Medication Policy Manual

Policy No: dru351

Topic: Intra-articular Hyaluronic Acid Derivatives:
- 1% sodium hyaluronate (Euflexxa®)
- high molecular weight hyaluronan (Orthovisc®)
- hylan G-F 20 (Synvisc®, Synvisc-One®)
- sodium hyaluronate (Gel-One®)
- sodium hyaluronate (Monovisc®)
- sodium hyaluronate (Hyalgan®)
- sodium hyaluronate (Supartz®)

Date of Origin: May 09, 2014

Committee Approval Date: March 20, 2015

Next Review Date: April 2016

Effective Date: July 1, 2015

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

High molecular weight hyaluronan (Orthovisc®), sodium hyaluronate (Gel-One®), sodium hyaluronate (Monovisc®), sodium hyaluronate (Hyalgan®), sodium hyaluronate (Supartz®), 1% sodium hyaluronate (Euflexxa®), and hylan G-F 20 (Synvisc®/Synvisc-One®) are hyaluronic acid derivatives that are injected directly into the knee joint to help improve the pain associated with osteoarthritis of the knee.
Policy/Criteria

I. Hyaluronic acids are considered not medically necessary for osteoarthritis of the knee.

II. Hyaluronic acids are considered not medically necessary for skin wrinkles or other cosmetic indications.

III. Hyaluronic acids are considered investigational when used for all other conditions, including but not limited to osteoarthritis in joints other than the knee.

Position Statement

- Hyaluronic acids are used as viscosupplementation and are injected directly into the knee joint to improve lubrication and reduce the pain associated with osteoarthritis of the knee.

- The American Academy of Orthopaedic Surgeons cannot recommend the use of hyaluronic acid for patients with symptomatic osteoarthritis of the knee. [1]

- There is limited evidence demonstrating that hyaluronic acids are more effective than placebo or non-pharmacologic therapy at increasing mobility and reducing pain associated with osteoarthritis of the knee.

- There are inadequate data to determine the benefit of multiple treatment courses of hyaluronic acids.

Clinical Efficacy

- Hyaluronic acids have not been proven in reliable clinical studies to be more effective than non-pharmacologic or generic analgesics such as acetaminophen and NSAIDs.

* Systematic reviews of randomized controlled trials evaluating viscosupplementation in patients with osteoarthritis of the knee conclude that there are low quality data available to determine efficacy and safety.

* Clinical trials studying the effect of viscosupplementation on knee pain and functional outcomes have reported inconsistent results.

* Several studies have reported no improvement in pain or mobility compared to placebo, simple analgesics, or exercise. [2-5]

- There is no reliable evidence, based on two comparative trials identified, to differentiate between hyaluronic acid products used for viscosupplementation in terms of safety or efficacy.

* One randomized controlled trial in 660 patients with osteoarthritis of the knee did not demonstrate a difference in efficacy or safety of Synvisc compared with Orthovisc. [6]
* A randomized trial comparing the effectiveness of Synvisc and Hyalgan is unreliable due to uncertain blinding which may have influenced patient reported outcomes. [7]

- Systematic reviews and clinical guidelines have concluded that there is limited evidence to support subsequent treatment courses with hyaluronic acids; however, individual patients may benefit from additional courses of hyaluronic acids. [8,9]

- Hyaluronic acids have been studied in the treatment of osteoarthritis of joints other than the knee, including the hip, shoulder, and ankle.

  * Small studies in patients with osteoarthritis of the ankle demonstrated that hyaluronic acid may be an effective treatment option [10,11]; however several larger, well-controlled trials have concluded that hyaluronic acid is not effective in this setting (no different than saline). [12,13]

  * A randomized trial found hyaluronic acid to be no more effective than placebo in the treatment of osteoarthritis of the hip. [14]

  * A randomized trial in patients with osteoarthritis of the shoulder did not demonstrate a significant difference in pain on movement between patients treated with sodium hyaluronate or placebo. [15]

- The American Academy of Orthopaedic Surgeons cannot recommend the use of hyaluronic acid for patients with symptomatic osteoarthritis of the knee. [1]

_Safety_

- The most common adverse events reported with hyaluronic acids include joint pain, stiffness and swelling, as well as injection site reactions. [16-23]

- Adverse reactions are usually mild and improve within a few days. Patients undergoing treatment should avoid strenuous activities (high-impact sports such as jogging, soccer, or tennis) and prolonged weight-bearing activities for approximately 48 hours immediately after an injection. [16-23]

**Cross References**

<table>
<thead>
<tr>
<th>Cross References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-articular Hyaluronan Injections for Osteoarthritis, BlueCross BlueShield Association Medical Policy, 2.01.31, Issue 08:2010</td>
</tr>
<tr>
<td>Codes</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>HCPCS</td>
</tr>
<tr>
<td>HCPCS</td>
</tr>
<tr>
<td>HCPCS</td>
</tr>
<tr>
<td>HCPCS</td>
</tr>
<tr>
<td>HCPCS</td>
</tr>
<tr>
<td>HCPCS</td>
</tr>
<tr>
<td>ICD-9</td>
</tr>
</tbody>
</table>

References


