

## Evidence Based Guideline

# Intra Articular Hyaluronan Injections for Osteoarthritis of the Knee

**File Name:** intra\_articular\_hyaluronan\_injections\_for\_osteoarthritis\_of\_the\_knee  
**Guideline Number:** EBG.MED1250  
**Origination:** 12/1997  
**Last Review:** 7/2008  
**Next Review:** 7/2010

### Description of Procedure or Service

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Osteoarthritis is a chronic non-inflammatory disorder of movable joints characterized by degenerative loss of articular cartilage, subchondral bony sclerosis and cartilage, bone proliferation at the joint margins with subsequent osteophyte formation and changes in the synovial membrane. Patients with osteoarthritis are usually over the age of 40, have pain in and around the joint that is typically worse with weight-bearing and improves with rest, as well as morning stiffness and gelling of the affected joints following periods of inactivity. There is no known cure for osteoarthritis and treatment goals are focused on reducing pain, maintaining and/or improving joint mobility, and limiting functional impairment.

Synovial fluid is a thick, stringy fluid found in the cavities of synovial joints. It reduces friction between the articular cartilage and other tissues in joint to lubricate and cushion them during movement. The inner membrane of synovial joints is called the synovial membrane. It secretes synovial fluid into the joint cavity which forms a thin layer at the surface of cartilage and fills all empty space. Synovial fluid contains hyaluronan.

Hyaluronan (also known as hyaluronate or hyaluronic acid) is a naturally occurring macromolecule that is a major component of synovial fluid and is thought to contribute to its viscoelastic properties. Its mechanism of action is poorly understood, but its effects may be due to regulation of cartilage synthesis, inhibition of inflammatory cytokines and nociception, and stimulation of natural hyaluronan synthesis. Intra-articular injection of hyaluronan has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in patient with osteoarthritis. This treatment has been called viscosupplementation.

### Evidence Based Guideline for Intra-articular Hyaluronan Injections

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Intra articular hyaluronan injections may be appropriate for the treatment of pain in osteoarthritis of the knee when conservative treatment has failed.

The medical record should document conservative therapy as follows:

- Diagnosis of osteoarthritis substantiated by x-ray or other imaging or arthroscopic findings, and
- Complaints of persistent pain while using simple analgesics and non-steroidal anti-inflammatory drugs, and
- Aspiration of the joint resulting in clear viscous aspirate, when effusion is present, followed by injection of steroid that results in unsatisfactory relief of pain or relief of pain that lasts less than three months.

Repeated courses of intra-articular hyaluronan injections may be appropriate when significant pain relief was achieved with the prior course of injections and at least six months have passed since the prior course of treatment.

## Policy: Intra Articular Hyaluronan Injections for Osteoarthritis of the Knee

### Medical Evidence regarding Intra-articular Hyaluronan Injections indicates it is not recommended in the following situations:

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Intra-articular hyaluronan injections are not recommended for any indication other than osteoarthritis or for treatment of osteoarthritis in any joint but the knee.

### Benefits Application

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Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: J7321, J7322, J7323, J7324*

### Medical Term Definitions

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Not applicable.

### Scientific Background and Reference Sources

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MEDLINE search January 1996 through December 1997

USPDI

Consultant Review, March 1997

Medical Policy Advisory Group, 5/28/98

Specialty Matched Consultant Advisory Group 11/1999

Medical Policy Advisory Group, 12/2/1999

BCBSA Medical Policy Reference Manual 8/18/2000, 2.01.31

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual 5/31/01; 2.01.31

Specialty Matched Consultant Advisory Panel - 8/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.31, 4/29/03

Hammesfahr JF, Knoop AB, Stitik T. (June 2003). Safety of intra-articular hyaluronates for pain associated with osteoarthritis of the knee. *Am J Orthop*, 32(6), 277-83. Retrieved on May 26, 2004 from [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=12834190](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12834190).

Hamburger MI, Lakhanpal S, Mooar PA, Oster D. (April 2003). Intra-articular Hyaluronans: a review of

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Waddell DD, Cefalu CA, Bricker DC. (2003). An open-label study of a second course of hylan G-F 20 for the treatment of pain associated with knee osteoarthritis. *Curr Med Res Opin*, 19(6), 499-507. Retrieved on May 26, 2004 from [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=14594522](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14594522).

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 on May 26, 2004 from [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=14626291](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14626291).

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Caborn D, Rush J, Lanzer W, Parenti D, Murray C; Synvisc 901 Study Group. (February 2004). A randomized, single-blind comparison of the efficacy and tolerability of hylan G-F 20 and triamcinolone hexacetonide in patients with osteoarthritis of the knee. *J Rheumatol*, 31(2), 333-43. Retrieved on May 26, 2004 from [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=14760806](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14760806).

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Specialty Matched Consultant Advisory Panel - 7/2004

BCBSA TEC Special Report [Electronic Version]. February 2005.

Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. The Cochrane Database of Systematic Reviews 2005, Issue 2. Art. No.: CD005321. DOI: 10.1002/14651858.CD005321.

Samson DJ, Grant MD, Ratko TA, Bonnell CJ, Ziegler KM, Aronson N. Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment No. 157 (Prepared by Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center under Contract No. 290-02-0026). AHRQ Publication No. 07-E012. Rockville, MD: Agency for Healthcare Research and Quality. September 2007. Retrieved 5/28/08 from <http://www.ahrq.gov/downloads/pub/evidence/pdf/oaknee.pdf>

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.31, 12/13/07

National Institute for Health and Clinical Excellence (NICE). National Collaborating Centre for Chronic Conditions. Osteoarthritis: national clinical guideline for care and management in adults. London: Royal College of Physicians, 2008. Retrieved 5/20/08 from <http://www.nice.org.uk/nicemedia/pdf/CG059FullGuideline.pdf>

## Policy: Intra Articular Hyaluronan Injections for Osteoarthritis of the Knee

### Policy Implementation/Update Information

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- 12/97 Original policy developed. Reviewed by the Plan's Medical Director and determined investigational.
- 3/98 Reviewed: Continues to appear investigational due to approval as device and no long term outcomes.
- 6/98 Reviewed: Medical Policy Advisory Group recommends approval of one time treatment cycle for individuals with osteoarthritis of the knee who have failed to respond to conservative therapy. Policy name changed from Sodium Hyaluronate.
- 9/98 Code changes. J3490 deleted. Codes W5184 and W5179 added.
- 6/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 10/00 Revised. Changed the indications to include repeat treatment cycles when specific criteria are met. Added comment that treatment cycles should include no more than 3 injections for Synvisc and 5 injections for Hyalgan. System coding changes. Medical Policy Advisory Group - Approved.
- 5/01 Changes in formatting.
- 9/02 Specialty Matched Consultant Advisory Panel meeting 8/2002. Revised policy to include Supartz. Added term Supartz to the Policy Key Word section. Code J7315 deleted and code Q3030 added. System coding changes.
- 3/25/04 Added code J7317 to the Billing/Coding section. Removed code Q3030 from the Billing/Coding section. Benefits Application and Billing/Coding sections updated for consistency.
- 8/12/04 Specialty Matched Consultant Advisory panel review 07/15/2004 with no changes made to policy criteria. References added. Statement added, "e.g., rest, anti-inflammatory medications, physical therapy" to define conservative measures.
- 9/9/04 Title changed from "Intra Articular Hyaluronan Injections for Treatment of Osteoarthritis of the Knee." to "Intra Articular Hyaluronan Injections for Osteoarthritis of the Knee" for purpose of reducing characters.
- 1/05/06 Added policy number to Key Words. CPT Code J7318 added to Billing/Coding section.
- 2/16/06 Deleted code J7318 from Billing/Coding section. This code was never made valid by Centers for Medicare & Medicaid Services (CMS).
- 3/2/06 Statement regarding documentation of conservative therapy moved from Billing/Coding section to section "When Intra-articular Hyaluronan Injections are covered." Statement regarding allergies to chickens or eggs deleted from the "not covered" section. Information regarding Euflexxa added to "Policy Guidelines" section. Euflexxa is free of animal proteins and can be administered to patients who are allergic to chickens, eggs or feathers.
- 8/21/06 References updated. Specialty Matched Consultant Advisory panel review 7/24/06. No changes to policy criteria. (adn)
- 9/18/06 Information regarding repeated treatment cycles deleted from the When Covered section. The following statement added to When Not Covered section: "Repeated treatment cycles are considered investigational." Also added a statement to Policy Guidelines section "There is limited evidence regarding the effectiveness of multiple courses of intra-articular hyaluronan injections, therefore repeated treatment cycles are considered investigational. BCBSNC does not provide coverage for investigational services." Notification date 9/18/06. Effective date 11/27/06. (adn)
- 2/12/07 Billing/Coding section updated to reflect 2007 code changes. (adn)
- 6/18/07 Code J7319 removed from policy. No longer a valid code.

## Policy: Intra Articular Hyaluronan Injections for Osteoarthritis of the Knee

- 12/31/07 Coding update. Deleted codes Q4083, Q4084, Q4085 and Q4086. Added codes J7321, J7322, J7323 and J7324 to Billing/Coding section. (adn)
- 2/11/08 Reformatted the When Covered section into a numbered list and added the following statement: "Repeated courses of intra-articular hyaluronan injections may be considered medically necessary under the following conditions: Significant pain relief was achieved with the prior course of injections; and at least six months have passed since the prior course." The statement regarding repeated treatment cycles was deleted from the Not Covered section. Rationale regarding repeated treatment cycles and use of hyaluronan on joints other than the knee added to the Policy Guidelines section. (adn)
- 8/25/08 Item A.1. in the When Covered section revised to read: Diagnosis of osteoarthritis substantiated by *x-ray or other imaging or arthroscopic findings*. References updated. Specialty Matched Consultant Advisory Panel review 6/17/08. No change to policy statement. (adn)
- 3/2/09 Description section revised for clarity. Medical Policy changed to Evidence Based Guideline.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.