

Origination Date: 2/05	Revision Date(s): 9/05, 1/06, 1/07, 1/08, 1/09
Developed By: Medical Criteria Committee	

Csaba Mera M.D.

Approved: Csaba Mera, MD Date: 01/22/09

Description:

Hyaluronan or hylan or hyaluronate sodium, is a temporary synovial fluid made from rooster combs. It is used for patients with osteoarthritis of the knee who have failed conservative treatment. The solution is injected into the knee joint once a week for a 3-5 week treatment cycle. The treatment cycle depends on the brand of the Hyaluronan used. This treatment is also called viscosupplementation. Examples of preparations of hyaluronate sodium are: Hyalgan®, Orthovisc®, Supartz® and Euflexxa™. An example of hyaluronate sodium derivative is Synvisc®.

Synovial fluid is a thick colorless lubricating fluid within a joint, bursa, or tendon sheath. It is secreted by the synovial membrane. When osteoarthritis affects the synovial membrane, the quantity of synovial fluid decreases and its quality deteriorates.

Osteoarthritis is a non-inflammatory degenerative joint disease that occurs with the aging process. It is characterized by degeneration of the articular cartilage, hypertrophy, or overgrowth of the bone at the margins, and changes in the synovial membrane. It is accompanied by pain and stiffness.

Criteria:

Viscosupplementation injections are indicated for osteoarthritis of the knee only

Viscosupplementation injections:

- Hyalgan- sodium hyaluronate (J7321)
- Supartz - sodium hyaluronate (J7321)
- Orthovisc – high-molecular-weight hyaluronic acid (J7324)
- Synvisc- hylan G-F 20 (J7322)
- Euflexxa- ultra-high purity hyaluronic acid (J7323)
- Nuflexxa – ultra-high purity hyaluronic acid

- I. The above intra-articular viscosupplementation injections will be covered to plan limitations when **ALL** the following are met:
 - A. The member has documented, symptomatic osteoarthritis of the knee; **and**
 - B. The member reports pain which interferes with functional activities (i.e. ambulation, prolonged standing); **and**
 - C. Conservative therapy (i.e. non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and topical capsaicin cream) has been used appropriately and has not resulted in functional improvement; **and**
 - D. Aspiration of the knee joint and steroid injection results in limited pain relief that last less than 3 months; **and**
 - E. The pain cannot be attributed to other forms of joint disease (i.e. active joint infection)
- II. Repeat treatment cycles will be covered when **ALL** of the following criteria are met:
 - A. There is documentation of significant improvement in pain and functional capacity as the result of the previous injections; **and**
 - B. There has been at least a 6-month period following the previous series of injections.
- III. Intra-articular viscosupplementation injections are considered investigational and are **NOT** covered for the

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following:

- A. For any indication other than osteoarthritis
- B. For treatment of osteoarthritis of any joint but the knee

Treatment Guidelines

For patients who meet the above criteria, authorization may be given for the following regimens:

1. Hyalgan 1 injection a week for 5 weeks
2. Supartz 1 injection a week for 5 weeks
3. Orthovisc 1 injection a week for 3 weeks
4. Synvisc 1 injection a week for 3 weeks
5. Euflexxa 1 injection a week for 3 weeks
6. Nuflexxa 1 injection a week for 3 weeks

Information to be Submitted:

1. Consultations and evaluations related to the diagnosis.
2. Medical records indicating conservative therapy.
3. Diagnosis of osteoarthritis substantiated by X-Ray.
4. For subsequent authorization: clinical documentation of symptom improvement utilizing the above mentioned assessment tools.

References:

- Adams ME, Atkinson MH, Lussier, AJ, et al. The role of viscosupplementation with Hylan G-F 20 (Synvisc) in the treatment of osteoarthritis of the knee; A Canadian multicenter trial comparing Hylan G-F 20 alone, Hylan G-F 20 with NSAIDs and NSAIDs alone. *Osteoarthritis Cartilage*. 1995;3(4):213-225. Retrieved from www.nlm.nih.gov/entrez/ on January 5, 2005.
- Lee S, Park D, Chmell SJ. (April 2004) Viscosupplementation with Hylan G-F 20 (Synvisc): pain and mobility observations from 74 consecutive patients. *J Knee Surg*, 17(2), 73-7. Retrieved from www.nlm.nih.gov/entrez/ January 5, 2005.
- Waddell DD. (2003). The tolerability of viscosupplementation: low incidence and clinical management of local adverse events. *Curr Med Res Opin*, 19(7). 575-80. Retrieved from www.nlm.nih.gov/entrez/ on January 5, 2005.
- Karlsson J., Sjogren LS, Lohmander LS, Comparison of two hyaluronan drugs and placebo in patients with knee osteoarthritis. A controlled, randomized, double-blind, parallel-design multicenter study. *Rheumatology*. 2002;41:1240-1248.
- U. S. Food and Drug Administration. (1997, May). Center for Devices and Radiological Health. *Hyalgan*. Retrieved January 19, 2006 from URL address: <http://www.fda.gov/cdrh/consumer/hyalgan.html>.
- U. S. Food and Drug Administration. (2001, January). Center for Devices and Radiological Health. *New Device Approvals: Supartz™ Dispo - P980044*. Retrieved January 19, 2006 from URL address: <http://www.fda.gov/cdrh/pdf/p980044.html>.
- U. S. Food and Drug Administration. (2004, December). Center for Devices and Radiological Health. *New Device Approvals: Nuflexxa™ - P010029*. Retrieved March 2, 2006 from URL address: <http://www.fda.gov/cdrh/mda/docs/p010029.html>.
- U. S. Food and Drug Administration. (2004, February). Center for Devices and Radiological Health. *New Device Approvals: Orthovisc® High Molecular Weight Hyaluronan - P980044*. Retrieved December 21, 2005 from URL address: <http://www.fda.gov/cdrh/pdf3/p030019.html>.
- Divine JG, Zazulak BT, Hewett TE. A systematic review of viscosupplementation for knee osteoarthritis. *Clin Orthop Relat Res*. 2006 Dec 7.
- Bellamy N, Campbell J, Robinson V, et al. Viscosupplementation for the treatment of osteoarthritis of the knee. *Cochrane Database Syst Rev*. 2006 Apr 19;(2):CD005321
- Physician Advisors