Effective Date:
Last P&T Approval/Version: 10/27/2021
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Policy Number: C14676-A

Hyaluronic Acid Injections_Viscosupplementation for Knee OA

PRODUCTS AFFECTED

Durolane (sodium hyaluronate injection), Euflexxa (sodium hyaluronate injection), Gel-One (sodium hyaluronate injection), Gelsyn-3 (sodium hyaluronate injection), GenVisc 850 (sodium hyaluronate injection), Hyalgan (sodiumhyaluronate injection), Hymovis (high molecular weight viscoelastic hyaluronan injection), Monovisc (high molecular weight hyaluronan injection), Orthovisc (high molecular weight hyaluronan injection), Supartz (sodium hyaluronate), Synvisc(hylan G-F 20 sodium hyaluronate injection), Synvisc-One (hylan G-F 20 sodium hyaluronate injection), TriVisc (sodium hyaluronate injection), Visco-3 (sodium hyaluronate injection), Synojoynt (sodium hyaluronate injection), Triluron (sodium hyaluronate injection), 1% Sodium Hyaluronate

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any./
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Osteoarthritis (OA) of the Knee

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. OSTEOARTHRITIS (OA) OF THE KNEE

1. Diagnosis of osteoarthritis of the knee confirmed by radiologic evidence of OA (i.e., joint space narrowing, subchondral sclerosis, osteophytes, and sub- chondral cysts) confirmed by ANY of the following: X-ray, Kellgren-Lawrence (K-L) Grade 2 or 3 in the index knee; MRI; CT scan; ultrasound]
   AND
2. Documentation of member's affected knee(s): Left, right or both knees to be treated.
   NOTE: Bilateral injections may be allowed only if both knees meet criteria.
   AND
3. Prescriber attestation that member has no evidence of inflammatory arthritis (*e.g., rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, and systemic lupus erythematosus)* and other causes of musculoskeletal pain, including referred pain, bursitis, and inflammatory rheumatic diseases have been ruled out.
   Informational Note: Safety and efficacy in joints with severe inflammation have not been established. 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.
   AND
4. Prescriber attests that member has NOT had a history of failure on hyaluronic intra-articular injection (applicable to member's medical history prior to, and as a Molina member). Requests will not be authorized for members who have failed to respond to ANY previous visco supplementation therapy.
   Informational Note: There is a lack of reliable evidence that any one brand of viscosupplement is more effective to other brands for medically necessary indications. There are also a lack of studies demonstrating that individuals who fail to respond to one brand of viscosupplement will respond to other brands of viscosupplements.
   AND
5. Prescriber attests that surgical knee replacement is not a planned treatment option within 6 months of intra-articular viscosupplementation administration
   Informational Note: There is no data to suggest efficacy of hyaluronate derivatives in patients who have had total knee arthroplasty in the targeted knee.
   AND
6. Documentation that the member has tried and has experienced Ineffectiveness/failure (*defined as symptoms inadequately controlled after an adherent 3-month trial unless specified*), clinical intolerance (defined as an intolerance to the drug or its excipients); or FDA-labeled contraindication(s)* in the affected joint to the following treatments. Documentation of TWO of the three following modalities of therapy required (a, b, or c)
   a. At least one course of physical therapy (PT) for knee osteoarthritis
      OR
   b. At least TWO of the following pharmacologic therapies [ii, iii, or iv] [verification of therapies required]:
      i. Non-steroidal anti-inflammatory drugs [Contraindications may include: 1) Compromised GI function or at risk of GI bleeding due to the adverse events of NSAIDs, 2) Concomitant anticoagulant therapy for any condition, 3) Cardiovascular or renal risk factors precluding use of COX-2 inhibitors]
      ii. Acetaminophen (up to 1 g 4 times/day)
      iii. Tramadol (Ultram/XR, generics)
      iv. Duloxetine (Cymbalta, generics)OR
   c. At least TWO injections of IA corticosteroids to the affected knee [Contraindications may include: increase in risk of local or systemic bacterial infection]

   Molina staff: Verify pharmacy claims data for above medications and compliance. For new members to Molina Healthcare, confirm medications use in medical or chart notes. Non- compliance or non-adherence does <u>not</u> constitute

AND

7. IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of CLINICAL MEDICAL rationale for the inability to utilize the preferred formulary hyaluronate products.
   OR
   FOR MEDICAL BENEFIT CLAIMS (i.e., HCPC billing by a prescriber) REQUESTS: Documentation of CLINICAL MEDICAL rationale for the inability to utilize the preferred hyaluronate product.

