

Specialty Guideline Management

Hyaluronates

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
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
Synjoynt	1% sodium hyaluronate
Synvisc	hylan G-F 20
Synvisc One	hylan G-F 20
Triluron	sodium hyaluronate
Trivisc	sodium hyaluronate
Visco-3	sodium hyaluronate

Indications

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

FDA-approved Indications¹⁻¹⁷

Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Osteoarthritis (OA) of the Knee¹⁻²⁴

Authorization of 12 months may be granted for treatment of osteoarthritis (OA) in the knee when all of the following criteria are met:

- The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts) or the member has at least 5 of the following signs and symptoms:
 - Bony enlargement
 - Bony tenderness
 - Crepitus (noisy, grating sound) on active motion
 - Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
 - Less than 30 minutes of morning stiffness
 - No palpable warmth of synovium
 - Over 50 years of age
 - Rheumatoid factor less than 1:40 titer (agglutination method)
 - Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm³)
- The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
- The member has experienced an inadequate response or adverse effects with non-pharmacologic treatment options (e.g., physical therapy, regular exercise, insoles, knee bracing, weight reduction).
- The member has experienced an inadequate response or intolerance or has a contraindication to a trial of an analgesic (e.g., acetaminophen up to 3 to 4 grams per day, non-steroidal anti-inflammatory drugs [NSAIDs], topical capsaicin cream) for at least 3 months.

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- The member has experienced an inadequate response or intolerance or has a contraindication to a trial of intraarticular steroid injections for at least 3 months.
- The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of osteoarthritis in the knee when all of the following criteria are met:

- Member meets all requirements in the coverage criteria.
- Member has experienced improvement in pain and functional capacity following the previous injections.
- At least 6 months has elapsed since the last injection in the prior completed series of injections.

References

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5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
6. Hyalgan [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
7. Hymovis [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; June 2021.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
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10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synjoynnt [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
12. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
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14. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
15. Trivisc [package insert]. Doylestown, PA: OrthogenRx, Inc.; September 2018.
16. Visco-3 [package insert]. Warsaw, IN: Zimmer; May 2017.
17. Jordan KM, Arden NK, Doherty M, et al. EULAR recommendations 2003: an evidence based approach to the management of knee osteoarthritis: report of a task force of the standing committee for international clinical studies including therapeutic trials (ESCISIT). *Ann Rheum Dis.* 2003;62:1145-1155.
18. 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.* 2012;64(4):465-474.
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21. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014;22(3):363-88.
22. Kolasinski SL, Tuhina N, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guidelines for the management of osteoarthritis of the hand, hip, and knee. *Arthritis Rheumatol*. 2020 Jan 6. doi: 10.1002/art.41142. [Epub ahead of print]
23. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage*. 2019;27(11):1578-1589.
24. Scali JJ. Intra-articular hyaluronic acid in the treatment of osteoarthritis of the knee: a long term study. *Eur J Rheumatol Inflamm*. 1995;15(1):57-62.