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

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

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.
• Hyaluronan for other knee conditions or joints other than the knee because it is considered investigational and unproven, including (but not limited to):
  o 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:
5. Eufllexxa™ (sodium hyaluronate) [product information]. Parsippany, NJ: Ferring Pharmaceuticals; September 2011.
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; January 2010
11. Synvisc One ((hylan G-F 20) [product information]. Ridgefield, NJ: Genzyme Biosurgery January 2010

Summary of Changes:

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
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<tbody>
<tr>
<td>3/17</td>
<td>Added new HCPCs added effective 1/1/2017</td>
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<tr>
<td>6/16</td>
<td>Added Hymovis to list of injections; updated references; clarified exclusions</td>
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<tr>
<td>12/15</td>
<td>Added Gel-Syn and Genvisc to list of injections</td>
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<tr>
<td>5/15</td>
<td>Delete limitation of 4 injections in 36 months.</td>
</tr>
<tr>
<td>2/15</td>
<td>Update list of approved prescribing specialists.</td>
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HPHC Medical Review Criteria

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Approved by UMCPC: 3/22/17
Revised: 1/15; 2/15; 5/15; 6/16; 3/17
Initiated: 10/1/14