

PHARMACY POLICY STATEMENT

Kentucky Medicaid

DRUG NAME	Durolane (sodium hyaluronate)
BILLING CODE	J3490/C9465
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) Alternative preferred products include Gelsyn-3, Supartz FX QUANTITY LIMIT— 1 injection (60 mg) = 1 unit
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Durolane (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 60 mg every 6 months.

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 Durolane (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
05/15/2018	New policy for Durolane created.

References:

1. Durolane [package insert]. Durham, NC: Bioventus LLC; 2017.
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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 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. *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. 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.
11. 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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