

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for hyaluronates under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen)

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Gel-One Visco-3

Note: products other than Gel-One and Visco-3 will not be covered.

Policy/Guideline:

Criteria for Initial Approval: Osteoarthritis (OA) of the Knee

Authorization of 12 months may be granted for treatment of osteoarthritis (OA) in the knee when all of the following criteria are met:

- A. The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts) or the member has at least 5 of the following signs and symptoms:
 - 1. Bony enlargement
 - 2. Bony tenderness
 - 3. Crepitus (noisy, grating sound) on active motion
 - 4. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
 - 5. Less than 30 minutes of morning stiffness
 - 6. No palpable warmth of synovium



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Coverage Policy/Guideline

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Effective D	Date: 8/17/2023		Last Review Date:	6/8/2023
Applies to:	⊠Illinois	□Florida	□Florida Kids	
	⊠New Jersey	⊠Maryland	⊠Michigan	
	🛛 Pennsylvania Kids	⊠Virginia	⊠Kentucky PRMD	

- 7. Over 50 years of age
- 8. Rheumatoid factor less than 1:40 titer (agglutination method)
- 9. Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm³)
- B. The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
- C. The member has experienced an inadequate response or adverse effects with nonpharmacologic treatment options (e.g., physical therapy, regular exercise, insoles, knee bracing, weight reduction).
- D. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of an analgesic (e.g., acetaminophen up to 3 to 4 grams per day, non-steroidal anti-inflammatory drugs [NSAIDs], topical capsaicin cream) for at least 3 months.
- E. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of intraarticular steroid injections for at least 3 months.
- F. The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

Continuation of Therapy:

Authorization of 12 months may be granted for continued treatment of osteoarthritis in the knee when all of the following criteria are met:

- A. Member meets all criteria for initial approval.
- B. Member has experienced improvement in pain and functional capacity following the previous injections.
- C. At least 6 months has elapsed since the last injection in the prior completed series of injections.

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

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- 4. Gelsyn-3 [package insert]. Durham, NC: Bioventus LLC; December 2017.
- 5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
- 6. Hyalgan [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; May 2014.
- 7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; September 2017.
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- 9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
- 10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
- 11. Synojoynt [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.



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Name:HyaluronatesPage:3 of 3Effective Date:8/17/2023Last Review Date:6/8/2023Applies to:IllinoisIFloridaFlorida KidsNew Jersey to:MarylandMichiganPennsylvania KidsVirginiaKentucky PRMD								
AppliesIllinoisIllinoisFloridaAppliesNew JerseyMarylandMichigan	Name:	Hyaluronates		Page:	3 of 3			
Applies to: New Jersey Maryland Michigan	Effective D	Date: 8/17/2023		Last Review Date:	6/8/2023			
to New Jersey Maryland Michigan		⊠Illinois	□Florida	□Florida Kids				
© Pennsylvania Kids ⊠Virginia ⊠Kentucky PRMD		⊠New Jersey	⊠Maryland	⊠Michigan				
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