

Pharmacy Medical Necessity Guidelines: Viscosupplementation for Osteoarthritis

Effective: September 15, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT / MM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>All plans except Tufts Health Public Plans: PRECERT: 617.972.9409</p> <p>Tufts Health Public Plans only: MM: 888.415.9055</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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 seems to be the most logical explanation, other mechanisms must exist. The following drugs containing hyaluronic acid derivatives are FDA-approved for 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, Synvisc, Synvisc One, and Visco-3.

COVERAGE GUIDELINES

The plan may authorize coverage of **Euflexxa** (sodium hyaluronate) for Members, when all of the following criteria are met:

Initial Treatment Course

1. The Member has a documented diagnosis of Kellgren-Lawrence Scale (Grade 2 or greater) osteoarthritis of the knee confirmed by radiology or documentation of moderate or severe degenerative arthritis.

AND

2. The medical record documents that the Member's condition is affecting activities of daily living

AND

3. The prescribing physician is a rheumatologist, orthopedic specialist, physiatrist, or sports medicine specialist.

AND

4. The Member has demonstrated an inadequate response, contraindication or inability to tolerate **ALL** of the following treatments:

- Non-pharmacologic (e.g., exercise, weight loss if overweight, physical therapy)
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- Intra-articular corticosteroids (efficacy lasted less than 6 to 8 weeks)

Note: Authorization is limited to one treatment course (3 injections of Euflexxa).

Reauthorization

The plan may authorize additional courses of Euflexxa based on clinical notes from the medical record documenting:

1. An objective measurable effect of a reduction in pain of at least 50% to support clinical improvement of the condition with the prior course of viscosupplementation and current status;

AND

2. There was a reduction in the dose of NSAIDs (or other analgesics or anti-inflammatory medication) during the 3-month period following the previous series of injections (Note: a dose reduction is not required if the member requires these medications for a comorbid medical condition in addition to knee osteoarthritis);

AND

3. The member experienced a significant improvement in BOTH knee pain AND function for activities of daily living.

- Authorization for additional courses of treatment will be given no sooner than 6 months apart.
- Reauthorization is limited to one treatment course.
- For additional courses beyond 12 months, clinical notes must indicate sustained clinical effectiveness and clinical inappropriateness of a total knee replacement.

LIMITATIONS

- The plan does not cover other hyaluronic acid derivatives for viscosupplementation of the knee unless the Member has met the above criteria **AND** has failed a treatment course (3 injections) or, has a contraindication to Euflexxa (Note: There is a lack of reliable evidence that any one brand of viscosupplement is superior to other brands for medically necessary indications. There are also lack of studies demonstrating that persons who fail to respond to one brand of viscosupplement will respond to other brands of viscosupplements).
- Initial coverage of **any** hyaluronic acid derivative is limited to one treatment course.
- Reauthorization for **any** hyaluronic acid derivative is limited to one treatment course.
- Authorization for additional courses of treatment will be given no sooner than 6 months apart.
- Coverage requests for **any** hyaluronic acid derivative for additional courses beyond 12 months must include clinical notes indicating sustained clinical effectiveness.
- 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.
- The plan does not cover hyaluronic acid derivatives for the treatment of isolated patella femoral arthritis or patella femoral syndrome because it is considered experimental, investigational or unproven.
- The plan does not cover ultrasound guidance for hyaluronic acid derivative injections because it is considered experimental, investigational or unproven.

CODES

The following HCPCS/CPT code(s) are:

Code	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 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

Code	Description
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, synojynt, 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

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APPROVAL HISTORY

July 14, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
2. February 16, 2010: Administrative Update: Removed medical billing code J7322 and added code J7325
3. May 11, 2010: Changed requirement of corticosteroid injections to at least one injection. Limited authorization to one treatment course (3 injections) with additional courses (if approved) to be given no sooner than 6 months apart.
4. May 10, 2011: No changes
5. January 1, 2012: Administrative Update: Added medical billing code J7326
6. April 10, 2012: No changes
7. March 12, 2013: No changes
8. February 11, 2014: No changes
9. June 10, 2014: Added Monovisc (hyaluronan) to Medication Necessity Guideline
10. January 1, 2015: Administrative Update: Added medical billing code J7327
11. February 10, 2015 (updates will be effective July 1, 2015): Updated coverage criteria with Kellgren-Lawrence Scale (Grade 2 or greater) osteoarthritis of the knee confirmed by radiology and activities of daily living impairment; added physiatrist and sports medicine specialist prescribers; added non-pharmacologic and non-narcotic analgesic treatment prerequisites; updated reauthorization criteria; added coverage limitations.
12. January 1, 2016: Administrative Update: Added medical billing codes J7328 and Q9980.
13. January 1, 2016: Administrative change to rebranded template.
14. March 8, 2016: No changes
15. April 1, 2016: Administrative Update: Added medical billing code C9471.
16. January 1, 2017: Administrative update: added new J codes (J7320, J7322) to Medical Necessity Guideline and removed expired C code (C9471).
17. January 10, 2017: Removed demonstration of an inadequate response, contraindication or inability to tolerate non-narcotic analgesics.
18. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
19. June 13, 2017: Effective October 1, 2017: Updated the reauthorization criteria with the following: An objective measurable effect of a reduction in pain of at least 50% to support clinical improvement of the condition with the prior course of viscosupplementation and current status;
AND There was a reduction in the dose of NSAIDs (or other analgesics or anti-inflammatory

medication) during the 3-month period following the previous series of injections (Note: a dose reduction is not required if the member requires these medications for a comorbid medical condition in addition to knee osteoarthritis); **AND** The member experienced a significant improvement in BOTH knee pain AND function for activities of daily living. For additional courses beyond 12 months, clinical notes must indicate sustained clinical effectiveness and clinical inappropriateness of a total knee replacement. Removed the limitation: Coverage for **any** hyaluronic acid derivative is limited to a maximum of 4 courses of treatment in 36 months. Added the following note to limitation #1: Note: There is a lack of reliable evidence that any one brand of viscosupplement is superior to other brands for medically necessary indications. There are also lack of studies demonstrating that persons who fail to respond to one brand of viscosupplement will respond to other brands of viscosupplements.

20. March 13, 2018: Added Durolane and Visco-3 to the Medical Necessity Guideline. Administrative update to update description of HCPC code J7321.
21. April 1, 2018: Administrative update: Added new C Code C9465 to Medical Necessity Guideline.
22. January 1, 2019: Administrative update: Added new J Codes J7329 and J7318 to the Medical Necessity Guideline and removed expired C Code C9465 from the Medical Necessity Guideline.
23. February 12, 2019: Administrative update: Added new J Code J7322 to the Medical Necessity Guideline and removed expired C Code C9471 from the Medical Necessity Guideline.
24. March 12, 2019: Added moderate or severe degenerative arthritis as an approvable diagnosis.
25. September 10, 2019: Effective January 1, 2020 added the limitation that the plan does not cover hyaluronic acid derivatives for the treatment of isolated patella femoral arthritis or patella femoral syndrome because it is considered experimental, investigational or unproven.
26. September 15, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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