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Medication Policy Manual

Policy No: dru351

Topic: Non-Preferred Intra-Articular Hyaluronic Acid Derivatives:

Date of Origin: May 09, 2014

- Durolane (sodium hyaluronate)
- Euflexxa (1% sodium hyaluronate)
- Gel-One (sodium hyaluronate)
- Gelsyn-3 (sodium hyaluronate)
- GenVisc 850 (sodium hyaluronate)
- Hyalgan (sodium hyaluronate)
- Hymovis (high molecular weight hyaluronan)

- Monovisc (sodium hyaluronate)
- Supartz FX (sodium hyaluronate)
- SynoJoynt (1% sodium hyaluronate)
- Triluron (1% sodium hyaluronate)
- Trivisc (sodium hyaluronate)
- Visco-3 (sodium hyaluronate)

Committee Approval Date: December 12, 2024

Next Review Date: 2025

Effective Date: March 1, 2025

IMPORTANT REMINDER

This Medication 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 Medication Policy is to provide a guide to coverage. Medication 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

Hyaluronic acid derivatives are injected directly into the knee joint to help improve the pain associated with osteoarthritis of the knee.

PLEASE NOTE: Preferred Intra-Articular Hyaluronic Acid (IAHA) products do not require pre-authorization. The preferred IAHA products are Synvisc, Synvisc-One, and Orthovisc.

Policy/Criteria

Most contracts require pre-authorization approval of non-preferred intra-articular hyaluronic acid derivatives prior to coverage.

- I. Continuation of therapy (COT): Non-preferred intra-articular hyaluronic acid derivatives may be considered medically necessary for COT when full policy criteria below are met, including quantity limit.

Please note: Medications obtained as samples, coupons, or promotions, paying cash for a prescription (“out-of-pocket”) as an eligible patient, or any other method of obtaining medications outside of an established health plan benefit (from your insurance) does NOT necessarily establish medical necessity. Medication policy criteria apply for coverage, per the terms of the member contract with the health plan.

- II. New starts (treatment-naïve patients): Non-preferred intra-articular hyaluronic acid derivatives may be considered medically necessary when criteria A and B are met.

- A. Treatment with both of the following has been ineffective, contraindicated, or not tolerated:

1. Orthovisc (high molecular weight hyaluronan).
2. Synvisc or Synvisc-One (hylan G-F 20).

AND

- B. The member has a documented diagnosis of osteoarthritis of the knee.

- III. Administration, Quantity Limitations, and Authorization Period

- A. Regence Pharmacy Services considers intra-articular hyaluronic acid derivatives coverable only under the medical benefit (as provider-administered medications).

B. Initial authorization:

1. When pre-authorization is approved, intra-articular hyaluronic acid derivatives may be authorized in quantities of up to 2 treatment courses per knee for the initial 1-year period according to the chart below.

Product Name	Number of Injections Per Treatment Course
Durolane (sodium hyaluronate)	1 dose per knee
Euflexxa (1% sodium hyaluronate)	3 doses per knee
Gel-One (sodium hyaluronate)	1 dose per knee
Gelsyn-3 (sodium hyaluronate)	3 doses per knee
GenVisc 850 (sodium hyaluronate)	5 doses per knee
Hyalgan (sodium hyaluronate)	5 doses per knee
Hymovis (high molecular weight hyaluronan)	2 doses per knee
Monovisc (sodium hyaluronate)	1 dose per knee
Supartz FX (sodium hyaluronate)	5 doses per knee
SynoJoynt (1% sodium hyaluronate)	3 doses per knee
Triluron (1% sodium hyaluronate)	3 doses per knee
Trivisc (sodium hyaluronate)	3 doses per knee
Visco-3 (sodium hyaluronate)	3 doses per knee

C. Continued authorization:

1. After the initial authorization, up to 2 courses per knee over a one-year period may be considered medically necessary if there is clinical documentation supporting clinical benefit from treatment, as defined by at least one of the following:
 - a. There is an improvement in pain or functional ability.
 - b. There has been a reduction in the use or frequency analgesics or anti-inflammatory medication.
2. Subsequent authorizations **may** be reviewed at least every 12 months to confirm that current medical necessity criteria are met, and that the medication is effective.

