



PHARMACY POLICY STATEMENT  Kentucky Medicaid	
DRUG NAME	Synvisc-One (sodium hyaluronate)
BILLING CODE	J7325
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Durolane, Supartz FX, Gelsyn-3 QUANTITY LIMIT— 1 injection (48 unit)
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	Click Here

Synvisc-One (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 ≥ 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 Durolane or Gelsyn-3 (documented in chart notes and confirmed by claims history).
- 9. Dosage allowed: Inject 48 mg (6 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 Synvisc-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	
05/23/2017	New policy for Synvisc-One created. Minimum age and BMI requirements changed. Limits	
	of additional courses of treatment changed. Trial of Supartz FX or Gel-One added.	
08/04/2017	Trial of Gelsyn-3 added as additional option to the other preferred products.	
05/15/2018	Trial of another preferred product Durolane was added. Non-preferred product Gel-One was	
	removed from trial requirements.	

## References:

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- 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 hyaluronic 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. Clini 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.
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- 12. McGrath AF, McGrath AM, Jessop ZM, et al. A comparison of intra-articular hyaluronic acid competitors in the treatment of mild to moderate knee osteoarthritis. J Arthritis. 2013; 2(1):108. doi:10.4172/2167-7921.1000108.
- 13. Leighton R, Åkermark C, Therrien R, et. al. NASHA hyaluronic acid vs methylprednisolone for knee osteoarthritis: a prospective, multi-centre, randomized, non-inferiority trial. Osteoarthritis Cartilage. 2014; 22(1):17-25.

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