Medicare Part B Step Therapy
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Medicare Part B Step Therapy		
MNG #: 040	**☒ SCO ☒ One Care** **☒ MA Medicare Premier** **☒ MA Medicare Value** **☒ RI Medicare Preferred** **☒ RI Medicare Value** **☒ RI Medicare Maximum**	**Prior Authorization Needed?** **☒ Yes (always required)** **☐ Yes (only in certain situations. See this MNG for details)** **☐ No**
Clinical: ☒	**Operational: ☒**	**Informational: ☐**
Benefit Type: **☒ Medicare** **☐ Medicaid**	**Approval Date:** 08/05/2020;	**Effective Date:** 12/18/2020; 12/24/2022;
Last Revised Date: 1/27/2021; 2/4/2021; 10/14/2021; 01/06/2022; 6/2/2022; 10/6/2022; 09/8/2023;	**Next Annual Review Date:** 10/13/2021; 10/14/2022; 10/6/2023; 9/8/2024;	**Retire Date:**

OVERVIEW:

This Commonwealth Care Alliance (CCA) Medical Benefit Medicare Part B Step Therapy Medical Necessity Guideline (MNG) is for informational purposes only and does not constitute or replace medical advice. Physicians, hospitals, and other providers are expected to care for their patients in such a way that they can use or administer drugs/biologicals in the most effective and clinically appropriate manner. Physicians and health care providers are solely responsible for making any decisions about medical care.

Each benefit plan contains its own provisions for coverage, limitations and exclusions as stated in the member's Evidence of Coverage (EOC). If there is a discrepancy between this policy and the member's EOC, the member's EOC provision(s) will govern.

Each class of medical benefit drugs covered under Medicare Part B referenced below includes preferred drugs(s)/product(s). Step therapy prior authorization for a non-preferred drug/product will generally require history of use of a preferred drug/product within the same medical benefit injectable class along with additional criteria.

The medical benefit injectables that include non- preferred drug(s)/product(s) are subject to prior authorization, and preferred drug(s)/product(s), can be found below.

Experimental and investigational procedures, items, and medications are not covered by CCA as outlined in Experimental and Investigational Drug MNG.

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DECISION GUIDELINES:
Commonwealth Care Alliance (CCA) follows applicable Medicare and when applicable Medicaid regulations and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists.

DESCRIPTION OF SERVICES:
Specific classes of medical benefit drugs covered under Medicare Part B will include non-preferred therapies that require prior authorization. Prior authorization for a non-preferred therapy will generally require a history of use of a preferred therapy within the same medical benefit injectable class, among other criteria.

MEDICAL THERAPEUTIC DRUG CLASSES
There are specific classes of medical benefit drugs covered under Medicare Part B that will include preferred and non-preferred drugs or products. The drugs or products may be biosimilars or products with multiple manufacturers.
There are an increasing number of FDA approved biosimilar drugs/products available in marketplace. A biosimilar is a biological product approved based on data demonstrating that it is similar to FDA- approved biological product, known as the reference product, and that there are no clinically significant differences between the biosimilar product and the reference product. Biosimilars produce equivalent therapeutic results and are lower cost than brand name alternatives. This policy only applies to biological agents being used for FDA approved indications. In instances where the preferred drug is unavailable, the non-preferred drug(s) may be requested and approved by CCA. Availability is defined by CCA as a regional or nationwide shortage of a drug that is not specific to a single distributor or provider.

Clinical Coverage Criteria:

CCA may authorize coverage for a non-preferred product when documentation of **one (1) of the following:**

- **Note:** If a provider administers a non-preferred product without obtaining prior authorization, CCA may deny claims for the non-preferred product.

a. History of use of at least one preferred product resulting in a substandard response to therapy **OR**
b. History of intolerance or adverse event to at least one preferred product **OR**
c. Rationale by the treating provider that the preferred product(s) is not clinically appropriate **OR**
   - Note: Convenience does not qualify as a rationale for clinical inappropriateness of a preferred product
d. Continuation of prior treatment with the requested non-preferred product within the past 365 days **OR**
   - Note: For the purposes of this policy, a current drug/product means the member has a paid claim or clear clinical documentation (not including drug samples) for the drug/product within the past 365 days (claims look-back period).

