Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 13.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Viscosupplementation using hyaluronan injections (Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Triluron, TriVisc, Visco-3)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Viscosupplementation using hyaluronan injections (Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Triluron, TriVisc, Visco-3)

II. Purpose/Objective:
To provide a policy of coverage regarding Viscosupplementation using hyaluronan injections

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Hyaluronan, also known as hyaluronic acid, is a naturally occurring macromolecule that is a major component of synovial fluid. In osteoarthritis, there are changes in the quality and quantity of hyaluronan in the synovial fluid and cartilage. Intra-articular injection of hyaluronan has been proposed as a means of restoring viscoelasticity of the synovial fluid in patients with osteoarthritis. This treatment is also known as viscosupplementation.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

NOTE: For commercial, exchange, and CHIP lines of business, Durolane, Euflexxa, Gelsyn-3, Supartz FX, Synvisc, and Synvisc One are preferred agents and DO NOT Require Prior Authorization

Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Triluron, TriVisc, and **Visco-3** require Prior Authorization and will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of "bone-on-bone", morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion **AND**

- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities **AND**

- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief **AND**

- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID's are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period **AND**

- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus **AND**

- Physician documentation of failure on, intolerance to or contraindication to three (3) of the following: Durolane, Euflexxa, Gelsyn-3, Supartz FX, Synvisc, and/or Synvisc One

AUTHORIZATION DURATION/QUANTITY LIMIT: Initial approval will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria). Subsequent approvals will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) when members meet the following criteria:

- Repeat treatment cycles are considered medically necessary when ALL of the following criteria are met:
  - Medical record documentation of significant improvement in pain and function following the previous injection **AND**
  - Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections **AND**
  - Six months or longer have elapsed since the last injection in the previous series.

LIMITATIONS:

- Durolane treatment course is limited to 1 injection in a 6-month period
- Euflexxa treatment course is limited to 3 injections, one week apart, in a 6-month period
- Gel-One treatment course is limited to 1 injection in a 6-month period.
- Gelsyn-3 treatment course is limited to 3 injections in a 6-month period.
- GenVisc 850 treatment course is limited to 5 injections in a 6-month period.
- Hyalgan (sodium hyaluronate) treatment course is limited to 5 injections in a 6-month period.
- Hymovis treatment course is limited to 2 injections in a 6-month period.
- Monovisc treatment course is limited to 1 injection in a 6-month period.
- Orthovisc treatment course is limited to 4 injections in a 6-month period.
- Supartz treatment course is limited to 5 injections in a 6-month period.

- Synojoynt treatment course is limited to 3 injections in a 6-month period.
- Synvisc (Hylan G-F 20) treatment course is limited to 3 injections in a 6-month period.
- Synvisc One treatment is limited to 1 injection in a 6-month period.
- Triluron treatment course is limited to 3 injections in a 6-month period.
- TriVisc treatment course is limited to 3 injections in a 6-month period.
- Visco-3 treatment course is limited to 3 injections in a 6-month period.
- Treatment requires referral to and should be rendered by a participating Orthopedic surgeon or Rheumatologist.
- Bilateral injections may be allowed if both knees meet the required coverage criteria.

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis.
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

NOTE: For the Medicare line of business, Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz FX, Synvisc, Synvisc-One, and Visco-3 are preferred agents and DO NOT require Prior Authorization.

Gel-One, Hymovis, Monovisc, Synojoynt, Triluron, and TriVisc require Prior Authorization and will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of "bone-on-bone", morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion **AND**

- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities **AND**

- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief **AND**

- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID's are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period **AND**

- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus **AND**

- Physician documentation of failure on, intolerance to or contraindication to two (2) of the following: Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz FX, Synvisc/Synvisc-One, and Visco-3

AUTHORIZATION DURATION/QUANTITY LIMIT: Initial approval will be for **six (6) months** and will be **limited to one (1) treatment course** to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria). Subsequent approvals will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) when members meet the following criteria:

- Repeat treatment cycles are considered medically necessary when ALL of the following criteria are met:
  - Medical record documentation of significant improvement in pain and function following the previous injection **AND**
  - Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections **AND**
  - Six months or longer have elapsed since the last injection in the previous series.

LIMITATIONS:

- Durolane treatment course is limited to 1 injection in a 6-month period
- Euflexxa treatment course is limited to 3 injections, one week apart, in a 6-month period
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- Monovisc treatment course is limited to 1 injection in a 6-month period.
- Orthovisc treatment course is limited to 4 injections in a 6-month period.
- Supartz treatment course is limited to 5 injections in a 6-month period.
- Synojoynt treatment course is limited to 3 injections in a 6-month period.
- Synvisc (Hylan G-F 20) treatment course is limited to 3 injections in a 6-month period.
- Synvisc One treatment is limited to 1 injection in a 6-month period.
- Triluron treatment course is limited to 3 injections in a 6-month period.
- TriVisc treatment course is limited to 3 injections in a 6-month period.
- Visco-3 treatment course is limited to 3 injections in a 6-month period.
- Treatment requires referral to and should be rendered by a participating Orthopedic surgeon or Rheumatologist.
- Bilateral injections may be allowed if both knees meet the required coverage criteria.

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- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

- Gel-One [prescribing information]. Tokyo, Japan: Seikagaku Corporation; May 2011.
- Hymovis [prescribing information]. Parsippany, NJ: Fidia Pharma; October 2015.
- Monovisc [prescribing information]. Bedford, MA: Anika Therapeutics; July 2020.
- Triluron [prescribing information]. Florham Park, NJ: Fidia Pharma USA Inc; July 2019.
- TriVisc [prescribing information]. Doylestown, Pennsylvania: OrthogenRx Inc; November 2019.
- Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis & Rheumatology. 2020 February; 72(2):220-233 [cited 2023 Dec 27]. Available from: https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Osteoarthritis
- American Academy of Orthopaedic Surgeons. Management of Osteoarthritis of the Knee (Non-Arthroplasty) – Evidence-Based Clinical Practice Guideline. Rosemont, IL: American Academy of Orthopaedic Surgeons; 2021 August 31 [cited 2022 January 26]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf

This policy will be revised as necessary and reviewed no less than annually.

Devised: 04/30/98

Revised: 7/02, 4/03, 9/04; 5/05 (Add Orthovisc, Supartz), 11/07 (Add Euflexxa); 10/08 (add prior auth requirement), 7/09 (revise PA requirement, add Synvisc One, Medicaid Business Segment) 08/14, 03/24/15 revised limitations, 7/19/16 (clarified form alternative criteria), 3/20/18 (form products, auth duration), 3/19/19 (Durolane and preferred products), 1/10/23 (LOB carve out), 8/25/23 (Added Trivisc, Triluron, Synojoynt, LCD language removal, add Medicare specific criteria, Medicaid Business Segment), 4/17/24 (Added Medicare preferred agents from Nov 2023 P&T, references added), 3/25/25 (LOB table, taglines, Spartz FX into criteria)

Reviewed: 10/06, 8/10, 10/11, 08/14, 09/14, 3/31/16, 5/16/17, 2/26/19, 2/1/20, 1/19/21, 1/13/22

MA UM Committee approval: 12/31/23, 12/31/24, 4/29/25