



Prior Authorization Approval Criteria

Calomist (cyanocobalamin)

Generic name:	Cyanocobalamin nasal spray
Brand name:	Calomist
Medication class:	Vitamin
FDA-approved uses:	Maintenance of vitamin B-12 concentrations after normalization with intramuscular vitamin B-12 therapy.
Available Dosage Forms:	18 ml canister spray; contains 25 mcg cyanocobalamin per dose
Usual dose range:	One spray in each nostril daily (25 mcg per nostril, total daily dose 50 mcg). May increase to twice daily for patients with an inadequate response.
Duration of therapy:	Indefinite
Cost (based on AWP 2007):	\$112.46 per canister

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

- Deficiency must already be corrected with vitamin B-12 injections.
- Patient must not have any nervous system involvement.
- Must have normal hematocrit, reticulocyte count, vitamin B-12 level, folate level and iron level (hematologic remission).
- Unable to absorb vitamin 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 B-12
Note: Usually only occurs in strict vegetarians.
 - OR**
 - Malabsorption of vitamin B-12 resulting from structural or functional damage to the stomach or to the ileum.
 - OR**
 - Inadequate utilization of vitamin B-12.
Note: This may occur if antimetabolites for the vitamin are employed in the treatment of neoplasia.
 - OR**
 - Competition for vitamin B-12.
Note: Usually occurs by intestinal parasites or bacteria.
 - OR**
 - Inadequate secretion of intrinsic factor.

Contraindications:

- Patients sensitive to cobalt, vitamin B-12 or to any component of the preparation.

Not approved if:

- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of Calomist.
- Being used to test vitamin B-12 absorption (Schilling test).
- Patient has persistently low levels of vitamin B-12.
- Patient with nasal congestion, allergic rhinitis, or upper respiratory infections should not use Calomist until these symptoms have resolved.

Special considerations:

- One canister should last 1 month if used once daily.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 10/12/05

First revision: 3/14/07

Second revision: 1/08/08