Pharmacy Medical Policy
Injections for Osteoarthritis

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Policy Number: 427
BCBSA Reference Number: 2.01.31

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td>Formulary Status</td>
</tr>
<tr>
<td>Durolane™® (sodium hyaluronate)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Euflexxa™® (sodium hyaluronate)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Gel-One®® (cross-linked hyaluronate)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Gel_Syn®® (sodium hyaluronate)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Genvisc®® (sodium hyaluronate)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Hyalgan®® (sodium hyaluronate)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Hymovis®® (High Molecular Wt. Viscoelastic Hyaluronan)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Monovisc®® (High Molecular Wt. Viscoelastic Hyaluronan)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Orthovisc®® (High Molecular Wt. Viscoelastic Hyaluronan)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Supartz®® (sodium hyaluronate)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Synvisc®® (hylan G-F 20)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Synvisc-One™® (hylan G-F 20)</td>
<td>Non-Covered</td>
</tr>
<tr>
<td>Visco-3®® (sodium hyaluronate)</td>
<td>Non-Covered</td>
</tr>
</tbody>
</table>
This non covered drug policy is based upon the review of the Blue Cross Blue Shield Association’s Policy 2.01.31 Intra-Articular Hyaluronan Injections for Osteoarthritis which states: “Intra-articular hyaluronan injections of the knee are considered not medically necessary. Intra-articular hyaluronan injections are considered investigational for all other joints.” All FDA approved uses and off-label uses are not covered due to insufficient scientific data to show that health outcomes will be improved.

*^ - This Drug is part of Medications covered only under the pharmacy benefit program.

**Individual Consideration**
All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

**Managed Care Authorization Instructions**
- Prior authorization is required when these medications are processed under the retail pharmacy benefit and home infusion therapy benefit.
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  Pharmacy Operations: (800)366-7778
- For retail pharmacy benefit and home infusion therapy benefit, physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at [https://provider.express-path.com](https://provider.express-path.com)

**PPO and Indemnity Authorization Instructions**
- Prior authorization is required when these medications are processed under the retail pharmacy benefit and home infusion therapy benefit.
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form for retail pharmacy exceptions to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- Physicians may also submit requests for retail pharmacy benefit and home infusion therapy benefit exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at [https://provider.express-path.com](https://provider.express-path.com)

**CPT Codes / HCPCS Codes / ICD Codes**
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:
**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7318</td>
<td>Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>J7329</td>
<td>Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg</td>
</tr>
</tbody>
</table>

**Description**

Knee osteoarthritis (OA) is common, costly, and a cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders. Currently, no curative therapy is available for OA, and thus the overall goals of management are to reduce pain, disability, and the need for surgery.

Intra-articular injection of hyaluronan has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in patients with OA and improving pain and function. This treatment may also be called viscosupplementation. Hyaluronan is a naturally occurring macromolecule that is a major component of synovial fluid and is thought to contribute to its viscoelastic properties. Chemical crosslinking of Hyaluronan increases its molecular weight; cross-linked hyaluronans are referred to as hylans. In OA, the overall length of HA chains present in cartilage and the HA concentration in the synovial fluid are decreased.

**Summary**

Intra-articular (IA) injection of hyaluronan into osteoarthritic joints is proposed to improve pain and function. It is thought to replace endogenous hyaluronan, restore the viscoelastic properties of the synovial fluid. Most studies to date have assessed hyaluronan injections for knee osteoarthritis, and this is the U.S. Food and Drug Administration–approved indication. Other joints (eg, hip, shoulder) are being investigated for IA hyaluronan treatment of osteoarthritis.

The evidence for IA hyaluronan injections in individuals who have osteoarthritis of the knee includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Many RCTs have been published over the last 2 decades. While outcomes of these RCTs are mixed, the RCT evidence base is characterized by studies that show small treatment effects of IA hyaluronan treatment. In many cases, these trials are at risk of bias, and it cannot be determined with certainty whether there is a true treatment effect or whether the reported differences are due to bias. Meta-analyses of RCTs have also resulted in mixed findings. Some meta-analyses estimating the magnitude of treatment benefit have concluded that there is no clinically significant benefit; however, others have concluded that there is a clinically significant benefit. These meta-analyses have also highlighted the limitations of this evidence base, most notably publication bias. Overall, given the lack of a definitive treatment benefit despite a large quantity of literature, and given the biases present in the available evidence, it is unlikely there is a treatment benefit that is clinically meaningful. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

The evidence for IA hyaluronan injections in individuals who have osteoarthritis of joints other than the knee includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Meta-analyses of RCTs either have not found statistically significant benefits of the technology on health outcomes or have found benefits that were statistically, but likely not clinically, significant (eg, 0.27-point improvement on a 10-point visual analog scale). The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/2019</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>5/2018</td>
<td>Updated to Include Durolane.</td>
</tr>
<tr>
<td>2/2018</td>
<td>Updated to Include Visco-3.</td>
</tr>
<tr>
<td>9/2017</td>
<td>Updated to clarified criteria.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
</tbody>
</table>
Updated to include Hymovis® also updated to align Summary & Description/Background with BCBSA National policy.

New references added from BCBSA National medical policy.

Updated to include BCBSA Background (description) & Summary also include Gel-Syn® & GenVisc®.

Updated to include updated language for Medications only available in the Pharmacy benefit.

Updated policy after review of BCBSA’s 2.01.31 Intra-Articular Hyaluronan Injections for Osteoarthritis policy.

Updated coverage criteria to require use of Orthovisc, Synvisc or Synvisc-One prior to other products.

Converted from a medical policy to a pharmacy medical policy. All prior authorization requests should be submitted to the Clinical Pharmacy Department.

Updated with specialty pharmacy contact information.

Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.

Reviewed MPG – Orthopedics, Rehabilitation and Rheumatology, no changes in coverage were made.

Updated to include prior authorization requirement for retail pharmacy requests.

Updated to include Synvisc-One course information as discussed at MPG.

Reviewed MPG - Orthopedics, Rehabilitation Medicine, and Rheumatology, no changes in coverage were made.

Policy updated to remove single treatment language for individual consideration.

Reviewed 7/08 MPG- orthopedics, no changes in coverage were made.

Updated to cover multiple courses of intra-articular hyaluronan injections of Hyalgan®, Euflexxa™, Orthovisc®, Supartz® or Synvisc® when all of the stated criteria are met; Update added based on BCBSA policy # 2.01.31, policy updated with literature review; reference numbers 15–18 added; policy statements revised; multiple courses may be medically necessary.

Reviewed MPG - Orthopedic/Rheumatology, no changes in coverage were made.

BCBSA policy review: additional references added and 2006 related summary of new references; BCBSA policy statement unchanged.

Reviewed MPG - Orthopedic/Rheumatology, no changes in coverage were made.

Updated to include Euflexxa and Orthovisc into coverage criteria.

Updated to include references 8 and 9 and rationale from the 2005 BCBSA National Policy.

Reviewed MPG-Orthopedic, no changes in coverage were made.

Reviewed MPG Orthopedic, no changes in coverage were made.

Reviewed MPG Orthopedic, no changes in coverage were made.

Policy reviewed 7/02, (paper review), by representatives of the Massachusetts Orthopedic Association. No changes were recommended.

Update to include coverage guidelines for Supartz.

Reviewed 7/00, no changes in coverage were made.

Updated to clarify that only one treatment course is allowed per knee; one course of treatment for Hyalgan is a series of five injections and one course of treatment for Synvisc is a series of three injections.


References


To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below: http://www.bluecrossma.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf