

PHARMACY POLICY STATEMENT Ohio Medicaid	
DRUG NAME	Monovisc (sodium hyaluronate)
BILLING CODE	J7327
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 (1 unit)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Monovisc (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 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).
- 8. Dosage allowed: Inject 88 mg (4 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 Monovisc (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 Monovisc 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.
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- 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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