Medical Coverage Policy | Intra-Articular Hyaluronan Injections for Osteoarthritis



EFFECTIVE DATE: 02|01|2016 **POLICY LAST UPDATED:** 07/17/2018

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 limitations of benefits/coverage when services are not medically necessary.

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

- 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
- [7324 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

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, September 2018 Provider Update, July 2017 Provider Update, March 2016 Provider Update, November 2015

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