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 (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

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^3)

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 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.

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; February 2016.
5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; September 2015.
6. Hyalgan [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; May 2014.
7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; October 2015.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; December 2013.
9. Orthovisc [package insert]. Raynham, MA: DePuy Mitek, Inc.; June 2005.
10. Supartz [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synojoynt [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
12. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
13. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
14. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.: March 2019.
15. Trivisc [package insert]. Doylestown, PA: OrthogenRX; September 2018.
16. Visco-3 [package insert]. Durham, NC: Bioventus LLC; December 2015.
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.

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.