Department:	Pharmacy Management	**Original Approval:**	07/24/2017
Policy No:	PM144	**Last Approval:**	02/06/2026
Policy Title:	Hyaluronic acid derivatives (such as Durolane®, Euflexxa®, Gel-One®, Gelsyn-3™, GenVisc® 850, Hyalgan®, Hymovis®, Hymovis One®, Monovisc®, Orthovisc®, Supartz FX™, Sodium hyaluronate, Synvisc®, Synvisc-One®, Triluron™, TriVisc™,Visco-3™) Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☐ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☐ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for Hyaluronic acid derivatives (Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Hymovis One®, Monovisc, Orthovisc, Supartz FX, Sodium hyaluronate, Synvisc, Synvisc-One, SynoJoynt, Triluron, TriVisc,Visco-3): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Medication list (current and past) -Current and past treatment modalities, including physical therapy -Product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physiatrist -Dosing and duration of therapy -Imaging/Radiology.

Background

Hyaluronic acid derivatives are indicated for the treatment of pain related to knee osteoarthritis in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics (e.g., acetaminophen).[1-16, 43] The use of intraarticular injections is to restore the normal properties (viscosity and elasticity) of the synovial fluid. Gel-One, Hyalgan, Supartz FX, Synvisc/Synvisc-One, Triluron, and Visco-3 are derived from rooster or chicken combs. The remaining products are derived from non-avian sources and may be useful for patients with allergies to eggs or poultry products. GenVisc 850 has data to support similarity to Supartz FX.[9] All of the products given as a series of five injections (GenVisc 850, Hyalgan, and Supartz FX) have a corresponding product that is equivalent to three injections (TriVisc, Triluron, and Visco-3, respectively). Although

retreatment data are limited, all of these products have data concerning efficacy and/or safety of repeat courses. In many cases, at least 6 months was required, or a minimum of 6 months had elapsed prior to injection of a repeat course.

Guidelines

Guidelines for the medical management of osteoarthritis of the hand, hip, and knee are available from the American College of Rheumatology (2019).[17] Multiple non-pharmacological modalities are recommended for knee osteoarthritis, including exercise, self-management programs, weight loss, Tai Chi, and use of assistive devices (i.e., bracing or a cane). Pharmacologic therapy for knee osteoarthritis consists of acetaminophen, oral and topical non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, intraarticular corticosteroid injections, duloxetine, and topical capsaicin. There is limited evidence establishing a benefit of hyaluronic acid intraarticular injections, which contributes to the conditional recommendation against use in knee osteoarthritis. However, when other alternatives have been exhausted or have failed to provide satisfactory benefit, use of intraarticular hyaluronic acid injections may be viewed more favorably than offering no intervention. In the guidelines, no distinction is made between the available intra-articular hyaluronic acid products or between products with various molecular weights.

The Osteoarthritis Research Society International also has guidelines for knee osteoarthritis (2019).[19] The guidelines note that use of intraarticular hyaluronic acid injections are conditionally recommended for patients with knee osteoarthritis. The guidelines comment on the long-term treatment effect with intraarticular hyaluronic acid injections which is associated with symptom improvement beyond 12 weeks and a move favorable safety profile than intraarticular corticosteroid injections.

Definitions

None.

Indications/Criteria

Medicaid Member	***Drugs are non-covered for Medicaid.***
Individual & Family (Cascade	***Continue to criteria for approval below*** ***Preferred products: Monovisc, Orthovisc, Synvisc, Synvisc One***

Select) Members	***Non-preferred products: Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Hymovis One, Supartz FX, Sodium hyaluronate injection, SynoJoynt , Triluron, TriVisc, Visco-3***
Medicare Members	***Continue to criteria for approval below*** ***Preferred products: Monovisc, Orthovisc, Synvisc, Synvisc One*** ***Non-preferred products: Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Hymovis One, Supartz FX, Sodium hyaluronate injection, SynoJoynt, Triluron, TriVisc, Visco-3***

Hyaluronic Acid FDA-Approved Indications (if requesting a Non-Preferred Product, please also see Recommended Exception Criteria)

1. Osteoarthritis of the Knee. Approve one course of therapy per treated knee for 6 months if the patient meets one of the following conditions (A or B)

A) Initial Therapy. Approve an initial course if the patient meets ALL of the following conditions (i, ii, and iii)

i. Diagnosis of the knee to be treated is confirmed by radiologic evidence of knee osteoarthritis; AND
Note: Examples of radiographic evidence includes x-ray, magnetic resonance imaging (MRI), computed tomography (CT) scan, ultrasound.

