850	Sodium hyaluronate	3 mL syringe
Gelsyn-3	Sodium hyaluronate	2.25 mL syringe
Hyalgan	Sodium hyaluronate (Hyalectin®)	2 mL vial or 2 mL syringe
Hymovis	Sodium hyaluronate (HYADD®4)	5 mL syringe
Monovisc‡	Cross-linked sodium hyaluronate	5 mL syringe
Orthovisc‡	Sodium hyaluronate	3 mL syringe
Supartz FX	Sodium hyaluronate	2.5 mL syringe
Synojoynt	Sodium hyaluronate	3 mL syringe
Synvisc	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	2.25 mL syringe

Drug Name	Active Ingredient	Availability**
Synvisc One	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	10 mL syringe
TriVisc	Sodium hyaluronate	3 mL syringe
Triluron	Sodium hyaluronate	2 mL syringe or 2 mL vial
VISCO-3	Sodium hyaluronate	2.5 mL syringe

** All syringes/vials are single-use (i.e., one injection/one knee); syringes are pre-filled.
‡Per product label, one injection of Monovisc is equivalent to 3 injections of Orthovisc.

VII. References

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Coding Implications
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.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review: no significant changes; added examples of positive but inadequate response to intra-articular glucocorticoids to Appendix D; moved examples of positive response to therapy from Appendix D to criterion 2 in section IIA; references reviewed and updated; revised HIM medical benefit to HIM line of business.	11.26.19	02.20
4Q 2020 annual review: added sports medicine physician as acceptable specialist; references reviewed and updated.	08.10.20	11.20
Revised requirement for diagnosis confirmation by radiologic imaging – generalized to imaging beyond just radiologic type (i.e., to include MRIs); imaging reference added.	12.09.20	02.21
Clarified physical therapy should be supervised by a physical therapist and added hyaluronate product preferencing in continued therapy section.	04.13.21	05.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: added allowable treatment number per duration to initial and continued criteria; references reviewed and updated.	07.20.21	11.21
4Q 2022 annual review: no significant changes; updated HCPCS code J7321; removed Supartz as the Medispan is obsolete and no longer available; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	08.17.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	08.11.23	11.23
Revised HIM line of business to HIM medical benefit as hyaluronates are excluded from the HIM pharmacy benefit.	02.12.24	
Removed specialty prescriber exception for New Mexico Community Care.	05.07.24	
4Q 2024 annual review: no significant changes; updated HCPCS code description for J7321 and removed J7333; references reviewed and updated.	07.19.24	11.24

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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.