

Drug Policy

Policy:	Cyanocobalamin Preferred Step Therapy	Annual Review Date: 09/19/2024
Impacted Drugs:	Nascobal (cyanocobalamin) nasal spray	Last Revised Date: 09/19/2024

OVERVIEW

Cyanocobalamin is the most widely used form of vitamin B-12. It plays a significant role in the metabolism of energy in the body and is vital to cell reproduction, growth, and synthesis of myelin and nucleoprotein. Cyanocobalamin is the preparation of choice for the prevention and treatment of vitamin B-12 deficiency states. Parenteral (intramuscular) administration of vitamin B-12 completely reverses the megaloblastic anemia and GI symptoms of vitamin B-12 deficiency. There are also increased vitamin B-12 requirements during pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic, and renal disease.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Preferred Medications

- Generic cyanocobalamin injection
- Generic cyanocobalamin oral formulations

Non-Preferred Medications

- Nascobal (cyanocobalamin) nasal spray

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 1 year (365 days)
- B) *Extended Approval:* 1 year (365 days)

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Step Therapy Exception Criteria

Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] **AND** meets **ONE** of the following:
 - 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period **AND** there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); **OR**
 - 2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days **AND** that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has **NOT** been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) **AND** there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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REFERENCES

1. Cyanocobalamin. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 7 September 2019. Accessed on 15 September 2019.
2. Nascobal [prescribing information]. Chestnut Ridge, NY: Par Pharmaceutical, Inc. November 2018. Accessed 9/9/2020.