



Step Therapy Requirements for Medicare Outpatient (Part B) Medications

Step Therapy will be required for the medications listed in the table below provided the following are met:

- The requested product meets the definition of a Medicare outpatient (Part B) drug; AND
- The proposed use of the requested product has been determined to be a medically accepted indication; AND
- The proposed use of the preferred alternative agent has been determined to be a medically accepted indication; AND
- The dose, frequency, and duration of use may not exceed the safety and efficacy data supporting the medically accepted indication; AND
- The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days); AND
- The requested product is necessary for treating the enrollee's condition as the preferred drug(s) has(have) been or is(are) likely to be less effective or have adverse effects; AND
- When there are multiple preferred drugs, unless otherwise specified, only one is required prior to approval of the non-preferred drug.

Requested Product (Non-Preferred)	Preferred Alternative Agent(s)	Special Comments	Effective Date
Euflexxa (J7323) Gel-One (J7326) Genvisc 850 (J7320) Hyalgan (J7321) Hymovis, Hymovis One (J7322) Monovisc (J7327) Orthovisc (J7324) Sodium hyaluronate 1% inj. (J7323, J7324, J7325) Synjoynt (J7331) Triluron (J7332)	Durolane (J7318) Gelsyn-3 (J7328) Supartz FX (J7321) Synvisc (J7325) Synvisc-One (J7325)		12-01-2026

Requested Product (Non-Preferred)	Preferred Alternative Agent(s)	Special Comments	Effective Date
TriVisc (J7329) Visco-3 (J7333, J7321)			

Requested Product (Non-Preferred)	Preferred Alternative Agent(s)	Special Comments	Effective Date

References

1. Centers for Medicare and Medicaid Services, Health Plan Management System (HPMS), MA_Step_Therapy_HPMS_Memo_8_7_18; available at <http://www.cms.gov> - last checked June 13, 2025 and found under Medicare > Enrollment & renewal > Health plans - General Information > Downloads.
2. Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02,; available at <http://www.cms.gov> - last checked June 13, 2025 and found under Medicare > Regulations & guidance > Manuals > Internet-Only Manuals (IOMs).
3. Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>.
4. National Coverage Determination (NCD). Centers for Medicare & Medicare Services. <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>.
5. U.S. Food & Drug Administration. FDA Approved Drug Products. <https://www.accessdata.fda.gov/scripts/cder/daf/>

Drug/Therapy Class	Change or Update	Effective Date
All Step Therapy Categories	Step Therapy Document Creation	10/15/2026
Agents for Viscosupplementation	Change (New)	12/01/2026