Drug and Biologic Coverage Policy

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Coverage Policy Number 1405

Viscosupplementation for Osteoarthritis

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This coverage policy addresses the use of the following Viscosupplementation (hyaluronate injection) products:

- **Durolane**® (hyaluronic acid)
- **Euflexxa**® (1% sodium hyaluronate)
- **Gel-One**® (cross-linked hyaluronate)
- **Gelsyn-3**™ (high molecular weight hyaluronan)
- **GenVisc 850**® (high molecular weight hyaluronan)
- **Hyalgan**® (sodium hyaluronate)
- **Hymovis**® (high molecular weight hyaluronan)
- **Monovisc**™ (high molecular weight hyaluronan)
- **Orthovisc**® (high molecular weight hyaluronan)
- **Supartz FX**™ (sodium hyaluronate)
- **Synojoynt** (sodium hyaluronate)
- **Synvisc**® (hylan G-F 20)
- **Synvisc-One**® (hylan G-F 20)
- **Triluron**™ (sodium hyaluronate)
- **Trivisc** (sodium hyaluronate)

- **Visco-3**™ (sodium hyaluronate)]

Click here for information on the hyaluronic acid source of each product

Coverage Policy

Viscosupplementation injections are considered medically necessary when ALL of the following criteria are met:

- Diagnosis of symptomatic osteoarthritis of the knee affecting activities of daily living, documented by radiologic evidence of osteoarthritis of the knee (for example, joint space narrowing, subchondral sclerosis, osteophytes, sub-chondral cysts)
- Inadequate response or not a candidate for BOTH of the following treatment options:
    - Conservative treatment including physical therapy and/or pharmacotherapy for at least 6 weeks
    - Intra-articular (IA) corticosteroids

Coverage for viscosupplementation (hyaluronate injections) varies across plans. Refer to the customer's benefit plan document for coverage details.

Where coverage requires the use of preferred products, the following criteria apply.

For Employer Group Plans:
Contraindication per FDA label or documented intolerance to BOTH of the following:

- Monovisc [high molecular weight hyaluronan] OR Orthovisc [high molecular weight hyaluronan]
- Synvisc [hylan G-F 20] OR Synvisc-One [hylan G-F 20])

Initial authorization is for up to 6 months.

Additional treatment courses of Viscosupplementation for Osteoarthritis are considered medically necessary when ALL of the following criteria are met:

- Initial criteria for use of the requested product were met
- History of clinical beneficial response with previous treatment course (for example, an improvement in an objective measurement of pain and/or functional status [Visual Analog Scale (VAS), Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index, or other validated objective measure])
- At least 6 months have lapsed since the completion of the prior treatment course

Reauthorization is for up to 6 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Viscosupplementation (hyaluronate injections) is considered experimental, investigational or unproven for ANY other use.

The combination of any other product, (for example, platelet rich plasma (PRP), stem cell products, amniotic products, corticosteroids) with a viscosupplement injection is not medically necessary because it is considered experimental, investigational or unproven.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

Product	FDA Approved Indication
Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synojoynt, Synvisc, Synvisc-One, Triluron, **Trivisc**, **Visco-3**	Treatment of pain in osteoarthritis (OA) of the knee in patients who have failed non-pharmacologic treatment and simple analgesics (e.g. acetaminophen).

