Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Hyaluronic Acid Products**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2007 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for formulary hyaluronic acid products.

Hyaluronic acid products improve elasticity and viscosity of synovial fluid. They are indicated to relieve pain associated with osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics.

For reference purposes only:

- Orthovisc® course-3-4 injections 1 week apart
- Euflexxa® course-3 injections 1 week apart
- Synvisc® course-3 injections 1 week apart
- Synvisc® course-1 single injection
- Supartz® course-5 injections 1 week apart
- Hyalgan® course-5 injections 1 week apart
- Gel-One® course-1 single injection

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DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The formulary hyaluronic acid products are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Monovisc, Orthovisc, and Supartz FX are subject to the preferred medical drug list program. This program applies to the hyaluronate products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are initiating a new treatment course with a targeted product. Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Hyaluronate products

	Products
Preferred	• Hyalgan (sodium hyaluronate) • Hymovis (high molecular weight viscoelastic hyaluronan) • Synvisc (hylan G-F 20) • Synvisc One (hylan G-F 20)
Non-Preferred	• Euflexxa (1% sodium hyaluronate) • Gel-One (cross-linked hyaluronate)

	• Gelsyn-3 (sodium hyaluronate) • Genvisc 850 (sodium hyaluronate) • Monovisc (high molecular weight hyaluronan) • Orthovisc (high molecular weight hyaluronan) • Supartz FX (sodium hyaluronate)

Requests for a non-preferred drug must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION CRITERIA *(Use for Non-Preferred Products Only)*

Coverage for a non-preferred product is provided when either of the following criteria is met:

A. Member is currently undergoing treatment and coverage is required to complete the current course of treatment.

Number of injections per treatment course

- Euflexxa: 3 injections (2 mL each; 6 mL total) per course
- Gel-One: 1 injection (3 mL each; 3 mL total) per course
- Gelsyn-3: 3 injections (2 mL each, 6 mL total) per course
- GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total)
- Monovisc: 1 injection (4 mL each, 4 mL total) per course
- Orthovisc: 3 or 4 injections (2 mL each; 8 mL total) per course
- Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per course

B. Member has tried and experienced a documented intolerable adverse event to ALL of the preferred products.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed under the respective diagnosis:

For All Diagnoses:

- Must have a diagnosis of osteoarthritis of the knee
- Must provide documentation of trial and failure of physician directed exercise or physical therapy program
- Must have trial and failure of or contraindication to conservative treatments for at least 3 months to include:
- Acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs)

- Intra-articular corticosteroid injection
- Must not have contraindications to hyaluronic injections such as:
- Active joint infection

Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be extended based upon chart documentation of significant improvement in pain and functional capacity.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• 2 yearly injection courses for each knee per 6 months • 2 fills per year for the treatment of 1 knee and 4 fills per year for treatment of both knees
Reauthorization	Case-by-case basis

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Orthovisc [package insert]. Woburn, MA: Anika Therapeutics, Inc.; June 2005.
2. Euflexxa [package insert]. Suffern, NY: Ferring Pharmaceuticals, Inc.; May 2006.
3. Synvisc [package insert]. Madison, NJ: Wyeth Pharmaceuticals, Inc.; December 2006.
4. Supartz [package insert]. Largo, FL: Smith & Nephew, Inc.; January 2006.
5. Hyalgan [package insert]. New York, NY: Sanofi-Synthelabo, Inc.; January 2005.
6. American College of Rheumatology. Arthritis & Rheumatism 2000; 43: 1905-1915. Accessed July 24, 2007. URL: http://www.rheumatology.org/publications/guidelines/oa-mgmt/oa-mgmt.asp.
7. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc; May 2011.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED

Annual Review	*02/16, 02/17, 02/18*
Preferred Product Update (effective 4/1/18)	*02/18*