



MASSACHUSETTS

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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. 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.

Drug	Formulary Information
	Standard
	Formulary Status
Durolane ^{TM*^} (sodium hyaluronate)	Non-Covered
Euflexxa ^{TM*^} (sodium hyaluronate)	Non-Covered
Gel-One ^{®*^} (cross-linked hyaluronate)	Non-Covered
Gel_Syn ^{®*^} (sodium hyaluronate)	Non-Covered
Genvisc ^{®*^} (sodium hyaluronate)	Non-Covered
Hyalgan ^{®*^} (sodium hyaluronate)	Non-Covered
Hymovis ^{®*^} (High Molecular Wt. Viscoelastic Hyaluronan)	Non-Covered
Monovisc ^{®*} (High Molecular Wt. Viscoelastic Hyaluronan)	Non-Covered
Orthovisc ^{®*^} (High Molecular Wt. Viscoelastic Hyaluronan)	Non-Covered
Supartz ^{®*^} (sodium hyaluronate)	Non-Covered
Synjoynt ^{*^} (hyaluronan)	Non-Covered
Synvisc ^{®*^} (hylan G-F 20)	Non-Covered
Synvisc-One ^{TM*^} (hylan G-F 20)	Non-Covered
Trivisc (hyaluronic acid)	Non-Covered
Triluron ^{*^} (hyaluronan)	Non-Covered
Visco-3 ^{®*^} (sodium hyaluronate)	Non-Covered

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

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.

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

HCPCS codes:	Code Description
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
J7320	Hyaluronan or derivative, Genuvisc 850, for intra-articular injection, 1 mg

J7321	Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
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, 1 mg
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, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, Synjoynt, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
J7333	Hyaluronan or derivative, VISCO-3, for intra-articular injection, per dose

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

Date	Action
6/2020	BCBSA National medical policy review. No changes to policy statements. New references added.
2/2020	Updated list of HCPCS codes.
10/2019	Add Triluron & Synojoynt to the policy with Med UM
5/2019	BCBSA National medical policy review. No changes to policy statements. New references added.
2/2019	Updated to include Trivisc.
1/2019	Clarified coding information.
5/2018	Updated to Include Durolane.
2/2018	Updated to Include Visco-3.
9/2017	Updated to clarified criteria.
6/2017	Updated address for Pharmacy Operations.
6/2016	Updated to include Hymovis® also updated to align Summary & Description/Background with BCBSA National policy.
5/2016	New references added from BCBSA National medical policy.
1/2016	Updated to include BCBSA Background (description) & Summary also include Gel-Syn® & GenVisc®.
10/2015	Updated to include updated language for Medications only available in the Pharmacy benefit.
7/2014	Updated policy after review of BCBSA's 2.01.31 Intra-Articular Hyaluronan Injections for Osteoarthritis policy.
1/2014	Updated coverage criteria to require use of Orthovisc, Synvisc or Synvisc-One prior to other products.
6/2012	Converted from a medical policy to a pharmacy medical policy. All prior authorization requests should be submitted to the Clinical Pharmacy Department.
4/2012	Updated with specialty pharmacy contact information.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
6/2011	Reviewed MPG – Orthopedics, Rehabilitation and Rheumatology, no changes in coverage were made.
3/2010	Updated to include prior authorization requirement for retail pharmacy requests.
7/2009	Updated to include Synvisc-One course information as discussed at MPG. Reviewed MPG - Orthopedics, Rehabilitation Medicine, and Rheumatology, no changes in coverage were made.
9/2008	Policy updated to remove single treatment language for individual consideration.
7/2008	Reviewed 7/08 MPG- orthopedics, no changes in coverage were made.
5/2008	Updated to cover multiple courses of intra-articular hyaluronan injections of Hyalgan®, Euflexxa™ ³ , 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.
7/2007	Reviewed MPG - Orthopedic/Rheumatology, no changes in coverage were made.
4/2007	BCBSA policy review: additional references added and 2006 related summary of new references; BCBSA policy statement unchanged.
7/2006	Reviewed MPG - Orthopedic/Rheumatology, no changes in coverage were made.
6/2006	Updated to include Euflexxa and Orthovisc into coverage criteria.
9/2005	Updated to include references 8 and 9 and rationale from the 2005 BCBSA National Policy.
7/2005	Reviewed MPG-Orthopedic, no changes in coverage were made.
7/2004	Reviewed MPG Orthopedic, no changes in coverage were made.
7/2003	Reviewed MPG Orthopedic, no changes in coverage were made.
7/2002	Policy reviewed 7/02, (paper review), by representatives of the Massachusetts Orthopedic Association. No changes were recommended.
7/2001	Update to include coverage guidelines for Supartz.

7/2000	Reviewed 7/00, no changes in coverage were made.
10/1998	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.
7/1998	New policy, issued 7/1998.

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To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>