CONTINUATION OF THERAPY:

Member meets ALL of the following criteria for re-treatment. Clinical documentation required.

1. Submission of relevant medical records or chart notes documenting continued efficacy. The prescribing physician should periodically reassess the need for continuation of therapy based on the member's condition and continued need at least ONCE annually.
   AND
2. Positive response to therapy documented by ALL of the following:
   a. Significant improvement in pain and functional capacity as the result of the previous series of injections as indicated by any type of objective/quantification method, such as Visual Analog Scale for pain, joint mobility, reduction in effusion, and/or patient-response-based questionnaires
      NOTE: If the initial or prior series of injections is not proven, or documented as beneficial to the member, it is not considered medically necessary to repeat the therapy and a repeat series of injections will not be authorized.
      AND
   b. A significant reduction in the dose/utilization of NSAIDs (or other analgesics or anti-inflammatory medication)
      AND
   c. A reduction in the number of accompanying intra-articular corticosteroid injections during the six (6) month period following the previous series of injections

   AND
3. At least six (6) months have elapsed since the initial or prior treatment cycle
   AND
4. Member has not had total or partial joint replacement surgery
   Informational Note: There are no clinical trials evaluating the use of sodium hyaluronate in persons following total or partial joint replacement surgery.

DURATION OF APPROVAL:

Initial authorization: A single course per joint every 6 months

Continuation of treatment: At least **six (6) months** have elapsed since the initial or prior treatment cycle for the respective joint. Re-authorization is required every **6 months** to determine effectiveness of therapy and continued need based on documented positive clinical response. *Refer to 'Continuation of Therapy' section.*

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified orthopedic surgeon, pain management specialist, rheumatologist, physical medicine and rehabilitation specialist, or a sports medicine specialist. Submit consultation notes if applicable.

NOTE: Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually.

AGE RESTRICTIONS:

18 years of age or older

The safety and effectiveness have not been established in pediatric patients

QUANTITY:

Table 1: FDA Labeled Dosage per Treatment Course per Joint		
Drug	**Dose**	**Total Injections**
Durolane (hyaluronic acid)	60 mg (3 ml) intra-articularly **once**	1 injection
Euflexxa (1% sodium hyaluronate)	20 mg (2 mL) intra-articularly once weekly for 3 weeks	3 injections
Gel-One (Cross-linked Hyaluronate)	30 mg (3 mL) intra-articularly **once**	1 injection
Gelsyn-3 (0.84% sodium hyaluronate)	16.8 mg (2 mL) intra-articularly once weekly for 3 weeks	3 injections
GenVisc 850 (sodium hyaluronate)	25 mg (2.5 mL) intra-articularly once weekly for 5 weeks. Some patients may benefit from 3 injections given at weekly intervals	3 to 5 injections
Hyalgan (sodium hyaluronate)	20 mg (2 mL) intra-articularly once weekly for 5 weeks. Some patients may benefit with 3 injections given at weekly intervals	5 injections
Hymovis (high molecular weight hyaluronan)	24 mg (3 mL) intra-articularly once weekly for 2 weeks (total of 2 injections)	2 injections
Monovisc (high molecular weight hyaluronan)	88 mg (4 mL) intra-articularly once	1 injection
Orthovisc (high molecular weight hyaluronan)	30 mg (2 mL) intra-articularly once weekly for 3 or 4 weeks	3 to 4 injections
Supartz FX	25 mg (2.5 mL) intra-articularly once weekly for 5 weeks. Some patients may benefit with 3 injections given at weekly intervals	3 to 5 injections
Synvisc One (Hylan G-F 20)	48 mg (6 mL) intra-articularly once	1 injection
Synvisc (Hylan G-F 20)	16 mg (2 mL) intra-articularly once weekly for 3 weeks	3 injections
Triluron (sodium hyaluronate)	20 mg (2 mL) once weekly for 3 weeks	3 injections
TriVisc (sodium hyaluronate)	25 mg (2.5 mL) once weekly for 3 weeks	3 injections
Visco-3	25 mg (2.5 mL) intra-articularly once weekly for 3 weeks	3 injections

Maximum Quantity Limits –
The dose of an injection and the number of injections per treatment cycle exceeding FDA labeling will not be authorized (refer to Table 1 above)

PLACE OF ADMINISTRATION:
The recommendation is that intra-articular injection medications in this policy will be for pharmacy or medical benefit coverage and be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intra-articular injection directly into the knee joint

DRUG CLASS:
Antirheumatic Miscellaneous

FDA-APPROVED USES:
Osteoarthritis of the Knee
Treatment of pain in osteoarthritis of the knee in patients who have failed nonpharmacologic treatment and simple analgesics
(*Durolane*, *Euflexxa*, *Gel-One*, *Gelsyn-3*, *GenVisc 850*, *Hyalgan*, *Hymovis*, *Monovisc*, *Orthovisc*, sodium hyaluronate [Teva], *Supartz FX*, *Synvisc-One*, *Triluron*, *TriVisc*, *Visco-3*) or nonsteroidal anti-inflammatory drugs(*Gel-One*)

COMPENDIAL APPROVED OFF-LABELED USES:
The FDA has not approved an intra-articular hyaluronan for joints other than the knee.

APPENDIX

APPENDIX:
Comparison of OA Management Guidelines

- Comparison of 2 guidelines (AAOS 2013, VA/DoD 2014) on nonsurgical management of osteoarthritis of the knee Reference: National Guideline Clearinghouse 2016 Jun 13:50210
- Comparison of 16 guidelines on the management of osteoarthritis
  Reference: Semin Arthritis Rheum 2014 Jun;43(6):701

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Clinical studies of sodium hyaluronate and hylan G-F-20 have demonstrated that injection of these agents into the joint space of osteoarthritic knees is sometimes marginally more effective than placebo procedures in reduction of pain and improvement in functional capacity in some patients. These marginal beneficial results are more pronounced with the larger molecular weight compound hylan G-F20.

There is no data indicating that these agents reverse or delay the osteoarthritic process in the injected joints. The long-term effects of repeated injections are unknown.

Clinical Practice Guidelines

- The majority of guidelines did not find sufficient evidence to make a recommendation for or against the use of HA for knee OA. Refer to 'Supplemental Information' section for additional

references andlinks for comparisons of guidelines.

- There is inconsistent evidence and limited effectiveness data that viscosupplementation, or HA products, produces clinically relevant improvements in pain and functioning for OA of the knee and no evidence to suggest it delays the progression of OA nor the progression to knee replacement.
- Several major practice guidelines have been unable to recommend intraarticular HA, with others recommending against its use with several other major organizations.

National and Specialty Organizations

American Academy of Orthopedic Surgeons (AAOS) In the second edition of the evidence-based guidelines on treatment of OA of the knee, the AAOS issued a "Strong" recommendation against the use ofHA for knee OA due to lack of efficacy (AAOS, 2013).

National Institute for Health and Care Excellence (NICE 2014) recommended against HA for knee OA

American College of Rheumatology (ACR 2012) clinical practice guidelines on osteoarthritis indicate they have no recommendations regarding the use of IAHA in the knee. Recommendations for the use of pharmacologic therapies in knee OA include acetaminophen, oral and topical NSAIDs, tramadol and intra- articular corticosteroid injections. The ACR conditionally recommends IA-HA for patients who had inadequate relief with initial treatment for knee OA in evidence-based guidelines (Hochberg et al., 2012). An update of this guideline is anticipated in 2018 (Osteoarthritis: Call for Public Comment on Project Plan).

American Medical Society for Sports Medicine (AMSSM) Based on findings from their systematic review with network meta-analysis, the AMSSM recommended IA-HA for appropriate patients with knee OA. Criteriafor appropriate patients were not reported. (Trojian et al., 2016)

Osteoarthritis Research Society International (OARSI) 2014 guideline update provided an "uncertain" ommendation for IAHA, indicating an overall small effect size on pain, inconsistent results among the available meta-analyses, and one meta-analysis signaling potential for serious safety concerns, influenced their recommendation.

