

**Nascobal (Cyanocobalamin)**  
**Effective 01/01/2020**

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

### Overview

Nascobal Nasal Spray is FDA-approved for the maintenance of normal hematologic status in pernicious anemia in patients in remission following intramuscular vitamin B-12 therapy with no nervous system involvement and treatment of dietary, drug-induced, or malabsorption-related vitamin B<sub>12</sub> deficiency not due to pernicious anemia; prevention of vitamin B<sub>12</sub> deficiency in patients with vitamin B<sub>12</sub> requirements in excess of normal.

### Coverage Guidelines

Approval of Nascobal will be granted for 6 months if the member meets all following criteria and documentation has been submitted:

1. The member has one of the following diagnoses:
  - a. Dietary deficiency of vitamin B12 occurring in strict vegetarian
  - b. Malabsorption of vitamin B12 resulting from structural or functional damage to the stomach, where intrinsic factor is secreted, or to the ileum, where intrinsic factor facilitates vitamin B12 absorption. These conditions include HIV infection, AIDS, Crohn's disease, tropical sprue, and non-tropical sprue (idiopathic steatorrhea, gluten-induced enteropathy)
  - c. Inadequate secretion of intrinsic factor, resulting from lesions that destroy the gastric mucosa (ingestion of corrosives, extensive neoplasia), and a number of conditions associated with a variable degree of gastric atrophy (such as multiple sclerosis, HIV infection, AIDS, certain endocrine disorders, iron deficiency, and subtotal gastrectomy). Total gastrectomy always produces vitamin B12 deficiency. Structural lesions leading to vitamin B12 deficiency include regional ileitis, ileal resections, malignancies, etc.
  - d. Competition for vitamin B12 by intestinal parasites or bacteria

- e. Inadequate utilization of vitamin B12. This may occur if antimetabolites for the vitamin are employed in the treatment of neoplasia. Requirements of vitamin B12 in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy)
- 2. The member has had an inadequate response to 90 days of therapy, adverse reaction, or contraindication to injectable vitamin B-12
- 3. The member has had an inadequate response, adverse reaction, or contraindication to all other comparable generic oral and sublingual vitamin B-12
- 4. The dosage is one spray (0.1ml) (500 mcg) administered in ONE nostril once weekly.

### **Limitations**

- 1. The following quantity limits apply: 1 package (4 sprays) per 28 days.

### **References**

- 1. Nascobal (cyanocobalamin) nasal spray [prescribing information]. Chestnut Ridge, NY: Par Pharmaceuticals, Inc; November 2018

### **Review History**

11/20/19 – P&T Reviewed

11/18/2020- Reviewed at P&T

09/21/2022 – Reviewed at Sept P&T; Separated Comm/Exch vs MH policy; no clinical updates

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