Reference number(s)
4877-A

Jurisdiction Specific Medicare Part B Intraarticular Knee Injections of Hyaluronan

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	**Generic Name**
Hyalgan, Supartz, Visco-3, Euflexxa, Gelsyn-3, Genvisc 850, Trivisc, Synojoynt, Triluron	sodium hyaluronate
Synvisc, Synvisc-One	hylan G-F 20
Gel-One	cross-linked hyaluronate
Durolane	hyaluronic acid
Monovisc, Orthovisc	high molecular weight hyaluronan
Hymovis	high molecular weight viscoelastic hyaluronan

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Osteoarthritis of the knee

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

Authorization of 6 months may be granted for treatment of osteoarthritis of the knee when all of the following criteria are met:

- The member is symptomatic. Such symptoms may include any of the following:
  - Pain which interferes with the activities of daily living such as ambulation and prolonged standing
  - Pain interrupting sleep
  - Crepitus
  - Knee stiffness
- The clinical diagnosis is supported by radiologic evidence of osteoarthritis of the knee such as joint space narrowing, subchondral sclerosis, osteophytes, and sub-chondral cysts.
- If appropriate, other diagnoses have been excluded by appropriate evaluation and management services, laboratory and imaging studies (i.e., the pain and functional disability is not considered likely to be due to a diagnosis other than osteoarthritis of the knee).
- The member has failed at least 3 months of conservative therapy. Conservative therapy is defined as both of the following:
  - Nonpharmacologic therapy (such as but not limited to home exercise program, education, weight loss, physical therapy if indicated), and
  - If not contraindicated, simple analgesics (e.g., acetaminophen) and/or nonsteroidal inflammatory drugs (NSAIDs)
- The member meets one of the following:
  - The member does not have effusion.
  - Effusion is present and the member did not respond to aspiration of the knee.
- The member meets one of the following:
  - Inflammation is not a significant component of the member's symptoms.
  - Inflammation is a significant component of the member's symptoms and either:
    - The member failed to respond to intra-articular corticosteroid injection therapy, or
    - Intra-articular corticosteroid injection therapy is contraindicated.
- Only fluoroscopy and ultrasound will be utilized for needle guidance. All other imaging procedures are considered not medically reasonable and necessary and will not be covered.
- The member will not receive intra-articular injections of other therapeutic agents, such as corticosteroids, performed in the same knee during the course of viscosupplementation therapy unless there is a documented medical necessity (e.g., for documented reactions requiring the use of the additional therapeutic agent).
- Knee arthroplasty is not being considered as a current treatment option.
- The requested product will not be administered following a total or partial knee arthroplasty.
- If the requested product will be administered following a knee surgical procedure, the member meets both of the following:
  - The requested product will not be used at the end of a knee surgical procedure or during the postoperative period following a knee surgical procedure (e.g., anterior cruciate ligament [ACL] reconstruction or arthroscopic meniscectomy), and

- Use of viscosupplementation will not be initiated until after the member has made a full recovery from the knee surgery and the member is symptomatic with a diagnosis of osteoarthritis and the clinical presentation meets the above requirements.

Continuation of Therapy

Authorization for 6 months may be granted for a repeat series for the treatment of osteoarthritis of the knee when all of the following criteria are met:

- The member's symptoms have recurred after the prior series of injections.
- At least 6 months have elapsed since the prior series of injections.
- One of the following applies to the member:
  - There was significant improvement in pain and functional capacity achieved with the prior series of injections using a standardized assessment tool.
  - There is significant reduction in the doses of NSAID medications taken or reduction in the number of intra-articular steroid injections to the knees during the 6-month period following the injection(s).
- Only fluoroscopy and ultrasound will be utilized for needle guidance. All other imaging procedures are considered not medically reasonable and necessary and will not be covered.
- The member will not receive intra-articular injections of other therapeutic agents, such as corticosteroids, performed in the same knee during the course of viscosupplementation therapy unless there is a documented medical necessity (e.g., for documented reactions requiring the use of the additional therapeutic agent).
- Knee arthroplasty is not being considered as a current treatment option.
- The requested product will not be administered following a total or partial knee arthroplasty.
- If the requested product will be administered following a knee surgical procedure, the member meets both of the following:
  - The requested product will not be used at the end of a knee surgical procedure or during the postoperative period following a knee surgical procedure (e.g., anterior cruciate ligament [ACL] reconstruction or arthroscopic meniscectomy), and
  - Use of viscosupplementation will not be initiated until after the member has made a full recovery from the knee surgery and the member is symptomatic with a diagnosis of osteoarthritis and the clinical presentation meets the above requirements.

Dosage and Administration

- The course of treatment must consist of the use of one agent for the entire course of treatment. Therefore, initiating a course of treatment with one agent, then switching before completion to a different agent is considered not medically reasonable and necessary.
- Approvals may be subject to dosing limits in accordance with FDA-approved labeling. Drugs and biologicals and other products approved for marketing by the FDA are considered safe and effective when used for the indications specified on the labeling. The labeling lists the safe and effective, i.e., medically reasonable and necessary dosage and frequency. Therefore, doses

and frequencies that exceed the accepted standard of recommended dosage and/or frequency, as described in the package insert, are considered not reasonable and necessary and therefore, not subject to coverage.

Hyaluronan Preparation	**Duration of Treatment per Series**
Synvisc-One, Gel-One, Monovisc, Durolane	Single injection per knee
Hymovis	2 weekly injections per knee
Euflexxa, Gelsyn-3, Synvisc, Visco-3, TriVisc, Synojoynt, Triluron	3 weekly injections per knee
Orthovisc	3-4 weekly injections per knee
Hyalgan, Supartz, Genvisc 850	3-5 weekly injections per knee

References

1. Intraarticular Knee Injections of Hyaluronan LCD (L39529) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed November 13, 2024.
2. Billing and Coding: Intraarticular Knee Injections of Hyaluronans (A56157) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed November 13, 2024.