Viscosupplementation for Osteoarthritis

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan members with certain types of knee pain may be eligible for treatment with hyaluronic acid injections to improve function and decrease pain. Osteoarthritis is an inflammatory-mediated joint condition that often affects one or both knee joints, with increasing prevalence in older adults. It can present as tenderness, stiffness, swelling, and/or instability.

Many patients will improve with conservative measures such as physical therapy, exercise, weight loss, oral medications such as acetaminophen and nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen, meloxicam, nabumetone), topical medications (e.g., capsaicin cream and diclofenac 1% gel), and/or intra-articular corticosteroid injections. Some patients with more severe symptoms or those who do not improve with conservative therapy may require further treatment. Surgery with total knee replacement is the standard of care for refractory osteoarthritis of the knee. However, some patients may benefit from a non-surgical treatment called viscosupplementation, which is an injection of a lubricating agent called hyaluronic acid to improve function and decrease pain. This guideline will provide criteria and exclusions for viscosupplementation with hyaluronic acid derivatives.

Table 1. Intra-articular Hyaluronic Acid Products

Brand Name	Dosing Guidelines / Injection Series (per 6-month period)
Durolane® (hyaluronic acid)	60 mg (3 mL) x 1 dose
Euflexxa® (1% sodium hyaluronate)	20 mg once weekly x 3 doses
Gel-One® (cross-linked hyaluronate)	30 mg (3 mL) x 1 dose
Gelsyn-3™ (sodium hyaluronate 0.84%)	16.8 mg (2 mL) once weekly x 3 doses
GenVisc® 850 (sodium hyaluronate)	25 mg once weekly x 3-5 doses
Hyalgan® (sodium hyaluronate)	20 mg once weekly x 5 doses
Hymovis® (high molecular weight viscoelastic hyaluronan)	24 mg (3 mL) once weekly x 2 doses
Monovisc® (high molecular weight hyaluronan)	88 mg (4 mL) x 1 dose
Orthovisc® (high molecular weight hyaluronan)	30 mg once weekly x 3-4 doses
Supartz™ (sodium hyaluronate)	10 mg once weekly x 3-5 doses
Supartz FX ™ (sodium hyaluronate)	25 mg once weekly x 5 doses
Synojoynt (sodium hyaluronate)	20 mg (2 mL) once weekly x 3 doses
Synvisc® (hylan G-F 20)	16 mg once weekly x 3 doses
Synvisc-One® (hylan G-F 20)	48 mg x 1 dose
Triluron™ (sodium hyaluronate)	20 mg (2 mL) once weekly x 3 doses
TriVisc™ (sodium hyaluronate)	25 mg (2.5 mL) once weekly x 3 doses
Visco-3™ (sodium hyaluronate)	2.5 mL once weekly x 3 doses

Sources: Prescribing Information (See References)

NOTE: The Plan may require that preferred products be used first. Please review the applicable Plan Clinical Guideline for a full list of our preferred and non-preferred products:

- Commercial Preferred Physician-Administered Specialty Drugs (CG052)
- Medicare B Step Therapy Preferred Physician-Administered Specialty Drugs (CG066)

Definitions

"Hyaluronan" or "**Sodium hyaluronate"** or "**Hyaluronic acid**" is a thick fluid similar to the fluid naturally inside the joint. When injected into the knee joint in a process known as "viscosupplementation", it can act as a lubricant and shock absorber in an effort to decrease symptoms and improve function.

"Osteoarthritis" is a joint disease caused by inflammation where the protective cartilage of the joint wears down over time resulting in bone-on-bone contact. This can cause pain, swelling, decreased mobility, and stiffness.

"**Viscosupplementation**" is a procedure where hyaluronic acid is injected into the joint space. Examples of viscosupplements, or hyaluronic acid injections, are listed above (Table 1).

