

Intra-Articular Administration of Hyaluronic Acid or Hylan G-F 20 (Viscosupplementation) for Osteoarthritis of the Knee

Criteria for Use

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VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive viscosupplementation.

- Known hypersensitivity or allergy to hyaluronate or hylan preparations (see supplementary information)
- Knee joint infection, skin disease or infection in the area of the injection site

Inclusion Criteria

The answers to all of the following must be fulfilled in order to meet criteria.

- Documented symptomatic (pain/stiffness) OA of the knee which interferes with functional activities (e.g. ambulation, prolonged standing, etc.) and/or is associated with significant pain.
- Adequate trial (e.g. 2 to 3 months) of non-pharmacologic measures, as appropriate, (e.g. cane/crutches, bracing/orthotics, weight loss, physical therapy/exercise) has not resulted in adequate improvement in pain/function.
- Therapeutic trial of at least 3 analgesics (*e.g. acetaminophen, topical capsaicin or topical NSAIDs, oral NSAIDs or duloxetine*) has not resulted in adequate improvement in pain/function; or patient is unable to tolerate or is not a candidate for NSAIDs or other oral therapies.
- Patient and/or provider have elected to continue conservative (nonsurgical) treatment for OA.

Supplementary Information

- It is recommended that the use of these agents be limited to specialists in Orthopedics, Rheumatology and Physical Medicine and Rehabilitation.
- There is some evidence to suggest that patients with more advanced stages of OA and near complete loss of joint space may be less likely to benefit from this therapy.
- All hyaluronic acid (HA) or Hylan products are for intra-articular (IA) use only.
- HAs are naturally occurring (derived from rooster combs or bacterial cells, purified and separated into non-inflammatory form) or synthetic, hylans.
- Refer to product labeling for specific warnings for individual agents (e.g., Gel-One should be used with caution in patients with an allergy to cinnamon, etc.).
- The origin of hyaluronic acid/hylan derivatives:
 - Avian source (Rooster Combs): Gel-One, Hyalgan, Supartz, Synvisc and Synvisc-One are from avian sources. Labeling for Gel-One, Hyalgan, Supartz, Synvisc and Synvisc-One suggest administering with caution in those patients with a known allergy to avian proteins, feathers or eggs.
 - Non-avian source (e.g., bacterial fermentation): Durolane, Euflexxa, Gel-Syn 3, GenVisc 850, Hymovis, Monovisc, Orthovisc, Synjoynt and Trivisc are not derived from avian sources and can be used in patients with an allergy to avian proteins.
- The safety/efficacy of concomitant administration of HA or hylan with other IA agents has not been established.
- Pseudosepsis or severe acute inflammatory reactions (SAIR) has been reported with Synvisc. Typically with the second or third injection in a course or with subsequent courses.
- Repeat courses should not be administered within 6 months of the last injection.

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