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5.85.041

Section:	Prescription Drugs	**Effective Date:**	April 1, 2023
Subsection:	Hematological Agents	**Original Policy Date:**	March 26, 2021
Subject:	Nascobal	**Page:**	1 of 6

Last Review Date: March 10, 2023

Nascobal

Description

Nascobal (cyanocobalamin)

Background
Nascobal (cyanocobalamin) nasal spray is a vitamin B_{12} supplement used for the maintenance therapy of vitamin B_{12} deficiency (low levels of vitamin B_{12}) in adults with pernicious anemia who achieved healthy vitamin B_{12} levels after receiving vitamin B_{12} shots and do not have nervous system problems; for the treatment of vitamin B_{12} deficiency caused by certain conditions not related to pernicious anemia; and for prevention of vitamin B_{12} deficiency in adults with vitamin B_{12} requirements in excess of normal (1).

Regulatory Status
FDA-approved indications: Nascobal is a vitamin B_{12} indicated for: (1)

1. Vitamin B_{12} maintenance therapy in adult patients with pernicious anemia who are in remission following intramuscular vitamin B_{12} therapy and who have no nervous system involvement
2. Treatment of adult patients with dietary, drug-induced, or malabsorption related vitamin B_{12} deficiency not due to pernicious anemia
3. Prevention of vitamin B_{12} deficiency in adult patients with vitamin B_{12} requirements in excess of normal

Limitations of Use: (1)

1. Should not be used for the vitamin B_{12} absorption test (Schilling test)

2. In patients with correctible or temporary causes of vitamin B_{12} deficiency the benefit of continued long-term use following correction of vitamin B_{12} deficiency and underlying disease has not been established
3. In patients with active symptoms of nasal congestion, allergic rhinitis or upper respiratory infection effectiveness has not been established

Patients with early Leber's disease (hereditary optic nerve atrophy) who were treated with vitamin B_{12} suffered severe and swift optic atrophy. Nascobal, is not recommended for use in patients with Leber's optic atrophy (1).

Hypokalemia and sudden death may occur in severe megaloblastic anemia that is treated intensely with vitamin B_{12}. Hypokalemia and thrombocytosis can occur upon conversion of severe megaloblastic anemia to normal erythropoiesis with vitamin B_{12} therapy. Therefore, serum potassium levels and platelet count should be monitored carefully during therapy (1).

Hematocrit, reticulocyte count, vitamin B_{12}, folate and iron levels should be obtained prior to treatment. Serum B_{12} levels should be monitored periodically during therapy to establish adequacy of therapy (1).

The recommended initial dose is one spray (500 mcg) in one nostril once weekly. If serum levels of B_{12} decline after one month of treatment, consider increasing the dose. Assess serum B_{12} level one month after each dose adjustment. If serum B_{12} levels are persistently low, consider alternative therapy (e.g., intramuscular or subcutaneous vitamin B_{12} therapy) (1).

Nascobal should be discontinued in patients whose underlying cause of vitamin B_{12} deficiency has been corrected and are deemed no longer at risk for vitamin B_{12} deficiency. The safety and effectiveness of continued long-term use in these individuals has not been established. In patients with pernicious anemia, continue appropriate vitamin B_{12} treatment indefinitely (1).

The safety and effectiveness of Nascobal in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nascobal may be considered **medically necessary** for patients 18 years and older for pernicious anemia; treatment of dietary, drug-induced, or malabsorption-related vitamin B_{12} deficiency; or prevention of vitamin B12 deficiency; and if the conditions indicated below are met.

Nascobal may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Pernicious anemia
    a. In remission following intramuscular (IM) vitamin B_{12} therapy
    b. Will be used as maintenance therapy
    c. **NO** nervous system involvement

2. Treatment of dietary, drug-induced, or malabsorption-related vitamin B_{12} deficiency
    a. **NOT** due to pernicious anemia

3. Prevention of vitamin B_{12} deficiency
    a. Patient has higher vitamin B_{12} requirements than normal

AND ALL of the following:

1. Baseline levels of hematocrit, reticulocyte count, vitamin B_{12}, folate and iron levels have been obtained
2. Prescriber agrees to monitor platelet count, potassium, and serum B_{12} levels periodically
3. Will not be used for the vitamin B_{12} absorption test (Schilling test)
4. **NO** active symptoms of nasal congestion, allergic rhinitis, or upper respiratory infection

5. **NO** diagnosis of Leber's disease (hereditary optic nerve atrophy)

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Pernicious anemia
    a. Patient continues to be in remission following intramuscular (IM) vitamin B_{12} therapy
    b. **NO** nervous system involvement

2. Treatment of dietary, drug-induced, or malabsorption-related vitamin B_{12} deficiency
    a. **NOT** due to pernicious anemia

3. Prevention of vitamin B_{12} deficiency
    a. Patient has higher vitamin B_{12} requirements than normal

AND ALL of the following:

1. Prescriber agrees to monitor platelet count, potassium, and serum B_{12} levels periodically
2. Will not to be used for the vitamin B_{12} absorption test (Schilling test)
3. **NO** active symptoms of nasal congestion, allergic rhinitis, or upper respiratory infection
4. **NO** diagnosis of Leber's disease (hereditary optic nerve atrophy)

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 12 single-use sprays per 84 days

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Nascobal (cyanocobalamin) nasal spray is a vitamin B_{12} supplement used for the maintenance therapy of vitamin B_{12} deficiency (low levels of vitamin B_{12}) in adults with pernicious anemia who achieved healthy vitamin B_{12} levels after receiving vitamin B_{12} shots and do not have nervous system problems; for the treatment of vitamin B_{12} deficiency caused by certain conditions not related to pernicious anemia; and for prevention of vitamin B_{12} deficiency in adults with vitamin B_{12} requirements in excess of normal. Nascobal should not be used for a vitamin B_{12} absorption test known as the Schilling test. The safety and effectiveness of Nascobal in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Nascobal while maintaining optimal therapeutic outcomes.

References

1. Nascobal [package insert]. Chestnut Ridge, NY. Par Pharmaceuticals, Inc. November 2018.

Policy History

Date	Action
March 2021	Addition to PA
June 2021	Annual review

March 2022	Separated out indications for treatment and prevention of vitamin B12 deficiency for clarity. Also removed renewal requirement that the B12 deficiency has not been corrected
June 2022	Annual review
March 2023	Annual review. Changed policy number to 5.85.041

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 10, 2023 and is effective on April 1, 2023.