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PHARMACY POLICY STATEMENT Kentucky Medicaid	
DRUG NAME	Hyalgan (sodium hyaluronate)
BILLING CODE	J7321
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— 5 injections (5 units)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

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 ≥ 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 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.

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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.	
08/04/2017	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:

- 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).

- 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 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.
- 9. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22.

Humana



- 10. 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.
- 11. 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.
- 12. Kotz R, Kolarz G. Intra-articular hyaluronic acid: duration of effect and results of repeated treatment cycles. Am J Ortho 1997(28):5-7.
- 13. Hyalgan. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 17, 2017.
- 14. Hyalgan. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 17, 2017.
- 15. 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.
- 16. 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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