Medical Necessity Criteria for Initial Authorization

The Plan considers initial requests for viscosupplement injections medically necessary when **ALL** of the following criteria are met:

1. Diagnosis of osteoarthritis (OA) of the knee **AND ALL** of the following:
    a. Radiologic evidence (e.g. x-ray or MRI) confirming OA of the knee, characterized by features such as joint space narrowing, subchondral sclerosis, osteophytes, and subchondral cysts; ***and***
    b. Persistent pain in the affected knee, significantly interfering with functional activities such as walking, standing for prolonged periods, or sleeping; ***and***
    c. Other forms of joint disease to which the pain may be attributed have been ruled out; ***AND***
2. The member is unable to use, or have failed to respond adequately (e.g. decrease pain or improve function) to at least a 3-month trial of **ALL** of the following:
    a. Nonpharmacologic therapy (e.g. low-impact exercise, aquatic exercise); ***and***
    b. Dietary weight management as part of a healthy lifestyle regimen for individuals presenting with body mass index ≥30 kg/m^2; ***and***
    c. Oral or topical pharmacologic therapy (e.g. nonsteroidal antiinflammatory drugs (NSAIDs), capsaicin, acetaminophen, duloxetine, tramadol); ***and***
    d. Intra-articular corticosteroid injection therapy; ***AND***
3. The member meets BOTH of the following:
    a. Is not a candidate for surgery (e.g. high risk, contraindication) **OR** surgery is not expected within 6 months of the injection series (e.g., member being considered for

knee arthroplasty (replacement) to treat arthritis or arthroscopy to treat a meniscal tear); ***and***

b. Has no contraindications to injection per FDA label (e.g. infections or skin diseases in the area of the injection site) **OR** as listed below under Experimental or Investigational / Not Medically Necessary.

If the above prior authorization criteria is met, the requested product will be approved for one injection series lasting up to six (6) months to determine effectiveness.

Medical Necessity Criteria for Reauthorization (i.e., Continuing Treatment Post Initial Trial)

The Plan considers subsequent requests for viscosupplement injections medically necessary when **ALL** of the following criteria are met:

1. The above "Initial Authorization" criteria continue to be met; ***and***
2. A minimum of 6 months have elapsed since the last injection series, with no more than one injection series performed in a 6-month period; ***and***
3. The patient demonstrated improvement in overall pain and function from the prior injection series, as evidenced by **ALL** the following:
    a. Documented reduction in pain demonstrated through objective measures such as increased range of motion, decreased tenderness upon examination, or reduction in the amount and/or frequency of medication use***; and***
    b. Documented enhancement in the ability to perform daily activities, such as walking, standing for extended periods, and improved quality of sleep.

Experimental or Investigational / Not Medically Necessary

The use of viscosupplementation for knee osteoarthritis where the above criteria are not met is considered *not medically necessary*. Viscosupplements for any other indication is considered not medically necessary or experimental or investigational. Non-covered indications include, but are not limited to, the following:

- Acute injury (e.g., sprain, fracture)
- Adhesive capsulitis of shoulder (frozen shoulder)
- Chondromalacia patellae
- Edema of the bone
- Infectious arthritis
- Knee joint infections

- Osteoarthritis for any joints other than the knee (e.g., shoulder, elbow, carpometacarpal, thumb, hip, ankle, metatarsophalangeal)
- Psoriatic arthritis for any joints including the knee
- Rheumatoid arthritis for any joints including the knee
- Skin disease or infections in the area of injection site
- Temporomandibular joint disorders
- Tendinopathy
- Trigger finger
- Viscosupplementation in combination with intra-articular corticosteroid, mesenchymal stem cell, amniotic product, or platelet rich plasma (PRP) injection

Applicable Billing Codes (HCPCS/CPT Codes, ICD-10 Codes)

CPT/HCPCS codes considered medically necessary if criteria are met:	
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

ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
M15.8	Other polyosteoarthritis
M15.9	Polyosteoarthritis, unspecified (generalized osteoarthritis NOS)
M17.0 - M17.9	Knee osteoarthritis

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