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Therapeutic Class	Preferred Drug		HCPC		Non-Preferred Drug		HCPC
Antineoplastic Monoclonal Antibodies Targeting CD20	Truxima	Rituximab-abbs	Q5115		Rituxan	Rituximab	J9312
	Ruxience	Rituximab-pvvr	Q5119		Riabni	Rituximab	Q5123
Antineoplastic Monoclonal Antibodies Targeting HER2	Ogivri	Trastuzumab-dkst	Q5114		Herceptin	Trastuzumab	J9355
					Ontruzant	Trastuzumab-dttb	Q5112
					Herzuma	Trastuzumab-pkrb	Q5113
					Trazimera	Trastuzumab-gyyp	Q5116
					Kanjinti	Trastuzumab-anns	Q5117
Colony Stimulating Factors (Long-acting)	Udenyca	Pegfilgrastim-cbqy	Q5111		Fulphilia	Pegfilgrastim-imdb	Q5108
	Ziextenzo	Pegfilgrastim-bmez	Q5120		Nyvepria	Pegfilgrastim-apgf	Q5122
					Fylnetra	Pegfilgrastim-pbbk	Q5130
					Stimufend	Pegfiltrastim-fpgk	Q5127
					Neulasta	Pegfilgrastim	J2506
Colony Stimulating Factors (Short-acting)	Zarxio	Filgrastim-sndz	Q5101		Neupogen	Filgrastim (G-CSF)	J1442
	Nivestym	Filgrastim-aafi	Q5110		Granix	Filgrastim-tbo	J1447
					Releuko	Filgrastim-ayow	Q5125
Erythropoiesis Stimulating Agents	Retacrit	Epoetin alfa-epbx	Q5106		Procrit	Epoetin alfa	J0885
					Epogen	Epoetin alfa	J0885
Hyaluronic Acid Derivatives (Viscosupplements)	Euflexxa	Sodium hyaluronate	J7323		Gel-One	Cross-linked hyaluronate	J7326
	Durolane	Sodium hyaluronate	J7318		Gen-Visc 850	Sodium hyaluronate	J7320
	Gelsyn-3	Sodium hyaluronate	J7328		Hyalgan	Sodium hyaluronate	J7321
	Supartz	Sodium hyaluronate	J7321		Hymovis	High molecular weight viscoelastic hyaluron	J7322
					Monovisc	High molecular weight viscoelastic hyaluron	J7327

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					Orthovisc	High molecular weight viscoelastic hyaluron	J7324
					Synojoynt	Hyalurronan	J7331
					Synvisc	Hylan G-F 20	J7325
					Synvisc One	Hylan G-F 20	J7325
					Triluron	Haluronan	J7332
					Trivisc	Hyaluronic acid	J7329
					Visco-3	Sodium hyaluronate	J7321
Retinal Disorders	Avastin	Bevacizumab	J9035		Beovu	Brolucizumab-dbll	J0179
					Byooviz	Ranibizumab-nuna	Q5124
					Cimerli	Ranibizumab-eqrn	J3590
					Eylea	Aflibercept	J0178
					Lucentis	Ranibizumab	J2778
					Susvimo	Ranibizumab	J2779
					Vabysmo	Faricimab-svoa	J2777
Tumor Necrosis Factor (TNF)	Avsola	Infliximab-axxq	Q5121		Remicade	Infliximab	J1745
	Inflectra	Infliximab-dyyb	Q5103		Renflexis	Infliximab-abda	Q5104
Vascular Endothelial Growth Factor (VEGF) Inhibitors (Non-Retinal Disorders)	Mvasi	Bevacizumab-awwb			Avastin	Bevacizumab	J9035
	Zirabev	Bevacizumab-bvzr			Alymsys	Bevacizumab-maly	Q5126
					Vegzelma	Bevacizumab-abda	Q5129

LIMITATIONS/EXCLUSIONS:
N/A

AUTHORIZATION:
The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

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REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria. This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:

1. https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf
2. https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses
3. https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs
4. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update
5. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS
6. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

REVISION LOG:

REVISION DATE	DESCRIPTION
12/31/23	Utilization Management Committee approval
12/4/23	Coding correction J0178
09/09/2023	Added Vegzelma, Q5129, bevacizumab-adcd, as non-preferred to Vascular Endothelial Growth Factor (VEGF) Inhibitors Added Fylnetra, Q5130, pegfilgrastim-pbbk, as non-preferred to Colony Stimulating Factors (long acting) Added Stimufend, Q5127, pegfilgrastim-fpgk, as non-preferred to Colony Stimulating Factors (long acting) Added Retinal disorder drug class, preferred and non-preferred drugs.

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9/12/2022	Alymsys added to policy (new biosimilar) HCPCS code J7321 has been updated to include Visco-3 Releuko added to policy (new biosimilar) HCPCS code Neulasta has been updated to J2506 Fulphila changed from preferred to non-preferred. Udenyca changed from non-preferred to preferred
6/2/2022	Template update
9/23/2021	Nyvepria and Riabni added to policy (new biosimilars) Changed Inflectra from preferred to non-preferred. Changed Ziextenzo and Ruxience from non-preferred to preferred Added epoetin alfa (Epogen/Procrit) and Retacrit to policy
12/27/2021	Added language related to drug shortages

Disclaimer

This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

APPROVALS:

CCA Business Process Owner	
Derek McFerran	Vice President, Pharmacy
Print Name	**Print Title**
Derek McFerran	9/14/2023
Signature	**Date**

CCA Senior Clinical/Operational Lead	
Print Name	**Print Title**

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Signature	Date

CCA CMO or Designee	
Nazlim Hagmann, MD	Chief Medical Officer
Print Name	**Print Title**
	9/14/2023
Signature	**Date**