ii. Patient has tried at least TWO of the following three modalities of therapy for osteoarthritis (a, b, or c):

a) At least one course of physical therapy for knee osteoarthritis; OR

b) At least TWO of the following pharmacologic therapies [(1), (2), (3), or (4)] [verification of therapies required]

1. Oral or topical nonsteroidal anti-inflammatory drug(s) [NSAID(s)]; OR
Note: Examples of oral NSAIDs include naproxen, ibuprofen, celecoxib. Examples of topical NSAIDs include diclofenac solution or diclofenac gel. A trial of two or more NSAIDs (oral and/or topical) counts as one pharmacologic therapy.

2. Acetaminophen; OR

3. Tramadol (Ultram®/XR, generic); OR

4. Duloxetine (Cymbalta®, generic); OR

c) At least TWO injections of intraarticular corticosteroids to the affected knee; AND

iii. The product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physical medicine and rehabilitation (physiatrist).

B) Patient has Already Received One or More Courses of a Hyaluronic Acid Derivative in the Same Knee. Approve one repeat course if the patient meets ALL of the following conditions (i, ii, and iii)

i. At least 6 months have elapsed since the last injection with any hyaluronic acid derivative; AND

ii. According to the prescriber, the patient had a response to the previous course of hyaluronic acid derivative therapy for osteoarthritis of the knee and now requires additional therapy for osteoarthritis symptoms; AND
Note: Examples of a response include reduced joint pain, tenderness, or morning stiffness, improved mobility.

iii. The product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physical medicine and rehabilitation (physiatrist).

Dosing. Approve the following dosing regimens if the above criteria are met:

A. Durolane, Gel-One, Hymovis One, Monovisc, Synvisc-One: Approve one injection.
B. Hymovisc: Approve up to two injections given 1 week apart.
C. Euflexxa, Gelsyn-3, sodium hyaluronate 1% injection, SynoJoynt, Synvisc, Triluron, TriVisc, Visco-3: Approve up to three injections given 1 week apart.
D. Orthovisc: Approve up to 4 injections given 1 week apart.
E. GenVisc 850, Hyalgan, Supartz FX: Approve up to 5 injections given 1 week apart.

Note: Dose listed is for one knee. If two knees are being treated, then each knee requires a syringe or vial of product

Recommended Exception Criteria

Non-Preferred Products	Exception Criteria
Individual & Family (Cascade Select) and	**1.** Approve one course of therapy per treated knee if the patient meets BOTH of the following (A and B): **A)** Patient meets Hyaluronic Acid Derivative criteria; AND **B)** Patient meets ONE of the following (i or ii):

Medicare Criteria Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Hymovis One, Supartz FX, Sodium hyaluronate injection, SynoJoynt , Triluron, TriVisc, Visco-3	**i.** Patient tried at least one course of therapy with at least TWO of the following products (a, b, c, or d): **a)** Monovisc (one course equals 1 injection); OR **b)** Orthovisc (one course equals 3 or 4 injections); OR **c)** Synvisc (one course equals 3 injections); OR **d)** Synvisc One (one course equals 1 injection); OR **ii.** Patient meets BOTH of the following (a and b): **a)** The request is for a product that requires more than one injection to complete a course; AND Note: Examples of products that are given as more than one injection to complete a course include Euflexxa, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Supartz FX, Sodium hyaluronate injection, SynoJoynt, Triluron, TriVisc, or Visco-3. **b)** Patient has already started a course of injections with one of these agents. Note: If a course of therapy has already been started, the patient can continue with the same product to complete the entire course. After completing this course, if further therapy is required with an intraarticular hyaluronic acid derivative, then Preferred Product(s) must be tried.
Medicare Criteria Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Hymovis One, Supartz FX, Sodium hyaluronate injection, SynoJoynt , Triluron, TriVisc, Visco-3	**1.** Approve one course of therapy per treated knee if the patient meets BOTH of the following (A and B): **A)** Patient meets Hyaluronic Acid Derivative criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient tried at least one course of therapy with at least TWO of the following products (a, b, c, or d): **a)** Monovisc (one course equals 1 injection); **b)** Orthovisc (one course equals 3 or 4 injections); **c)** Synvisc (one course equals 3 injections); **d)** Synvisc One (one course equals 1 injection); OR **ii.** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.

Duration of Therapy. Duration of therapy varies depending on product. The course may be repeated if the patient had a response to the previous course.

Labs/Diagnostics. For initial approval, radiologic evidence of osteoarthritis of the affected knee is required as noted in the criteria section.

