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Department: PHARMACY	**MMC Review/ Approval Date(s):** 1/14/2020, 12/17/2020, 01/18/22, 12/28/22	**Total Page(s):** 11

Policy Number: 012.005

Title: Coverage Determination Policy for Intra-articular Hyaluronic Acid (HLA) Polymers

Regions: ☒ **Texas** ☐ **Florida** ☐ **Indiana** ☐ **New Jersey** ☒ **New Mexico**

Impacted Areas:

☒ Network Management/Provider Services	☒ Utilization Management
☐ Member services	☐ Case management
☐ Quality Management	☐Disease management
☐ Credentialing	☒ Claims
☐ IT	☐ Human resources
☐ Administration	☐ Finance
☐ Complaince/delegation	☒ Pharmacy
	☐ ALL

Available LCD/NCD/LCA:

LCA for Billing and Coding Hyaluronan Acid Therapies for Osteoarthritis of the Knee : A55036

LCD for Hyaluronan Acid Therapies for Osteoarthritis of the Knee: L35427

LCD for Hyaluronic Acid (HLA) Polymers L33767 L35427 A57256 A55036 A56412

Disclaimer:

WellMed Coverage Determination Policies are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support WellMed coverage decision making. WellMed may modify these Policy Guidelines at any time. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the WellMed Coverage Determination Policies is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

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Table of Contents **Page**

Coverage Policy Number: 012.005

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage Determination:

Step Therapy Criteria

This policy supplements the Medicare guidelines such as NCDs, LCDs, and other Medicare manuals for the purposes of determining coverage under the Part B medical benefits. This Step Therapy Policy is implemented to enforce a step therapy requirement for new starts only. This policy is not applicable to members continuing therapy within the past 365 days. Coverage is granted if Medicare Coverage requirements PLUS these step criteria are met.

Non-preferred product(s): Genvisc 850, Hyalgan, Supartz, Supartz FX, Hymovis, Orthovisc, Euflexxa, Gel-One, Monovisc, Synojoynt, Triluron, TriVisc, Visco-3

Preferred product(s): *Durolane, Gelsyn, Synvisc, Synvisc-One*

Non-Preferred Product Step Therapy Criteria
Coverage of Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz FX, Synojoynt, Triluron, TriVisc, or **Visco-3** may be covered when the criteria listed under Sections **A., B., or C.** are satisfied:

A. Trial and failure of **all** of the following: *Durolane, Gelsyn-3, **and** Synvisc/Synvisc-One,* resulting in minimal clinical response to therapy

OR

B. History of intolerance or adverse event to **all** of the following: *Durolane, Gelsyn-3, **and** Synvisc/Synvisc-One*

OR

C. Continuation of prior therapy within the past 365 days.

Coverage Policy:

Initial/ New Requests

If the above step therapy criteria is met, requests for injected hyaluronate polymer will be covered when medically necessary as follows:

WellMed Medical Management will cover injected hyaluronate polymer for the treatment of pain in patients with Osteoarthritis of the knee as medically necessary when **ALL** the following criteria are met:

a. Knee pain associated with radiographic evidence of osteophytes in the knee joint, sclerosis in bone adjacent to knee or joint space narrowing.
b. The patient has failed to respond to aspiration of the knee when effusion is present and intra-articular corticosteroid injection therapy when inflammation is a significant component of the patient's symptoms and intra-articular corticosteroids are not contraindicated.
c. The pain cannot be attributed to other forms of joint disease.
d. Pain that interferes with functional activities (e.g., ambulation, prolonged standing, ability to sleep), crepitus on motion of the knee and/or knee stiffness.
e. Lack of functional improvement following a trial of at least three months of conservative therapy (which may include home exercise program, education, physical therapy if indicated and use of simple non-narcotic analgesics including acetaminophen), or the patient is unable to tolerate Non-Steroidal Anti-Inflammatory Drug (NSAID) therapy because of adverse side effects.
f. Patient does not have contraindications to the injections (e.g., active joint infection, bleeding disorder, skin infections at the injection site).
g. Dosing regimen consistent with **Approved Dosing** section. Bilateral injections may be allowed if both knees meet the criteria.

Renewal/Continuation of Therapy requests

WellMed Medical Management **will cover** a repeat series of hyaluronic knee injections(s) for patients who have responded to the first series as medically necessary when **ALL** of the following criteria are met:

a. Either:
   - **i.** There is significant improvement in pain and functional capacity using a standardized assessment tool

   OR

   - **ii.** There is significant reduction in the doses of non-steroidal anti-inflammatory medications taken or reduction in the number of intra-articular steroid injections to the knees during the six-month period following the injection

b. At least six months have elapsed since the prior series of injections
c. Dosing regimen is consistent with **Approved Dosing** section
d. Patient does not have contraindications to the injections (e.g., active joint infection, bleeding disorder, skin infections at the injection site).

