Part B Drugs Requiring Prior Authorization
Medical Necessity Guideline

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**
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; 11/14/2024	**Next Annual Review Date:** 6/02/2023; 11/3/2023; 11/9/24; 11/14/2025	**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/providers/forms-and-referrals/

https://www.commonwealthcarealliance.org/ri/providers/forms-and-referrals/

DEFINITIONS:
Compendia – Per CMS, 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

Indication - A diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given.

Off-label Use - A use for a non-FDA approved indication, i.e., one that is not listed on the drug's official label/prescribing information; giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication.

Part B Drug – Per the Centers for Medicare & Medicaid Services (CMS), outpatient prescription drugs and biologicals under certain conditions, for example, drugs provided as part of (or incident to) a physicians' service, and drugs furnished for use with covered durable medical equipment. Many Part B covered drugs are infused or injected by physicians such as oncologists, rheumatologists, and urologists. Generally, Part B covers only drugs that are not usually self-administered.

DECISION GUIDELINES:
Clinical Coverage Criteria:
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) published by National Government Services.

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.
    e. Treatment of microscopic colitis deemed refractory because of lack of response to standard pharmacologic therapy.
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).
5. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs - NGS has approved Leuprolide Acetate for the following:
    a. Carcinoma, breast (treatment): palliative treatment of advanced breast carcinoma in premenopausal and perimenopausal women
    b. Suspected endometriosis causing chronic (6 months or more) pelvic pain after an appropriate pretreatment evaluation (to exclude other causes) and failure of initial treatment with OCs and NSAIDs; not to continue beyond 3 months if there is not significant symptomatic improvement
    c. Head and Neck cancers-salivary gland tumors
6. Paclitaxel (e.g., Taxol®/Abraxane ™) - NGS has approved paclitaxel for the following:
    a. Hormone refractory prostate carcinoma
    b. Carcinoma of the renal pelvis and ureter
    c. Rhabdomyosarcoma
    d. Leiomyosarcoma

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:

1. 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).

2. Services related to non-covered services or drugs are also not covered (e.g., administration services).
3. The route of administration must be reasonable and necessary as well as the drug. [(Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50.2 - Determining Self-Administration of Drug or Biological (Rev. 157; Issued: 06-08-12; Effective/Implementation Date: 07-01-12)]. National Government Services will use evidence-based clinical guidelines to determine medical necessity of the route of administration.

REFERENCES

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 8/1/2024. Accessed November 5, 2024. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33394
2. Medicare Claims Processing Manual Chapter 17 - Drugs and Biologicals (Rev. 12511; Issued: 02-15-24). Accessed November 5, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf
3. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services. CMS publication 100-2, Chapter 15, Section 50, Drugs and Biologicals (Rev. 1, 10-01-03). Accessed November 5, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
4. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services. CMS publication 100-2, Chapter 15, Section 50.4.5. Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen (Rev 212, Issued: 11-06-15, Effective: 08-12-15, Implementation: 02-10-16). Accessed November 5, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
5. Centers for Medicare & Medicaid Services Compendia 1861 (t)(2) - Anti-cancer (Page Last Modified: 09/10/2024). Accessed 11/5/2024. https://www.cms.gov/medicare/coverage/determination-process/basics/compendia-1861-t2-anti-cancer

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, 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. 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.

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. 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).

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.

Part B Drugs Requiring Prior Authorization
Medical Necessity Guideline

REVISION LOG:

REVISION DATE	DESCRIPTION
11/14/2024	Annual review: Updated to current template; Updated to reflect the 8/1/2024 revision to LCD 33394 – added new off-label use for Infliximab; Added off-label use descriptions for Luteinizing Hormone-Releasing Hormone (LHRH) Analogs and Paclitaxel (e.g., Taxol®/Abraxane ™); Added 2 Limitations from LCD 33394; Added definitions; Updated references.
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, MD — **CCA Senior Clinical Lead [Print]**

Senior Medical Director, Utilization Review and Medical Policy — **Title [Print]**

David Mello — **Signature**

11/14/2024 — **Date**

Nazlim Hagmann, MD — **CCA CMO or Designee [Print]**

Chief Medical Officer — **Title [Print]**

Nazlim Hagmann — **Signature**

11/14/2024 — **Date**