Hyaluronic Acid Derivatives

Description

Durolane, Euflexxa, GelSyn-3*, GenVisc 850, Hyalgan*, Supartz*, Visco-3 (sodium hyaluronate)

Gel-ONE*, Hymovis, Monovisc, Orthovisc (hyaluronan)

Synvisc, Synvisc - One (hylan G-F 20)

*Preferred Product

Background

Osteoarthritis of the knee is a disease in which the elastoviscous property of the synovial fluid in the knee joint becomes diminished, resulting in less protection and shock absorption. Durolane, Orthovisc, Monovisc, Euflexxa, Supartz, Hymovis, Gel-ONE, GelSyn-3, GenVisc 850, Hyalgan, Visco-3, Synvisc and Synvisc-One are hyaluronan derivatives that are injected into the knee joints to increase the elastoviscous properties of arthritic joint fluid and slow its outflow from the joint. The goal of therapy is to restore the viscoelasticity in the affected joints, thereby decreasing pain, improving mobility, and restoring the natural protective functions (1).

The American College of Rheumatology (ACR) updated its guidelines for the treatment of osteoarthritis (OA) of the knee in 2012. In mild symptomatic OA, treatment may be limited to patient education, physical and occupational therapy and other non-pharmacologic modalities. Nonpharmacologic modalities strongly recommended for the management of knee OA were aerobic, aquatic, and/or resistance exercises as well as weight loss for overweight patients. Nonpharmacologic modalities conditionally recommended for knee OA included medial wedge insoles for valgus knee OA, subtalar strapped lateral insoles for varus knee OA, medially directed patellar taping, manual therapy, walking aids, thermal agents, tai chi, self-management
programs, and psychosocial interventions. Pharmacologic modalities conditionally recommended for the initial management of patients with knee OA included acetaminophen, oral and topical NSAIDs, tramadol, and intraarticular corticosteroid injections (1).

**Regulatory Status**

FDA-approved indication: Hyaluronic acid derivatives are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy, simple analgesics (e.g., acetaminophen), NSAIDs, tramadol, or intra-articular steroid injections (2-13).

The hyaluronic acid derivatives are contraindicated for use in patients with known hypersensitivity to hyaluronan (sodium hyaluronate) preparations. Orthovisc lists hypersensitivity to gram positive bacterial proteins as an additional contraindication (4). Caution should be exercised when Gel-One, Hyalgan, Visco-3, Synvisc, Synvisc-One and Supartz are administered to patients with allergies to avian proteins, feathers, and egg products (3-8). Hyaluronic acid derivatives are contraindicated to treat patients with knee joint infections, infections or skin diseases in the area of the injection site (2-13).

A treatment cycle for most of the hyaluronan derivatives typically involves multiple weekly injections. Euflexxa, GelSyn-3, Visco-3 and Synvisc are given for a total of three injections. Orthovisc is given for three or four injections. GenVisc 850, Supartz and Hyalgan are given for a total of three or five injections. Durolane, Gel-One and Synvisc-One differ from the other hyaluronan derivatives in that it only requires one injection. Repeat courses of hyaluronan derivatives may be administered if symptoms return (2-13).

Upon the basis of high quality supporting evidence, the American Academy of Orthopedic Surgeons cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee (14).

**Related policies**

Hyaluronate Powder

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Hyaluronic acid derivatives may be considered **medically necessary** for the treatment of osteoarthritis of the knee when two conservative non-pharmacologic therapies; two simple analgesic therapies have failed to provide relief; there has been an inadequate response,
intolerance, or contraindication to intra-articular steroid injections in which efficacy lasted less than 8 weeks; radiologic confirmation of Kellgren-Lawrence Scale score of grade 2 or greater.

Hyaluronic acid derivatives may be considered *investigational* for all other indications.

