This policy applies to the following:

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	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

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POLICY Document for HYALURONATE PRODUCTS

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
HYALURONATES

PREFERRED PRODUCTS: ORTHOVISC, SYNVISC AND SYNVISC ONE

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the hyaluronate products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are initiating a new treatment course with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Hyaluronate products

	Products
Preferred	• **Orthovisc** (high molecular weight hyaluronan) • **Synvisc** (hylan G-F 20) • **Synvisc One** (hylan G-F 20)
Targeted	• **Durolane** (hyaluronic acid) • **Euflexxa** (1% sodium hyaluronate) • **Gel-One** (cross-linked hyaluronate) • **Gelsyn-3** (sodium hyaluronate)

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	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

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	• **GenVisc 850** (sodium hyaluronate) • **Hyalgan** (sodium hyaluronate) • **Hymovis** (high molecular weight viscoelastic hyaluronan) • **Monovisc** (high molecular weight hyaluronan) • **Supartz FX** (sodium hyaluronate) • **Trivisc** (sodium hyaluronate) • **Visco-3** (sodium hyaluronate)

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the requested targeted product in the past 365 days.

B. Member has tried and experienced a documented intolerable adverse event to at least two of the preferred products: a) Orthovisc, and b) Synvisc or Synvisc One.

Section 2: Clinical Criteria

JURISDICTION SPECIFIC MEDICARE PART B

HYALURONAN ACID THERAPIES FOR OSTEOARTHRITIS OF THE KNEE

HYALGAN, SUPARTZ, VISCO-3, EUFLEXXA, MONOVISC, GELSYN-3, GENVISC 850, DUROLANE, TRIVISC, SYNOJOYNT, TRILURON (sodium hyaluronate)

SYNVISC, SYNVISC-ONE (hylan G-F 20)

GEL-ONE (hyaluronic acid)

ORTHOVISC (high molecular weight hyaluronan)

HYMOVIS (high molecular weight viscoelastic hyaluronan)

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POLICY

I. COVERED USES

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

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications are listed below:

Osteoarthritis of the knee

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. Medical record documentation must support the medical necessity of the services as stated in this policy.
B. Medical record must document that the patient has symptomatic osteoarthritis of the knee, the nature of the symptoms and the functional limitations using a standardized assessment tool.
C. Radiographic confirmation of osteoarthritis of the knee in the form of an x-ray report and/or notation in the record must accompany the clinical description
D. The medical record must include documentation that supports that conservative therapy was attempted prior to viscosupplementation therapy. If conservative therapy and/or corticosteroid therapy were contraindicated or failed, the reason(s) must be supported in the documentation for review.
E. The medical record must indicate whether one or both knees are being treated and in the former instance, which knee is being treated.

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F. If fluoroscopy or ultrasound is used for needle guidance with the intra-articular injection, documentation must support that the presentation of the patient's affected knee on the day of the procedure makes needle insertion problematic.
G. If intra-articular injections of other therapeutic agents, such as corticosteroids, are performed in the same knee during the course of viscosupplementation therapy, the reason(s) for requiring the use of the additional therapeutic agent must be documented.
H. The frequency of the injections and dosage given must be clearly indicated.
I. The response to treatment must be noted. Medical records should describe the assessment tool utilized. Repeat courses of viscosupplementation in the absence of documentation of response to the previous course of treatment will be considered not reasonable and necessary and not subject to coverage.
J. Documentation of training and licensures of the provider as described in section III.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by a provider who meets all of the following:

A. All aspects of the procedure and its related care are within the scope of the practice of the provider's professional licensure.
B. All procedures are performed by appropriately trained providers in the appropriate setting. Patient safety and quality of care mandate that healthcare professionals who perform intra-articular injections for treatment of osteoarthritis of the knee are appropriately trained and are competent to perform all aspects of these procedures safely and effectively. The core curriculum of any training program should include the performance and management of the procedures addressed in this policy with documentation of trainee competency assessment included by formal examination and case history document review.
C. Acceptable training or certification may be evidenced by any one of the following means:
    1. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) accredited residency and/or fellowship program in a relevant specialty
    2. Board certification in a relevant specialty by an American Board of Medical Specialties (ABMS) member board or equivalent AOA board
    3. Satisfactory completion of an accredited non-physician practitioner educational program that provides substantially equal content and scope as those mentioned in 1 and 2 above and includes the minimum requirements stated in D below with trainee competency directly assessed by state licensure examination or certification examination by a nationally recognized accrediting agency and maintenance of case log of procedures performed. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics, proficiency in evaluation, diagnosis and management of diseases necessitating the procedures, technical performance of the procedure, and performing and interpreting medically reasonable imaging modalities required for procedure performance (imaging technique, contrast material use, and image interpretation) as well as the evaluation, diagnosis, and management of potential complications from the intervention.
    4. Demonstration of satisfactory performance of the specific services in this policy on a regular basis over the 5 years immediately preceding implementation of this policy. Medicare considers an average of 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.

