DRUG POLICY

Viscosupplementation for Osteoarthritis

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the viscosupplementation for osteoarthritis policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. There are eleven (11) intra-articular hyaluronic acid derivatives approved by the Food and Drug Administration for the treatment of osteoarthritis of the knee in patients who have failed to respond to conservative non-pharmacologic therapy, simple analgesics, and/or nonsteroidal anti-inflammatory drugs (NSAIDs):

- Euflexxa®, Gelsyn-3®, Genvisc 850®, Supartz®, Hylgan® and Visco-3® (sodium hyaluronate)
- Hymovis®, Orthovisc®, and Monovisc® (high molecular weight hyaluronan)
- Synvisc® and Synvisc-One® (hylan G-F 20)
- Gel-One® (cross-linked hyaluronate)

The FDA has not approved viscosupplementation products for joints other than the knee.

Wellmark’s preferred product is Synvisc-One. While multiple brands of viscosupplementation are commercially available, there’s no evidence, to date, that any have superior efficacy or safety for the treatment of osteoarthritis of the knee. Euflexxa can be approved as an alternative agent, only in the event a patient meets the medical necessity criteria below, but has a contraindication to use Synvisc-One, that does not also extend to Euflexxa (e.g., patient has a documented allergy to avian proteins, feathers or eggs). All other viscosupplementation agents, including but not limited to, Visco-3, Supartz, Synvisc, Hylgan, Hymovis, Orthovisc, Monovisc, Gelsyn-3, Genvisc 850, and Gel-One, are non-preferred and considered not medically necessary.

POLICY

I. Synvisc-One® is considered medically necessary for the treatment of painful osteoarthritis of the knee when all of the following criteria are met:

- The patient is 18 years of age or older
- The patient has tried and failed at least ONE non-pharmacologic therapy (e.g. cane, bracing/orthotics, physical therapy, exercise program, weight management)
- The patient has tried and failed adequate therapeutic trials of at least THREE analgesics (e.g. acetaminophen, NSAIDs, cyclooxegenase (COX-2) inhibitors, tramadol, duloxetine, opiates, topical capsaicin or NSAIDs) unless contraindicated.
• The patient has tried and failed intra-articular corticosteroid injections (IACI) unless contraindicated
• The patient and provider have elected to continue conservative/non-surgical management of OA (e.g. no surgery planned within 6 months of viscosupplementation therapy)
• There are no contraindications to viscosupplementation therapy (e.g. knee infection, bleeding disorder, skin infections at or near the injection site, known allergy/hypersensitivity to hyaluronic acid, known hypersensitivity to gram positive bacterial proteins)

Approval is for 1 course of therapy per affected joint(s)

II. Euflexxa® is considered medically necessary for the treatment of painful osteoarthritis of the knee when all of the following criteria are met:
• The patient is 18 years of age or older
• The patient has tried and failed at least ONE non-pharmacologic therapy (e.g. cane, bracing/orthotics, physical therapy, exercise program, weight management)
• The patient has tried and failed adequate therapeutic trials of at least THREE analgesics (e.g. acetaminophen, NSAIDs, cyclooxygenase (COX-2) inhibitors, tramadol, duloxetine, opiates, topical capsaicin or NSAIDs) unless contraindicated.
• The patient has tried and failed intra-articular corticosteroid injections (IACI) unless contraindicated
• The patient and provider have elected to continue conservative/non-surgical management of OA (e.g. no surgery planned within 6 months of viscosupplementation therapy)
• There are no contraindications to viscosupplementation therapy (e.g. knee infection, bleeding disorder, skin infections at or near the injection site, known allergy/hypersensitivity to hyaluronic acid, known hypersensitivity to gram positive bacterial proteins)
• The patient has a documented avian allergy or previous adverse reaction/hypersensitivity to Synvisc/Synvisc-One

Approval is for 1 course of therapy per affected joint(s)

III. An additional course of the previously approved viscosupplementation therapy (Synvisc-One or Euflexxa) may be considered medically necessary for treatment of painful osteoarthritis of the knee when all of the following criteria are met:
• Significant pain relief was achieved with the prior course and documented in the medical record as one of the following:
  o Reduction in the dose of analgesic medication; OR
  o Improvement in pain and functional capacity
• At least 6 months has elapsed since the prior course of treatment
• The patient and provider have elected to continue conservative/non-surgical management of OA (e.g. no surgery planned within 6 months of viscosupplementation therapy)

Approval is for 1 course of therapy per affected joint(s)

IV. Intra-articular hyaluronan injections are considered not medically necessary for patients who do not meet the criteria set forth above.

Prior approval is required.

Quantity limits apply. Synvisc-One 1 injection per 6 months, Euflexxa 3 injections per 6 months
Osteoarthritis (OA) is the result of an imbalance between the breakdown and repair of the tissues in the synovial joint and occurs as a result of multiple risk factors including trauma, overuse and genetic predisposition. Pathological presentation in the knee is characterized by deterioration and loss of articular cartilage along with increased osteophyte formation. The elastoviscous properties of the synovial fluid deteriorate over time, resulting in less protection and shock absorption. Ultimately, joint pain and stiffness result, which limit mobility.

