I. Medication Description

Pomalidomide, an analogue of thalidomide, is an immunomodulatory agent with antineoplastic activity. In *in vitro* cellular assays, pomalidomide inhibited proliferation and induced apoptosis of hematopoietic tumor cells. Additionally, pomalidomide inhibited the proliferation of lenalidomide-resistant multiple myeloma cell lines and synergized with dexamethasone in both lenalidomide-sensitive and lenalidomide-resistant cell lines to induce tumor cell apoptosis.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of is granted when Pomalyst when prescribed by an oncologist or hematologist for the following indications:

- **Multiple Myeloma**
  - Patient has received at least two prior therapies, including bortezomib and an immunomodulatory agent **AND**
  - Patient has demonstrated disease progression on or within 60 days of completion of last therapy **AND**
  - Drug is used in combination with dexamethasone unless the patient is steroid-intolerant.

- **Systemic Light Chain Amyloidosis**
  - Drug is used as primary treatment **AND**
  - Drug is being used in combination with dexamethasone

IV. Quantity Limitations

21 capsules per each 28 day cycle are covered

V. Coverage Duration

Coverage is granted for 6 months and may be renewed.
<table>
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<tr>
<th>Drug Therapy Guidelines</th>
<th>Pomalyst® (pomalidomide)</th>
<th>Last Review Date: 9/2016</th>
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### VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

### VII. Billing/Coding Information

Pomalyst is available as 1mg, 2mg, 3mg, and 4mg oral capsules.

### VIII. Summary of Policy Changes

- 6/15/13: New policy
- 6/15/14: addition of coverage for systemic light chain amyloidosis
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 9/15/16: no policy changes

### IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.