

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Hyaluronan Injections: [Durolane, Euflexxa, Gel-One, Gelsyn, GenVisc, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz/FX, Sodium hyaluronate, Synojoint, Synvisc/-One, Triluron, TriVisc, Visco-3]	MP-RX-FP-38-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth

Service Category

- | | |
|--|---|
| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Part B Drugs |

Service Description

This document addresses the use of viscosupplement agents *Hyalgan, Hymovis, Euflexxa, Orthovisc, Synvisc, Monovisc*, drugs approved by the Food and Drug Administration (FDA) for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics, eg, acetaminophen.

Background Information

Osteoarthritis (OA) of the knee is a common and debilitating joint condition that significantly impacts a patient's quality of life. It is characterized by the breakdown of cartilage and the diminished elastoviscous properties of synovial fluid, leading to pain, reduced mobility, and loss of joint function. As the protective articular cartilage deteriorates, bones begin to rub against each other, resulting in significant discomfort and impaired motion. OA can be classified as primary, caused by unknown factors triggering the release of proteolytic enzymes, or secondary, caused by mechanical damage due to trauma, obesity, or muscle atrophy.

The goal of OA treatment is to alleviate pain and improve joint function, as there are currently no therapies to prevent or reverse the disease process. According to guidelines from the American Academy of Orthopaedic Surgeons, baseline therapy includes physical therapy and exercise programs, which may involve general conditioning, muscle strengthening, and range of motion exercises. Supportive devices such as braces, appropriate footwear, and ambulation aids may also be considered.

For symptom management, patients typically begin with simple analgesics such as acetaminophen or NSAIDs, with treatment reassessed in 1-4 weeks. If first-line therapies fail, imaging tests, patient education, and advanced physical therapy may be warranted. Additional pharmacological options include tramadol, opioids for severe pain, and topical agents such as capsaicin or topical NSAIDs for short-term use. Some patients with mild to moderate OA may benefit from glucosamine and chondroitin supplementation.

In cases where conservative measures and simple analgesics are insufficient, intra-articular injections may be considered. Glucocorticoid injections are approved for short-term relief, though prolonged use can further damage the joint. Viscosupplementation, another injectable option, introduces hyaluronan—a naturally occurring

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glycosaminoglycan found in synovial fluid—into the knee joint to restore its lubricating and shock-absorbing properties. This treatment is particularly effective in reducing pain and improving mobility in patients with mild to moderate OA who have not responded to other therapies.

Viscosupplementation aims to restore the viscoelasticity of synovial fluid, providing both immediate pain relief and long-term improvements in joint function. Short-term benefits are attributed to the elastoviscous properties of the injected fluid, while long-term benefits result from restored joint mobility, improved synovial fluid dynamics, and metabolic homeostasis. Studies show that viscosupplementation can improve symptoms in patients with mild to moderate degenerative joint disease of the knee.

Viscosupplements, including products such as Euflexxa, Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synvisc, Synvisc-One, and TriVisc, are specifically indicated for patients with knee OA who have not responded adequately to conservative non-pharmacologic therapy and simple analgesics. While these injections may be effective in the knee, their safety and efficacy in other joints have not been established.

In summary, viscosupplementation provides a valuable treatment option for knee OA, offering relief to patients who have not benefited from other therapies. This approach addresses both the symptoms and the underlying synovial fluid deficits that contribute to the progression of osteoarthritis.

In 2019, the American College of Rheumatology (ACR) published updated guidelines for the management of osteoarthritis of the hand, hip and knee (Kolasinski 2019). The guidelines conditionally recommend against intraarticular hyaluronic acid injections in individuals with knee osteoarthritis. ACR states hyaluronic acid injection benefit has been primarily found in studies with higher risk of bias. The current guidance is based on a systemic review limited to trials with low risk of bias. This meta-analysis has shown the effect size of hyaluronic acid injections compared to saline injections approaches zero.

The American Academy of Orthopedic Surgeons (AAOS) published their Clinical Practice Guideline for Treatment of Osteoarthritis of the Knee in 2013. In their recommendations, the AAOS states that they “cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.” It was noted that the recommendation was based on lack of efficacy, not on potential harm. In their 2021 Management of Osteoarthritis of the Knee (Non-Arthroplasty) guideline update, AAOS revised their recommendation to state hyaluronic acid intraarticular injection is not recommended for routine use in the treatment of symptomatic osteoarthritis of the knee. The updated review of the evidence found that statistically significant improvements were associated with high-molecular cross-linked hyaluronic acid but when compared to mid-range molecular weight, statistical significance was not maintained. This newer analysis did not demonstrate clinically relevant differences when compared to controls.