Viscosupplementation involves the injection of hyaluronic acid derivatives into the knee to supplement the elastoviscous properties of the synovial fluid, with the intended purpose of improving mobility, decreasing pain and restoring protective function on the joint. A treatment cycle for most hyaluronic acid derivatives involves a series of weekly injections, with the exception of Synvisc One®, Gel One®, and Monovisc®, which require only one injection. Improvements in symptoms can last one to six months.

Individual trials show inconsistent results in pain and functional outcomes for viscosupplementation compared to placebo or active control. Several meta-analyses of randomized controlled trials (RCTs) demonstrate statistically significant improvements in pain and function, yet these improvements fail to meet minimum thresholds for clinical significance. There have been no trials to date that demonstrate intra-articular hyaluronan (IAHA) delays progression of OA, progression to surgery, nor reduces the need, for other pain management options, including NSAIDs and opiates. Treatment guidelines from the American Academy of Orthopaedic Surgeons (AAOS) include the following statement, “we cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee”, based on moderate-high quality evidence. The 2014 guidelines on osteoarthritis from the National Institute for Health and Care Excellence (NICE) conclude more strongly, “Do not offer intra-articular hyaluronan injections for the management of osteoarthritis”.

The 2012 American College of Rheumatology (ACR) clinical practice guidelines on osteoarthritis indicate they have no recommendations regarding the use of IAHA in the knee. Their recommendations for the use of pharmacologic therapies in knee OA include acetaminophen, oral and topical NSAIDs, tramadol and intra-articular corticosteroid injections (IACI). Similar to the ACR guidelines the Osteoarthritis Research Society International (OARSI) 2014 guideline update provided an “uncertain” recommendation for IAHA, indicating an overall small effect size on pain, inconsistent results among the available meta-analyses, and one meta-analysis signaling potential for serious safety concerns, influenced their recommendation.

Studies comparing IAHA to NSAIDS have led to conflicting results and have not clearly demonstrated IAHA to be superior. In one, more recent randomized, open label trial in 200 patients with osteoarthritis of the knee, IAHA was found to be non-inferior to oral NSAIDs. While there are a limited number of studies comparing IAHA to IACI, the studies available indicate IACI is as effective as IAHA in the short-term management of OA of the knee. Unlike IAHA, NSAIDs and IACI are consistently recommended by guidelines (for the appropriately selected patient) and offer a much more cost-effective treatment approach for the management of osteoarthritis of the knee.

Recently, evidence regarding repeat courses of IAHA for knee OA was evaluated by the California Technology Assessment Forum. Their findings indicate repeated IAHA injections have shown symptomatic relief of knee OA, but have not demonstrated slowing in the progression of knee OA or progression to knee replacement. Ultimately, the efficacy and safety of multiple courses of IAHA has not been established.
The evidence for the efficacy and safety of IAHA injections for use in joints other than the knee has not been established. Given the limited and inconsistent data available, use of viscosupplementation for joints other than the knee is not considered medically necessary.

While multiple brands of viscosupplementation are commercially available, there’s no evidence, to date, that any have superior efficacy or safety for the treatment of osteoarthritis of the knee. Synvisc-One is the preferred product as it is least costly for Wellmark.

Ultimately, there is inconsistent evidence that viscosupplementation produces clinically relevant improvements in pain and functioning for OA of the knee and no evidence to suggest it delays the progression of OA nor the progression to knee replacement. Based on this evidence, several major practice guidelines are unable to recommend IAHA, with others recommending against its use. IAHA should be reserved last-line when other guideline recommended treatments, both non-pharmacologic and pharmacologic, have been exhausted (or are contraindicated), in patients who will continue to pursue non-surgical management of their osteoarthritis.

In summary, the use of viscosupplementation, or hyaluronic acid products, for the treatment of osteoarthritis (OA) of the knee has debatable clinical utility. Over the past few years they have largely fallen from favor, with several major organizations, including the American Academy of Orthopaedic Surgeons (AAOS), citing conflicting and limited evidence as the basis of their inability to make a recommendation for, or against, their use. Given viscosupplementation has been unable to demonstrate clear, consistent, patient centered outcomes, some health plans have discontinued coverage of these products. Wellmark recognizes that while the evidence and guidelines offer conflicting recommendations for the use viscosupplementation, these products may provide benefit for some. Given the limited effectiveness data and high cost of these products, it is paramount that Wellmark balance access and cost, ensuring the most cost-effective, clinically appropriate use of this therapy.

**PROCEDURES AND BILLING CODES**

*To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.*

- 20610, 20611 for professional services for intra-articular injection
- J7320 Genvisc® 850, inj, 1mg (effective 1/1/17)
- J7321 Hyaluronan or derivative, Supartz® or Hylgan®, for intra-articular injection, per dose
- J7322 Hyaluronan or derivative, Hymovis®, for intra-articular injection, per dose (effective 1/1/17)
- 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, 1mg
- 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, Gelsyn-3®, for intra-articular injection, per dose
- J3490 Unclassified drugs

**REFERENCES**


POLICY HISTORY

Policy #: 02.01.12
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