Waste Management.

The number of injections depends on which product is used. The entire vial or syringe is injected. If both knees are being treated, then two syringes/vials will be needed.

Conditions Not Recommended for Approval

Hyaluronic acid derivatives have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage of these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Acute Ankle Sprain.** A randomized, controlled, prospective trial was conducted which assessed the use of IA HA in acute ankle sprains.[18-19] Patients treated with IA HA (n = 79) within 48 hours of injury and again on Day 4 reported a time to pain-free and disability-free return to sport of 11 days (± 8 days) compared with 17 days (± 8 days) for placebo ($P < 0.05$).[18] All patients were also treated with standard of care (rest, ice, compression, and elevation [RICE]). At 24 months, the placebo group experienced an increase in repeat sprains when compared with those treated with HA (21 recurrent ankle sprains in the placebo group compared with 7 recurrent ankle sprains in the HA treatment group [$P < 0.001$]) as well as a significant difference in missed days from participation in sport activity (49 days vs. 12 days for the placebo and HA groups, respectively; $P < 0.001$).[19] More data are needed to determine the role of IA HA products in the treatment of acute ankle sprains.
2. **Osteoarthritis (OA) and Other Pathologic Conditions Involving Joints Other than the Knee** (e.g., hand, hip, ankle, shoulder OA, temporomandibular joint [TMJ], adhesive capsulitis of the shoulder, subacromial impingement). The prescribing information for these agents state in the precautions section that the safety and effectiveness of hyaluronic acid derivatives injections into joints other than the knee have not been established.[1-10] Due to the absence of evidence to support use of IA HA and potential for harm, the guidelines for the management of hand, hip, and knee OA by ACR (2012) do not recommend use of IA HA in patients with hand or hip OA.12 AAOS has published guidelines that mention HA as an option for glenohumoral (shoulder) joint OA.20 The guidelines note that the strength of evidence for using HA to treat this joint is weak even though each outcome in the

single study evaluated did result in statistically significant improvement in pain relief, range of motion, and quality of life for patients with shoulder pain. Small trials have also investigated IA HA in other joints, including ankle OA21-28 and hip OA.[29-36] More data are needed to determine if there is a role for IA HA for the treatment of OA involving other joints. A small trial (n = 70) found that IA HA did not result in increased benefit for adhesive capsulitis of the shoulder (also known as frozen shoulder) in patients who were already receiving PT.37 Another small study (n = 159) did not show benefit of IA HA over corticosteroid or placebo injections in patients with subacromial impingement.[38]

3. **Pathologic Conditions of the Knee Other than Osteoarthritis (OA)** [e.g., chondromalacia patellae, osteochondritis dissecans, patellofemoral syndrome, post-anterior cruciate ligament {ACL} reconstruction]. HA products are indicated in knee OA.[1-10] Adequate, well-designed trials have not clearly established the use of IA HA in other conditions of the knee.[39-40]

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Special Considerations

None.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Individual & Family (Cascade Select)	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

List of Appendices

None.

Citations & References

CFR	42 CFR § 438.210	
WAC	WAC 284-43-2050	
RCW		
LOB & Contract Citation	☐ **WAHIMC**	
	☐ **BHSO**	
	☐ **Wraparound**	
	☐ **SMAC**	
	☐ **HH**	
	☐ **AHE**	
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	**1.** Durolane® intraarticular injection [prescribing information]. Durham, NC: Bioventus; not dated. **2.** Euflexxa® intraarticular injection [prescribing information]. Parsippany, NJ: Ferring; July 2016. **3.** Gel-One® intraarticular injection [prescribing information]. Warsaw, IN: Zimmer; May 2011. **4.** Gelsyn-3® intraarticular injection [prescribing information]. Durham, NC: Bioventus; 2016. **5.** GenVisc® 850 intraarticular injection [prescribing information]. Doylestown, PA: OrthogenRx; not dated. **6.** Hyalgan® intraarticular injection [prescribing information]. Parsippany, NJ: Fidia Pharma; May 2014. **7.** Hymovis® intraarticular injection [prescribing information]. Parsippany, NJ: Fidia Pharma; October 2015. **8.** Monovisc® intraarticular injection [prescribing information]. Bedford, MA: Anika; not dated. **9.** Orthovisc® intraarticular injection [prescribing information]. Bedford, MA: Anika; September 2014. **10.** Sodium hyaluronate 1% intraarticular injection [prescribing information]. North Wales, PA: Teva; March 2019. **11.** Supartz FX™ intraarticular injection [prescribing information]. Durham, NC: Bioventus; April 2015.	

