Part B Drugs Requiring Prior Authorization
Medical Necessity Guidelines

Medical Necessity Guideline (MNG) Title: Part B Drugs Requiring Prior Authorization		
MNG #: 107	**☒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:** 6/02/2022	**Effective Date:** 8/23/2022; 11/9/23
Last Revised Date: 11/3/2022; 11/9/23	**Next Annual Review Date:** 6/02/2023; 11/3/2023; 11/9/24	**Retire Date:**

OVERVIEW:
Commonwealth Care Alliance (CCA) requires prior authorization for certain Part B drugs that have specific indications for use, are expensive, or pose significant safety concerns.

1. For Part B drugs that belong to a specific class that has a CCA preferred biosimilar, this MNG applies to both the preferred and non-preferred biologic agent. For Step Therapy requirements for non-preferred part B drugs where preferred biosimilars are available, refer to MNG 040 Medicare Part B Step Therapy.
2. In the case of drugs used in an anti-cancer chemotherapeutic regimen, off-label uses are covered for a medically accepted indication as defined in the *Medicare Benefit Policy Manual* (CMS publication 100-2, Chapter 15, Section 50.4.5).

Part B drugs that do not require CCA prior authorization can be found on the PA Select Drug Exception List for applicable product:

https://www.commonwealthcarealliance.org/ma/wp-content/uploads/2024/01/2024_SCO_Onecare_PM_Sect4_SelectDrug-Final.pdf

https://www.commonwealthcarealliance.org/ma/wp-content/uploads/2024/01/13_2023_MedicareAdvantage_PM_Sect4_SelectDrug_NO_PA_Requirements_final_11.7.2022-1.pdf

https://www.commonwealthcarealliance.org/ri/wp-content/uploads/2022/11/2024_MA-RI_MedicareAdvantage_PM_Sect4_SelectDrug-Final.pdf

DECISION GUIDELINES:
Clinical Coverage Criteria:

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Commonwealth Care Alliance (CCA) follows applicable Medicare and 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.

CCA follows applicable Medicare and Medicaid regulations. InterQual Smart Sheets are used to evaluate prior authorization requests for medical necessity when available.

Part B Drugs, Chemotherapeutics, and Biologicals:

CCA may approve requests for Part B drugs that require Prior Authorization for the following medically accepted indications:

1. An FDA approved, labeled indication or a use supported in the American Hospital Formulary Service Drug Information (AHFS-DI), NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex®, Elsevier/Gold Standard Clinical Pharmacology and Wolters Kluwer Lexi-Drugs® as the acceptable compendia based on CMS' Change Request 6191 (Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen);

   The compendia listed above will be accepted at the following levels:

   - American Hospital Formulary Service-Drug Information (AHFS-DI) – indication is supportive.
   - NCCN Drugs and Biologics Compendium - indication is a Category 1 or 2A.
   - Micromedex DrugDex® – indication is Class I, Class IIa, or Class IIb.
   - Clinical Pharmacology – indication is supportive.
   - Lexi-Drugs - indication is rated as “Evidence Level A.”

   [OR]

2. Articles or Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs). Specific LCDs

The following drugs will be covered for off-label uses described below in addition to their FDA-approved use and approved compendia uses as per Local Coverage Determination L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses.

1. Eculizumab - NGS has approved eculizumab for biopsy proven dense deposit disease.
2. Ibandronate Sodium - NGS has approved ibandronate for senile osteoporosis in male patients.
3. Infliximab and biosimilars - NGS has approved infliximab for the following:
   a. Behçet’s Disease (BD), also known as Behçet’s Syndrome, in patients without an adequate response to initial therapy, for the treatment of clinical manifestations of BD such as severe ocular involvement, major organ involvement, severe gastrointestinal or neurological involvement and resistant cases of joint or mucocutaneous involvement (i.e., painful oral and genital ulcers).
   b. Pyoderma gangrenosum with coexisting inflammatory bowel disease.

c. Sarcoid refractory to treatment with steroids and other standard drug regimens.
d. Severe immune-related colitis that does not respond promptly (within 1 week) to therapy with high-dose steroids. A single dose of infliximab is sufficient to resolve immune-related colitis in most patients.

4. Goserelin Acetate - NGS has approved Goserelin Acetate for the following:
   Treatment of leiomyomata: 3.6 mg per month for short duration (3-6 months).

CCA may create and maintain a Medical Necessity Guideline (MNG) for a specific Part B drug that incorporates all applicable criteria as outlined above.

LIMITATIONS/EXCLUSIONS:

Upon review, if the drug use is not indicated by CMS on the FDA label, or if a use is specifically identified as not indicated in the American Hospital Formulary Services (AHFS), Elsevier/Gold Standard Clinical Pharmacology, NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex® and/or Wolters Kluwer Lexi-Drugs® compendium or there is not an applicable LCD or article covering the off-label use, then the request may be denied. However, determinations as to whether medication is reasonable and necessary for an individual patient may be made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

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).

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. Local Coverage Determination L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses. National Government Services, Inc. Original effective date 10/1/2015, revision effective date 11/1/2022. Accessed November 1, 2023. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf

2. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services. CMS publication 100-2, Chapter 15, Section 50.4.5. Rev 11399, 8/3/2023. Accessed November 1, 2023. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf

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RELATED REFERENCES

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Disclaimer

This Medical Necessity Guideline is not a rigid rule. As with all of 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.

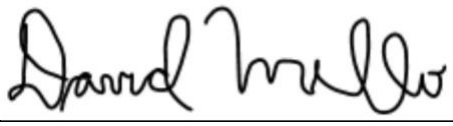
ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B:	

REVISION LOG:

REVISION DATE	DESCRIPTION
12/31/23	Utilization Management Committee approval
11/9/23	Updated to reflect the 11/1/2022 revision to LCD 33394, removed references to rituximab
11/3/2022	Updated to reflect the 11/1/2022 revision to LCD 33394

APPROVALS:

David Mello	Senior Medical Director, Utilization Review and Medical Policy
CCA Senior Clinical Lead [Print]	**Title [Print]**
	12/31/23
Signature	**Date**

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Charlotte Finn	Medical Policy Manager
CCA Senior Operational Lead [Print]	**Title [Print]**
Charlotte Finn	12/1/23
Signature	**Date**
Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee [Print]	**Title [Print]**
Nazlim Hagmann	12/1/23
Signature	**Date**