IV. Non-preferred intra-articular hyaluronic acid derivatives are considered not medically necessary for the following uses:

- A.** Osteoarthritis in joints other than the knee.
- B.** Skin wrinkles or other cosmetic indications.

V. Non-preferred intra-articular hyaluronic acids are considered investigational when used for all other conditions, including but not limited to:

- A.** Temporomandibular joint degenerative disorders.
- B.** Trigger finger.

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.
- Given the inconclusive evidence for safety and efficacy, as well as inconsistent support from evidence-based clinical guidelines, the use of hyaluronic acids is limited to patients with significant functional impairment that impacts quality of life or employment who have tried and failed conservative management strategies (analgesics and physical therapy/exercise) and/or intra-articular corticosteroid injections.
 - * Standard therapies for treatment of knee pain related to arthritis include oral NSAIDs (such as ibuprofen, naproxen, or diclofenac), intra-articular corticosteroid injections, and physical therapy/exercises. These therapies are effective for providing pain relief for the vast majority of patients.
 - * Hyaluronic acids are not recommended for routine use by the 2021 American Academy of Orthopedic Surgeons (AAOS) guidelines for management of osteoarthritis of the knee. The strength of this recommendation is characterized as “moderate” as it is based on multiple moderate-quality studies. ^[1,2]
 - * 2019 American College of Rheumatology (ACR)/Arthritis Foundation (AF) guidelines conditionally recommend against the use of hyaluronic acids for osteoarthritis of the knee. The recommendation is based on lack of benefit in high-quality studies and the potential for harm associated with injections. The authors of a systematic review conducted as part of ACR/AF guideline development stated that benefit is restricted to low-quality studies and that in higher quality studies the benefit diminishes compared to saline injections alone. ^[3]

- * 2019 Guidelines by the Osteoarthritis Research Society International (OARSI) conditionally recommend the use of intra-articular hyaluronic acid when core treatments (exercise programs, dietary weight management, etc.) and pharmacologic therapies have been ineffective. [4]
- * 2020 Veteran’s Administration (VA) guidelines suggest offering intra-articular hyaluronic acid derivatives for patients with persistent pain due to osteoarthritis of the knee inadequately relieved by other interventions. Although the recommendation is in favor of use, the guideline working group noted that the quality of evidence is low. [5]
- Several intra-articular hyaluronic acid products are available and there is little comparative evidence to differentiate the various products. Orthovisc, Synvisc, and Synvisc-One offer the best value for members.
- The use of intra-articular hyaluronic acids for osteoarthritis of the hip is considered not medically necessary. The majority of guidelines strongly or conditionally recommend against use in the hip due to high-quality evidence demonstrating a lack of benefit. [3,4] VA guidelines also noted the use of intra-articular hyaluronic acids in the hip have a higher risk profile due to proximity to the neurovascular structures. [5]
- There is inadequate evidence to support the use of hyaluronic acids in temporomandibular joint degenerative disorders or trigger finger.

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. The overall body of evidence is conflicting and additional high-quality studies are needed.
 - * 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. Intra-articular injections are associated with a robust placebo-response; it is unclear if hyaluronic acid differs from placebo in a clinically meaningful way.
 - * Several studies have reported no improvement in pain or mobility compared to placebo, simple analgesics, or exercise. [6-9]
 - * Despite these limitations, authors of the Veteran’s Administration (VA) guideline on knee osteoarthritis noted that large systemic reviews have shown some benefit and despite downgrades in the quality of evidence due to risk of bias, the outcomes were consistent across study groups. Thus, they have a weak recommendation in favor of offering hyaluronic acids as a treatment option. [5]
 - * A 2015 Agency for Healthcare Research and Quality (AHRQ) review of clinical trials found no significant association between treatment with HLA and time to total knee arthroplasty (TKA). [10,11] The authors concluded that there is insufficient data to make any conclusions regarding the effect of HLA treatment on the time to TKA.
- 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. [12]
- * A randomized trial comparing the effectiveness of Synvisc and Hyalgan is unreliable due to uncertain blinding which may have influenced patient reported outcomes. [13]

