

5.85.41

Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Hematological Agents	Original Policy Date:	March 26, 2021
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Last Review Date: June 16, 2022

Nascobal

Description

Nascobal (cyanocobalamin)

Background

Nascobal (cyanocobalamin) nasal spray is a vitamin B₁₂ supplement used for the maintenance therapy of vitamin B₁₂ deficiency (low levels of vitamin B₁₂) in adults with pernicious anemia who achieved healthy vitamin B₁₂ levels after receiving vitamin B₁₂ shots and do not have nervous system problems; for the treatment of vitamin B₁₂ deficiency caused by certain conditions not related to pernicious anemia; and for prevention of vitamin B₁₂ deficiency in adults with vitamin B₁₂ requirements in excess of normal (1).

Regulatory Status

FDA approved indications: Nascobal is a vitamin B₁₂ indicated for: (1)

1. Vitamin B₁₂ maintenance therapy in adult patients with pernicious anemia who are in remission following intramuscular vitamin B₁₂ therapy and who have no nervous system involvement
2. Treatment of adult patients with dietary, drug-induced, or malabsorption related vitamin B₁₂ deficiency not due to pernicious anemia
3. Prevention of vitamin B₁₂ deficiency in adult patients with vitamin B₁₂ requirements in excess of normal

Limitations of Use: (1)

1. Should not be used for the vitamin B₁₂ absorption test (Schilling test)

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2. In patients with correctible or temporary causes of vitamin B₁₂ deficiency the benefit of continued long-term use following correction of vitamin B₁₂ 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 B₁₂ 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 B₁₂. Hypokalemia and thrombocytosis can occur upon conversion of severe megaloblastic anemia to normal erythropoiesis with vitamin B₁₂ therapy. Therefore, serum potassium levels and platelet count should be monitored carefully during therapy (1).

Hematocrit, reticulocyte count, vitamin B₁₂, folate and iron levels should be obtained prior to treatment. Serum B₁₂ 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 B₁₂ decline after one month of treatment, consider increasing the dose. Assess serum B₁₂ level one month after each dose adjustment. If serum B₁₂ levels are persistently low, consider alternative therapy (e.g., intramuscular or subcutaneous vitamin B₁₂ therapy) (1).

Nascobal should be discontinued in patients whose underlying cause of vitamin B₁₂ deficiency has been corrected and are deemed no longer at risk for vitamin B₁₂ 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 B₁₂ 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.

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Nascobal may be considered **medically necessary** for patients 18 years and older for pernicious anemia; treatment of dietary, drug-induced, or malabsorption-related vitamin B₁₂ 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 B₁₂ therapy
 - b. Will be used as maintenance therapy
 - c. **NO** nervous system involvement
2. Treatment of dietary, drug-induced, or malabsorption-related vitamin B₁₂ deficiency
 - a. **NOT** due to pernicious anemia
3. Prevention of vitamin B₁₂ deficiency
 - a. Patient has higher vitamin B₁₂ requirements than normal

AND ALL of the following:

1. Baseline levels of hematocrit, reticulocyte count, vitamin B₁₂, folate and iron levels have been obtained
2. Prescriber agrees to monitor platelet count, potassium, and serum B₁₂ levels periodically
3. Will not be used for the vitamin B₁₂ absorption test (Schilling test)
4. **NO** active symptoms of nasal congestion, allergic rhinitis, or upper respiratory infection

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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 B₁₂ therapy
 - b. **NO** nervous system involvement
2. Treatment of dietary, drug-induced, or malabsorption-related vitamin B₁₂ deficiency
 - a. **NOT** due to pernicious anemia
3. Prevention of vitamin B₁₂ deficiency
 - a. Patient has higher vitamin B₁₂ requirements than normal

AND ALL of the following:

1. Prescriber agrees to monitor platelet count, potassium, and serum B₁₂ levels periodically
2. Will not to be used for the vitamin B₁₂ 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

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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 B₁₂ supplement used for the maintenance therapy of vitamin B₁₂ deficiency (low levels of vitamin B₁₂) in adults with pernicious anemia who achieved healthy vitamin B₁₂ levels after receiving vitamin B₁₂ shots and do not have nervous system problems; for the treatment of vitamin B₁₂ deficiency caused by certain conditions not related to pernicious anemia; and for prevention of vitamin B₁₂ deficiency in adults with vitamin B₁₂ requirements in excess of normal. Nascobal should not be used for a vitamin B₁₂ 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

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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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.