Pharmacy Medical Necessity Guidelines: Viscosupplementation for Osteoarthritis

Effective: March 13, 2018

Prior Authorization Required

<table>
<thead>
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<th>Not Covered</th>
<th>Type of Review – Care Management</th>
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<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Type of Review – Clinical Review</td>
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<tr>
<td>MED</td>
<td>Department to Review</td>
<td>PRECERT / MM</td>
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</table>

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RiTogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

Fax Numbers:
- All plans except Tufts Health Public Plans: PRECERT: 617.972.9409
- Tufts Health Public Plans only: MM: 888.415.9055

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

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.
   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
1. 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).
2. Initial coverage of any hyaluronic acid derivative is limited to one treatment course.
3. Reauthorization for any hyaluronic acid derivative is limited to one treatment course.
4. Authorization for additional courses of treatment will be given no sooner than 6 months apart.
5. Coverage requests for any hyaluronic acid derivative for additional courses beyond 12 months must include clinical notes indicating sustained clinical effectiveness.
6. The plan does not cover viscosupplementation for the treatment of osteoarthritis in locations other than the knee because it is considered experimental, investigational or unproven.
7. The plan does not cover ultrasound guidance for viscosupplement injections because it is considered experimental, investigational or unproven.

CODES
The following HCPCS/CPT code(s) are:

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C9471</td>
<td>Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg</td>
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<tr>
<td>C9465</td>
<td>Hyaluronan or derivative, Durolane, for intra-articular injection, per dose</td>
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<tr>
<td>J7321</td>
<td>Hyaluronan or derivative, Hyalgan or Supartz or Visco-3, for intra-articular injection, per dose</td>
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<td>J7323</td>
<td>Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose</td>
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<tr>
<td>J7324</td>
<td>Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose</td>
</tr>
<tr>
<td>J7325</td>
<td>Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>J7326</td>
<td>Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose</td>
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<td>Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose</td>
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<td>Hyaluronan or derivative, Gel-Syn, for intra-articular injection, 0.1 mg</td>
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<td>J7329</td>
<td>Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg</td>
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REFERENCES


12. Gel-Syn (sodium hyaluronate) [product information]. Pambio, Noranco, Switzerland: Institut Biochimique SA (IBSA); May 2014.


25. Trivisc (sodium hyaluronate) [prescribing information]. Doylestown, PA: OrthogenRx, Inc.

**APPROVAL HISTORY**

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

Subsequent endorsement date(s) and changes made:
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
- 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.
- May 10, 2011: No changes.
- April 10, 2012: No changes.
- March 12, 2013: No changes.
- February 11, 2014: No changes.
- 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.
- January 1, 2016: Administrative Update: Added medical billing codes J7328 and Q9980.
- January 1, 2016: Administrative change to rebranded template.
- March 8, 2016: No changes.
- April 1, 2016: Administrative Update: Added medical billing code C9471.
- January 1, 2017: Administrative update: added new J codes (J7320, J7322) to Medical Necessity Guideline and removed expired C code (C9471).
- January 10, 2017: Removed demonstration of an inadequate response, contraindication or inability to tolerate non-narcotic analgesics.
- 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
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.


**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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.