

Medical Policy: HYALURONATE INJECTIONS FOR OSTEOARTHRITIS OF THE KNEE –MEDICAL (NOT MEDICAID)

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|-------------------|-------------|
| MG.MM.PH.28 | November 10, 2023 | |

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EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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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 |
| Synjoynt | 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

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, Synjoynt, 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, Synjoynt, 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, Synjoynt, for intra-articular injection, 1 mg |

Applicable NDCs

| Code | Description |
|---------------|-------------------------------------|
| 89130-2020-01 | Durolane 60mg/3ml Prefilled Syringe |

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|---------------|---|
| 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 | Synjoynt 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 | 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" |

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|-----------------------------|------------|---|
| 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. |

References

1. American Academy of Orthopedic Surgeons. Clinical practice guideline. Treatment of osteoarthritis of the knee. May 2013. Available at: <http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf>. Accessed September 18, 2017.
2. California Technology Assessment ForumTM. Hyaluronic acid for treatment of osteoarthritis of the knee: repeated injections and progression to knee replacement. February 2012. [http://www.ctaf.org/sites/default/files/assessments/1424 file HYAL ACID F2012.pdf](http://www.ctaf.org/sites/default/files/assessments/1424_file_HYAL_ACID_F2012.pdf). Accessed September 18, 2017.
3. Centers for Disease Control and Prevention. Arthritis. October 2015. <http://www.cdc.gov/arthritis/basics/osteoarthritis.htm>. Accessed September 18, 2017.

4. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res (Hoboken)*. 2012; 64(4):465-474.
http://www.rheumatology.org/practice/clinical/guidelines/ACR_2012_OA_Guidelines.pdf#toolbar=1&pagemode=bookmarks. Accessed September 18, 2017.
5. Jüni P, Hari R, Rutjes AWS, et al. Joint corticosteroid injection for knee osteoarthritis. *Cochrane Database Syst Rev*. 2015; (10):CD005328.
6. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Osteoarthritis. April 2015.
http://www.niams.nih.gov/Health_Info/Osteoarthritis/default.asp#7. Accessed September 18, 2017.
7. U.S. Food and Drug Administration Premarket Notification Database. Euflexxa[®]. P010029. Rockville, MD: FDA. October 11, 2011. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p010029s008a.pdf. Accessed September 18, 2017.
8. U.S. Food and Drug Administration Premarket Notification Database. Gel-One[®]. P080020. Rockville, MD: FDA. March 22, 2011. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf8/p080020a.pdf. Accessed September 14, 2016.
9. U.S. Food and Drug Administration Premarket Notification Database. Gel-Syn[™]. P110005. Rockville, MD: FDA. May 9, 2014. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110005a.pdf. Accessed September 18, 2017.
10. U.S. Food and Drug Administration Premarket Notification Database. Orthovisc[®]. P030019. Rockville, MD: FDA. February 4, 2004. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/p030019a.pdf. Accessed September 18, 2017.
11. U.S. Food and Drug Administration Premarket Notification Database. Supartz[™]. P980044. Rockville, MD: FDA. January 24, 2001. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/P980044a.pdf. Accessed September 18, 2017.
12. U.S. Food and Drug Administration Premarket Notification Database. Synvisc-One[®]. No. P940015. Rockville, MD: FDA. February 26, 2009. http://www.accessdata.fda.gov/cdrh_docs/pdf/P940015S012a.pdf. Accessed September 18, 2017.
13. U.S. Food and Drug Administration Premarket Notification Database. Himovis[®]. P150010. Rockville, MD: FDA. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p150010>. Accessed December 6, 2017.
14. Durolane (sodium hyaluronate) [prescribing information]. Durham, NC: Bioventus; October 2017.
15. Trivisc [package insert]. Doylestown, PA; OrthogenRx, Inc; November 2017. Accessed December 2018.