New To Market Part B Medications
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: New To Market Part B Medications		
MNG: 118	☒ **CCA Senior Care Options (HMO D-SNP) (MA)** ☒ **CCA One Care (Medicare-Medicaid) (MA)**	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Benefit Type: ☒ **Medicare** ☐ **Medicaid**	**Original Approval Date:** 4/18/2023;	**Effective Date:** 11/21/2024**;** 1/1/2025
Last Revised Date: 11/14/2024; 3/26/2025	**Next Annual Review Date:** 4/18/2024; 11/14/2025	**Retire Date:**

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

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) Indication: A new purpose (indication) of a medication, approved by the U.S. Food and Drug Administration (FDA) due to new evidence suggesting that the medication can be used for the new indication, or in addition to the original use of the medication.

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.

Off-Label Use: Unapproved use of an FDA-approved drug; the FDA-approved drug labeling does not include information regarding the use of the medication for treatment of a specific disease or medical condition for which the medication has been prescribed by the physician. From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.

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 may cover a new-to-market medication or a new-to-market indication of an existing medication when all the following criteria are met:

1. The medication requested is covered by Medicare Part B; and
2. 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
3. **One** (a - c **or** d - f) of the following is met:
    a. There is an existing comparable or relevant coverage guideline for a different medication with an FDA-approved 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 FDA-approved 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 FDA-approved 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.

*In the case where there is an absence of Medicare and Medicaid regulations, CMS NCD and LCD, state-specific 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.

LIMITATIONS/EXCLUSIONS:

1. 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.

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
    d. Products that have been determined to be less-than-effective due to the lack of substantial evidence of effectiveness for all labelled indications

**Refer to MNG 010 Experimental and Investigational Services for more information.

CODING:

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

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

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).

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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.

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REVISION LOG:

REVISION DATE	DESCRIPTION
3/26/2025	Template update
11/19/2024	Utilization Management Committee approval
11/14/2024	Annual review: Update to current template, added definitions, formatting.
12/31/23	Utilization Management Committee approval

Approvals:

Stefan Topolski — **CCA Senior Clinical Lead [Print]**

Medical Director — **Title [Print]**

3/26/2025

Signature — **Date**

Nazlim Hagmann — **CCA CMO or Designee**

Chief Medical Officer — **Title**

3/26/2025

Signature — **Date**