UM-CDG-003 Viscosupplementation	Approved By: Director, Health Services	Effective Date: 11/10/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address Part B hyaluronates, viscosupplementation, also known as intra-articular injection of hyaluronic acid (HA).

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to Part B drug requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

Viscosupplementation has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in individuals with osteoarthritis. It is most used for osteoarthritis of the knee.

Typical candidates for viscosupplementation are those with knee osteoarthritis who have failed to improve with other non-surgical treatments. There exist multiple synthetic preparations of hyaluronic acid based polymers approved by the US Food and Drug Administration (FDA) and are indicated for the treatment of osteoarthritis pain associated with the knee. The goal of treatment is to facilitate better knee movement, pain reduction, and potentially slow the progression of the osteoarthritis in the knee. However, slowing progression has not been proven.

Viscosupplementation therapy for the knee via intra-articular injection of hyaluronic acid preparations will be considered medically necessary by SECUR Health Plan when all the following conditions are met:

1. The patient is symptomatic showing signs of interference with activities of daily living (ADLs), ambulation, prolonged standing, sleep disturbance associated with the pain, crepitus, and/or knee stiffness.
2. The clinical diagnosis must be supported by radiological evidence of osteoarthritis of the knee such as joint space narrowing, subchondral sclerosis, osteophytes, and subchondral cysts.
3. If appropriate, other diagnoses have been excluded.
4. The member has failed at least three (3) months of conservative therapy defined as nonpharmacologic therapy and if not contraindicated, simple analgesics or non-steroidal anti-inflammatories (NSAIDs) per hyaluronan product prescribing information.
5. The member has failed to respond to aspiration of the knee when effusion is present and intraarticular corticosteroid injection therapy when inflammation is a significant component of the member's symptoms and intraarticular corticosteroids are not contraindicated.

A repeat series, defined as a set of injections for each joint and each treatment, of hyaluronan knee injection(s) for members who have responded to a prior series is medically necessary under the following circumstances:

1. Symptoms have recurred, and
2. There has been at least six (6) months since the prior series, and
3. The member experienced significant improvement in pain and functional ability achieved with the prior series using a standard assessment tool, and
4. Member has had a significant reduction in NSAID medications taken or a reduction in the number of intraarticular steroid injections to the knees during the six (6) month period following the injection(s).

SECUR Health Plan considers the below list (not all inclusive) to not be reasonable of medically necessary:

1. Drugs, biologicals, and other products approved for marketing by the FDA contain labeling that lists the reasonable and necessary dosage as well as frequency. Doses and frequencies that exceed these standards (contained in the package insert) are considered not medically necessary.
2. Intraarticular injections of other therapeutic agents should not be performed in the same knee during viscosupplementation unless there is a documented medical necessity requiring the use of additional agents.
3. Viscosupplementation of joints other than the knee(s) is/are considered not medically necessary.
4. Imaging procedures for the purpose of visualization of the knee to provide guidance for needle placement are considered not medically necessary. The only imaging procedures that may be considered as medically necessary are for the purpose of needle guidance for viscosupplementation are fluoroscopy or ultrasound. Should needle guidance be utilized, documentation must support that the presentation of the member's impacted knee on the day of the procedure proved problematic for needle insertion.
5. If the hyaluronan preparation is denied, all associated treatments would be considered not medically necessary.
6. Treatment must consist of the use of one agent for the entirety of the course. If a subsequent treatment modality is initiated, the agent will be considered not medically necessary.
7. Coverage of viscosupplementation therapy of the knee assumes that knee arthroplasty is not being considered as a treatment option for the member.
8. Viscosupplementation is not considered medically necessary following a total or partial knee arthroplasty.
9. Viscosupplementation is not considered medically necessary at the end of a surgical procedure or during the postoperative period following a knee surgical procedure. Initiation of the treatment should not occur until the member has made a full recovery from the surgery and only if the member is symptomatic with a diagnosis of osteoarthritis and presentation meets the stated covered indications.
10. Viscosupplementation is considered not medically necessary for the following and will not be covered:
    - The diagnosis is anything other than osteoarthritis
    - The viscosupplementation is utilized as initial treatment
    - Failure and/or contraindication to conservative therapy and/or corticosteroid injections are not documented in the medical record
    - Repeat series of injections is initiated prior to six (6) months following completion of previous treatment
    - Repeat series of injections is administered when there was no symptomatic/functional improvement evidenced from the previous series
    - Topical application of hyaluronate preparations

Providers who utilize viscosupplementation must meet the following criteria:

1. All aspects of the procedure and related continued care are within the scope of the provider's professional license, and

2. All procedures are performed by appropriately trained providers in the appropriate setting. Core curriculum of any training program should include the performance and management of procedures and a competency assessment by formal examination and case history document review.

