

**Effective Date: April 14, 2017**

**Subject: Hyaluronate Preparations for Osteoarthritis of the Knee**

**Authorization:**

Prior authorization is required for all hyaluronate preparations administered to members enrolled in HPHC commercial (HMO, POS, PPO) products.

**Policy and Coverage Criteria:**

Harvard Pilgrim Health Care (HPHC) covers hyaluronate preparations (e.g., hyaluronan, hyaluronic acid, sodium hyaluronate, hylan polymers, cross-linked hyaluronate) approved by the Food and Drug Administration (FDA), and medically necessary for treatment of pain associated with osteoarthritis (OA) of the knee in patients who have not had an adequate response to nonpharmacological conservative treatment and simple (non-opioid) analgesics.

HPHC authorizes an initial course\* of treatment with Synvisc-One™ or Euflexxa™ when medical record documentation confirms ALL the following:

- Treatment is ordered by a physician with appropriate specialist expertise (e.g., rheumatologist, orthopedic specialist, physiatrist, sports medicine specialist, anesthesiologist/pain specialist);
- Hyaluronate preparation is requested for member with Kellgren-Lawrence Scale (Grade 2 or greater) osteoarthritis of the knee (radiologic confirmation required);
- Member has obtained insufficient pain relief from conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen, non-steroidal anti-inflammatory drugs, topical capsaicin);
- Member has had insufficient response after intra-articular corticosteroid injection (i.e., efficacy lasted less than 6-8 weeks).

**A course of treatment consists of the following:**

- **Synvisc-One™ (hylan G-F 20): 1 dose administered as a single injection**
- **Euflexxa™ (1% sodium hyaluronate): 1 dose administered weekly x3 weeks (total 3 doses)**

HPHC authorizes an initial course of treatment with other agents (e.g. Gel-One®, Gel-Syn™, Genvisc®, Hyalgan®, Monovisc™, Orthovisc®, Supartz®, or Synvisc®) only when above criteria are met, AND medical record documentation confirms previous treatment failure, or a contraindication to use of Synvisc-One™ AND Euflexxa™.

HPHC covers a repeat course of intra-articular hyaluronan injections only when documentation confirms ALL the following:

- Treatment is ordered by a physician with appropriate specialist expertise, AND
- At least six months have passed since the prior course of treatment, AND
- Significant pain relief was achieved with the prior course of injections.

**Exclusions:**

Harvard Pilgrim Health Care (HPHC) does not cover:

**HPHC Medical Review Criteria**

**Hyaluronate Preparations for Knee OA**

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*HPHC policies are based on medical science, and written for the majority of people with a given condition.*

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- Hyaluronan for other knee conditions or joints other than the knee because it is considered investigational and unproven, including (but not limited to):
  - Chondromalacia
- Injections of viscosupplementation products that are not FDA-approved
- Ultrasound guidance for viscosupplement injections because it is considered investigational and unproven

### Coding:

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

### References:

1. 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.
2. Brzusek D, Petron D. Treating knee osteoarthritis with intra-articular hyaluronans. *Curr Med Res Opin*. 2008; 24(12):3307–3322.
3. 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.
4. 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.
5. Euflexxa™ (sodium hyaluronate) [product information]. Parsippany, NJ: Ferring Pharmaceuticals; September 2011.
6. Gel-One® (sodium hyaluronate) [product information]. Warsaw, IN: Zimmer Inc.; May 2011.
7. Gel-One® 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.
8. Hyalgan (sodium hyaluronate) [product information]. Parsippany, NJ: Fidia Pharma; October 2013.
9. Orthovisc® (High Molecular Weight Hyaluronan) [product information]. Woburn, MA: Anika Therapeutics, Inc.; June 2005
10. Supartz® (hyaluronic acid) [product information]. Durham, NC: Bioventus LLC; June 2012
11. Synvisc One ((hylan G-F 20) [product information]. Ridgefield, NJ: Genzyme Biosurgery January 2010
12. Waddell DD, Bricker DC. Total knee replacement delayed with Hylan G-F 20 use in patients with grade IV osteoarthritis. *J Manag Care Pharm*. 2007 Mar;13(2):113-121.
13. Hymovis® (high molecular weight viscoelastic hyaluronan) [product information]. <http://www.hymovis.com/pdf/HYMOVIS%20PI.pdf>
14. O'Connor, FG., Mulvaney, SW. Patellofemoral pain syndrome. In: UpToDate, Post, TW (ed) < Waltham, MA, 2016.

### Summary of Changes:

| Date  | Revision  |
|-------|---|
| 3/17  | Added new HCPCs added effective 1/1/2017                                      |
| 6/16  | Added Hymovis to list of injections; updated references; clarified exclusions |
| 12/15 | Added Gel-Syn and Genvisc to list of injections                               |
| 5/15  | Delete limitation of 4 injections in 36 months.                               |
| 2/15  | Update list of approved prescribing specialists.                              |

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**Approved by UMPCP: 3/22/17**

**Revised: 1/15; 2/15; 5/15; 6/16; 3/17**

**Initiated: 10/1/14**

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