BlueCross BlueShield of North Carolina

Medicare Part B Step Therapy

PART B STEP THERAPY CRITERIA FOR APPROVAL

The requested Part B medication will be approved when BOTH of the following are met:

1. ONE of the following:
   A. There is an applicable national coverage determination (NCD) or local coverage determination (LCD) from the Medicare Administrative Contractor (MAC) for the jurisdiction and the patient meets all of the requirements listed within the NCD or LCD
   OR
   B. There is NOT an applicable NCD or LCD and the requested medication is being used for an FDA approved indication or in accordance with a CMS supported compendia (i.e., NCCN, Clinical Pharmacology, Lexicomp Lexi-Drugs, Merative Micromedex, & AHFS-DI) or published peer-reviewed literature

   AND
2. ONE of the following:
   A. Information has been provided that indicates the patient has been treated with the requested medication in the past 365 days
   OR
   B. There is documentation that the patient has had an ineffective treatment response to the active ingredient(s) of ALL* preferred medications supported for the diagnosis
   OR
   C. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to the active ingredient(s) of ALL preferred medications supported for the diagnosis
   OR
   D. The prescriber has submitted documentation indicating ALL preferred medications supported for the diagnosis are likely to be ineffective or are likely to cause an adverse reaction or other harm to the patient

Length of Approval: See Table 1 below

*Unless otherwise noted in the preferred medications column of Table 1

NOTES:

- Preferred medication is not required if the indication is not shared by the non-preferred medication in supported compendia or clinical literature.
- Preferred medications may require prior review under Medicare Part D or Medicare Part B. Medicare Part D preferred medications will not be required for Medical Only members.
- Length of approval may be shorter due to provider network participation status.
- Coverage of one Medicare Part B Step Therapy medication could equate to multiple medication authorizations when they share the same Medicare Part B Step Therapy criteria.

Table 1: Part B Step Therapy

HCPCS	Medication	Preferred Medication(s)**	Length of Approval	NCD/LCD
IL-5 Inhibitors				
J2786	Cinqair	For severe asthma aged 18 years and older with eosinophilic phenotype: **Part D** formulary inhaled corticosteroid	12 months	N/A
J0517	Fasenra	For severe asthma aged 18 years and older with eosinophilic phenotype: **Part D** formulary inhaled corticosteroid	12 months	N/A
J2182	Nucala	For severe asthma aged 18 years and older with eosinophilic phenotype: **Part D** formulary inhaled corticosteroid	12 months	N/A
Xolair				
J2357	Xolair	For moderate to severe persistent asthma aged 18 years and older: **Part D** formulary inhaled corticosteroid	12 months	N/A
Tezspire				
J2356	Tezspire	**Part D** formulary inhaled corticosteroid	12 months	N/A
Ocular Angiogenesis Inhibitors				
J0179	Beovu	**(Part B)** Avastin	12 months	N/A
Q5124	Byooviz	**(Part B)** Avastin	12 months	N/A
Q5128	Cimerli	**(Part B)** Avastin	12 months	N/A
J0178	Eylea	**(Part B)** Avastin	12 months	N/A
J0177	Eylea HD	**(Part B)** Avastin	12 months	N/A
J2778	Lucentis	**(Part B)** Avastin	12 months	N/A
J2779	Susvimo	**(Part B)** Avastin	12 months	N/A
J2777	Vabysmo	**(Part B)** Avastin	12 months	N/A
Healthcare Administered MS Agents				
J0202	Lemtrada	**TWO of the following: (Part D)** Avonex, Betaseron, dimethyl fumarate, fingolimod, glatiramer (brand names Copaxone and Glatopa), Mayzent, Plegridy, Vumerity	12 months	N/A

