

PHARMACY POLICY STATEMENT Arkansas PASSE	
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	Click Here
NOT MEDICALLY NECESSARY	

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 ≥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 <u>reauthorization</u>:

- 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:

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- 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.
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- 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.
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- 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.
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