Pharmacy Management Drug Policy

SUBJECT: Viscosupplementation with Hyaluronic Acid for Osteoarthritis of the Knee
POLICY NUMBER: PHARMACY-75
EFFECTIVE DATE: 10/15/2018
LAST REVIEW DATE: 9/23/2019

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. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

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**
Durolane	1 injection (60 mg) x 1 dose
Euflexxa	1 injection (20 mg) once weekly x 3 doses
Gelsyn-3	1 injection (16.8 mg) once weekly x 3 doses
Supartz FX	1 injection (25 mg) once weekly x 3-5 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**
Gel-One	1 injection (30 mg) x 1 dose
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
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

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Policy:

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. Durolane, Euflexxa, Gelsyn-3, Supartz FX, Synvisc, and Synvisc One are preferred products and will be covered without prior authorization.
4. For non-preferred products, a trial of **TWO** preferred products will be required prior to coverage.
    a. Approval will be for 2 years at a time.
    b. 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.

Policy Guidelines:

1. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
2. This policy is not applicable to Medicare plans.
3. For Medicaid Managed Care (MMC), viscosupplementation is not a covered benefit for a diagnosis of osteoarthritis of the knee.
4. Viscosupplementation is administered by a health care professional and is therefore covered under the medical benefit.
5. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required
    a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    d. The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability

as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

6. Conditions considered investigational will not be covered. Conditions considered investigational 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
    - Pain due to temporomandibular joint (TMJ) disorder
    - Any other form of arthritis (including rheumatoid arthritis)
    - Pain following total or partial knee joint replacement

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
J7320	Genvisc 850
J7321	Supartz FX, Visco-3, Hyalgan
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
9/2019	Revised
7/2019	Revised
5/2019	P & T 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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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.
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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.
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