**Prior-Approval Requirements**

**Age**  18 years or older (22 or older for Synvisc and Synvisc-One)

**Diagnosis**

Patient must have the following:

Osteoarthritis of the knee

**AND ALL** of the following:

1. Inadequate response to **TWO** or more of the following conservative non-pharmacologic therapy:
   a. Cardiovascular (aerobic) activity, such as: walking, biking, stationary bike, aquatic exercise
   b. Resistance exercise
   c. Weight reduction (for persons who are overweight)
   d. Participation in self-management programs
   e. Wear of medially directed patellar taping
   f. Wear of wedged insoles
   g. Thermal agents
   h. Walking aids
   i. Physical therapy
   j. Occupational therapy

2. Inadequate response, intolerance, or contraindication to **TWO** or more of the following:
   a. Acetaminophen
   b. Oral NSAIDs
   c. Topical NSAIDs

3. Inadequate response, intolerance, or contraindication to intra-articular steroid injections in which efficacy lasted less than 8 weeks
4. Radiologic confirmation of Kellgren-Lawrence Scale score of grade 2 or greater

5. NO dual therapy with another hyaluronic acid injectable

Prior – Approval Renewal Requirements

Age 18 years or older (22 or older for Synvisc and Synvisc-One)

Diagnosis

Patient must have the following:

Osteoarthritis of the knee

AND ALL of the following:
1. Documentation of improvement in pain with previous course of treatment
2. At least 12 months has elapsed since last injection of the prior treatment cycle
3. Documentation of reduction of dosing of NSAIDs or other analgesics during the 12 month period following the last injection of the prior treatment cycle
4. NO dual therapy with another hyaluronic acid injectable

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Quantity One course of therapy for each knee
Prior – Approval Renewal Limits

Duration 12 months

Quantity One course of therapy for each knee

Rationale

Summary

Osteoarthritis of the knee is a disease in which the elastoviscous property of the synovial fluid in the knee joint becomes diminished, resulting in less protection and shock absorption. Durolane, Orthovisc, Monovisc, Euflexxa, GelSyn-3, GenVisc 850, Supartz, Hymovis, Gel-One, Hylgan, Visco-3, Synvisc and Synvisc-One are hyaluronan derivatives that are injected into the knee joints to increase the elastoviscous properties of arthritic joint fluid and slow its outflow from the joint. The goal of therapy is to restore the viscoelasticity in the affected joints, thereby decreasing pain, improving mobility, and restoring the natural protective functions (1-13).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of the hyaluronic acid derivatives while maintaining optimal therapeutic outcomes.

References


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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>January 2012</td>
<td>Added minimum age - only approved for adults</td>
<td></td>
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<tr>
<td>December 2012</td>
<td>Annual editorial review and reference update</td>
<td></td>
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<tr>
<td>December 2013</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>March 2014</td>
<td>Annual editorial review</td>
<td>Addition of examples of non-pharmacological agents and agents of prior failure medications.</td>
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<tr>
<td>April 2014</td>
<td>Line-Addition of Monovisc to PA</td>
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<tr>
<td>March 2015</td>
<td>Annual criteria review and reference update</td>
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<tr>
<td>March 2016</td>
<td>Change from one tried and failed to two tried and failed non-pharmacologic and pharmacologic therapies and addition of the tried and failed of intra-articular steroid and radiologic confirmation of Kellgren-Lawrence Scale score of grade 2 or greater</td>
<td>Addition of Hymovis Policy # change from 5.11.04 to 5.75.09</td>
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<tr>
<td>May 2016</td>
<td>Addition of GelSyn-3 and GenVisc 850</td>
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<td>December 2016</td>
<td>Annual editorial review and reference update</td>
<td>Added: no dual therapy with another hyaluronic acid injectable</td>
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<tr>
<td>March 2017</td>
<td>Bolded preferred products in the title page</td>
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<tr>
<td>July 2017</td>
<td>GelSyn-3 has been changed to preferred</td>
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<tr>
<td>September 2017</td>
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<td>December 2017</td>
<td>Addition of Durolane and Visco-3</td>
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<tr>
<td>March 2018</td>
<td>Annual editorial review</td>
<td>Removal of Tramadol from the T/F list</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 16, 2018 and is effective on April 1, 2018.