Pharmacy Management Drug Policy

SUBJECT: Viscosupplementation with Hyaluronic Acid
POLICY NUMBER: PHARMACY-75
EFFECTIVE DATE: 10/15/2018
LAST REVIEW DATE: 09/08/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Hyaluronic acid (also known as hyaluronan or hyaluronate) is found in normal synovial fluid in the joints and acts as a joint lubricant and shock absorber. Viscosupplementation is the intra-articular injection of hyaluronic acid as a treatment for pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative, non-pharmacological therapy, and simple analgesics. The proposed purpose of Viscosupplementation is to restore normal viscoelasticity in the synovial fluid and replace any loss of synovial fluid. It may reduce pain for up to 6 to 12 months. There are several FDA-approved hyaluronic acid preparations. The various preparations differ in their molecular weights and are derived from either bacterial cells or avian sources; however, there is no clinical difference between the various preparations in terms of efficacy, safety, and outcomes on treatment.

This policy is applicable to the following products that are FDA-approved for the treatment of osteoarthritis of the knee:

Preferred Products:	
Name	**Dose**
Euflexxa	1 injection (20 mg) once weekly x 3 doses
Synvisc	1 injection (16 mg) once weekly x 3 doses
Synvisc One	1 injection (48 mg) x 1 dose

Non-Preferred Products:	
Name	**Dose**
Durolane	1 injection (60 mg) x 1 dose
Gel-One	1 injection (30 mg) x 1 dose
Gelsyn-3	1 injection (16.8 mg) once weekly x 3 doses
Genvisc 850	1 injection (25 mg) once weekly x 3-5 doses
Hyalgan	1 injection (20 mg) once weekly x 5 doses
Hymovis	1 injection (24 mg) once weekly x 2 doses
Monovisc	1 injection (88 mg) x 1 dose
Orthovisc	1 injection (30 mg) once weekly x 3-4 doses
Supartz FX	1 injection (25 mg) once weekly x 3-5 doses
Synojoynt	1 injection (20 mg) once weekly x 3 doses
Triluron	1 injection (20 mg) once weekly x 3 doses
TriVisc	1 injection (25 mg) once weekly x 3 doses
Visco-3	1 injection (25 mg) once weekly x 3 doses

POLICY:

For Essential Plan, Commercial and Exchange Plans:

1. The patient must have a diagnosis of osteoarthritis (OA) of the knee.
2. The patient must be 21 years of age or above, as the safety and efficacy of intra-articular injection has not been established in pediatric patients younger than 21 years old.
3. All requests for viscosupplementation with Hyaluronic Acid will require use of Euflexxa or Synvisc/Synvisc One. No other Hyaluronic Acid preparation will be covered.
4. Euflexxa, Synvisc and Synvisc One are covered without prior authorization.
5. Approval will be for 6 months at a time.

For Medicare Advantage Plans:

1. The patient must have a diagnosis of osteoarthritis (OA) of the knee, osteoarthritis (OA) of the shoulder, or impingement syndrome of the shoulder.
2. The patient must be 21 years of age or above, as the safety and efficacy of intra-articular injection has not been established in pediatric patients younger than 21 years old.
3. Euflexxa, Synvisc, and Synvisc One are preferred products and will be covered without prior authorization.
4. A trial and failure of Euflexxa **AND** Synvisc/Synvisc One will be required prior to coverage of a non-preferred product UNLESS the patient is currently established on a non-preferred product.
5. Approval is for 2 years at a time.
   a. Recertification is allowed if there is documentation of significant improvement in pain and functional capacity from prior series of injections **AND** the last injection (in a prior course) was given at least 6 months ago.
   b. For a diagnosis of osteoarthritis of the shoulder, re-treatment is limited to ONE course by CMS guidelines (patient is allowed to have 2 total courses, initial course and one repeat course).
   c. For a diagnosis of osteoarthritis of the knee and impingement syndrome of the shoulder, there is no limit to re-treatment.

For Medicaid Managed Care (MMC) Plans:

Viscosupplementation with J7321 (Hylagan, Supartz, Visco-3), J7323 (Euflexxa) and J7326 (Gel-One), coverage will be available for compendia- supported uses (see table below).

******* Please note, Viscosupplementation for any J code listed in this policy is not a covered benefit for MMC for a diagnosis of osteoarthritis of the knee (see table below). *******

April 2022 New York State Medicaid Update:

There will be no reimbursement provided by Medicaid when the Healthcare Common Procedure Code System (HCPCS) codes, provided in the table below, are used for the treatment of osteoarthritis of the knee:

HCPCS Code	Code Description
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
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
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, Synojoynt, 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

*Coverage will be available for compendia-supported uses.

Please note: Medicaid will only cover administration fees for covered services. Coverage will continue for viscosupplementation for compendia-supported uses. For additional guidance regarding viscosupplementation claim requirements, the viscosupplementation *Clinical Criteria Worksheet* can be found on the NYS Department of Health (DOH) "New York State Medicaid Fee-for-Service Practitioner Administered Drug Policies and Billing Guidance" web page, located at: https://www.health.ny.gov/health_care/medicaid/program/practitioner_administered/ffs_practitioner_administer.htm.