HCPCS	Medication	Preferred Medication(s)**	Length of Approval	NCD/LCD
J2350	Ocrevus	**TWO of the following: (Part D)** Avonex, Betaseron, dimethyl fumarate, fingolimod, glatiramer (brand names Copaxone and Glatopa), Mayzent, Plegridy, Vumerity	12 months	N/A
J2323	Tysabri	**For MS, TWO of the following: (Part D)** Avonex, Betaseron, dimethyl fumarate, fingolimod, glatiramer (brand names Copaxone and Glatopa), Mayzent, Plegridy, Vumerity; **For Crohn's Disease ONE of the following: (Part D)** Corticosteroids, methotrexate, and immunomodulators such as azathioprine or 6-mercaptopurine	12 months	N/A
Intra-articular Hyaluronan Injections				
J7318	Durolane	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7323	Euflexxa	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7326	Gel-One	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7328	Gelsyn-3	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7320	GenVisc 850	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7321	Hyalgan	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7322	Hymovis	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7327	Monovisc	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7321	Supartz FX	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7332	Triluron	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7329	TriVisc	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
J7321	Visco-3	**(Part B)** Orthovisc, Synvisc/Synvisc One	6 months	L39260
IV Iron Agents				

HCPCS	Medication	Preferred Medication(s)**	Length of Approval	NCD/LCD
J1439	Injectafer (ferric carboxymaltose)***	**TWO of the following: (Part B)** Venofer (iron sucrose), INFeD (iron dextran), Ferrlecit (sodium ferric gluconate complex), Feraheme (ferumoxytol), ferumoxytol	12 months	N/A
J1437	Monoferric (ferric derisomaltose)***	**TWO of the following: (Part B)** Venofer (iron sucrose), INFeD (iron dextran), Ferrlecit (sodium ferric gluconate complex), Feraheme (ferumoxytol), ferumoxytol	12 months	N/A
Bevacizumab (Oncology)				
Q5126	Alymsys	Mvasi, Zirabev	12 months	N/A
J9035	Avastin	Mvasi, Zirabev (only for oncology indications)	12 months	N/A
Trastuzumab				
J9355	Herceptin	Kanjinti, Ogivri	12 months	N/A
J9356	Herceptin Hylecta	Kanjinti, Ogivri	12 months	N/A
Q5113	Herzuma	Kanjinti, Ogivri	12 months	N/A
Q5112	Ontruzant	Kanjinti, Ogivri	12 months	N/A
Q5116	Trazimera	Kanjinti, Ogivri	12 months	N/A
Rituximab				
Q5123	Riabni	Ruxience, Truxima	12 months	L35026
J9312	Rituxan	Ruxience, Truxima	12 months	L35026
J9311	Rituxan Hycela	Ruxience, Truxima	12 months	L35026
Long-Acting Colony Stimulating Factors				
Q5108	Fulphila	Udenyca, Ziextenzo	12 months	L37176
J2506	Neulasta, Neulasta OnPro	Udenyca, Ziextenzo	12 months	L37176
Q5122	Nyvepria	Udenyca, Ziextenzo	12 months	L37176
Short-Acting Colony Stimulating Factors				
J1447	Granix	Zarxio, Nivestym	12 months	L37176
Q5125	Releuko	Zarxio, Nivestym	12 months	L37176
J1442	Neupogen	Zarxio, Nivestym	12 months	L37176
Soliris				

HCPCS	Medication	Preferred Medication(s)**	Length of Approval	NCD/LCD
J1300	Soliris	**For Paroxysmal nocturnal hemoglobinuria:** Ultomiris, Empaveli; **For atypical hemolytic uremic syndrome**: Ultomiris; **For generalized myasthenia gravis:** Ultomiris, Vyvgart; **For neuromyelitis optica spectrum disorder:** Enspryng, Uplizna	12 months	N/A
Infliximab				
J1745	Remicade	**(Part B)** Avsola, Inflectra	12 months	L35677
Q5104	Renflexis	**(Part B)** Avsola, Inflectra	12 months	L35677

**This list is subject to change.

***These products do not require review for patients on dialysis when submitted for reimbursement as part of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS), or "bundled" PPS amount.

Revision History

April 2024: Coding change: Added HCPCS code Q5126 for Alymsys; deleted HCPCS code Q5125 for Alymsys effective (4/8/2024); Added LCD L35677 for Remicade (J1745) and Renflexis (Q5104); deleted LCD L36577 from Remicade (J1745) and Renflexis (Q5104) effective (4/8/2024). Added HCPCS code J0177 for Eylea HD effective 4/8/2024. Added HCPCS code Q5128 for Cimerli effective 4/8/2024