Acceptable training and/or certification may be evidenced by any one of the following (not an all-inclusive list):

1. Accreditation Council for Graduate Medical Education (ACGME) accredited residency and/or fellowship in a relevant specialty, or
2. American Osteopathic Association (AOA) accredited residency and/or fellowship in a relevant specialty, or
3. Board certification in a relevant specialty by an American Board of Medical Specialties (ABMS) member board or equivalent AOA board, or
4. Satisfactory completion of an accredited non-physician practitioner education program that provides substantially equivalent content and scope as mentioned above and includes the minimum requirements of covering and developing an understanding of anatomy and drug pharmacodynamics and kinetics, proficiency in evaluation, diagnosis, and management of diseases necessitating this procedure, technical performance of the procedure, and performing/interpreting reasonable imaging modalities required for procedure performance as well as evaluation, diagnosis, and management of potential complications from the intervention. Trainee competency must have been directly assessed by state licensure exam or certification exam by a nationally recognized accrediting agency and maintenance of a case log of procedures performed, or
5. Demonstration of satisfactory performance of the specific services over the five (5) years immediately preceding implementation of this Coverage Determination Guideline. Medicare considers on average ten (10) services per month to meet this requirement and may be substantiated by Medicare or other payer claim history supported by patient medical records of appropriate care, procedural performance, and outcomes.

The maximum allowable frequency of injection(s) for the initial or repeated series is as follows:

Hyaluronan Preparation	**Duration of Treatment per Series**
Synvisc-One, Gel-One, Monovisc, Durolane	Single injection per knee
Hymovis	2 weekly injections per knee
Euflexxa, Gelsyn-3, Synvisc, Visco-3, TriVisc, Synojoynt, triluron	3 weekly injections per knee
Orthovisc	3-4 weekly injections per knee
Hyalgan, Supartz, Genvisc 850	3-5 weekly injections per knee

The US Food and Drug Administration (FDA) has approved compendial use of hyaluronates for specific indications provided that all criteria are met, and the member has no exclusions to prescribed therapy.

Compendial Uses:

1. Treatment of pain of arthropathy of the shoulder
2. Treatment of subacromial impingement

All other indications will be assessed on an individual basis. Any requests submitted for indications aside from what is included in this CDG, must be accompanied by supporting evidence from Medicare approved compendia.

Criteria for Initial Approval

1. Osteoarthritis of the shoulder – authorization of twelve (12) months may be granted for treatment of osteoarthritis of the shoulder when the following criteria are met:
   - Member has previously received therapy in the same joint with a hyaluronate product, and

- Member will receive first injection after at least six (6) months from the last injection of the completed course and the medication has been effective for treating the condition or a different hyaluronate product is being requested due to an adverse event with the previous course of treatment.

2. Subacromial impingement – authorization of three (3) months may be granted for the treatment of subacromial impingement when the following criteria are met:
   - Hyaluronate product is being used to treat this condition, and
   - The hyaluronate product requested has been effective for treating the diagnosis or condition.

All members, including new members, requesting authorization for continuation therapy must be currently receiving therapy with the requested agent.

Hyaluronates included in this Coverage Determination Guideline include:

- DUROLANE (hyaluronic acid)
- EUFLEXXA (1% sodium hyaluronate)
- GEL-ONE (cross-linked hyaluronate)
- GELSYN-3 (sodium hyaluronate 0.84%)
- GENVISC 850 (sodium hyaluronate)
- HYALGAN (sodium hyaluronate)
- HYMOVIS (high molecular weight viscoelastic hyaluronan)
- MONOVISC (high molecular weight hyaluronan)
- ORTHOVISC (high molecular weight hyaluronan)
- SUPARTZ FX (sodium hyaluronate)
- SYNOJOYNT (1% sodium hyaluronate)
- SYNVISC (hylan G-F 20)
- SYNVISC ONE (hylan G-F 20)
- TRILURON (sodium hyaluronate)
- TRIVISC (sodium hyaluronate)
- VISCO-3 (sodium hyaluronate)
- 1% sodium hyaluronate

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