Guidelines

- The majority of guidelines offer conflicting recommendations with regard to intra-articular hyaluronic acids for the knee. Guidelines range from strong recommendations against use to conditional or weak recommendations in favor of use. Despite conflicting recommendations on hyaluronic acids, all guidelines recommend the use of conservative management strategies such as physical therapy, exercise, weight management, and NSAIDs.
- Systematic reviews 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. [2,14] While there are conflicting recommendations among guidelines, the highest quality evidence supports minimal or no benefit.
- American College of Rheumatology (ACR)/Arthritis Foundation (AF) guidelines conditionally recommend against the use of hyaluronic acids for osteoarthritis of the knee. [3] The recommendation is based on a systematic review that concluded that the evidence supporting efficacy is limited to low-quality trials. When the analysis was limited to higher quality studies, the benefit of hyaluronic acid injections approached zero. Thus, the ACR/AF concluded that the best evidence does not demonstrate a benefit and there may be harms associated with the injections.
 - * Conditional recommendations are used when the evidence is of low or very low-quality or the balances of benefits to harms is close. Conditional recommendations meant to describe that the majority of informed patients would choose to follow the recommended course of action, but some would not.
 - * ACR/AF Guidelines strongly recommend the use of intra-articular glucocorticoid injections for knee osteoarthritis and conditionally recommends them over other intra-articular injections (including hyaluronic acid). The recommendation is based on high-quality evidence for short-term efficacy. The guidelines do acknowledge that steroid injections may contribute to cartilage loss, but the clinical significance is unclear as change in cartilage thickness has not been shown to be associated with a worsening in pain, functioning, or other radiographic features. [3]
- The American Academy of Orthopedic Surgeons (AAOS) guidelines cannot recommend the routine use of hyaluronic acid for patients with symptomatic osteoarthritis of the knee. The use of hyaluronic acid was downgraded one level (from “strong” to “moderate”) due to a lack of generalized study results and moderate strength of supporting evidence. [1]
 - * The AAOS position is based on assessment of the clinical meaningfulness of the result. The AAOS analysis concluded that the point estimate for the improvement in pain and function was less than half the pre-defined magnitude for clinically meaningful improvement. [1,2]

- * 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.^[1]
- * Crosslinking features of the viscosupplementation products was assessed in two high quality studies. In patients with osteoarthritis, there was no difference between cross-linked and non-cross-linked HA.^[1]
- * These guidelines also state that a specific subset of patients might benefit from intra-articular hyaluronic acids for the knee based on previous research reporting benefits in their use.^[1]
- Osteoarthritis Research Society International (OARSI) guidelines conditionally recommend the use of hyaluronic acids after non-pharmacologic and NSAIDs/acetaminophen have been tried. The recommendations were also based on systematic reviews and meta-analyses of the available evidence though the guideline did account for differences in efficacy in high versus low-quality studies or address the impact of publication bias. ^[4]
- 2020 Veteran’s Administration (VA) guidelines suggest offering intra-articular hyaluronic acid derivatives for patients with persistent pain due to osteoarthritis of the knee inadequately relieved by other interventions. Although the recommendation is in favor of use, the guideline working group noted that the quality of evidence is low. ^[5]

SAFETY

- The most common adverse events reported with hyaluronic acids include joint pain, stiffness and swelling, as well as injection site reactions. ^[15-22]

