Medical Necessity Guidelines:
Viscosupplements

Effective: December 31, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Osteoarthritis (OA) is the most common form of arthritis in the United States. Patients with OA have pain that typically worsens with weight bearing and activity and improves with rest, as well as morning stiffness and gelling of the involved joint after periods of inactivity. Although there is no known cure for OA, treatment designed for the individual patient can reduce pain, maintain and/or improve joint mobility and limit functional impairment.

Osteoarthritis is characterized by a loss of articular cartilage, which has a highly limited capacity to heal itself. Along with these cartilage changes, a reduction in the elastic and viscous properties of the synovial fluid occurs. The molecular weight and concentration of the naturally occurring hyaluronic acid decreases. Theoretically, this loss of elastoviscosity decreases the lubrication and protection of the joint tissues and is one postulated mechanism of pain production in osteoarthritis. Pharmacologic treatment generally consists of analgesics and/or nonsteroidal anti-inflammatory drugs (NSAIDs). Physical therapy can be used, with exercises to maintain range of motion and strength. Intra-articular corticosteroid injections are often used for transient symptom relief. When conservative measures fail, surgical treatments limited to arthroscopic debridement, osteotomies to redistribute load and total joint replacements have been the only options until recently.

Viscosupplementation involves a series of intra-articular injections of hyaluronic acid into the knee. The exact mechanism of action of viscosupplementation is unclear. Although restoration of the elastoviscous properties of synovial fluid seem to be the most logical explanation; other mechanisms must exist. The following drugs containing hyaluronic acid derivatives are FDA-approved for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesic: Euflexxa, Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3.

Note: Euflexxa does not require prior authorization for all senior products.

STEP THERAPY:

Some medically administered Part B drugs may have additional requirements or limits on coverage. These requirements and limits may include step therapy. This is when we require you to first try certain preferred drugs to treat your medical condition before we will cover another non-preferred drug for that condition.

This policy supplements Medicare Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) for the purpose of determining coverage under Medicare Part B medical benefits and applies step therapy for Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3.

This policy applies step therapy for Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3. This list indicates the common uses for which Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3 is prescribed. This list can change from time to time.

Drug Class	Non-Preferred Product(s)	Preferred Product(s)
Viscosupplements	Durolane Gel-One Gel-Syn GenVisc 850 Hyalgan Hymovis Monovisc Orthovisc Supartz Synojoynt Synvisc Synvisc One Triluron Trivisc Visco-3	Euflexxa® (1% sodium hyaluronate)

Clinical Guideline Coverage Criteria

Initial Authorization Criteria:

The Plan may cover Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3 when documentation of one of the following is met:

1. History of prior treatment with Euflexxa (1% sodium hyaluronate) resulting in a substandard response to therapy

OR

2. History of intolerance or adverse event to treatment with Euflexxa (1% sodium hyaluronate)

OR

3. Rationale that treatment with Euflexxa (1% sodium hyaluronate) is not clinically appropriate (Note: Convenience does not qualify as clinical rationale for inappropriateness of a Euflexxa)

OR

4. Continuation of prior therapy with the requested non-preferred product within the past 365 days

Reauthorization Criteria:

The Plan may cover Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3 when all the following criteria are met:

1. Documentation of significant improvement in pain and functional capacity from the prior series of injections

AND

2. The most recent injection was given no sooner than six (6) months ago

Limitations

- Initial authorization of Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3 will be for **six (6)** months
- Reauthorization of Durolane, Gel-One, Gel-Syn, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synvisc, Synvisc One, Triluron, Trivisc and Visco-3 for knee arthritis will be for **six (6)** months
- The plan does not cover hyaluronic acid derivatives for the treatment of osteoarthritis in locations other than the knee because it is considered experimental, investigational or unproven.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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

HCPCS Codes	Description
J7321	Hyaluronan or derivative, hyalgan or 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
J7332	Hyaluronan or derivative, triluron, for intra -articular injection, 1 mg

References:

1. Billing and Coding: Hyaluronans Intra-articular Injections of. Centers for Medicare & Medicaid Services (CMS). Last updated August 1, 2021. Accessed online April 7, 2022 at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52420&ver=58&=.
2. Hyaluronan Acid Therapies for Osteoarthritis of the Knee. L35427. Centers for Medicare & Medicaid Services (CMS). Last updated October 1, 2019. Accessed online May 12, 2022 at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35427#:~:text=Intra%2Darticular%20injection%20of%20hyaluronic,of%20osteoarthritis%20of%20the%20knee.
3. Durolane [package insert]. Durham NC. Bioventus LLC; 2022.
4. Euflexxa (sodium hyaluronate) [product information]. Parsippany, NJ: Ferring Pharmaceuticals; July 2016.
5. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
6. GelSyn-3 (sodium hyaluronate) [product information]. Pambio -Noranco, Switzerland: Institut Biochimique SA (IBSA); December 2017.
7. GenVisc 850 (sodium hyaluronate) [product information]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
8. Hyalgan. [package insert]. Parsippany, NJ. Fidia Pharma, USA, Inc. May 2014.
9. Hymovis. [package insert]. Florham Park, NJ. Fidia Pharma USA, Inc. September 2017.
10. Monovisc. [package insert]. Bedford, MA. Anika Therapeutics, Inc. 2022.
11. Orthovisc. [package insert]. Bedford, MA. Anika Therapeutics, Inc. 2022.
12. Supartz [package insert]. Durham, NC: Bioventus LLC; April 2015.
13. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
14. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
15. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.: March 2019.
16. Trivisc (sodium hyaluronate) [prescribing information]. Doylestown, PA: OrthogenRx, Inc. November 2019.
17. Visco-3 [package insert]. Durham, NC: Bioventus LLC; December 2015.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

December 12, 2023: Retire Medical Necessity Guideline on December 31, 2023. Refer to Part B Step Therapy Policy effective January 1, 2024.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.