In 2019, Osteoarthritis Research Society International (OARSI) published updated guidelines for the non-surgical management of knee, hip and polyarticular osteoarthritis (Bannuru 2019). In the 2014 guidance, intra-articular hyaluronic acid was listed as a treatment of “uncertain appropriateness.” The 2019 guidance updated intra-articular hyaluronic acid to conditionally recommended (low consensus) for knee osteoarthritis for longer-term

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treatment effect (symptom improvement beyond 12 weeks) and favorable safety profile. Treatment modalities with a strong recommendation for knee osteoarthritis include arthritis education, structured land-based exercise programs and topical NSAIDs. The American Medical Society for Sport Medicine (AMSSM) published a consensus statement in 2016 recommending the use of hyaluronic acid for the appropriate individuals with knee osteoarthritis. The recommendation is based on network meta-analysis of 11 articles showing a small but statistically significant improvement for participants treated with hyaluronic acid compared to those treated with intra-articular corticosteroids or placebo. Potential for bias was present among the majority of studies included in the metaanalysis, including incomplete data reporting, selective reporting or the absence of blinding of participants and personnel.

In 2017, a workgroup of clinicians published Appropriate Use Criteria (utilizing existing literature supplemented with expert opinion) for use of hyaluronic acid in the treatment of osteoarthritis of the knee (Bhadra and colleagues). The authors found that hyaluronic acid is appropriate for 6 of 17 described clinical scenarios – namely individuals with mild to moderate disease, including those who have experienced an incomplete response or have failed other therapies. The authors concede that evidence on hyaluronic acid is limited – that when compared with active treatments, effects are smaller or there are no clear differences. While the authors conclude that hyaluronic acid injections play a positive role in the treatment of knee OA, they also note that additional research is needed.

Approved Indications

- A. for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics, eg, acetaminophen.

Approved Indication 2 Description

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan, Supartz, or Visco-3 for intra-articular injection, per dose
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 4
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, Gel-Syn, for intra-articular injection, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, SYNOJOYNT, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg

ICD-10	Description
M13	Polyarthrititis, Unspecified
M17.0	Bilateral primary osteoarthritis of knee
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Hyaluronan Injections

A. Criteria For Initial Approval

- i. Individual has a diagnosis of osteoarthritis of the knee supported by radiologic evidence; **AND**
- ii. Documentation is provided that individual has knee pain which interferes with functional activities (e.g., walking, prolonged standing, or pain interrupting sleep, crepitus, and/or knee stiffness); **AND**
- iii. Individual has used for at least three months and failed or experienced adverse effects or have contraindication to both of the following:
 - a. Non-pharmacologic treatment options (e.g., physical therapy, regular exercise, insoles, knee bracing, weight reduction);
 - AND**
 - b. A trial of an analgesic, such as:
 1. Acetaminophen up to 3 to 4 grams per day; **OR**
 2. Non-steroidal anti-inflammatory drugs [NSAIDs]; **OR**
 3. Topical capsaicin cream for at least 3 months;
- AND**
- iv. Individual has used and experienced an inadequate response or intolerance or has a contraindication to a trial of intraarticular steroid injections.

B. Criteria for Continuation of therapy

MMM considers a repeat series of hyaluronan knee injections medically necessary for patients who meet the following criteria:

- i. Documentation is received stating that symptoms have returned; **AND**
- ii. At least six months have passed since the previous series of injections; **AND**
- iii. Documentation is received confirming that there was a significant improvement in pain and functional ability with the prior injections.

C. Authorization Duration

- i. Initial authorization: 1 course of injections for 6 months
- ii. Reauthorization: 6 months

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D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Individual will use to treat osteoarthritis in joints other than the knees (e.g., hip osteoarthritis, temporomandibular joint osteo; **OR**
- ii. When the above criteria are not met and for all other indications

Limits or Restrictions

A. Therapeutic Alternatives:

This medical policy may be subject to Step Therapy. Please refer to the document published on the MMM Website: <https://www.mmm-pr.com/planes-medicos/formulario-medicamentos>

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Number of Injections	Drug	Number of Injections
Durolane	1 injection	Hymovis	2 injections
Euflexxa	3 injections	Monovisc	1 injection
Gel-One	1 injection	Orthovisc	3 to 4 injections
GenVisc	3 to 5 injections	Synvisc One	1 injection
Hyalgan	5 injections	Triluron	3 injections
Supartz/FX	3 to 5 injections	Visco-3	3 injections
TriVisc	3 injections	Gelsyn-3	3 injections
Synojynt	3 injections	Synvisc	3 injections
Exceptions			
N/A			

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Reference Information

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Choose an item.			
Annual Review	Added initial and continuation criteria; modified background information; added frequency of administration in the Quantity Limits Section.	12/9/2024	12/17/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 10/31/2024