



## New To Market Part B Medications Medical Necessity Guideline

<b>Medical Necessity Guideline (MNG) Title: New To Market Part B Medications</b>		
<b>MNG: 118</b>	<input checked="" type="checkbox"/> <b>SCO</b> <input checked="" type="checkbox"/> <b>One Care</b> <input checked="" type="checkbox"/> <b>MA Medicare Preferred</b> <input checked="" type="checkbox"/> <b>MA Medicare Value</b> <input checked="" type="checkbox"/> <b>MA Medicare Premier</b> <input checked="" type="checkbox"/> <b>RI Medicare Preferred</b> <input checked="" type="checkbox"/> <b>RI Medicare Value</b> <input checked="" type="checkbox"/> <b>RI Medicare Maximum</b>	<b>Prior Authorization Needed?</b> <input checked="" type="checkbox"/> <b>Yes (always required)</b> <input type="checkbox"/> <b>Yes (only in certain situations. See this MNG for details)</b> <input checked="" type="checkbox"/> <b>No</b>
<b>Clinical:</b> <input checked="" type="checkbox"/>	<b>Operational:</b> <input type="checkbox"/>	<b>Informational:</b> <input type="checkbox"/>
<b>Benefit Type:</b> <input checked="" type="checkbox"/> <b>Medicare</b> <input type="checkbox"/> <b>Medicaid</b>	<b>Approval Date:</b> 4/18/2023;	<b>Effective Date:</b>
<b>Last Revised Date:</b>	<b>Next Annual Review Date:</b> 4/18/2024;	<b>Retire Date:</b>

### OVERVIEW:

Commonwealth Care Alliance (CCA) covers a wide range of over-the-counter, brand-name and generic prescription drugs for its members in accordance with their benefit plan. CCA partners with its Pharmacy Benefit Manager (PBM) to provide reimbursements for part D drug prescriptions. For *Part B medications*, CCA covers select drugs that are determined to be *medically necessary* and meet the accepted standards of medical practice. For example, these may include medications that are administered by infusion and injection in physician offices and hospital outpatient facilities or are furnished by pharmacies and suppliers in accordance with applicable Medicare and Medicaid regulations.

If coverage for a *new-to-market (NTM) medication* or recognized off-label use of an FDA-approved prescription medication is requested, CCA will apply this policy to make a coverage decision until the status of the drug is changed, after which CCA may apply an LCD or NCD if available or develop its own MNG to make coverage determinations. NTM medications are new treatment options that may never have been used in clinical practice or new products that are similar or related to already established therapies. NTM medications may offer improved tolerability and provide more convenient dose frequencies compared to existing guideline-supported medications, yet the relative efficacy of NTM medications may be mixed in comparison to existing therapies. As such, there is a need to analyze the current literature, standards of practice or clinical practice guidelines, and pharmacoeconomic studies to determine the benefits, risks, and value of these medications.

### DEFINITIONS:

**Drug (or Medication):** Drug means (A) Article recognized in the Official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other



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animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

**Less-than-effective (in the context of medications):** A product (including identical, similar, or related drug) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.

**Medically Necessary:** In the context of healthcare, medically necessary refers to a service or product that is needed for the purpose of evaluating, diagnosing, or treating an illness or disease in a manner that is: (1) in accordance with generally accepted standards of medical practice, (2) clinically appropriate in terms of type, frequency, extent, site, and duration and considered to be effective for the member's specific illness or disease, and (3) not primarily for the convenience of the member, prescribing healthcare provider, or other healthcare providers.

**Medically Accepted Indication (with respect to the use of a drug):** Any use which has been approved by the U.S. Food and Drug Administration for the drug and includes another use of the drug if (i) the drug has been approved by the Food and Drug Administration; and (ii) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer-reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

**New-to-Market (NTM) Medications:** Medication that has been approved by the U.S. Food and Drug Administration (FDA) but has only been available in the United States drug market for a short period of time. Often, these medications do not have billing codes assigned under the Healthcare Common Procedure Coding System (HCPCS) yet. For the scope of this policy, NTM medications may be a product that has never been used in clinical practice, or that is similar or related to a previously approved product.

**Part B Medications:** Drugs that are covered by Medicare Part B. There are general limitations for coverage of Part B drugs, but Medicare authorizes coverage for certain (1) durable medical equipment supply drugs, (2) immunosuppressive drugs, (3) hemophilia clotting factors, (4) oral anti-cancer drugs, (5) oral anti-emetic drugs, (6) vaccines, (7) antigens, (8) erythropoietin, (9) parenteral nutrition, and (10) intravenous immune globulin.

### DECISION GUIDELINES:

#### Clinical Coverage Criteria:

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart



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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.

