



RX.PA.015.CCH HYALURONIC ACID DERIVATIVES

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

| PREFERRED – PA REQUIRED | NON-PREFERRED – PA REQUIRED |
|----------------------------|--------------------------------|
| Single Injection | |
| Durolane (J7318) | Gel-One (J7326) |
| Synvisc-One (J7325) | Monovisc (J7327) |
| | |
| Multiple Injections | |
| Euflexxa (J7323) | Genvisc 850 (J7320) |
| Gelysn-3 (J7328) | Hymovis (J7322) |
| Hyalgan (J7321) | Orthovisc (J7324) |
| Supartz (J7321) | Synvisc (J7325) |
| Visco-3 (J7321) | Triluron (J7332) |
| | Trivisc (J7329) |

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:

- Durolane® course – 1 single injection
- Euflexxa® course – 3 injections 1 week apart
- Gel-One® course – 1 single injection
- Gelsyn-3® course – 3 injections 1 week apart
- Genvisc 850® course – 3 to 5 injections 1 week apart
- Hyalgan® course – 3 to 5 injections 1 week apart
- Hymovis® course – 2 injections 1 week apart
- Monovisc® course – 1 single injection
- Orthovisc® course – 3 to 4 injections 1 week apart
- Supartz® course – 3 to 5 injections 1 week apart
- Synvisc® course – 3 injections 1 week apart
- Synvisc-One® course – 1 single injection

- Trilon® course – 3 injections 1 week apart
- Trivisc® course – 3 injections 1 week apart
- Visco-3® course – 3 injections 1 week apart

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 and approval by the Medical Policy Committee.

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

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

For All Products:

- Must have a diagnosis of mild-to-moderate osteoarthritis or degenerative joint disease of the knee
- Must have documentation of a previous trial and failure (at least 3 months), contraindication, or intolerance to ONE of the following:
 - Simple analgesics (such as acetaminophen-containing products)
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
- Must have documentation of a trial of steroid injections and aspiration for effusion without success, or have a documented medical reason to not utilize steroid injections
- Must have documentation of a trial and failure of physician-directed exercise or a physical therapy program
- **For non-preferred products:**
 - Must have documentation of a previous trial and failure, contraindication, or intolerance to at least TWO of the same type of preferred product(s) (e.g., if requesting a single injection series non-preferred product, the member must try and fail the preferred single injection products)

Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be extended based upon the following:

- Must have chart documentation of significant improvement in pain and functional capacity following previous series
- Must be at least 6 months since the prior treatment series was administered in the respective joint

Limitations:

| Length of Authorization (if above criteria met) | |
|--|--|
| Initial Authorization | Up to 12 months <ul style="list-style-type: none"> • 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, if required for the plan and level of request.

HCPCS Codes:

| CPT Code | Brand | Description |
|----------|---------------------------|---|
| J7318 | DUROLANE | HYALURONAN OR DERIVATIVE, DUROLANE, FOR INTRA-ARTICULAR INJECTION, 1 MG |
| J7320 | GENVISC 850 | HYALURONAN OR DERIVATIVE, GENVISC 850, FOR INTRA-ARTICULAR INJECTION, 1 MG |
| J7321 | HYALGAN, SUPARTZ, VISCO-3 | HYALURONAN OR DERIVATIVE HYALGAN, SUPARTZ OR VISCO-3, FOR INTRA-ARTICULAR INJECTION, PER DOSE |
| J7322 | HYMOVIS | HYALURONAN OR DERIVATIVE, HYMOVIS, FOR INTRA-ARTICULAR INJECTION, 1 MG |
| J7323 | EUFLEXXA | HYALURONAN OR DERIVATIVE, EUFLEXXA, FOR INTRA-ARTICULAR INJECTION, PER DOSE |
| J7324 | ORTHOVISC | HYALURONAN OR DERIVATIVE, ORTHOVISC, FOR INTRA-ARTICULAR INJECTION, PER DOSE |
| J7325 | SYNVISC, SYNVISC-ONE | HYALURONAN OR DERIVATIVE, SYNVISC OR SYNVISC-ONE, FOR INTRA-ARTICULAR INJECTION, 1 MG |
| J7326 | GEL-ONE | HYALURONAN OR DERIVATIVE, GEL-ONE, FOR INTRA-ARTICULAR INJECTION, PER DOSE |
| J7327 | MONOVISC | HYALURONAN OR DERIVATIVE, MONOVISC, FOR INTRA-ARTICULAR INJECTION, PER DOSE |
| J7328 | GELSYN-3 | HYALURONAN OR DERIVATIVE, GELSYN-3, FOR INTRA-ARTICULAR INJECTION, 0.1 MG |
| J7329 | TRIVISC | HYALURONAN OR DERIVATIVE, TRIVISC, FOR INTRA-ARTICULAR INJECTION, 1 MG |
| J7332 | TRILURON | HYALURONAN OR DERIVATIVE, TRILURON, FOR INTRA-ARTICULAR INJECTION, 1 MG |

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 |
|--|----------------------|
| Initial Review | 3/22 |
| Added Durolane & Gelsyn-3 as preferred agents; updated criteria to only require ONE trial of NSAIDs/APAP | XX/XX |