

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

HPCPS	Medication	Preferred Medication(s)** Step 1	Non-Preferred Medication(s)** Step 2	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	Byooviz, Cimerli, Lucentis, Vabysmo, Eylea, Eylea HD	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	Byooviz, Cimerli, Lucentis, Vabysmo, Eylea, Eylea HD	12 months	N/A
J2777	Vabysmo	(Part B) Avastin		12 months	N/A

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HPCPS	Medication	Preferred Medication(s)** Step 1	Non-Preferred Medication(s)** Step 2	Length of Approval	NCD/LCD
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
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

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HCPCS	Medication	Preferred Medication(s)** Step 1	Non-Preferred Medication(s)** Step 2	Length of Approval	NCD/LCD
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					
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	Monoferic (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
Q5129	Vegzelma	Mvasi, Zirabev		12 months	N/A
Trastuzumab					
J9355	Herceptin	Kanjinti, Trazimera		12 months	N/A
J9356	Herceptin Hylecta	Kanjinti, Trazimera		12 months	N/A
Q5113	Herzuma	Kanjinti, Trazimera		12 months	N/A
Q5112	Ontruzant	Kanjinti, Trazimera		12 months	N/A
Q5114	Ogivri	Kanjinti, Trazimera		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					
Q5130	Fylnetra	Fulphila, Nyvepria		12 months	A56748

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HPCPS	Medication	Preferred Medication(s)** Step 1	Non-Preferred Medication(s)** Step 2	Length of Approval	NCD/LCD
J2506	Neulasta, Neulasta OnPro	Fulphila, Nyvepria		12 months	L37176
J1449	Rolvedon	Fulphila, Nyvepria		12 months	A56748
Q5127	Stimufend	Fulphila, Nyvepria		12 months	A56748
Q5111	Udenyca/Udenyca Onbody	Fulphila, Nyvepria		12 months	A56748
Q5120	Ziextenzo	Fulphila, Nyvepria		12 months	A56748
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
Complement C5 Inhibitors					
J1299	Soliris	For Paroxysmal nocturnal hemoglobinuria: Ultomiris, Empaveli; For atypical hemolytic uremic syndrome: Ultomiris; For generalized myasthenia gravis: Ultomiris, Vyvgart, Vyvgart Hytrulo; 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
Immune Globulin (SC)					
J1555	Cuvitru	HyQvia, Hizentra, Xembify, Cutaquiq		12 months	L33794
Immune Globulin (IV)					
J1599	Alyglo	Gammagard, Gammaked, Gamunex-C, Octagam, Privigen		12 months	A56718 L34580
J1554	Asceniv	Gammagard, Gammaked, Gamunex-C, Octagam, Privigen		12 months	L34580
J1556	Bivigam	Gammagard, Gammaked, Gamunex-C, Octagam, Privigen		12 months	L34580
J1572	Flebogamma	Gammagard, Gammaked, Gamunex-C, Octagam, Privigen		12 months	L34580

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HCPCS	Medication	Preferred Medication(s)** Step 1	Non-Preferred Medication(s)** Step 2	Length of Approval	NCD/LCD
J1557	Gammaflex	Gammagard, Gammaked, Gamunex-C, Octagam, Privigen		12 months	L34580
J1576	Panzyga	Gammagard, Gammaked, Gamunex-C, Octagam, Privigen		12 months	L34580

**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

Date	Summary of Changes
12/2/2024	<ul style="list-style-type: none"> • Soliris <ul style="list-style-type: none"> ○ Added Vyvgart Hytrulo as a preferred medication for generalized myasthenia gravis • Bevacizumab (Oncology) <ul style="list-style-type: none"> ○ Added HCPCS code Q5129 for Vegzelma • Long-Acting Colony Stimulating Factors <ul style="list-style-type: none"> ○ Added HCPCS code Q5130 for Fylnetra ○ Added HCPCS code Q5127 for Stimufend
12/11/2024	<ul style="list-style-type: none"> • Changed formulary (Preferred and Nonpreferred medications) for the following drug classes: <ul style="list-style-type: none"> ○ Ocular Angiogenesis Inhibitors <ul style="list-style-type: none"> ▪ Added Byooviz, Cimerli, Lucentis, Vabysmo, Eylea, Eylea HD to the Non-Preferred Medication(s) Step 2 column for Beovu and Susvimo ○ Trastuzumab <ul style="list-style-type: none"> ▪ Removed Ogivri from Preferred Medications and added to nonpreferred medications; Added Trazimera to Preferred Medications; ○ Long-Acting Colony Stimulating Factors <ul style="list-style-type: none"> ▪ Removed Udenyca and Ziextenzo from Preferred Medications and added to nonpreferred

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Date	Summary of Changes
	<p>medications; Added Fulphila and Nyvepria to Preferred Medications</p> <ul style="list-style-type: none"> ○ Immune Globulin (SC) <ul style="list-style-type: none"> ▪ Added HCPCS code J1555 for Cuvitru ○ Immune Globulin (IV) <ul style="list-style-type: none"> ▪ Added HCPCS code J1557 for Gammaplex ▪ Added HCPCS code J1576 for Panzyga ▪ Added HCPCS code J1556 for Bivigam ▪ Added HCPCS code J1554 for Asceniv ▪ Added HCPCS code J1599 for Alyglo ▪ Added HCPCS code J1572 for Flebogamma
3/27/2025	<ul style="list-style-type: none"> • Soliris <ul style="list-style-type: none"> ○ Added HCPCS code J1299 effective 4/1/2025; deleted J1300 termed 3/31/2025