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Viscosupplementation for Osteoarthritis

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

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 drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Orthovisc, Synvisc, and Synvisc One are the preferred products. The criteria will require the use of the health plan's preferred products before the use of targeted products (Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Monovisc, sodium hyaluronate inj 20mg/2mL, Supartz FX, Synojoynt, Triluron, Trivisc, Visco-3), unless there are clinical circumstances that exclude the use of the preferred products and may be based on previous use of a product. While multiple brands of viscosupplementation are commercially available, there is no evidence, to date, that any have superior efficacy or safety.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen)

Table. Hyaluronate products

Medication	Generic Name
Preferred Products:	
Orthovisc	high molecular weight hyaluronan

Synvisc	hylan G-F 20
Synvisc One	hylan G-F 20
Targeted Products:	
Durolane	hyaluronic acid
Euflexxa	1% sodium hyaluronate
Gel-One	cross-linked hyaluronate
Gelsyn-3	sodium hyaluronate
Genvisc 850	sodium hyaluronate
Hyalgan	sodium hyaluronate
Hymovis	high molecular weight viscoelastic hyaluronan
Monovisc	high molecular weight hyaluronan
sodium hyaluronate inj 20mg/2mL (manufactured by Teva)	sodium hyaluronate
Supartz FX	sodium hyaluronate
Synjoynt	sodium hyaluronate
Triluron	sodium hyaluronate
TriVisc	sodium hyaluronate
Visco-3	sodium hyaluronate

POLICY

Must meet BOTH the Preferred Drug Plan Design (for the specific drug) and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

- I. Coverage for a targeted product is provided when either of the following criteria is met:
 - A. Member is currently undergoing treatment and coverage is required to complete the current course of treatment.

Number of injections per treatment course

- Euflexxa: 3 injections (2 mL each; 6 mL total) per course
- Gelsyn-3: 3 injections (2 mL each, 6 mL total) per 180 day course
- GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
- Hyalgan: 3 to 5 injections (2 mL each; 10 mL total) per 180 day course
- Hymovis: 2 injections (3 mL each; 6 mL total) per 180 day course
- sodium hyaluronate inj 20mg/2mL: 3 injections per 180 day course
- Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
- Synjoynt: 3 injections per 180 day course

- Triluron: 3 injections per 180 day course
 - TriVisc: 3 injections (2.5 mL each, 7.5 mL total) per 180 day course
- B. Member has tried and experienced an intolerable adverse event to at least two of the preferred products: a) Orthovisc, AND b) Synvisc or Synvisc One.

Initial Criteria for Approval

- I. Authorization of 12 months may be granted for treatment of osteoarthritis (OA) in the knee when all of the following criteria are met:
- A. The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts) or the member has at least 5 of the following signs and symptoms:
 1. Bony enlargement
 2. Bony tenderness
 3. Crepitus (noisy, grating sound) on active motion
 4. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
 5. Less than 30 minutes of morning stiffness
 6. No palpable warmth of synovium
 7. Over 50 years of age
 8. Rheumatoid factor less than 1:40 titer (agglutination method)
 9. Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm³)
 - B. The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
 - C. The member has experienced an inadequate response or adverse effects with non-pharmacologic treatment options (e.g., physical therapy, regular exercise, insoles, knee bracing, weight reduction).
 - D. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of an analgesic (e.g., acetaminophen up to 3 to 4 grams per day, non-steroidal anti-inflammatory drugs [NSAIDs], topical capsaicin cream) for at least 3 months.
 - E. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of intraarticular steroid injections for at least 3 months.
 - F. The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

Continuation of Therapy

- I. Authorization of 12 months may be granted for continued treatment of osteoarthritis in knee when all of the following criteria are met:
- A. Member meets all criteria for initial approval
 - B. Member has experienced improvement in pain and functional capacity following the previous injections.

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

Dosing and Administration

Approvals may be subject to age and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity limits apply:

Synvisc-One: 1 injection (6 mL each; 6 mL total) per 180 day course

Synvisc: 3 injections (2 mL each; 6 mL total) per 180 day course

Hyalgan: 3 to 5 injections (2 mL each; 10 mL total) per 180 day course

Hymovis: 2 injections (3 mL each; 6 mL total) per 180 day course

Euflexxa: 3 injections (2 mL each; 6 mL total) per 180 day course

Gel-One: 1 injection (3 mL each; 3 mL total) per 180 day course
Gelsyn-3: 3 injections (2 mL each, 6 mL total) per 180 day course
GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
Monovisc: 1 injection (4 mL each, 4 mL total) per 180 day course
Orthovisc: 3 or 4 injections (2 mL each; 8 mL total) per 180 day course
sodium hyaluronate inj 20mg/2mL: 3 injections per 180 day course
Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per 180 day course
Synjoynt: 3 injections per 180 day course
Triluron: 3 injections per 180 day course
Durolane: 1 injection (3 mL each, 3 mL total) per course
TriVisc: 3 injections (2.5 mL each, 7.5 mL total) per 180 day course

CLINICAL RATIONALE

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. Orthovisc, Synvisc-One, and Synvisc are the preferred products as they are 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.

- J7320 GenVisc 850, inj, 1mg
- J7321 Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose
- J7322 Hyaluronan or derivative, Hymovis, for intra-articular injection, per 1mg
- 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 0.1mg
- J7329 Hyaluronan or derivative, TriVisc, for intra-articular injection, per 1mg
- J7318 Hyaluronan or derivative, Durolane, for intra-articular injection, per 1mg
- J3490 Unclassified drugs (sodium hyaluronate inj 20mg/2mL)

- J7331 Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1 mg
- J7332 Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
- J7333 Hyaluronan or derivative, Visco-3, for intra-articular injection, per dose

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*Some content reprinted from CVSHealth

POLICY HISTORY

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