POLICY GUIDELINES:

1. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
2. Viscosupplementation is administered by a health care professional and is therefore covered under the medical benefit.
3. For Medicare Advantage plans, this only applies to patients who are new to therapy and will not affect patients who are currently established on therapy with non-preferred products.
4. Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) (Step Therapy Override) is not applicable as the Viscosupplements are considered devices, not drugs.
5. Certain conditions are excluded due to lack of peer-reviewed literature for which efficacy or safety data is not yet available include, but are not limited to:
   - Pain due to osteoarthritis in any other joint besides the knee (except for Medicare, which covers the shoulder)
   - Pain due to temporomandibular joint (TMJ) disorder
   - Any other form of arthritis (including rheumatoid arthritis)
   - Pain following total or partial knee joint replacement
6. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
7. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
8. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is

not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

9. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
10. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

APPROVAL TIME PERIODS:

Line of Business	Medical Initial approval	Medical Recertification
Commercial, Exchange, SafetyN (Medicaid, Harp, CHP, Essential Plan)	All sites of service – 6 months	All sites of service – 6 months
Medicare	All sites of service – 2 years	All sites of service – 2 years

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. Codes may not be covered under all circumstances. Please read the policy and guidelines statements carefully.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT	
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa (e.g., shoulder, hip, knee joint, subacromial bursa); without ultrasound guidance
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

HCPCS	
J7318	Durolane
J7323	Euflexxa
J7326	Gel-One
J7328	Gelsyn-3
J7320	Genvisc 850
J7322	Hymovis
J7327	Monovisc
J7324	Orthovisc

J7321	Supartz, Hyalgan, Visco-3
J7331	Synojoynt
J7325	Synvisc, Synvisc One
J7332	Triluron
J7329	TriVisc

UPDATES:

Date:	**Revision**
09/08/2025	Revised
03/06/2025	Revised
01/01/2025	Revised/Updates approved by P&T Committee 11/21/2024
08/15/2024	Reviewed/P&T Committee Approval
06/2024	Revised
08/2023	Reviewed/P&T Committee Approval
03/2023	Revised
09/2022	Reviewed/P&T Committee Approval
06/2022	Revised
05/2022	Revised
09/2021	Reviewed /P&T Committee Approval
08/2021	Revised
04/2021	Revised
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10/2020	Revised
9/2020	Revised
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9/2019	Revised
7/2019	Revised
5/2019	P & T Committee Approval
12/2018	Revised
11/2018	Revised
10/2018	Revised
7/2018	Created

REFERENCES:

In addition to the full FDA approved prescribing information for each individual product, the following references have been utilized in creating this policy and specific criteria:

1. Navarro-Sarabia F, Coronel P, Collantes E, Navarro FJ, de la Serna AR, Naranjo A, Gimeno M, Herrero-Beaumont G; AMELIA study group. A 40-month multicentre, randomised placebo-controlled study to assess the efficacy and carry-over effect of repeated intra-articular injections of hyaluronic acid in knee osteoarthritis: the AMELIA project. Ann Rheum Dis. 2011 Nov;70(11):1957-62
2. Day, R. et al. A double blind, randomized, multicenter, parallel group study of the effectiveness and tolerance of intraarticular hyaluronan on osteoarthritis of the knee. J Rheumatol 2004; 31: 755-782.

3. Strand V et al. An integrated analysis of five double-blind, randomized controlled trials evaluating the safety and efficacy of a hyaluronan product for intra-articular injection in osteoarthritis of the knee. Osteoarthritis Cartilage. 2006;14(9):858-866.
4. Arden NK, Åkermark C, Andersson M, Todman MG, Altman RD. A randomized saline-controlled trial of NASHA hyaluronic acid for knee osteoarthritis. Curr Med Res Opin. 2014 Feb;30(2):279-86.
5. Leighton R, Akermark C, Therrien R, Richardson JB, Andersson M, Todman MG, Arden NK; DUROLANE Study Group. NASHA hyaluronic acid vs. methylprednisolone for knee osteoarthritis: a prospective, multi-centre, randomized, non-inferiority trial. Osteoarthritis Cartilage. 2014 Jan;22(1):17-25.
6. Zhang H, Zhang K, Zhang X, Zhu Z, Yan S, Sun T, Guo A, Jones J, Steen RG, Shan B, Zhang J, Lin J. Comparison of two hyaluronic acid formulations for safety and efficacy (CHASE) study in knee osteoarthritis: a multicenter, randomized, double-blind, 26-week non-inferiority trial comparing Durolane to Artz. Arthritis Res Ther. 2015 Mar 10;17:51.
7. McGrath AF, McGrath AM, Jessop MA, et al (2013). A Comparison of Intra-Articular Hyaluronic Acid Competitors in the Treatment of Mild to Moderate Knee Osteoarthritis. J Arthritis 2: 108.
8. Altman RD, Akermark C, Beaulieu AD, Schnitzer T. Osteoarthritis and cartilage: Efficacy and safety of a single intra-articular injection of a non-animal stabilized hyaluronic acid (NASHA) in patients with osteoarthritis of the knee. OsteoArthritis and Cartilage 2004;12:642-649.
9. Arden NK, Akermark C, Andersson M, Todman MG, Altman RD. A randomized saline-controlled trial of NASHA hyaluronic acid for knee osteoarthritis. Curr Med Res Opin 2014;30:279-86.
10. Akermark C, Berg P, Bjorkman A, Malm P. Non-Animal stabilized hyaluronic acid in the treatment of osteoarthritis of the knee: A tolerability study. Clin Drug Invest 2002:22(3):157-166.
11. Krocker D, Matziolis G, Tuischer J, Funk J, Tohtz S, Buttgereit F, et al. Reduction of arthritis associated knee pain through a single intra-articular injection of synthetic hyaluronic acid. Rheumatol 2006;65:327-331.
12. Skwara A, Ponelis R, Tibesku CO, Rosenbaum D, Fuchs-Winkelmann S. Gait patterns after intraarticular treatment of patients with osteoarthritis of the knee – Hyaluronan versus triamcinolone: A prospective, randomized, doubleblind, monocentric study. Eur J Med Res 2009;14:157-164.
13. Viscosupplementation of the Knee: Non-Coverage Decision - https://www.health.ny.gov/health_care/medicaid/program/update/2014/2014-03.htm#vis
14. Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses - https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses