

**Medical Coverage Policy | Intra-Articular
Hyaluronan Injections for Osteoarthritis**



EFFECTIVE DATE: 02|01|2016
POLICY LAST UPDATED: 04|16|2020

OVERVIEW

Knee osteoarthritis (OA) is common, costly, and a cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders. Currently, no curative therapy is available for OA, and thus the overall goals of management are to reduce pain, disability, and the need for knee replacement surgery. Intra-articular injection of hyaluronan (IAHA) into osteoarthritic joints is thought to replace endogenous hyaluronan, restore the viscoelastic properties of the synovial fluid, and improve pain and function.

This policy is applicable to Commercial Products only. For Blue CHIP for Medicare, see related policy section.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

Intra-articular hyaluronan injections of the knee and all other joints are considered not medically as the evidence is insufficient to determine the effects of the technology on health outcomes.

Individual Consideration

All of our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Individual Consideration Unit of Basic Claims
Administration Blue Cross & Blue Shield of Rhode Island
500 Exchange Street
Providence, RI 02903-2699

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

Knee osteoarthritis (OA) is common, costly, and a cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders.

Currently, no curative therapy is available for OA, and thus the overall goals of management are to reduce pain, disability, and need for surgery. Intra-articular (IA) injection of hyaluronan has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in patients with OA and reducing pain and

improving function. This treatment may also be called viscosupplementation. Hyaluronan is a naturally occurring macromolecule that is a major component of synovial fluid and is thought to contribute to its viscoelastic properties. Chemical crosslinking of hyaluronan increases its molecular weight; cross-linked hyaluronans are referred to as hylans. In OA, the overall length of hyaluronan chains present in cartilage and the hyaluronan concentration in the synovial fluid are decreased.

Intra-articular (IA) injection of hyaluronan into osteoarthritic joints is proposed to reduce pain and improve function. It is thought to replace endogenous hyaluronan and restore the viscoelastic properties of the synovial fluid. Most studies to date have assessed hyaluronan injections for knee osteoarthritis (OA), and this is the U.S. Food and Drug Administration-approved indication. Other joints (eg, hip, shoulder) are being investigated for IA hyaluronan treatment of OA.

For individuals who have OA of the knee who receive IA hyaluronan injections, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Many RCTs have been published over the last 2 decades. While outcomes of these RCTs have been mixed, the RCT evidence base is characterized by studies showing small treatment effects of IA hyaluronan injections. In many cases, these trials are at risk of bias, and it cannot be determined with certainty whether there is a true treatment effect or whether the reported differences are due to bias. Meta-analyses of RCTs have also had mixed findings. Some meta-analyses estimating the magnitude of treatment benefit have concluded that there is no clinically significant benefit; others have concluded that there is a clinically significant benefit. These meta-analyses have also highlighted the limitations of this evidence base, most notably publication bias and small trial bias. For example, a meta-analysis (2016) found more than a 3-fold larger treatment effect in small trials than in larger trials (ie, >100 participants). Overall, given the lack of a definitive treatment benefit despite a large quantity of literature, and given the biases present in the available evidence, it is unlikely there is a treatment benefit that is clinically meaningful. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

For individuals who have OA of joints other than the knee who receive IA hyaluronan injections, the evidence includes RCTs, systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Meta-analyses of RCTs either have not found statistically significant benefits of the procedure on health outcomes or have found benefits that were statistically, but likely not clinically, significant (eg, 0.27-point improvement on a 10-point visual analog scale for hip OA). The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Commercial Products

The following HCPCS codes are not medically necessary

- J7318** Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg (effective 1/1/2019)
- J7320** Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg;
- J7321** Hyaluronan or derivative, Hyalgan or Supartz, 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, Gel-syn, for intra-articular injection, 0.1 mg
- J7329** Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg (Effective 1/1/2019)
- J7331** Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg (Effective 10/1/2019)
- J7332** Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg (Effective 10/1/2019)

The following CPT codes are not medically necessary when used with one of the HCPCS codes listed above:

- 20610** Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee joint, subacromial bursa)
- 20611** Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

RELATED POLICIES

BlueCHIP for Medicare National and Local Coverage Determinations

PUBLISHED

- Provider Update, June 2020
- Provider Update, August 2019
- Provider Update, September 2018
- Provider Update, July 2017
- Provider Update, March 2016

REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intra-Articular Hyaluronan Injections for Treatment of Osteoarthritis of the Knee. *TEC Assessments* 1998;Volume 13:Tab 17.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special Report: intra-articular hyaluronan for osteoarthritis of the knee. *TEC Assessments*. 2004;Volume 19:Tab 17.
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intra-articular hyaluronic acid for osteoarthritis of the knee. *TEC Assessments*. 2014;Volume 29:Tab 6.
4. Samson DJ, Grant MD, Ratko TA, et al. *Treatment of primary and secondary osteoarthritis of the knee (Evidence Reports/Technology Assessments No. 157)*. Rockville, MD: Agency for Healthcare Research and Quality; 2007.
5. Agency for Healthcare Research and Quality. Evidence-based Practice Center Systematic Review Protocol: Treatment of Osteoarthritis of the Knee: An Update. 2016 July; https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/osteoarthritis-knee-update_research-protocol.pdf. Accessed March 13, 2018.
6. Rutjes AW, Juni P, da Costa BR, et al. Viscosupplementation for osteoarthritis of the knee: a systematic review and meta-analysis. *Ann Intern Med*. Aug 7 2012;157(3):180-191. PMID 22868835
7. American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee: Evidence-based guidelines. 2nd Edition. 2013; <http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf>. Accessed March 13, 2018.
8. Bannuru RR, Natov NS, Dasi UR, et al. Therapeutic trajectory following intra-articular hyaluronic acid injection in knee osteoarthritis--meta-analysis. *Osteoarthritis Cartilage*. Jun 2011;19(6):611-619. PMID 21443958
9. Colen S, van den Bekerom MP, Mulier M, et al. Hyaluronic acid in the treatment of knee osteoarthritis: a systematic review and meta-analysis with emphasis on the efficacy of different products. *BioDrugs*. Aug 1 2012;26(4):257-268. PMID 22734561
10. Miller LE, Block JE. US-approved intra-articular hyaluronic acid injections are safe and effective in patients with knee osteoarthritis: systematic review and meta-analysis of randomized, saline-controlled trials. *Clin Med Insights Arthritis Musculoskelet Disord*. Sep 2013;6:57-63. PMID 24027421
11. Johansen M, Bahrt H, Altman RD, et al. Exploring reasons for the observed inconsistent trial reports on intra-articular injections with hyaluronic acid in the treatment of osteoarthritis: Meta-regression analyses of randomized trials. *Semin Arthritis Rheum*. Aug 2016;46(1):34-48. PMID 27139169
12. Jevsevar D, Donnelly P, Brown GA, et al. Viscosupplementation for osteoarthritis of the knee: a systematic review of the evidence. *J Bone Joint Surg Am*. Dec 16 2015;97(24):2047-2060. PMID 26677239
13. Richette P, Chevalier X, Ea HK, et al. Hyaluronan for knee osteoarthritis: an updated meta-analysis of trials with low risk of bias. *RMD Open*. Oct 2015;1(1):e000071. PMID 26509069

14. Trojian TH, Concoff AL, Joy SM, et al. AMSSM scientific statement concerning viscosupplementation injections for knee osteoarthritis: importance for individual patient outcomes. *Br J Sports Med.* Jan 2016;50(2):84-92. PMID 26729890
15. Ammar TY, Pereira TA, Mistura SL, et al. Viscosupplementation for treating knee osteoarthritis: review of the literature. *Rev Bras Ortop.* Sep-Oct 2015;50(5):489-494. PMID 26535192
16. Strand V, McIntyre LF, Beach WR, et al. Safety and efficacy of US-approved viscosupplements for knee osteoarthritis: a systematic review and meta-analysis of randomized, saline-controlled trials. *J Pain Res.* May 2015;8:217-228. PMID 26005358
17. Wang F, He X. Intra-articular hyaluronic acid and corticosteroids in the treatment of knee osteoarthritis: A meta-analysis. *Exp Ther Med.* Feb 2015;9(2):493-500. PMID 25574222
18. Newberry SJ, Fitzgerald JD, Maglione MA, et al. Systematic Review for Effectiveness of Hyaluronic Acid in the Treatment of Severe Degenerative Joint Disease (DJD) of the Knee. Rockville, MD: Agency for Healthcare Research and Quality; 2015.
19. Bannuru RR, Schmid CH, Kent DM, et al. Comparative effectiveness of pharmacologic interventions for knee osteoarthritis: a systematic review and network meta-analysis. *Ann Intern Med.* Jan 6 2015;162(1):46-54. PMID 25560713
20. O'Hanlon CE, Newberry SJ, Booth M, et al. Hyaluronic acid injection therapy for osteoarthritis of the knee: concordant efficacy and conflicting serious adverse events in two systematic reviews. *Syst Rev.* Nov 04 2016;5(1):186. PMID 27814744
21. Tammachote N, Kanitnate S, Yakumpor T, et al. Intra-articular, single-shot Hylan G-F 20 hyaluronic acid injection compared with corticosteroid in knee osteoarthritis: a double-blind, randomized controlled trial. *J Bone Joint Surg Am.* Jun 01 2016;98(11):885-892. PMID 27252432
22. Askari A, Gholami T, NaghiZadeh MM, et al. Hyaluronic acid compared with corticosteroid injections for the treatment of osteoarthritis of the knee: a randomized control trail. *Springerplus.* Apr 12 2016;5:442. PMID 27104130
23. Witteveen AG, Hofstad CJ, Kerkhoffs GM. Hyaluronic acid and other conservative treatment options for osteoarthritis of the ankle. *Cochrane Database Syst Rev.* Oct 17 2015;10(10):CD010643. PMID 26475434
24. Migliore A, Giovannangeli F, Bizzi E, et al. Viscosupplementation in the management of ankle osteoarthritis: a review. *Arch Orthop Trauma Surg.* Jan 2011;131(1):139-147. PMID 20697901
25. Munteanu SE, Zammit GV, Menz HB, et al. Effectiveness of intra-articular hyaluronan (Synvisc, hylan G-F 20) for the treatment of first metatarsophalangeal joint osteoarthritis: a randomised placebo-controlled trial. *Ann Rheum Dis.* Oct 2011;70(10):1838-1841. PMID 21791454
26. Kroon FP, Rubio R, Schoones JW, et al. Intra-articular therapies in the treatment of hand osteoarthritis: a systematic literature review. *Drugs Aging.* Feb 2016;33(2):119-133. PMID 26650235
27. Trelle S, Dadoun S, Berenbaum F, et al. Intra-articular injections in thumb osteoarthritis: A systematic review and meta-analysis of randomized controlled trials. *Joint Bone Spine.* Oct 2015;82(5):315-319. PMID 25776442
28. Lieberman JR, Engstrom SM, Solovyova O, et al. Is intra-articular hyaluronic acid effective in treating osteoarthritis of the hip joint? *J Arthroplasty.* Mar 2015;30(3):507-511. PMID 25542833
29. Wu B, Li YM, Liu YC. Efficacy of intra-articular hyaluronic acid injections in hip osteoarthritis: a meta-analysis of randomized controlled trials. *Oncotarget.* Oct 17 2017;8(49):86865-86876. PMID 29156841

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

