

Pharmacy Medical Necessity Guidelines: Viscosupplementation for Osteoarthritis

Effective: June 10, 2014

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|---|-----|--|----------|
| Clinical Documentation and Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Precertification Fax: 617-972-9409 | √ |
| Pharmacy (RX) or Medical (MED) Benefit | MED | Department to Review | Pre-Cert |

Note: This pharmacy medical necessity guideline applies to commercial products. 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®, Hyalgan®, Gel-One®, Monovisc®, Orthovisc®, Supartz®, Synvisc®, Synvisc One™.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan may authorize coverage of **Euflexxa** (sodium hyaluronate) for Members, when **ALL** of the following criteria are met:

1. The Member has a documented diagnosis of osteoarthritis of the knee.
- AND**
2. The prescribing physician is a rheumatologist or orthopedic specialist.
- AND**
3. The Member has demonstrated an inadequate response to or is unable to tolerate **BOTH** of the following treatments:
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
 - At least one corticosteroid injection

Note: Authorization will be limited to one treatment course (3 injections). For additional courses, please submit documentation of clinical improvement. Authorization for additional courses of treatment will be given no sooner than 6 months apart.

LIMITATIONS

1. Tufts Health Plan will 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. Coverage of other hyaluronic acid derivatives will be limited to one treatment course. For additional courses, please submit documentation of clinical improvement. Authorization for additional courses of treatment will be given no sooner than 6 months apart.

CODES

The following HCPCS/CPT code(s) are:

| Code | Description |
|-------|---|
| J7321 | Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose |
| 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 |

REFERENCES

1. Altman RD, Rosen JE, Bloch DA, Hatoum HT. Safety and efficacy of retreatment with a bioengineered hyaluronate for painful osteoarthritis of the knee: results of the open-label Extension Study of the FLEXX Trial. *Osteoarthritis Cartilage*. 2011 Oct; 19(10):1169-75.
2. Altman RD, Rosen JE, Bloch DA, Hatoum HT, Korner P. A double-blind, randomized, saline-controlled study of the efficacy and safety of EUFLEXXA for treatment of painful osteoarthritis of the knee, with an open-label safety extension (the FLEXX trial). *Semin Arthritis Rheum*. 2009 Aug; 39(1):1-9.
3. American College of Rheumatology Subcommittee on Osteoarthritis Guidelines. Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee. *Arthritis and Rheumatism*. Vol. 43, No. 9, September 2000, pp. 1905-1915.
4. Arden NK, Akermark C, Andersson M et al. A randomized saline-controlled trial of NASHA hyaluronic acid for knee osteoarthritis. *Curr Med Res Opin*. 2014 Feb;30(2):279-86
5. Brzusek D, Petron D. Treating knee osteoarthritis with intra-articular hyaluronans. *Curr Med Res Opin*. 2008; 24(12):3307–3322.
6. Euflexxa (sodium hyaluronate) [product information]. Parsippany, NJ: Ferring Pharmaceuticals; September 2011.
7. Facts and Comparisons 4.0 online, 2013. HYALURONIC ACID DERIVATIVES, INTRA-ARTICULAR. URL: www.online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandc-hcp11029. Available from Internet. Accessed February 22, 2013.
8. Hochberg MC, Altman RD, April KT et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res (Hoboken)*. 2012 Apr; 64(4):465-74.
9. Pagnano M, Westrich G. Successful nonoperative management of chronic osteoarthritis pain of the knee: safety and efficacy of retreatment with intra-articular hyaluronans. *Osteoarthritis Cartilage* 2005; 13(9):751-61.
10. Rutjes AW, Jüni P, da Costa BR et al. Viscosupplementation for osteoarthritis of the knee: a systematic review and meta-analysis. *Ann Intern Med*. 2012 Aug 7; 157(3):180-91.
11. Van den Bekerom M, Lamme B, Sermon A, Mulier M: What is the evidence for viscosupplementation in the treatment of patients with hip osteoarthritis? Systemic review of the literature. *Arch Orthop Trauma Surg* 2008, 128:815-23.
12. Wen, DY. Intra-articular Hyaluronic Acid Injections for Knee Osteoarthritis. *American Family Physician*. August 1, 2000.

