

EFFECTIVE DATE: 2/3/2015

POLICY LAST UPDATED: 1/13/2015

OVERVIEW

Intra-articular injection of hyaluronan (HA) into osteoarthritic joints is thought to replace endogenous HA, restore the viscoelastic properties of the synovial fluid, and improve pain and function. 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.

PRIOR AUTHORIZATION

Preauthorization review is not required

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Hyaluronan viscosupplementation injections of the knee are covered with the diagnosis of osteoarthritis of the knee

The use of intra-articular hyaluronan injections in joints other than the knee is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the service is effective.

MEDICAL CRITERIA

None

BACKGROUND

Knee 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 surgery. IAHA has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in patients with OA and improving pain and function. This treatment may also be called viscosupplementation. HA 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 HA chains present in cartilage and the HA concentration in the synovial fluid are decreased.

Purified natural hyaluronans have been approved by the FDA for the treatment of pain associated with osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics. The synovial fluid's capacity to lubricate and absorb shock is typically reduced in joints affected by osteoarthritis. These changes are partly due to a reduction in the concentration and size of hyaluronic acid molecules that are naturally present in synovial fluid. A recent approach in the management of osteoarthritis of the knee is to inject hyalonurate, or derivatives of this molecule, into the joint. This policy defines coverage criteria for the injection of the knee with either sodium hyaluronate (Hyalgan®, Supartz®, Euflexxa™), Hylan G-F 20 (Synvisc®, Synvisc-One), or high molecular weight hyaluronan (Orthovisc®).

The evidence on the efficacy of IAHA for joints other than the knee is less robust. While some studies show benefit, others do not, and systematic reviews have not concluded that there is a clinically significant benefit.

Intra-articular injection of hyaluronan into osteoarthritic joints is thought to replace hyaluronan, restore the viscoelastic properties of the synovial fluid, and improve pain and function. The largest amount of evidence is on treatment of osteoarthritis (OA) of the knee. Individual trials show inconsistent results in pain and functional outcomes for intra-articular injection of hyaluronan (IAHA) compared with placebo or active control. Meta-analyses of randomized controlled trials (RCTs) show improvements in pain and function that are statistically significant, but have not been demonstrated to be clinically significant in an appreciable number of patients.

IAHA continues to be investigated for off-label uses in other joints. Current evidence on these off-label uses is limited, consisting of small RCTs and case series. Some RCTs on IAHA injections for OA of the ankle, foot, hand and shoulder have shown treatment benefits; however, these studies are not consistent in reporting improvements that are significantly greater than placebo and/or control treatments. RCTs on IAHA injections for OA of the hip have also been inconsistent, with some RCTs reporting improvements in outcomes with IAHA hip injections and others reporting no improvement. Currently, given the limited and inconsistent available data, and the low likelihood that IAHA for joints other than the knee are more effective than IAHA for the knee, these uses are also considered not medically necessary.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage document or Subscriber Agreement for the applicable physician administered injected medication and surgery benefits/coverage.

CODING

BlueCHiP for Medicare and Commercial

The following codes are covered when billed with one of the diagnosis codes listed below
J7321 Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose
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

The following codes for the administration of the viscosupplementation are covered only if the drug has been approved.

20610
20611.

ICD9: 715.16, 715.26, 715.36, 715.96

ICD10: M17.10, M17.5, M17.9

RELATED POLICIES

None

PUBLISHED

Provider Update, Mar 2015
Provider Update, April 2013
Provider Update, May 2012
Provider Update, May 2011
Provider Update, June 2010
Provider Update, May 2009
Provider Update, June 2008
Policy Update, July 2006
Policy Update, Sept 2004

REFERENCES

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

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

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*. 2013;6:57-63. PMID 24027421

McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. Mar 2014;22(3):363-388. PMID 24462672

N. Bellamy, J., et al. Update 2006: Abstract:Cochrane Review Of Viscosupplementation For The Treatment Of Osteoarthritis Of The Knee. *Annals of the Rheumatic Diseases*2006;65(Suppl 2):224. Retrieved 3/19/08 from http://eular.bmj.com/cgi/content/abstract/65/Suppl_2/224

Leopold S., et al. Increased Frequency of Acute Local Reaction to Intra-Articular Hylan GF-20 (Synvisc) in Patients Receiving More Than One Course of Treatment. *The Journal of Bone and Joint Surgery (American)* 84:1619-1623 (2002). Retrieved 3/19/08 from <http://www.ejbs.org/cgi/content/abstract/84/9/1619>

Moreland, L. W. Intra-articular hyaluronan (hyaluronic acid) and hylans for the treatment of osteoarthritis: mechanisms of action. *Arthritis Res Ther*2003, 5:54-67. Retrieved 3/19/08 from <http://arthritis-research.com/content/5/2/54>

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

