

## PHARMACY POLICY STATEMENT

### Kentucky Medicaid

DRUG NAME	Hyalgan (sodium hyaluronate)
BILLING CODE	J7321
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Gel-One, SupartzFX QUANTITY LIMIT – 5 injections (5 units)
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Hyalgan (sodium hyaluronate) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### OSTEOARTHRITIS OF THE KNEE

For **initial** authorization:

1. Member must be 40 years old or older; AND
2. Member must have a diagnosis of osteoarthritis confirmed by radiological evidence (e.g. Kellgren-Lawrence Scale score of grade 2 or greater); AND
3. Medication must be prescribed by an orthopedic surgeon, interventional pain physicians, rheumatologists, physiatrists (PM&R) and all sports medicine subspecialties; AND
4. Member tried and failed an intra-articular corticosteroid injection(s) in which efficacy was < 4 weeks duration; AND
5. Documentation that member tried and failed ALL of the following:
  - a) Weight loss attempts or attempts at lifestyle modifications to promote weight loss (only for members with BMI  $\geq$ 30); AND
  - b) Sufficient trial (e.g. 2 to 3 months) of non-pharmacologic therapies (bracing/orthotics, physical/occupational therapy); AND
  - c) At least 3 simple analgesic therapies (acetaminophen, NSAIDs, oral or topical salicylates); AND
6. Member is not using medication for hip or shoulder related conditions; AND
7. Member is not allergic to avian proteins, feathers, and egg products; AND
8. Member has tried and failed to respond to treatment with Supartz FX or Gel-One (documented in chart notes and confirmed by claims history).
9. **Dosage allowed:** Inject 20 mg (2 mL) once weekly for up to 5 weeks (total of 5 injections).

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Member must have documented significant pain relief that was achieved with the initial course of treatment; AND
2. Initial course of treatment has been completed for 6 months or longer; AND
3. Member meets all of the criteria for the initial approval.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.***

**CareSource considers Hyalgan (sodium hyaluronate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Refractory interstitial cystitis
- Arthropathy - Disorder of shoulder
- Intravitreal tamponade
- Keratoconjunctivitis sicca
- Subacromial impingement, Syndrome of the shoulder

DATE	ACTION/DESCRIPTION
05/23/2017	New policy for Hyalgan created. Minimum age and BMI requirements changed. Limits of additional courses of treatment changed. Trial of Supartz FX or Gel-One added.

References:

1. Hyalgan [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; May, 2014.
2. American Academy of Orthopaedic Surgeons. Treatment of Osteoarthritis of the Knee. Evidence-based guideline 2nd Edition. May 2013. Available at: <http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf> (December 31, 2015).
3. American College of Rheumatology, Subcommittee on Osteoarthritis Guidelines. Recommendations for the medical management of osteoarthritis of the hip and knee: 2012 update. Arthritis Care & Research 2012; 64(4):465-474. Agency for Healthcare Research and Quality (AHRQ). Three Treatments for Osteoarthritis of the Knee: Evidence Shows Lack of Benefit. Clinician's Guide. March, 2011.
4. Goldberg VM, Buckwater MD. Hyaluronans in the treatment of osteoarthritis of the knee: evidence for disease modifying activity. Osteoarthritis and Cartilage March 2005;13(3):216-224.
5. Majeed M. Relationship between serum hyaluronin acid level and disease activity in early rheumatoid arthritis. Ann Rheum Dis September 2004; 63(9): 1166-8.
6. Tascioglu F, Oner C. Efficacy of intra-articular sodium hyaluronate in the treatment of knee osteoarthritis. Clin Rheumatol. 2003;22:112-117.
7. Lo, G H, et al. JAMA. 2003;290:3115-3121. Intra-articular Hyaluronic Acid in Treatment of Knee Osteoarthritis: A Meta- analysis. Retrieved 3/17/2011 from <http://jama.ama-assn.org/cgi/reprint/290/23/3115>.
8. Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. Cochrane Database Syst Rev. 2006;(2):CD005321.
9. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22.
10. Hymovis [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; August 2015. Accessed March 2016.
11. Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and meta-analysis. Ann Rheum Dis. 2007; 66(4):433-9.
12. Carraba, M et al. 1991 Hyaluronic acid sodium salt (Hyalgan) in the treatment of patients with osteoarthritis of the knee: a controlled trial versus Orgotein, Final report. April 1991. Data on file.



13. Kotz R, Kolarz G. Intra-articular hyaluronic acid: duration of effect and results of repeated treatment cycles. *Am J Ortho* 1997(28):5-7.
14. Hyalgan. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed May 17, 2017.
15. Hyalgan. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed May 17, 2017.

Effective date: 05/23/2017

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