

## PHARMACY POLICY STATEMENT

### Kentucky Medicaid

DRUG NAME	Gel-One (sodium hyaluronate)
BILLING CODE	J7326
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) Alternative preferred products include Supartz FX, Gelsyn-3 QUANTITY LIMIT— 1 injection (1 unit)
LIST OF DIAGNOSES CONSIDERED <b>NOT MEDICALLY NECESSARY</b>	<a href="#">Click Here</a>

Gel-One (sodium hyaluronate) is a **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.
7. **Dosage allowed:** Inject 30 mg (3 mL) once.

***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 Gel-One (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
05/17/2017	New policy for Gel-One created. Minimum age and BMI requirements changed. Limits of additional courses of treatment changed.

References:

1. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May, 2011.
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. Chevalier X, Jerosch J, Goupille P, et al. Single, intra-articular treatment with 6 ml hylan G-F 20 in patients with symptomatic primary osteoarthritis of the knee: a randomized, multicenter, double-blind, placebo controlled trial. *Ann Rheum Dis*. 2010 Jan;69(1):113-9.
5. 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.
6. Majeed M. Relationship between serum hyaluronic acid level and disease activity in early rheumatoid arthritis. *Ann Rheum Dis* September 2004; 63(9): 1166-8.
7. Tascioglu F, Oner C. Efficacy of intra-articular sodium hyaluronate in the treatment of knee osteoarthritis. *Clin Rheumatol*. 2003;22:112-117.
8. 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>.
9. 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.
10. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. *Clin Orthop Relat Res*. 2007; 455:113-22.
11. Petrella RJ, Wakeford C. Pain relief and improved physical function in knee osteoarthritis patients receiving ongoing hylan G-F 20, a high-molecular-weight hyaluronan, versus other treatment options: data from a large real-world longitudinal cohort in Canada. *Drug Des Devel Ther*. 2015;9:5633-40.
12. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; August 2015. Accessed March 2016.
13. 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.
14. Gel-One. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed May 17, 2017.
15. Gel-One. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed May 17, 2017.

**Humana**®

Effective date: 05/17/2017  
Revised date: 05/17/2017

  
**CareSource**™