Recommended Dosing

Product	FDA Recommended Dosing
Durolane (hyaluronic acid)	Single intra-articular injection into the knee joint. Inject the full 3 mL of Durolane into knee. If treatment is being administered to both knees, use a separate syringe of Durolane for each knee.
Euflexxa (1% sodium hyaluronate)	A dose of 2 mL is injected intra-articularly into the affected knee at weekly intervals for three weeks, for a total of three injections. Inject the full syringe contents, 2 ml into one knee only. If treatment is being administered to both knees, use a separate syringe for each knee.
Gel-One (cross-linked hyaluronate)	Single intra-articular injection into the knee joint. Inject the full 3 mL of Gel-One into knee. If treatment is being administered to both knees, use a separate syringe of Gel-One for each knee. Injection of subcutaneous lidocaine or similar local anesthetic may be performed prior to injection of Gel-One.
Gelsyn-3 (high molecular weight hyaluronan)	Inject 2 mL (16.8 mg sodium hyaluronate) intra-articularly once a week for a total of 3 injections. If treatment is bilateral, use a separate 2 mL syringe for each knee. Avoid any strenuous activities or prolonged weight-bearing activities for approximately 48 hours after the injection.
GenVisc 850 (high molecular weight hyaluronan)	GenVisc 850 is administered by intra-articular injection. A treatment cycle consists of five injections given at weekly intervals. Some patients may experience benefit with three injections given at weekly intervals. Injection of subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of GenVisc 850.
Hyalgan (sodium hyaluronate)	Administered by intra-articular injection. A treatment cycle consists of 5 injections (2 mL) given at weekly intervals. Some patients may experience benefit with 3 injections given at weekly intervals. This has been noted in studies reported in the literature in which patients treated with 3 injections were followed for 60 days. Inject the full 2 mL in one knee only. If treatment is bilateral, a separate vial should be used for each knee.
Hymovis (high molecular weight hyaluronan)	Hymovis is intended to be injected into the knee joint and is administered as a two intra-articular injection regimen. Inject the full 3 mL in one knee only (do not overfill the joint). If treatment is bilateral, a separate syringe should be used for each knee. Administer the second injection of Hymovis in the same joint in a week after the first injection following the same guidelines.
Monovisc (high molecular weight hyaluronan)	Injected into the knee joint and is administered as a single intra-articular injection of 4 mL. The effectiveness of Monovisc has not been established for more than one course of treatment. Inject the full 4 mL in one knee only. If treatment is bilateral, a separate syringe should be used for each knee.
Orthovisc (high molecular weight hyaluronan)	2 mL injected into the knee joint in a series of intra-articular injections one week apart for a total of three or four injections. Inject the full contents of the syringe into one knee only. If treatment is bilateral, a separate syringe should be used for each knee. If symptoms return, repeat courses of Orthovisc may be administered.
Supartz FX (sodium hyaluronate)	Administered by intra-articular injection once a week (1 week apart) for a total of 5 injections. Some patients may experience benefit with 3 injections given at weekly intervals. This has been noted in a study in which patients with 3 injections were

Product	FDA Recommended Dosing
	followed for 90 days. Injection of subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of Supartz FX. Inject the full 2.5 mL in one knee only. If treatment is bilateral, a separate syringe should be used for each knee.
Synojoynt (sodium hyaluronate)	Administered by intra-articular injection into the knee joint in a series of injections one week apart for a total of three injections. The effectiveness of repeated injection cycles of Synojoint has not been established.
Synvisc (hylan G-F 20)	Administered by intra-articular injection once a week (one week apart) for a total of 3 injections. Inject the full 2 mL in one knee only.
Synvisc-One (hylan G-F 20)	Administered as a single intra-articular injection. Inject the full 6 mL in one knee only.
Triluron (sodium hyaluronate)	Administered by intra-articular injection. A treatment cycle consists of three (3) injections given at weekly intervals. Injection of subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of Triluron.
Trivisc (sodium hyaluronate)	Administered by intra-articular injection. A treatment cycle consists of three (3) injections given at weekly intervals. Injection of subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of TriVisc.
Visco-3 (sodium hyaluronate)	2.5 mL injected into the knee joint in a series of intra-articular injections one week apart for a total of three injections. Inject the full contents of the syringe into one knee only. If treatment is bilateral, a separate syringe should be used for each knee.

General Background

Disease Overview

The Centers for Disease Control and Prevention (CDC) define osteoarthritis as a disease characterized by degeneration of cartilage and its underlying bone within a joint as well as bony overgrowth resulting in symptoms of joint stiffness and pain. The joints most commonly affected include knees, hips, and those in the hands and spine. An estimated 14% of adults aged 25 years and older and 34% of adults aged 65 years and older are affected. There is not a cure for the underlying disease process; therefore, treatment is targeted at relieving the symptoms. Various non-pharmacologic (e.g., weight loss, physical therapy) and pharmacologic (e.g., acetaminophen, non-steroidal anti-inflammatory [NSAIDs], intra-articular injections of corticosteroids, intra-articular hyaluronates) treatment modalities are utilized. Viscosupplements contain hyaluronate. Hyaluronates are also referred to as hyaluronic acid or hyaluronan. (CDC, 2015)

Pharmacology

Intra-articular (IA) injection of hyaluronates restores the viscoelasticity and protection provided by synovial hyaluronic acid, which is decreased with OA. It also decreases joint pain and improves joint mobility. The hyaluronates have different molecular weights; the clinical impact of molecular weight is not defined. The available products are derived from either bacterial cells or avian sources.

