DRUG POLICY

Viscosupplementation for Osteoarthritis

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Viscosupplementation for Osteoarthritis drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Hyalgan, Hymovis, Synvisc, and Synvisc One are the preferred products. The criteria will require the use of the health plan's preferred products before the use of targeted products (Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Monovisc, Orthovisc, Supartz FX, Visco-3), unless there are clinical circumstances that exclude the use of the preferred products and may be based on previous use of a product. While multiple brands of viscosupplementation are commercially available, there's no evidence, to date, that any have superior efficacy or safety.

Trivisc is excluded from the preferred product requirement.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen)

Compendial Uses
- Treatment of pain in osteoarthritis of the shoulder
- Treatment of pain in osteoarthritis of the hip

Table: Hyaluronate products

<table>
<thead>
<tr>
<th>Medication</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred Products:</td>
<td></td>
</tr>
<tr>
<td>Hyalgan</td>
<td>sodium hyaluronate</td>
</tr>
<tr>
<td>Hymovis</td>
<td>high molecular weight viscoelastic hyaluronan</td>
</tr>
<tr>
<td>Medication</td>
<td>Generic Name</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td><strong>Preferred Products:</strong></td>
<td></td>
</tr>
<tr>
<td>Synvisc</td>
<td>hylan G-F 20</td>
</tr>
<tr>
<td>Synvisc One</td>
<td>hylan G-F 20</td>
</tr>
<tr>
<td><strong>Targeted Products:</strong></td>
<td></td>
</tr>
<tr>
<td>Durolane</td>
<td>hyaluronic acid</td>
</tr>
<tr>
<td>Euflexxa</td>
<td>1% sodium hyaluronate</td>
</tr>
<tr>
<td>Gel-One</td>
<td>cross-linked hyaluronate</td>
</tr>
<tr>
<td>Gelsyn-3</td>
<td>sodium hyaluronate</td>
</tr>
<tr>
<td>Genvisc 850</td>
<td>sodium hyaluronate</td>
</tr>
<tr>
<td>Monovisc</td>
<td>high molecular weight hyaluronan</td>
</tr>
<tr>
<td>Orthovisc</td>
<td>high molecular weight hyaluronan</td>
</tr>
<tr>
<td>Supartz FX</td>
<td>sodium hyaluronate</td>
</tr>
<tr>
<td>Visco-3</td>
<td>sodium hyaluronate</td>
</tr>
<tr>
<td><strong>Other Products:</strong></td>
<td></td>
</tr>
<tr>
<td>TriVisc</td>
<td>sodium hyaluronate</td>
</tr>
</tbody>
</table>

**POLICY**

Criteria for Initial Approval

A. Hyalgan, Hymovis, Synvisc, and Synvisc-One are considered **medically necessary** for the treatment of osteoarthritis (OA) in the knee, hip or shoulder.

Approval is for **12 months**

B. Coverage for a targeted product (Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Monovisc, Orthovisc, Supartz FX, and Visco-3) is considered **medically necessary** for the treatment of osteoarthritis (OA) in the knee, hip or shoulder when either of the following criteria are met:
   - Member is currently undergoing treatment and coverage is required to complete the current course of treatment.
   - OR
   - Member has tried and experienced an intolerable adverse event to Hyalgan, Hymovis, and Synvisc or Synvisc One.

Approval is for **12 months**

C. Coverage for TriVisc is considered **medically necessary** for the treatment of osteoarthritis (OA) in the knee, hip or shoulder.

Approval is for **12 months**.
Intra-articular hyaluronan injections are considered not medically necessary for patients who do not meet the criteria set forth above.

**Continuation of Therapy**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Prior approval is required.

**Quantity Limits Apply:**

- Synvisc-One: 1 injection (6 mL each; 6 mL total) per 180 day course
- Synvisc: 3 injections (2 mL each; 6 mL total) per 180 day course
- Hyalgan: 5 injections (2 mL each; 10 mL total) per 180 day course
- Hymovis: 2 injections (3 mL each; 6 mL total) per 180 day course
- Euflexxa: 3 injections (2 mL each; 6 mL total) per 180 day course
- Gel-One: 1 injection (3 mL each; 3 mL total) per 180 day course
- Gelsyn-3: 3 injections (2 mL each, 6 mL total) per 180 day course
- GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
- Monovisc: 1 injection (4 mL each, 4 mL total) per 180 day course
- Orthovisc: 3 or 4 injections (2 mL each; 8 mL total) per 180 day course
- Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
- Durolane: 1 injection (3 mL each, 3 mL total) per course
- TriVisc: 3 injections (2.5 mL each, 7.5 mL total) per 180 day course

**CLINICAL RATIONALE**

Osteoarthritis (OA) is the result of an imbalance between the breakdown and repair of the tissues in the synovial joint and occurs as a result of multiple risk factors including trauma, overuse and genetic predisposition. Pathological presentation in the knee is characterized by deterioration and loss of articular cartilage along with increased osteophyte formation. The elastoviscous properties of the synovial fluid deteriorate over time, resulting in less protection and shock absorption. Ultimately, joint pain and stiffness result, which limit mobility.

Viscosupplementation involves the injection of hyaluronic acid derivates into the knee to supplement the elastoviscous properties of the synovial fluid, with the intended purpose of improving mobility, decreasing pain and restoring protective function on the joint. A treatment cycle for most hyaluronic acid derivatives involves a series of weekly injections, with the exception of Synvisc One®, Gel One®, and Monovisc®, which require only one injection. Improvements in symptoms can last one to six months.