ECRI Institute. Viscosupplementation for Treating Osteoarthritic Knee Pain A 2019 ECRI report on viscosupplementation summarized evidence from 8 systematic reviews and 6 RCTs (total patients = 12,775) to be inconclusive for treating knee pain due to OA. While IA HA injections may provide relief in some patients, uncertainty remains about the most effective formulations, which populations benefit most, and whether HA should be combined with other agents to increase efficacy. (ECRI; 2019)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

The following are considered **contraindications/exclusions** based on insufficient evidence: -

1. Hypersensitivity to hyaluronan preparations, or allergies to avian or avian-derived products (including eggs, feathers, or poultry) NOTE: Not applicable to Orthovisc
   Informational Note: HA is derived from chicken combs (Gel-One, Hyalgan, Supartz FX, Synvisc, Synvisc-One, Visco-3) or bacterial cells (Euflexxa, Gelsyn-3, Hymovis, Monovisc, Orthovisc)
2. Hymovis, Monovisc and Orthovisc only: known hypersensitivity to gram positive bacterial proteins
3. Monovisc and Durolane only: known systemic bleeding disorders
4. Any of the following conditions:
   a. Active inflammatory joint disease or synovitis affecting the knee, such as crystal induced synovitis, rheumatoid arthritis
   b. Knee joint infections (septic arthritis) or a local skin disease or infection in the area of the injection site

c. Pregnant or nursing

The following are considered conditions for **discontinuation of treatment** and re-treatment may not be authorized:-

1. Intolerable adverse effects or absence of unacceptable toxicity from the drug
2. Persistent and uncorrectable problems with adherence to treatment
3. Poor response to treatment as evidenced by physical findings and/or clinical symptoms

The following are considered **experimental, investigational and unproven** based on insufficient evidence:

1. Any indications other than those listed above (i.e., Injection of these products for indications other than the diagnosis OA, or use of the requested products for injection into any joint other than the knee)

COSMETIC USE IS NOT A COVERED BENEFIT

The FDA has approved several products containing a transparent HA gel to improve the contours of the skin. These products are used to treat acne, scars and wrinkles on the skin by temporarily adding volume to facial tissue and restoring a smoother appearance to the face (may not be an all-inclusive list):

- Restylane injectable gel received Premarket approval (PMA) approval March 25, 2005
- Perlane injectable gel received PMA approval May 2, 2007
- Hylaform received PMA approval April 22, 2004
- Juvéderm 24HV, Juvéderm 30 & Juvéderm 30HV Gel Implants received PMA approval June 2, 2006

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS	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 Effective Date: 04/01/2021
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, GelSyn-3, 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
J7333	Hyaluronan or derivative, VISCO-3, for intra-articular injection, per dose--Effective July 1, 2020 Discontinue existing HCPCS code J7333 "Hyaluronan or derivative, visco-3, for intra-articular injection, per dose." --Effective Date: 03/31/2021

AVAILABLE DOSAGE FORMS:

Several HA agents are available, with varying molecular weights and injections per course of treatment (single injection HAs and those requiring 3 to 5 injections per course of treatment). Refer to Table 1 in 'Coverage Policy' section above

REFERENCES

Government Agency

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2. Centers for Disease Control and Prevention. Osteoarthritis Fact Sheet. Available at https://www.cdc.gov/arthritis/basics/osteoarthritis.htm. February 7, 2018; Accessed February 2021.

Prescribing Information and Drug Compendia

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4. Euflexxa (sodium hyaluronate) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc; July 2016.
5. Hyalgan (hyaluronic acid derivative) [prescribing information]. Parsippany, NJ: Fidia Pharma; May 2014.
6. Hymovis (hyaluronic acid derivative) [prescribing information]. Parsippany, NJ: Fidia Pharma; October 2015.
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12. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
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14. Supartz FX (sodium hyaluronate) [prescribing information]. Durham, NC: Bioventus; April 2015.
15. Triluron (sodium hyaluronate) [prescribing information]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
16. TriVisc (sodium hyaluronate) [prescribing information]. Doylestown, Pennsylvania: OrthogenRx Inc; September 2018.
17. Visco-3 (sodium hyaluronate) [prescribing information]. Warsaw, IN: Zimmer; received April 2017.
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Peer Reviewed Publications

24. Bannuru RR, Schmid CH, Kent DM, et al. Comparative Effectiveness of Pharmacologic Interventions for Knee Osteoarthritis: a systematic review and network meta-analysis. Ann Intern Med. 2015 Jan 6;162(1):46-54. doi: 10.7326/M14-1231. PMID: 25560713. Accessed Mar 2021

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National and Specialty Organizations

26. Agency for Healthcare Research and Quality. Treatment of Osteoarthritis of the Knee: An Update Review. Comparative Effectiveness Review No. 190. (Prepared by the RAND Southern California Evidence-based Practice Center under Contract No. 290-2015-00010-I.) AHRQ Publication No.17-EHC011-EF. May 2017. Available at: Link Accessed Feb 2021
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29. American College of Rheumatology (ACR).
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