Product	Hyaluronic Acid Source
Durolane (hyaluronic acid)	Bacteria cells
Euflexxa (1% sodium hyaluronate)	Bacterial cells
Gel-One (cross-linked hyaluronate)	Avian (chicken combs)
Gelsyn-3 (high molecular weight hyaluronan)	Bacterial fermentation
GenVisc 850 (high molecular weight hyaluronan)	Bacterial fermentation
Hyalgan (sodium hyaluronate)	Avian (rooster combs)
Hymovis (high molecular weight hyaluronan)	Bacterial fermentation
Monovisc (high molecular weight hyaluronan)	Bacterial cells
Orthovisc (high molecular weight hyaluronan)	Bacterial cells
Supartz FX (sodium hyaluronate)	Avian (chicken combs)
Synojoynt (sodium hyaluronate)	Bacterial fermentation
Synvisc (hylan G-F 20)	Avian (chicken combs)
Synvisc-One (hylan G-F 20)	Avian (chicken combs)

Product	Hyaluronic Acid Source
Triluron (sodium hyaluronate)	Avian (rooster combs)
Trivisc (sodium hyaluronate)	Bacterial fermentation
Visco-3 (sodium hyaluronate)	Avian (chicken combs)

Professional Societies/Organizations
American College of Rheumatology (ACR) guidelines for the medical management of osteoarthritis of the hand, hip, and knee state initial pharmacologic therapy for knee osteoarthritis consists of acetaminophen, oral and topical non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, and intraarticular corticosteroid injections. Intraarticular hyaluronic acid derivatives, duloxetine, and opioids are recommended in certain conditions, including patients who failed to respond to initial therapies for knee osteoarthritis. Intraarticular hyaluronic acid derivatives is not recommended in patients with hand or hip osteoarthritis. In the guidelines, no distinction is made between the available intraarticular hyaluronic acid derivative products or between products with various molecular weights. (Hochberg, 2012)

American Academy of Orthopaedic Surgeons (AAOS) for the treatment of osteoarthritis of the knee (non-arthroplasty) mention hyaluronic acid derivative products. However, the guidelines note that hyaluronic acid derivatives cannot be recommended for patients with symptomatic osteoarthritis of the knee. This recommendation is based on an analysis that included 14 studies demonstrating that the effect of hyaluronic acid derivative injections was unlikely to provide a clinically important benefit for pain. AAOS noted that when the high- and low-molecular weight products were analyzed, most of the statistically significant outcomes were associated with the high-molecular cross-linked hyaluronic acids, but when compared to mid-range molecular weight products, statistical significance was not maintained. The guidelines specifically note that treatment comparisons between any weights higher than 750 kDa were not significantly different. It is also noted that other reviews (e.g., by the Agency for Healthcare Research and Quality [AHRQ]) demonstrate a statistically significant treatment effect using different selection criteria. AAOS acknowledges that lower-strength studies were excluded from the AAOS review based on selection criteria, and states that other agencies have acknowledged that there is evidence of potential publication bias with hyaluronic acid derivative products. (Jevsevar, 2013)

Osteoarthritis Research Society International (OARSI) guidelines for knee osteoarthritis, based on good evidence from systematic reviews and meta-analyses of randomized controlled trials, the use of intraarticular hyaluronic acid derivatives is uncertain in knee osteoarthritis and not appropriate for multiple joint osteoarthritis. It was noted that inconsistent conclusions among the meta-analyses and conflicting results regarding safety influenced the recommendation. (McAlindon, 2014)

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative:
No recommendations are available for viscosupplementation injections for Osteoarthritis.

Centers for Medicare & Medicaid Services - National Coverage Determinations (NCDs)
There are no CMS National Coverage Determinations for viscosupplementation injections for Osteoarthritis.

Other Covered Uses
AHFS Drug Information 2020 Edition does not have a monograph for Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synojoint, Synvisc, Synvisc-One, Triluron, TriVisc or Visco-3.

Compendium and Other Published Studies
Case series, randomized controlled trials, systematic reviews and/or meta-analysis have investigated hyaluronate injections for numerous conditions/indications, including acute ankle sprain (Jevsevar, 2013; Petrella, 2007; Petrella, 2009), first metatarsophalangeal joint osteoarthritis (Munteanu, 2011), lateral epicondylitis (Krogh, 2013), osteoarthritis of the ankle (Cohen, 2008), osteoarthritis of the foot (Cohen, 2008), osteoarthritis of the hip (DeGroot, 2012; Richette, 2009; Qvistgaard, 2006), post-traumatic osteoarthritis of the elbow (van Brakel, 2006) and tempomandibular joint disorders, including osteoarthritis (de Souza, 2012; Machado, 2013).

There is insufficient evidence in the peer-reviewed published scientific literature to support safety and efficacy of the injection of platelet rich plasma (PRP) and/or corticosteroid into the same joint on the same date of service as a viscosupplement. (Dallari, 2016)

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan, Supartz or visco-3, 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, GELSYN, for intra-articular injection, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1mg
J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose (Code deleted 03/31/2021)

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