12. Synvisc® intraarticular injection [prescribing information]. Ridgefield, NJ: Genzyme; September 2014.
13. Synvisc-One® intraarticular injection [prescribing information]. Ridgefield, NJ: Genzyme; September 2014.
14. Triluron intraarticular injection [prescribing information]. Florham Park, NJ: Fidia Pharma; March 2019.
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16. Visco-3 intraarticular injection [prescribing information]. Durhan, NC: Bioventus; not dated.
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prospective randomized trial with long-term follow-up. Clin Exp Rheumatol. 2008;26(2):288-294.
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30. Sun SF, Hsu CW, Sun HP, et al. The effect of three weekly intra-articular injections of hyaluronate on pain, function, and balance in patients with unilateral ankle arthritis. J Bone Joint Surg Am. 2011;93(18):1720-1726.
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43. SynoJoynt™ injection [prescribing information]. Naples, FL: Arthrex; 2022.
44. Hymovis® One injection [prescribing information]. Florham Park, NJ: Fidia; 2025.

Revision History

Revision Date	Revision Description	Revision Made By
07/24/2017	*NEW*	Michael Sporck, Pharmacy Intern Sophia Yun, PharmD
07/25/2017	Approval	MMLT
03/09/2018	Reassigned from UM to PM	Cindy Bush
04/25/2018	Revised	Jennifer Farley PharmD

05/14/2018	Revised, added HTA/LCD box	Catherine Vu, PharmD
11/27/2018	Updated LCD reference	Jennifer Farley PharmD
12/12/2018	Approval	UM Committee
03/01/2019	Revised (addition of new product)	Jennifer Farley PharmD
03/14/2019	Approval	UM Committee
09/06/2019	Removed reference to Local Coverage Article as it should not be used as criteria.	Jennifer Farley PharmD
09/12/2019	Approval	UM Pharmacy Subcommittee
08/04/2020	Annual review. No changes	Jennifer Farley PharmD
08/20/2020	Approval	UM Pharmacy Subcommittee
6/30/2020	Annual review. Updated LCA. Removed obsolete product Supartz. Update Sodium hyaluronate 1% to sodium hyaluronate 1% (aligns with how product is marketed in the US). Updated Guidelines section. Updated dosing table. Divided criteria into Medicaid/Cascade Select and Medicare criteria. Clarified dosing.	Catherine Vu, PharmD
07/28/2021	Approval	UM Pharmacy Subcommittee
05/04/2022	Annual review. Updated verbiage under Medicaid criteria to “Documented trial and failure to other forms of non-surgical care…”. Included pain management as an appropriate specialist to administer medication.	Alan Gabot, PharmD
05/05/2022	Approval	UM Pharmacy Subcommittee
11/30/2022	Early update. Criteria updated to Medicaid LOB which includes designating preferred and non-preferred products.	Alan Gabot, PharmD
12/02/2022	Approval	UM Pharmacy Subcommittee
08/15/2023	Annual review. SynoJoynt was added to the policy. For Medicare, Monovisc, Orthovisc, Synvisc, and	Alan Gabot, PharmD

	Synvisc One are listed as preferred products, while Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Supartz FX, Sodium hyaluronate injection, SynoJoynt, Triluron, TriVisc, Visco-3 are listed as non-preferred products. Criteria for Medicare was updated to be the same as the criteria for Medicaid and Cascade Select.	
09/07/2023	Approval	UM Pharmacy Subcommittee
06/11/2024	Annual review. Hyaluronic acid derivatives are non-covered for Medicaid starting 7/1/24 according to the Washington Health Care Authority.	Alan Gabot, PharmD
06/12/2024	Approval	UM Criteria Subcommittee
04/08/2025	Annual review. No criteria changes.	Alan Gabot, PharmD
04/09/2025	Approval	UM Criteria Subcommittee
09/09/2025	Early update. Made additional criteria for Medicare patients requesting non-preferred products. Medicare patients may receive a non-preferred drug if the patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.	Alan Gabot, PharmD
09/10/2025	Approval	UM Criteria Subcommittee
02/05/2026	Annual review. Removed how supplied table of each hyaluronic acid derivative. Added Hymovis One to the policy, which is listed as a non-preferred products. Separated the non-preferred criteria from the clinical criteria and placed it in the Recommended Exception Criteria section.	Alan Gabot, PharmD
02/06/2026	Approval	UM Criteria Subcommittee