Individual trials show inconsistent results in pain and functional outcomes for viscosupplementation compared to placebo or active control. Several meta-analyses of randomized controlled trails (RCTs) demonstrate statistically significant improvements in pain and function, yet these improvements fail to meet minimum thresholds for clinical significance. There have been no trials to date that demonstrate intra-articular hyaluronan (IAHA) delays progression of OA, progression to surgery, nor reduces the need, for other pain management options, including NSAIDs and opiates. Treatment guidelines from the American Academy of Orthopaedic Surgeons (AAOS) include the following statement, “we cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee”, based on moderate-high quality evidence. The 2014 guidelines on osteoarthritis from the National Institute for Health and Care Excellence (NICE) conclude more strongly, “Do not offer intra-articular hyaluronan injections for the management of osteoarthritis”. 
The 2012 American College of Rheumatology (ACR) clinical practice guidelines on osteoarthritis indicate they have no recommendations regarding the use of IAHA in the knee. Their recommendations for the use of pharmacologic therapies in knee OA include acetaminophen, oral and topical NSAIDs, tramadol and intra-articular corticosteroid injections (IACI). Similar to the ACR guidelines the Osteoarthritis Research Society International (OARSI) 2014 guideline update provided an "uncertain" recommendation for IAHA, indicating an overall small effect size on pain, inconsistent results among the available meta-analyses, and one meta-analysis signaling potential for serious safety concerns, influenced their recommendation.

Studies comparing IAHA to NSAIDS have led to conflicting results and have not clearly demonstrated IAHA to be superior. In one, more recent randomized, open label trial in 200 patients with osteoarthritis of the knee, IAHA was found to be non-inferior to oral NSAIDs. While there are a limited number of studies comparing IAHA to IACI, the studies available indicate IACI is as effective as IAHA in the short-term management of OA of the knee. Unlike IAHA, NSAIDs and IACI are consistently recommended by guidelines (for the appropriately selected patient) and offer a much more cost-effective treatment approach for the management of osteoarthritis of the knee.

Recently, evidence regarding repeat courses of IAHA for knee OA was evaluated by the California Technology Assessment Forum. Their findings indicate repeated IAHA injections have shown symptomatic relief of knee OA, but have not demonstrated slowing in the progression of knee OA or progression to knee replacement. Ultimately, the efficacy and safety of multiple courses of IAHA has not been established.

The evidence for the efficacy and safety of IAHA injections for use in joints other than the knee has not been established. Given the limited and inconsistent data available, use of viscosupplementation for joints other than the knee is not considered medically necessary.

While multiple brands of viscosupplementation are commercially available, there’s no evidence, to date, that any have superior efficacy or safety for the treatment of osteoarthritis of the knee. Synvisc-One, Synvisc, Hyalgan, and Hymovis are the preferred products as they are least costly for Wellmark.

Ultimately, there is inconsistent evidence that viscosupplementation produces clinically relevant improvements in pain and functioning for OA of the knee and no evidence to suggest it delays the progression of OA or the progression to knee replacement. Based on this evidence, several major practice guidelines are unable to recommend IAHA, with others recommending against its use. IAHA should be reserved last-line when other guideline recommended treatments, both non-pharmacologic and pharmacologic, have been exhausted (or are contraindicated), in patients who will continue to pursue non-surgical management of their osteroarthritis.

In summary, the use of viscosupplementation, or hyaluronic acid products, for the treatment of osteoarthritis (OA) of the knee has debatable clinical utility. Over the past few years they have largely fallen from favor, with several major organizations, including the American Academy of Orthopaedic Surgeons (AAOS), citing conflicting and limited evidence as the basis of their inability to make a recommendation for, or against, their use. Given viscosupplementation has been unable to demonstrate clear, consistent, patient centered outcomes, some health plans have discontinued coverage of these products. Wellmark recognizes that while the evidence and guidelines offer conflicting recommendations for the use viscosupplementation, these products may provide benefit for some. Given the limited effectiveness data and high cost of these products, it is paramount that Wellmark balance access and cost, ensuring the most cost-effective, clinically appropriate use of this therapy.

**PROCEDURES AND BILLING CODES**

*To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.*
• 20610, 20611 for professional services for intra-articular injection
• J7320 Genvisc® 850, inj, 1mg (effective 1/1/17)
• J7321 Hyaluronan or derivative, Supartz®, Hyalgan®, Visco-3®, for intra-articular injection, per dose
• J7322 Hyaluronan or derivative, Hymovis®, for intra-articular injection, per dose (effective 1/1/17)
• 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, 1mg
• J7326 Hyaluronan or derivative, Gel-One®, for intra-articular injection, per dose
• J7327 Hyaluronan or derivative, Monovisc®, for intra-articular injection, per dose
• J7328 Hyaluronan or derivative, Gelsyn-3®, for intra-articular injection, per dose
• J7329 Hyaluronan or derivative, TriVisc, for intra-articular injection, per dose (1/1/19)
• C9465 Hyaluronan or derivative, Durolane®, for intra-articular injection, per dose
• J7318 Hyaluronan or derivative, Durolane®, for intra-articular injection, per dose (effective 1/1/19)
• J3490 Unclassified drugs

REFERENCES

• Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.

POLICY HISTORY

Policy #: 02.01.12
Original Effective Date: August 1998
Reviewed: April 2019
Revised: January 2019
Current Effective Date: January 2019