

This document applies to the following:

Product	Applies
Medicare Part B	<input checked="" type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input checked="" type="checkbox"/>

# Medicare Part B Step Therapy Hyaluronates

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

## Plan Design Summary

This program applies to the hyaluronate products specified in this document. Coverage for the non-preferred product is provided based on clinical circumstances that would exclude the use of the preferred products 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 new to treatment with the non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

## Table 1. Hyaluronate Products (Osteoarthritis-Multi)

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	<ul style="list-style-type: none"> <li>Euflexxa (1% sodium hyaluronate)</li> <li>Synvisc (hylan G-F 20)</li> </ul>

	Product(s)
Non-preferred	<ul style="list-style-type: none"> <li>• Gelsyn-3 (sodium hyaluronate)</li> <li>• GenVisc 850 (sodium hyaluronate)</li> <li>• Hyalgan (sodium hyaluronate)</li> <li>• Hymovis (high molecular weight viscoelastic hyaluronan)</li> <li>• Orthovisc (high molecular weight hyaluronan)</li> <li>• Supartz FX (sodium hyaluronate)</li> <li>• Triluron (sodium hyaluronate)</li> <li>• Trivisc (sodium hyaluronate)</li> <li>• Visco-3 (sodium hyaluronate)</li> </ul>

**Table 2. Hyaluronate Products (Osteoarthritis-Single)**

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	<ul style="list-style-type: none"> <li>• Durolane (hyaluronic acid)</li> <li>• Synvisc-One (hylan G-F 20)</li> </ul>
Non-preferred	<ul style="list-style-type: none"> <li>• Gel-One (cross-linked hyaluronate)</li> <li>• Monovisc (high molecular weight hyaluronan)</li> </ul>

## Step Therapy Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

### Osteoarthritis-Multi

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

- Member has received treatment with the requested non-preferred product in the past 365 days.
- Member has a documented intolerable adverse event to both of the preferred products, Euflexxa and Synvisc.

### Osteoarthritis-Single

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

- Member has received treatment with the requested non-preferred product in the past 365 days.

Reference number(s)
4664-D

- Member has a documented intolerable adverse event to both of the preferred products, Durolane and Synvisc-One.

## References

1. Durolane [package insert]. Durham, NC: Bioventus, LLC; September 2017.
2. Euflexxa [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
3. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
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]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; September 2017.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
12. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
13. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
14. Trivisc [package insert]. Doylestown, PA: OrthogenRX; September 2018.
15. Visco-3 [package insert]. Warsaw, IN: Zimmer Inc.; May 2017.