Medical Policy:

Hyaluronate Injections for Osteoarthritis of the Knee –MEDICAL (NOT MEDICAID)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.28	June 17, 2024	

Definitions

Hyaluronan (HA), also known as hyaluronate or hyaluronic acid, is a naturally occurring macromolecule that is a major component of synovial fluid and is thought to contribute to its viscoelastic properties. Chemical cross-linking of hyaluronan increases its molecular weight; cross-linked HA are referred to as hylans.

In osteoarthritis (OA), the overall length of HA chains present in cartilage and the HA concentration in the synovial fluid are decreased. Intra-articular injection of HA has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in patients with osteoarthritis. This treatment has been referred to as visco supplementation.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Product	Dose	Quantity Limitations
Euflexxa	20mg once weekly x 3 doses	Maximum 6 injections per 180 days
Gel-One	30mg x 1 dose	Maximum 2 injection per 180 days
Gelsyn-3	16.8 mg once weekly x 3 doses	Maximum 6 injections per 180 days
Hyalgan	20mg once weekly x 5 doses	Maximum 10 injections per 180 days
Hymovis	24mg once weekly x 2 doses	Maximum 4 injections per 180 days
Monovisc	88mg x 1 dose	Maximum 2 injections per 180 days
Orthovisc	30mg once weekly x 3 or 4 doses	Maximum 8 injections per 180 days
Sodium Hyaluronate 1%	20 mg once weekly x 3 doses	Maximum 6 injections per 180 days
Supartz FX	25mg once weekly x 5 doses	Maximum 10 injections per 180 days
Synvisc	16mg once weekly x 3 doses	Maximum 6 injections per 180 days
Synvisc-One	48mg x 1 dose	Maximum 2 injection per 180 days
Trivisc	25mg once weekly x 3 doses	Maximum 3 injections per 180 days
Durolane	60mg (3mL) x 1 dose	Maximum 2 injections per 180 days
Triluron	20 mg once weekly x 3 doses	Maximum 3 injections per 180 days
Synojoynt	1% once weekly x 3 doses	Maximum 3 injections per 180 days
GenVisc 850	25mg once weekly x 5 doses	Maximum 10 injections per 180 days
Visco-3	25mg once weekly x 3 doses	Maximum 6 injections per 180 days

Guideline

****For Medicare members –Hyaluronate Injections please refer to our separate LCD/NCD Medicare criteria**

Hyaluronate injections are considered medically necessary for OA of the knee(s)† when all-of the following criteria are met:

Gel-One and Synvisc/Synvisc-One are the preferred agents for **MEDICAL**

Documented symptomatic OA of the knee. †

1. Trial and failure of conservative therapy (including physical therapy, pharmacotherapy [e.g., non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen (up to 1 g 4 times/day) and/or topical capsaicin cream]) has been attempted and has not resulted in functional improvement after at least 3 months or the member is unable to tolerate conservative therapy because of adverse side effects.
2. Member has failed to adequately respond to injection of intra-articular steroids.
3. Member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing).
4. No contraindications to the injections (e.g., active joint infection, bleeding disorder).
5. Failed trial of Gel-One **AND** Synvisc/Synvisc-One prior to using Sodium Hyaluronate, Orthovisc, Euflexxa, Supartz Fx, Hyalgan, GenVisc 850, Hymovis, Monovisc, Synojoynt, Triluron, TriVisc, Visco-3, Gelsyn-3, and Durolane**††.**

† FDA Approved Indication(s); **not a covered benefit for Medicaid members**

†† MEDICAL members are subject to step therapy

Renewal Criteria

Coverage may be renewed when **all-**of the following criteria are met:

1. Medical record demonstrates reduction in dose of NSAIDS (or other analgesics or anti- inflammatory medication) during the 12-month period following the previous series of injections

2. The medical record objectively documents significant improvement in pain and functional capacity as the result of the previous injections
3. Absence of unacceptable toxicity from the previous injections
4. Failed trial of Gel-One **AND** Synvisc/Synvisc-One prior to using Sodium Hyaluronate, Orthovisc, Euflexxa, Supartz Fx, Hyalgan, GenVisc 850, Hymovis, Monovisc, Synojoynt, Triluron, TriVisc, Visco-3, Gelsyn-3, and Durolane**††.**

†† MEDICAL members are subject to step therapy

Criteria Exclusions

1. Treatment for diagnoses not FDA approved
2. Hyaluronate injections are not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value

Black Box Warnings

N/A

Contraindications

1. Do not use in patients with known hypersensitivity to hyaluronate derivatives.
2. Do not use in the presence of joint infections or skin diseases or infections in the area of the injection site.

Applicable Procedure Codes

Code	Description
20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose
J7320	Hyaluronan or derivative, Genvisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan or Supartz, or Visco-3, for intra-articular injection, per dose (Revision eff. 01/01/2018)
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-3 for intra-articular injection, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7332	Effective 10/1/19, Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
J7331	Effective 10/1/19, Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1 mg

Applicable NDCs

Code	Description
89130-2020-01	Durolane 60mg/3ml Prefilled Syringe
50653-0006-01	Genvisc 850 10mg/mL Solution
50016-0957-21	Visco-3 10mg/mL Solution Prefilled Syringe

89130-4444-01	Supartz Fx 10mg/mL Solution
89122-0724-12	Hyalgan 10mg/mL Solution
89122-0724-20	Hyalgan 10mg/mL Solution
89122-0496-63	Hymovis 24mg/3mL Solution Prefilled Syringe
55566-4100-01	Euflexxa 20mg/2mL Solution
55566-4100-00	Euflexxa 20mg/2mL Solution
59676-0360-01	Orthovisc 30mg/2mL Solution
58468-0090-01	Synvisc 16mg/2mL Solution
58468-0090-03	Synvisc One 48mg/6mL Solution
50016-0957-11	Gel-One 30mg/3mL Prefilled Syringe
59676-0820-01	Monovisc 88mg/4mL Solution
89130-3111-01	Gelsyn-3 8.4mg/mL Solution
50653-0006-04	Trivisc 10mg/mL Solution Prefilled Syringe
89122-0879-01	Triluron 20mg/2mL Solution
82197-0721-16	Synojoynt 10mg/mL Syringe

ICD-10 Diagnoses

Code	Description
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	6/17/2024	Annual Review: Added Statement: "**For Medicare members – Hyaluronate Injections please refer to our separate LCD/NCD Medicare criteria"
EmblemHealth & ConnectiCare	11/10/2023	Removed Medicare Pharmacy coverage and language from policy effective 1/1/2024
EmblemHealth & ConnectiCare	2/21/2023	Removed Commercial Pharmacy criteria from policy (Please refer to pharmacy policy for commercial criteria)
EmblemHealth & ConnectiCare	12/21/2022	Updated criteria to remove aspiration: "Member has failed to adequately respond to aspiration"

EmblemHealth & ConnectiCare	7/6/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/1/2021	Added Visco-3 as a preferred agent for commercial members.
EmblemHealth & ConnectiCare	6/2/2021	Added GenVisc 850 to the policy.
EmblemHealth & ConnectiCare	12/19/2021	Clarified Gelsyn-3 dosage and quantity limits; added sodium hyaluronate
EmblemHealth & ConnectiCare	11/2/2020	Effective 01/01/2021, Member must fail trial of Gel-One AND Synvisc/Synvisc-One prior to using Orthovisc, Euflexxa, Supartz Fx, Hyalgan, Hymovis, Monovisc, Synojoynt, Triluron, TriVisc, Visco-3, Gelsyn-3 and Durolane. (Medicare members are subject to this step therapy).
EmblemHealth & ConnectiCare	06/11/2020	Added J-Code (J7333): Effective 07/01/2020, Hyaluronan or derivative, (Visco-3), for intra-articular injection.
EmblemHealth & ConnectiCare	11/20/2019	Gel-One and Synvisc/Synvisc-One are the preferred agents for Medicare members. (Step protocol not mandated for Medicare members)
EmblemHealth & ConnectiCare	12/03/2018	Added J7318 and removed C9465 from Applicable Procedure Codes
EmblemHealth & ConnectiCare	12/03/2018	Added J7329 to Applicable Procedure Codes, added TriVisc to Guideline section 6, Renewal section 4, Dosage/Administration, Quantity Limits, and TriVisc package insert to references.
EmblemHealth & ConnectiCare	12/03/2018	Added Failed trial of Gel-One AND Synvisc/Synvisc-One prior to other treatments to Guideline section.
EmblemHealth & ConnectiCare	12/12/2018	Added Hymovis to guideline text commensurate with coding previously included
EmblemHealth & ConnectiCare	08/14/2019	Added Triluron (J7332) and Synojoynt (J7331), codes effective 10/1/19.

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