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**Title:** Cyanocobalamin inhalation (Nascobal®)

**Policy #:** Rx.01.181

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for cyanocobalamin inhalation (Nascobal®) as provided under the member's prescription drug benefit.

**Description:**

Cells that rapidly divide such as bone marrow and myeloid cells require vitamin B<sub>12</sub> to mature and proliferate. Vitamin B<sub>12</sub> is necessary for hematopoiesis, nucleoprotein synthesis, and myelin synthesis. Additionally, it is required for fat and carbohydrate breakdown and protein synthesis. Vitamin B<sub>12</sub> is bound to protein rich foods and comes from the diet. Hydrochloric acid and gastric protease break it down into its free form. The free form of vitamin B<sub>12</sub> must be combined with intrinsic factor, which is produced by gastric parietal cells, in order to be absorbed in the distal ileum. Pernicious anemia is an autoimmune disease that is associated with the destruction of the parietal cells that secrete intrinsic factor. The inability to absorb vitamin B<sub>12</sub> results in a severe deficiency which, if left untreated, can lead to megaloblastic anemia, GI lesions, or neurologic defects.

Cyanocobalamin is the most widely used form of vitamin B<sub>12</sub> to treat and maintain normal hematologic status in patients with pernicious anemia. It has identical hematopoietic activity to the anti-anemic factor that is present in the liver. Cyanocobalamin is also indicated as a supplement for other vitamin B<sub>12</sub> deficiencies, such as dietary deficiency and malabsorption of vitamin B<sub>12</sub>,

Cyanocobalamin is available in oral, sublingual, and injection dosage forms. Cyanocobalamin nasal spray, a new route of administration, provides an alternative route of administration for vitamin B<sub>12</sub> deficiency.

Cyanocobalamin inhalation (Nascobal®) is indicated for:

- A. Vitamin B<sub>12</sub> maintenance therapy in adult patients with pernicious anemia who are in remission following intramuscular vitamin B<sub>12</sub> therapy and who have no nervous system involvement.
- B. Treatment of adult patients with dietary, drug-induced, or malabsorption-related vitamin B<sub>12</sub> deficiency not due to pernicious anemia.
- C. Prevention of vitamin B<sub>12</sub> deficiency in adult patients with vitamin B<sub>12</sub> requirements in excess of normal.

**Policy:**

**INITIAL CRITERIA** Cyanocobalamin inhalation (Nascobal®) is approved when ALL of the following are met:

1. Diagnosis of ONE of the following:
  - a. Pernicious anemia in members requiring maintenance therapy who are in remission following intramuscular vitamin B<sub>12</sub> therapy and who have no nervous system involvement; or
  - b. Dietary deficiency of vitamin B<sub>12</sub> due to strict vegetarian diet; or
  - c. Malabsorption of vitamin B<sub>12</sub> due to a structural or functional damage to the stomach or ileum; or
  - d. Inadequate secretion of intrinsic factor; or

- e. Competition for vitamin B12 by intestinal parasites or bacteria (e.g., tapeworm, blind loop syndrome); or
  - f. Inadequate utilization of vitamin B12 (e.g., antimetabolites are employed in treatment of neoplasia); and
2. Member is 18 years of age or older; and
  3. Inadequate response or inability to tolerate oral and sublingual cyanocobalamin

Initial authorization duration: 6 months

**REAUTHORIZATION CRITERIA** Cyanocobalamin inhalation (Nascobal®) is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

**Black Box Warning as shown in the drug Prescribing Information:**

N/A

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Nascobal (cyanocobalamin inhalation) prescribing information. Spring Valley (NY). Par Pharmaceutical Companies, Inc. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/021642Orig1s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021642Orig1s015lbl.pdf). Revised November 2018. Accessed September 29, 2021.

National Institutes of Health: Vitamin B12 Dietary Supplement Fact Sheet [Internet]. Bethesda (MD):National Institutes of Health; [updated 2020 March 30]. Available from: <https://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/>. Accessed September 29, 2021.

Schrier SL. Clinical manifestations and diagnosis of vitamin B12 and folate deficiency. UpToDate website. Last updated April 28, 2020. Available at: <http://www.uptodate.com/>. Accessed September 29, 2021..

Schrier SL. Causes and pathophysiology of vitamin B12 and folate deficiencies. UpToDate website. Last updated October 22, 2019. Available at <http://www.uptodate.com/> Accessed September 29, 2021.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

| Brand Name | Generic Name   |
|------------|----------------|
| Nascobal   | Cyanocobalamin |

**Cross References:**

Off-Label Use Rx.01.33

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| <b>Policy Version Number:</b>     | 7.00               |
| <b>P&amp;T Approval Date:</b>     | September 23, 2021 |
| <b>Policy Effective Date:</b>     | January 01, 2022   |
| <b>Next Required Review Date:</b> | September 23, 2022 |

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

