MEDICAL MUTUAL®

Drug Policy

Policy:	**201936**	**Initial Effective Date: 01/01/2020**
Code(s):	**See Table Below**	**Annual Review Date: 11/18/2021**
SUBJECT:	**Medicare Part B Step Therapy**	**Last Revised Date: 09/22/2022**

POLICY STATEMENT

This policy applies to initial authorizations only. If it is believed that a member has already satisfied the step therapy requirement or a non-preferred agent is medically necessary, the provider should follow the Medical Mutual of Ohio coverage determination process to request the non-preferred agent.

Preferred Products	Non-Preferred Products
Inflectra (Q5103) Remicade (J1745) ***Change in preferred products effective June 15, 2022***	Orencia IV (J0129)* *Preferred biosimilar trial only applies to Rheumatoid arthritis and Psoriatic Arthritis (excluding polyarticular Juvenile Idiopathic Arthritis) Ilumya (J3245) Avsola (Q5121) Renflexis (Q5104) Actemra IV (J3262)** **Step therapy only applies to rheumatoid arthritis
Docetaxel (J9171) Paclitaxel (J9267)	Abraxane (J9264)* *Only applies to non-small cell lung cancer and breast cancer (**Excluding triple negative breast cancer**)
Retacrit (Q5106)	Epogen/Procrit (J0885) Mircera (J0888) Aranesp (J0881)
Vincristine sulfate (J9370)	Marqibo (J9371)

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Pamidronate (J2430) Zoledronic Acid (J3489)* *Osteoporosis does not require prior authorization	Xgeva (J0897) *Step therapy only applies to bone metastases (**excluding prostate cancer**), multiple myeloma, hypercalcemia
Zarxio (Q5101)	Neupogen (J1442) Nivestym (Q5110) Granix (J1447) Releuko (J3590, C9399)
Kanjinti (Q5117) Trazimera (Q5116) Ogivri (Q5114) Herzuma (Q5113) Ontruzant (Q5112)	Herceptin (J9355)
Truxima (Q5115) Ruxience (Q5119)	Rituxan (J9312)* *Biosimilar step therapy requirement excludes NMOSD and pemphigus vulgaris indications. Riabni (J9999) Rituxan Hyclea (J9311)
Avastin (J9035)	Byooviz (Q5124) Cimerli (J3590) Eylea (J0178) Lucentis (J2778) Visudyne (J3396) Beovu (J0179) Macugen (J2305) *Susvimo (J2779) [effective 1/1/2023]* *Vabysmo (J3590, C9097)[effective 1/1/2023]*
Triamcinolone inj. (J3302)	Zilretta (J3304)
Leucovorin (J0640)	Khapzory (J0642) Fusilev (J0641)

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Kanjinti (Q5117) Trazimera (Q5116) Ogivri (Q5114) Herzuma (Q5113) Ontruzant (Q5112)	Herceptin Hylecta (J9356)
Mvasi (Q5107) Zirabev (Q5118)	Avastin (J9035) (oncology)
Ultomiris (J1303)	Soliris (J1300) [ST only applies for Atypical hemolytic uremic syndrome (aHUS) and Paroxysmal nocturnal hemoglobinuria (PNH)]
Neulasta (J2505) Fulphila (Q5108)	Nyvperia (Q5122) Udenyca (Q5111) Ziextenzo (Q5120)
Euflexxa (J7323)* *No prior authorization required	Durolane (J7318) Genvisc 850 (J7320 Orthovisc (J7324) Monovisc (J7327) Gel-One (J7326) Gel-Syn (J7328) Hyalgan (J7321) Hymovis (J7322) Supartz & Supartz FX (J7321) Synvisc & Synvisc- One (J7325) Synojoynt (J3490) Triluron (J3490) TriVisc (J7329) Visco-3 (J7321)

Step Therapy will be required for the medications listed in the table above effective 1/1/2021**, provided the following are met:**

a) The requested product meets the definition of a Medicare outpatient (Part B) drug; AND
b) The proposed use of the requested product has been determined to be a medically accepted indication; AND
c) The proposed use of the preferred alternative agent has been determined to be a medically accepted indication; AND
d) The proposed use of the preferred alternative agent will be limited to new administrations of Part B drugs using a 365-day lookback period; AND
e) The dose, frequency, and duration of use may not exceed the safety and efficacy data supporting the medically accepted indication

Step Therapy Exception Requirements:
The utilization review process shall grant a step therapy exception/override upon receipt of information that includes supporting rationale and documentation from a health care provider which demonstrates that the medication(s) being required by the health insurer:

a) Is not available due to a national drug shortage (in all dosage strengths and all listed manufacturers) as confirmed by the FDA Drug Shortage webpage; OR
b) Is not available due to a compounding shortage when the preferred drug is only available in compounded form; OR
c) Is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information for the medication; OR
d) Has been tried by the patient and was discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event; OR
e) Is likely to cause an adverse reaction, decrease the ability of the patient to achieve or maintain reasonable functional ability in performing daily activities, or cause physical or mental harm to the patient; OR
f) Is expected to be ineffective based on the patient's known clinical history, condition, and prescription drug regimen; OR
g) Is already stable on the medication(s) being requested by his or her health care professional for his or her medical condition. Stable is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected.

References

- 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 August 31, 2018 and found under Medicare > Health Plans > Health Plans - General Information >

Downloads.

- Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100- 02, Chapter 15, Sec. 50 (Rev. 241, Feb. 2, 2018); available at http://www.cms.gov - last checked August 31, 2018 and found under Medicare > Regulations and Guidance > Manuals > Internet- Only Manuals (IOMs).
- Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
- National Coverage Determination (NCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
- U.S. Food & Drug Administration. FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.