NOT MEDICALLY NECESSARY USES

- The use of intra-articular hyaluronic acids for osteoarthritis of the hip is considered not medically necessary.
 - * 2019 ACR/AF Guidelines strongly recommend against the use of hyaluronic acid for the treatment of hip osteoarthritis due to high-quality evidence for lack of benefit. ^[3]
 - * 2020 VA Guidelines conditionally recommend against the use of intra-articular hyaluronic acids in the hip due to high-quality evidence demonstrating a lack of benefit and safety concerns associated with the administration, specially the proximity to neurovascular structures. ^[5]

INVESTIGATIONAL USES

Use in Joints Other than the Knee

- 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; however, several larger, well-controlled trials have concluded that hyaluronic acid is not effective in this setting (no different than saline). ^[19-22]

- * 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. [23]
- * 2019 ACR/AF Guidelines strongly recommend against the use of hyaluronic acid for the treatment of hip osteoarthritis due to high-quality evidence for lack of benefit. [3]

Temporomandibular Joint (TMJ) degenerative disorders

- Several small studies have evaluated hyaluronic acids in the treatment of symptoms of TMJ degenerative disorders (pain, range-of-motion, chewing efficiency). Larger, well-controlled studies are needed to confirm the benefit of hyaluronic acids and to determine the optimal frequency, dose, and product. [24-27]

Trigger finger

- One small randomized, controlled trial (N=36) evaluated patients with a diagnosis of trigger finger. Patients were randomized to hyaluronic acid or steroid injections, after the months of follow-up the percent of patients without triggering effect was numerically lower in the hyaluronic acid group, but not statistically significant. While promising, the results must be confirmed in larger studies. Additionally, the optimal frequency, dose, and hyaluronic acid product has not been determined. [28]

Cross References	
BlueCross BlueShield Association Medical Policy, 2.01.31 - Intra-articular Hyaluronan Injections for Osteoarthritis. [May 2024]	

Codes	Number	Description
HCPCS	J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
HCPCS	J7323	Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
HCPCS	J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
HCPCS	J7328	Hyaluronan or derivative, Gelsyn-3, for intra-articular injection, 0.1 mg
HCPCS	J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
HCPCS	J7321	Hyaluronan or derivative, Hyalgan, Supartz FX, or Visco-3, for intra-articular injection, per dose
HCPCS	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
HCPCS	J7327	Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
HCPCS	J7331	Hyaluronan or derivative, Synjoynt, for intra-articular injection, 1 mg
HCPCS	J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
HCPCS	J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg

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Revision History

Revision Date	Revision Summary
12/12/2024	No criteria changes with this annual review.
12/7/2023	No criteria changes with this annual review.
12/9/2022	No changes to criteria with this annual update.
9/23/2022	Updated preferred intra-articular hyaluronic acid (IAHA) products to Orthovisc, Synvisc, and Synvisc One. Added Synjoynt (1% sodium hyaluronate) to policy. Effective 1/1/2023.
7/16/2021	Effective 10/1/2021: <ul style="list-style-type: none"> • Preferred intra-articular hyaluronic acid (IAHA) products will not require pre-authorization. • Revised policy to allow coverage of non-preferred IAHA products in patients with osteoarthritis of the knee who have tried and failed all preferred IAHA products. • Products may be authorized for up to 1 year initially. Re-authorization requires documentation of ongoing clinical benefit.
4/22/2020	No criteria changes with this annual update. Policy position statements were updated to include updated guidelines from the American College of Rheumatology/Arthritis Foundation and Osteoarthritis Research Society International.
1/22/2020	<ul style="list-style-type: none"> • Added continuation of therapy (COT) criteria (no change to intent of coverage criteria). • Added sodium hyaluronate (Trivisc, Durolane, and Triluron) to policy.
1/31/2019	No criteria changes with this annual update.
12/14/2018	No criteria changes with this annual update.
12/8/2017	No criteria changes with this annual update. Added sodium hyaluronate (Durolane) to policy.
4/14/2017	No criteria changes with this annual update.
4/8/2016	Added temporomandibular joint disorders and trigger finger as investigational uses.
5/9/2014	New policy.

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