PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Gel-One (sodium hyaluronate)</th>
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<tbody>
<tr>
<td>BILLING CODE</td>
<td>J7326</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
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<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient Hospital</td>
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<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Durolane, Supartz FX, Gelsyn-3</td>
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<tr>
<td>QUANTITY LIMIT</td>
<td>1 injection (1 unit)</td>
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Gel-One (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;
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 30 mg (3 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 Gel-One (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

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/17/2017</td>
<td>New policy for Gel-One created. Minimum age and BMI requirements changed. Limits of additional courses of treatment changed.</td>
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<tr>
<td>05/15/2018</td>
<td>Changed to non-preferred status. Trial of Supartz FX or Gel-One or Durolane added to criteria.</td>
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References: