

Reference number
1765-A

## SPECIALTY GUIDELINE MANAGEMENT

**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**

### POLICY

#### I. 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 Indication

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.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Osteoarthritis (OA) of the Knee**

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

- A. 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:
  1. Bony enlargement

Reference number
1765-A

2. Bony tenderness
  3. Crepitus (noisy, grating sound) on active motion
  4. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
  5. Less than 30 minutes of morning stiffness
  6. No palpable warmth of synovium
  7. Over 50 years of age
  8. Rheumatoid factor less than 1:40 titer (agglutination method)
  9. Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm<sup>3</sup>)
- B. The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
- C. 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).
- D. 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.
- E. 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.
- F. The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

### III. 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:

- A. Member meets all criteria for initial approval.
- B. Member has experienced improvement in pain and functional capacity following the previous injections.
- C. At least 6 months has elapsed since the last injection in the prior completed series of injections.

### IV. REFERENCES

1. Durolane [package insert]. Durham, NC: Bioventus LLC; September 2017.
2. Euflexxa [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
3. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
4. Gelsyn-3 [package insert]. Durham, NC: Bioventus LLC; December 2017.
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.
9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synjoynt [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
12. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
13. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
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. 1% Sodium Hyaluronate [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
18. 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.

Reference number
1765-A

19. 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.
20. Neustadt DH. Intra-articular injections for osteoarthritis of the knee. *Cleve Clin J Med.* 2006;73(10):897-911.
21. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage.* 2008;16(2):137-162.
22. 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.
23. 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]
24. 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.
25. 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.