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IV. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of osteoarthritis of the knee when all of the following criteria are met:

A. The member is symptomatic. Such symptoms may include any of the following:
   1. Pain which interferes with the activities of daily living such as ambulation and prolonged standing
   2. Pain interrupting sleep
   3. Crepitus
   4. Knee stiffness

B. The clinical diagnosis is supported by radiologic evidence of osteoarthritis of knee such as joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts.

C. If appropriate, other diagnoses have been excluded by appropriate evaluation and management services, laboratory and imaging studies (i.e., the pain and functional disability is not considered likely to be due to a diagnosis other than osteoarthritis of the knee).

D. The member has failed at least 3 months of conservative therapy. Conservative therapy is defined as both of the following:
   1. Non pharmacologic therapy (such as but not limited to home exercise program, education, weight loss, physical therapy if indicated)
   2. If not contraindicated, simple analgesics (e.g., acetaminophen) and/or nonsteroidal anti-inflammatory drugs (NSAIDs) per hyaluronan product prescribing information.

E. The member has failed to respond to aspiration of the knee when effusion is present.

F. The member has failed to respond to intra-articular corticosteroid injection therapy when inflammation is a significant component of the member's symptoms and intra-articular corticosteroids are not contraindicated.

G. Only fluoroscopy and ultrasound will be utilized for needle guidance. All other imaging procedures are considered not medically reasonable and will not be covered.

H. The member will not receive intra-articular injections of other therapeutic agents, such as corticosteroids, should not be performed in the same knee during the course of viscosupplementation therapy unless there is a documented medical necessity (e.g., for documented reactions requiring the use of the additional therapeutic agent).

I. Knee arthroplasty is not being considered as a current treatment option.

J. The requested product will not be administered following a total or partial knee arthroplasty.

K. If the requested product will be administered following a knee surgical procedure, the member meets both of the following:
   1. The requested drug will not be used at the end of a knee surgical procedure or during the postoperative period following a knee surgical procedure (e.g., anterior cruciate ligament [ACL] reconstruction or arthroscopic meniscectomy).
   2. Use of viscosupplementation would not be initiated until after the patient has made a full recovery from the knee surgery and the member is symptomatic with a diagnosis of osteoarthritis and the clinical presentation meets the above requirements.

V. CRITERIA FOR CONTINUATION OF THERAPY

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Authorization for 6 months may be granted for a repeat series for the treatment of osteoarthritis of the knee when all of the following criteria are met:

A. The member's symptoms have recurred.
B. At least 6 months have elapsed since the prior series of injections
C. One of the following applies to the member:
    1. There was significant improvement in pain and functional capacity achieved with the prior series of injections using a standardized assessment tool
    2. There is significant reduction in the doses of NSAID medications taken or reduction in the number of intra-articular steroid injections to the knees during the 6 month period following the injection(s).
D. Only fluoroscopy and ultrasound will be utilized for needle guidance. All other imaging procedures are considered not medically reasonable and will not be covered.
E. The member will not receive intra-articular injections of other therapeutic agents, such as corticosteroids, should not be performed in the same knee during the course of viscosupplementation therapy unless there is a documented medical necessity (e.g., for documented reactions requiring the use of the additional therapeutic agent).
F. Knee arthroplasty is not being considered as a current treatment option.
G. The requested product will not be administered following a total or partial knee arthroplasty.
H. If the requested product will be administered following a knee surgical procedure, the member meets both of the following:
    1. The requested drug will not be used at the end of a knee surgical procedure or during the postoperative period following a knee surgical procedure (e.g., anterior cruciate ligament [ACL] reconstruction or arthroscopic meniscectomy).
    2. Use of viscosupplementation would not be initiated until after the patient has made a full recovery from the knee surgery and the member is symptomatic with a diagnosis of osteoarthritis and the clinical presentation meets the above requirements.

VI. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling. Drugs and biologicals and other products approved for marketing by the FDA are considered safe and effective when used for the indications specified on the labeling. The labeling lists the safe and effective, i.e., medically reasonable and necessary dosage and frequency. Therefore, doses and frequencies that exceed the accepted standard of recommended dosage and/or frequency, as described in the package insert, are considered not reasonable and necessary and therefore, not subject to coverage.

Hyaluron 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

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	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

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SECTION 2

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