APPROVAL HISTORY

- July 14, 2009: Reviewed by the Pharmacy and Therapeutics Committee
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
- February 16, 2010: Administrative Update: Removed medical billing code J7322 and added code J7325
- 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
- January 1, 2012: Administrative Update: Added medical billing code J7326
- April 10, 2012: No changes
- March 12, 2013: No changes
- February 11, 2014: No changes
- June 10, 2014: Added Monovisc (hyaluronan) to Medication Necessity Guideline

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health 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). Tufts Health 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 Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. Check the applicable formulary in the Pharmacy section of our website at www.tuftshealthplan.com/providers to determine if the drug requires you to get prior authorization. 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 CareLinkSM 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.

New patient
 Current

Viscosupplements PRESCRIPTION & ENROLLMENT FORM

3 CLINICAL INFORMATION

Primary diagnosis _____ ICD-9/ICD-10 code _____
 Current weight _____ kg/lbs Date recorded _____
 NKDA Known drug allergies _____
 Medical history _____
 Special instructions: (non-English speaking patients, etc.) _____

1 PATIENT INFORMATION

Patient name _____
 Date of birth _____ Male Female Last 4 digits of SSN _____ Apt # _____
 Street address _____ City _____ State _____ Zip _____
 Parent/guardian (if applicable) _____ Principle contact
 Home phone _____ Work phone _____
 Cell phone _____ Evening phone _____
 E-mail address _____
 Insurance company name _____
 Insurance company phone # _____
 Insured name _____ Last 4 digits of SSN _____
 Insured employer _____
 Relationship to patient _____
 Identification # _____ Policy/group # _____
 Secondary insurance company name _____
 Secondary insurance company phone # _____ Last 4 digits of SSN _____
 Secondary insured name _____
 Secondary insured employer _____
 Secondary relationship to patient _____
 Secondary identification # _____ Policy/group # _____
 Prescription card No Yes If yes, carrier _____
 Policy # _____ Group # _____
 Is patient eligible for Medicare? No Yes
 Is patient eligible for Medicaid? No Yes
 Please attach copy of front and back of patient's insurance cards, if available.

4 PRESCRIBING INFORMATION

Euflexxa® is the Preferred Product for Tufts Health Plan Effective 10/1/2009
Euflexxa (hyaluronic acid)
 20 mg/2 mL Syringe
 NDC 55566-4100-1
 3 Syringes

Direction: To be administered only by physician

Requests for *Euflexxa* will require **Prior Authorization** for coverage.

- Full coverage criteria are posted on the Tufts Health Plan web site and require documentation of an inadequate response or inability to tolerate non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injections

Tufts Health Plan will not cover the following viscosupplements (hyaluronic acid derivatives) for osteoarthritis:

- Gel-One® (J7326)
- Hyalgan® (J7321)
- Orthovisc® (J7324)
- Supartz® (J7321)
- Synvisc® and Synvisc One™ (J7325)

By signing below, I certify that the above therapy is medically necessary.

2 PRESCRIBER INFORMATION

Date _____ Date requested in medical office _____
 Prescriber name and title _____
 If NP or PA, under direction of Dr. _____
 Street address _____ Suite # _____
 City _____ State _____ Zip _____
 Phone _____ Fax _____
 License # _____
 DEA #/NPI # _____
 Physician Medicaid UPIN # _____
 MD specialty _____

Prescriber printed name _____
 Prescriber signature _____ Date _____
 (No stamps) (Dispense as written)

Prescriber signature _____ Date _____
 (No stamps) (Substitutions permitted)

This prescription is valid only if transmitted by means of a facsimile machine. The document(s) accompanying this transmission may contain confidential health information that is legally privileged. This information is intended only for the use of the individual or entity named above. The authorized recipient of this information is prohibited from disclosing this information to any other party unless required to do so by law or regulation. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately and arrange for the return or destruction of these documents.

Accredo contact phone number — 866.759.1557.
 Please fax completed form to 866.697.5901.



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