1. Commonwealth Care Alliance may cover a new-to-market medication or a new-to-market indication of an existing medication when **all** the following criteria are met:
    - a. The medication requested is covered by Medicare Part B *and*
    - b. The request for coverage is for a medication or indication that is FDA-approved or for a recognized off-label use of an FDA-approved medication *and*
      - a. In the case where there is an absence of Medicare and Medicaid regulations, CMS NCD and LCD, statespecific or CCA medical necessity guideline, and/or CMS-approved compendia reference to be used for medical necessity determinations, the Pharmacy Operations Team may be consulted to assist the UR Medical Director by providing other relevant information, including but not limited to package insert details, to make an informed determination. Please follow the process outlined in the *SOP # 037 Utilization Review Medical Director Review*.
    - c. **One** of the following is met:
      - a. There is an existing comparable or relevant coverage guideline for a different medication with an FDAapproved indication that is the same as the requested NTM medication. The coverage will be determined by using that criteria; *and*
      - b. The documentation submitted shows that **all** other available lines of treatment for the same FDAapproved indication as the requested NTM medication had been tried in accordance with clinical best practice and/or guidelines from nationally recognized entities for the diagnosis being treated, and is consistent with scientific literature; *and*
      - c. The member has had an inadequate treatment response, intolerance, or contraindication to **all** alternative medications;
- OR**
- d. There are no existing clinical coverage criteria for a different but comparable medication with an FDAapproved indication that is the same as the requested NTM medication. The coverage will be determined by using documentation from the requesting provider; *and*
  - e. The documentation submitted shows that **all** other available alternative lines of treatment, that are consistent with scientific literature, clinical best practice, and/or guidelines from a nationally recognized entity for the diagnosis being treated, had been tried; *and*
  - f. The member has had an inadequate treatment response, intolerance, or contraindication to **all** alternative medications.

### LIMITATIONS/EXCLUSIONS:

1. Commonwealth Care Alliance will limit the following:
  - a. NTM medications requested will be covered for 6 months or up to a complete course of therapy (if the therapy duration is less than 6 months) in a manner and for the purpose that complies with the U.S. FDA's Guideline or approved package insert or deemed medically necessary by CCA.



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2. Commonwealth Care Alliance will not cover **any** of, but not limited to, the following:
  - a. Products that are not FDA-approved or that have no FDA-approved indications; *or*
  - b. Products that would be used for cosmetic purposes and are determined to be not medically necessary; *or*
  - c. Products that would be considered experimental, investigational, or unproven; *or*
    - a. Refer to *MNG 010 Experimental and Investigational Services* for more information.
  - d. Products that have been determined to be *less-than-effective* due to the lack of substantial evidence of effectiveness for all labelled indications

### AUTHORIZATION:

**Prior authorization is required for all New-to-Market Part B Medications or Indications. If the Part B treatment has been determined to be medically necessary by meeting the criteria listed above for the indication requested, then the associated drug administration or application procedure may also be approved in accordance with CCA’s billing and coding guidelines.**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of 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).

HCPCS Code	Description	Coverage	
		SCO/One Care	Medicare Advantage
C9399	Unclassified Drugs Or Biologicals	Yes	Yes
J3490	Unclassified drugs	Yes	Yes
J3590	Unclassified Biologics	Yes	Yes
J3591	Unclassified drug or biological used for ESRD on dialysis	Yes	Yes
J7699	NOC drugs, inhalation solution administered through DME	Yes	Yes
J7799	NOC drugs, other than inhalation drugs, administered through DME	Yes	Yes
J9999	Not otherwise classified, antineoplastic drugs	Yes	Yes
Q4082	Drug or biological, not otherwise classified, Part B drug competitive acquisition program (CAP)	Yes	Yes

### 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. Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual: Chapter 6 – Part D Drugs and Formulary Requirements, Effective date: 01/15/2016
2. MassHealth, 130 CMR 406.000: Pharmacy Services, Subchapter 4: Program Regulations, Effective date: 01/24/2022
3. United States Code, Title 21: Food and Drugs, Chapter 9 – Federal Food, Drug, and Cosmetic Act, Subchapter II: Definitions, 2010 Edition
4. United States Code, Title 42: The Public Health and Welfare, Chapter 7 – Social Security, Subchapter XVIII: Health Insurance for Aged and Disabled, Part E: Miscellaneous Provisions, 2010 Edition

#### **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.

#### **RELATED REFERENCES:**

1. Centers for Medicare & Medicaid Services. (2023). *Glossary: Medically necessary*. Retrieved from <https://www.cms.gov/apps/glossary/search.asp?Term=medically+necessary&Language=English&SubmitTermSrch=Search>
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8. The United States Pharmacopeia. (2023). *USP guideline on drugs approved for inclusion*. Retrieved from <https://www.usp.org/donate/submission-guidelines/guideline-on-drugs-approved-for-inclusion>
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10. U.S. Government Publishing Office. (2010). *United States Code, Title 21 – Food and drugs, Chapter 9 – Federal food, drug, and cosmetic act, Subchapter II – Definitions*. Retrieved from [https://www.govinfo.gov/content/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapII.htm#:~:text=\(g\)\(1\)%20The%20term,mitigation%2C%20treatment%2C%20or%20prevention%20of](https://www.govinfo.gov/content/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapII.htm#:~:text=(g)(1)%20The%20term,mitigation%2C%20treatment%2C%20or%20prevention%20of)
11. U.S. Government Publishing Office. (2010). *United States Code, Title 42 – The Public health and welfare, Chapter 7 - Social Security, Subchapter XVII – Health insurance for aged and disabled, Part E – Miscellaneous provisions*. Retrieved from <https://www.govinfo.gov/content/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7subchapXVIII-partE.htm>

REVISION LOG:

REVISION DATE	DESCRIPTION
12/31/23	Utilization Management Committee approval

\_\_\_\_\_  
 David Mello  
 CCA Senior Clinical Lead [Print]

\_\_\_\_\_  
 Senior Medical Director, Utilization Review and Medical Policy  
 Title [Print]

  
 \_\_\_\_\_  
 Signature

12/31/23  
 \_\_\_\_\_  
 Date

Click here to enter text.

\_\_\_\_\_  
 CCA Senior Operational Lead [Print]

\_\_\_\_\_  
 Title [Print]



**New To Market Part B Medications  
Medical Necessity Guideline**

Signature	Date
Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee [Print]	Title [Print]
<i>Nazlim Hagmann</i>	12/31/23