



## Prior Authorization Approval Criteria

### *Nascobal (cyanocobalamin)*

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|---|---|
| <b>Generic name:</b>                            | cyanocobalamin nasal spray  |
| <b>Brand name:</b>                              | Nascobal  |
| <b>Medication class:</b>                        | Vitamin   |
| <b>FDA-approved uses:</b>                       | treatment of vitamin B12 deficiency   |
| <b>Available dosage forms:</b>                  | 2.3ml nasal spray   |
| <b>Usual dose:</b>                              | Administer one 500 mcg / 0.1ml dose intranasally in one nostril once a week.        |
| <b>Approximate cost:</b><br>(based on AWP 2010) | \$296.90 (per 2-month supply). Each Nascobal unit is a two-month supply of 8 doses. |
| <b>Duration of therapy:</b>                     | Indefinite  |

#### **Criteria for use** *(bullet points below are all inclusive unless otherwise noted):*

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Deficiency must already be corrected with vitamin B-12 injections.
- Must have normal hematocrit, reticulocyte count, vitamin B-12 level, folate level and iron level (hematologic remission).
- Unable to absorb Vit B-12 orally.
- Patient must have a well documented reason why they cannot use the injectable form of vitamin B-12 such as bleeding diathesis or abnormal schilling test.
- Patient must have one of the following conditions:
  - Pernicious anemia-only in patients who are in hematologic remission with no nervous system involvement.Or
  - Dietary deficiency of vitamin B12  
note: usually only occurs in strict vegetariansOr
  - Malabsorption of vitamin B12 resulting from structural or functional damage to the stomach or to the ileum.Or
  - Inadequate utilization of vit B-12.  
note: this may occur if antimetabolites for the vitamin are employed in the treatment of neoplasia.Or
  - Competition for vit. B-12.  
note: usually occurs by intestinal parasites of bacteria.Or
  - Inadequate secretion of intrinsic factor.

**Contraindication:**

- Patients sensitive to cobalt, vitamin B-12 or to any component of the preparation.
- Patient with nasal congestion, allergic rhinitis, or upper respiratory infections should not use Nascobal until these symptoms have resolved.

**Not approved if:**

- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of Nascobal.
- Being used to test Vitamin B12 absorption (Schilling test).
- Patient has persistently low levels of Vit. B-12.

**Special considerations:**

- One bottle will deliver 8 doses. Patient will have to pay 2 copays since it is a 2 month supply

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 2006  
Rev. 09/08/10