NOTE: If the initial series of injection(s) using sodium hyaluronate did NOT prove to be beneficial to the patient, it would not be reasonable to repeat the therapy again using any of these products. Thus, a repeat series of injections would not be covered.

FDA Approved Indications

- Osteoarthritis of the knee

Viscosupplements are indicated for the treatment of pain in patients with osteoarthritis of the knee who has failed to respond to conservative nonpharmacological and pharmacologic therapy with simple analgesics.

FDA Approved Dosing

Brand Name	Dose	Injection Frequency
GenVisc 850® **Supartz®**	25 mg (2.5 mL)	once a week (1 week apart) for a total of 3 to 5 injections per knee
Hyalgan®	20 mg (2 mL)	
Monovisc™	88 mg (4 ml)	Single injection per knee
Synvisc-One®	48 mg (6ml)	
Gel-One®	30 mg (3 mL)	
Durolane	60 mg (3 mL)	
Orthovisc®	30 mg	once a week (1 week apart) for a total of 3 to 4 injections per knee
Hymovis®	24 mg (3 ml)	once a week (1 week apart) for a total of 2 injections per knee
Synvisc® **Euflexxa®** **Visco-3™** **Gelsyn-3™** **TriVisc™** Triluron Synojoynt	16 mg (2 mL) 20 mg (2 mL) 25 mg (2.5 mL) 16.8 mg (2 mL) 25 mg (2.5 mL) 20 mg (2 mL) 20 mg (2 mL)	once a week (1 week apart) for a total of 3 injections per knee

General Background:

Degenerative joint disease, also known as Osteoarthritis (OA) is a common cause of joint pain and disability. The goal of treatment for patients with OA is to reduce symptoms (pain and swelling) and prevent disability. Management should be individualized to the joints involved, the patient's expectations, level of function and activity, the severity of the patient's disease, occupational and avocational needs and interests, and the nature of any coexisting medical problems.

Viscosupplementation is an available option for patients with symptomatic knee osteoarthritis and it involves a series of intra-articular injections of hyaluronic acid. The exact mechanism of action is unclear, although increasing the viscoelasticity of the synovial fluid appears to play a role. Although the exact indications for viscosupplementation are still evolving, it can be considered for use in patients who have significant residual symptoms despite traditional non-pharmacologic pharmacologic treatments. In addition, patients who are intolerant of traditional treatments (e.g., gastrointestinal problems related to anti-inflammatory medications) can be considered for these injections.

No relevant National Coverage Determination (NCD) criteria are currently available. One Local Coverage Determination (LCD): Hyaluronan Acid Therapies for Osteoarthritis of the Knee (L35427) is available at CMS.gov. One relevant Local Coverage Article (LCA): Hyaluron Acid Therapies for Osteoarthritis of the Knee (A55036) is available. The relevant LCD and LCA criteria have been incorporated into this policy.

Summary of Clinical Studies /guidelines

The 3rd edition of the American Academy of Orthopaedic Surgeons (AAOS) evidence based guideline "Management of Osteoarthritis of the Knee (Non-Arthroplasty)" was published August 31, 2021. In these guidelines, the AAOS does not recommend the use of viscosupplementation for routine use for treatment of knee OA.

The 2013 edition of the guideline strongly recommended against the use of viscosupplementation, but the 2021 version found that statistically significant improvements were associated with high-molecular cross-linked hyaluronic acid but when compared to mid-range molecular weight, statistical significance was not maintained. This newer analysis did not demonstrate clinically relevant differences when compared to controls. However, as previous research reported benefits in their use, the group (investigators) felt that a specific subset of patients might benefit from its use.

Historically, the "American College of Rheumatology 2012 Recommendations for the Use of

Non-pharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee" from the American College of Rheumatology (ACR) makes both "strong" and "conditional" recommendations for management of OA of the Knee. Pharmacologic modalities *conditionally* recommended for the initial management of patients with knee OA included acetaminophen, oral and topical NSAIDs, and tramadol. Intraarticular corticosteroid injections and intraarticular hyaluronate injections, duloxetine, and opioids were conditionally recommended in patients who had an inadequate response to initial therapy. Opioid analgesics were strongly recommended in patients who were either not willing to undergo or had contraindications for total joint arthroplasty after having failed medical therapy.

Coding Information:

HCPCS 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, 1mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1mg

Acronyms:

Osteoarthritis (OA), Non-Steroidal Anti-Inflammatory Drug (NSAID), American Academy of Orthopaedic Surgeons (AAOS), American College of Rheumatology (ACR), National Coverage Determination (NCD), Local Coverage Determination (LCD)

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