Clinical Policy: Hyaluronate Derivatives

Reference Number: PA.CP. PHAR.05
Effective Date: 01/18
Last Review Date: 08/17
Line of Business: Medicaid

Coding Implications
Revision Log

Description
The following are hyaluronate derivatives requiring prior authorization: sodium hyaluronate (Euflexxa®, Gelsyn-3™, GenVisc®850, Hyalgan®, Supartz FX™), hyaluronic acid (Durolane®), cross-linked hyaluronate (Gel-One®), hyaluronan (Hymovis®, Orthovisc®, Monovisc®), and hylan polymers A and B (Synvisc®, Synvisc One®).

FDA approved indication
Hyaluronate derivatives are indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (e.g., acetaminophen) or non-steroidal anti-inflammatory drugs (NSAIDs).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that hyaluronate derivatives are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoarthritis of the Knee (must meet all)**:**

1. Diagnosis of osteoarthritis of the knee supported by radiologic imaging;
2. Prescribed by or in consultation with a rheumatologist or an orthopedist;
3. Inadequate response to physical therapy or a physician directed exercise program;
4. Failure of ≥ -4 week trial of one of the following (a or b), as evidenced by claims history, unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Oral NSAID at continuous therapeutic (prescription strength) dosing;
   b. Topical NSAID* if member is ≥ 75 years old or unable to take oral NSAID;
   **Topical NSAID may require prior authorization*
5. Trial of intraarticular glucocorticoid injections with a positive but inadequate response unless contraindicated or history of intolerance;
6. Member does not have any of the following (a or b):
   a. Coexistent active inflammatory arthritis other than OA (e.g., rheumatoid arthritis, spondylitis, gouty arthritis) in the targeted knee;
   b. History of total knee arthroplasty in the targeted knee.

Approval duration: 6 months (one treatment cycle) (*refer to section V*)

B. Other diagnoses/indications

1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Osteoarthritis of the Knee (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member has not had total knee arthroplasty in the targeted knee;
4. Six or more months have elapsed since the last treatment cycle.

Approval duration: 6 months (one treatment cycle) *(refer to section V).*

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drug

V. Dosage and Administration

Drug Name	Active Ingredient	Dose of Active Ingredient per Injection	Treatment Cycle*
Durolane	Hyaluronic acid	60 mg (3 mL)	1 injection
Euflexxa	Sodium hyaluronate	20 mg (2 mL)	3 injections
Gel One	Cross-linked sodium hyaluronate	30 mg (3 mL)	1 injection
GenVisc 850	Sodium hyaluronate	25 mg (2.5 mL)	3-5 injections
Gelsyn-3	Sodium hyaluronate	16.8 mg (2 mL)	3 injections
Hyalgan	Sodium hyaluronate (Hyalectin®)	20 mg (2 mL)	3-5 injections
Hymovis	Sodium hyaluronate (HYADD®4)	24 mg (3 mL)	2 injections
Monovisc‡	Cross-linked sodium hyaluronate	88 mg (4 mL)	1 injection

Drug Name	Active Ingredient	Dose of Active Ingredient per Injection	Treatment Cycle*
Orthovisc‡	Sodium hyaluronate	30 mg (2 mL)	3-4 injections
Supartz FX	Sodium hyaluronate	25 mg (2.5 mL)	3-5 injections
Synvisc	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	16 mg (2 mL)	3 injections
Synvisc One	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	48 mg (6 mL)	1 injection

*Treatment cycle: Total number of injection per cycle per knee (if treating both knees, double the number of injections per treatment cycle).
‡Per product label, one injection of Monovisc is equivalent to 3 injections of Orthovisc.

VI. Product Availability

Drug Name	Active Ingredient	Availability**
Durolane	Hyaluronic acid	3 mL syringe
Euflexxa	Sodium hyaluronate	2.25 mL syringe
Gel One	Cross-linked sodium hyaluronate	3 mL syringe
GenVisc 850	Sodium hyaluronate	3 mL syringe
Gelsyn-3	Sodium hyaluronate	2.25 mL syringe
Hyalgan	Sodium hyaluronate (Hyalectin®)	2 mL vial or 2 mL syringe
Hymovis	Sodium hyaluronate (HYADD®4)	5 mL syringe
Monovisc‡	Cross-linked sodium hyaluronate	5 mL syringe
Orthovisc‡	Sodium hyaluronate	2mL syringe
Supartz FX	Sodium hyaluronate	2.5 mL syringe
Synvisc	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	2.25 mL syringe
Synvisc One	Cross-linked hylan G-F 20 (hylan A and hylan B polymers)	10 mL syringe

** All syringes/vials are single-use (i.e., one injection/one knee); syringes are pre-filled.

VII. References

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27.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
J7323	Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
J7327	Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
J7328	Hyaluronan or derivative, Gel-Syn, for intra-articular injection, 0.1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed, specialist reviewed	09/08	10/08
Reviewed with no clinical changes	11/12	12/12
Updated Appendix C for duplicative language	01/14	02/14
Removed requirement for enteric coated formulations Added requirement to fail physical therapy, Monovisc and Gel-One to available therapies Changed approval of Gel-One every 13 weeks and other products every 6 months Added need to document interference with ADLs, failure of tramadol	01/15	02/15

Reviews, Revisions, and Approvals	Date	Approval Date
Specialist reviewed		
Removed limit of two injections Converted to bullet points and new template Removed max dosing of APAP and NSAIDs appendix Combined all safety related appendices into one appendix	08/15	10/15
Converted policy to new template. Added two new products approved in 2015: Hymovis and GenVisc850. Approval duration edited to one treatment course every 6 months rather than every 13 weeks. Removed "interference with ADLs" requirement. Edited step therapy to require an inadequate response to all of the following drugs: a two-week trial of oral NSAIDs if <75 years of age or unable to use oral NSAID, topical NSAID for ≥ 2 weeks, tramadol if no opioid abuse or dependence. Removed acetaminophen requirement.	09/16	10/16
Converted to new template. Added Gelsyn-3 to available therapies and prescriber specialty. Modified tramadol requirement to exclude members currently receiving an opioid analgesic Removed requirements related to contraindications and hypersensitivity to hyaluronate preparations (initial) and reasons to discontinue (re-auth) per new safety approach/template update; HCPCS codes added. Specialist reviewed.	04/17	
Tramadol trial removed. Failure of glucocorticoid injections changed to partial response requirement.	08/17	08/17
2Q 2018 annual review: policies combined for commercial and Medicaid lines of business; Commercial: modified failure of glucocorticoid injections to partial response requirement; Commercial and Medicaid: modified NSAID trial duration to 4 weeks, added requirement that member must not have coexistent active inflammatory arthritis other than OA or history of total knee arthroplasty in the targeted knee; added Durolane; references reviewed and updated.	03.06.18	