Pharmacy Management Drug Policy

SUBJECT: Viscosupplementation with Hyaluronic Acid
POLICY NUMBER: PHARMACY-75
EFFECTIVE DATE: 10/15/2018
LAST REVIEW DATE: 08/24/2023

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.

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. 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.
5. Approval will be for 2 years at a time.
    a. Continued approval at time of recertification will require documentation that the product is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that 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.

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.

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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

APPROVAL TIME PERIODS:

Line of Business	Medical Initial approval	Medical Recertification
Commercial, Exchange, SafetyNet (Medicaid, Harp, CHP, Essential Plan)	All sites of service – 2 years	All sites of service – 2 years
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).
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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
J7320	Genvisc 850
J7321	Supartz, Hyalgan, Visco-3
J7322	Hymovis
J7323	Euflexxa
J7324	Orthovisc
J7325	Synvisc, Synvisc One
J7326	Gel-One
J7327	Monovisc
J7328	Gelsyn-3
J7329	TriVisc
J7331	Synojoynt
J7332	Triluron

UPDATES:

Date:	Revision
8/2023	Reviewed/P&T Committee Approval
3/2023	Revised
9/2022	Reviewed/P&T Committee Approval
6/2022	Revised
5/2022	Revised
9/2021	Reviewed /P&T Committee Approval

8/2021	Revised
4/2021	Revised
2/2021	Revised
10/2020	Revised
9/2020	Revised
7/2020	Revised
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:

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