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Medical Necessity Guidelines:

New to Market (NTM) Drug Evaluation Process Under The Medical Benefit

Effective: January 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956

☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

In order to promote clinically appropriate and cost-effective prescription drug use, the plan has several programs in place, one of which is the New-to-Market (NTM) Drug Evaluation Process described below:

NTM Drug Evaluation Process

Due to the faster Food and Drug Administration (FDA) approval process for new drugs, the plan delays coverage determination of many new drug products until the Pharmacy and Therapeutics (P&T) Committee and physician specialists have reviewed the drug. During the evaluation period, beginning when the drug first becomes available on the market, the P&T Committee reviews any additional information on the safety and effectiveness of these new products.

Clinical Guideline Coverage Criteria

When the following criteria are met, the plan may authorize coverage of prescription medications otherwise not covered due to the NTM Drug Evaluation Process:

1. The request for coverage is for an FDA-approved indication for a use that is covered in the Member's benefit document or for a recognized off-label use of an FDA-approved prescription medication used in the treatment of cancer, HIV/AIDS, or a disabling or life-threatening chronic disease

AND

2. Coverage is determined based on the NTM drug classification as follows:
   Step 1: Does the plan have existing Clinical Coverage Criteria for previously reviewed prescription medications with an FDA-approved indication that is the same indication as the NTM drug?
   a. If **YES**, then coverage for the NTM drug is determined by using those criteria and by using documentation from the requesting physician showing that the Member has had a treatment failure of, or is unable to tolerate, two (2) or more alternative medications covered under the Medical Benefit.
   b. If **NO** Existing Clinical Coverage Criteria, then proceed to step 2.
   Step 2: Does the NTM drug have available alternative medications covered under the Medical Benefit to treat the same condition?
   a. If **YES**, then coverage for the NTM drug is determined by using documentation from the requesting physician showing that the Member has had a treatment failure of, or is unable to tolerate, two (2) or more alternative medications covered under the Member's Medical Benefit.
   b. If **NO**, then proceed to step 3.
   Step 3: Is the NTM drug a novel agent, defined as a "first of its kind drug" in a new class of drugs?
   a. If **YES,** then coverage for the NTM drug is determined by using documentation from the requesting physician showing that all other available lines of treatment that are consistent with generally accepted principles of professional medical practice and/or with guidelines from a nationally recognized entity for the disease for which the Member is being treated, have been exhausted.

Limitations

- The duration of coverage will be limited to one year, or up to a complete course of therapy if less than one year as noted in the medication's FDA-approved package insert, or as deemed clinically necessary by the plan.
- For excluded drug classes please refer to the Member Handbook or Evidence of Coverage document.
- Coverage for any new agent indicated for the treatment of Duchene muscular dystrophy will not be authorized for Members who are not ambulatory at the time of the request.
- Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
	None

References:

1. None

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.