UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Pomalyst

Program	Prior Authorization
Medication	Pomalyst® (pomalidomide)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2017
Effective Date	7/2017

1. Background:

Pomalyst® (pomalidomide) is a thalidomide analogue indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including Revlimid® (lenalidomide) and a proteasome inhibitor [e.g., Velcade® (bortezomib)] and have demonstrated disease progression on or within 60 days of completion of the last therapy. The National Comprehensive Cancer Network (NCCN) also recommends use of Pomalyst for treatment of steroid intolerant multiple myeloma and for treatment of systemic light chain amyloidosis when used in combination with dexamethasone.

Due to embryo-fetal risk (pregnancy category X) associated with Pomalyst; it is available only through the Pomalyst Risk Evaluation and Mitigation Strategy (REMS) Program. Prescribers and pharmacies must be certified with the Pomalyst REMS Program by enrolling and complying with the REMS requirements. Patients must sign a Patient-Physician agreement form and comply with the REMS requirements. Specifically, female patients who are not pregnant but can become pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements. Pharmacies must only dispense to patients who are authorized to receive the drug and must comply with REMS requirements. Additional information may be found at: https://www.celgeneriskmanagement.com/REMSPortal/rems/portal/REMSPortal.portal.

2. Coverage Criteria:

A. Multiple Myeloma

1. Initial Authorization

a. **Pomalyst** will be approved based on **both** of the following criteria:

(1) Diagnosis of multiple myeloma

-AND-

(2) History of failure, contraindication, or intolerance to **both** of the

following:

(a) Immunomodulatory agent [e.g. Revlimid (lenalidomide)]
(b) Proteasome inhibitor [e.g.,Velcade (bortezomib)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Pomalyst** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Pomalyst therapy

Authorization will be issued for 12 months.

B. Systemic Light Chain Amyloidosis (off-label)

1. Initial Authorization

a. **Pomalyst** will be approved based on **both** of the following criteria:

(1) Diagnosis of systemic light chain amyloidosis

-AND-

(2) Used in combination with dexamethasone

Authorization will be issued for 12 months.

2. Reauthorization

a. **Pomalyst** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Pomalyst therapy

Authorization will be issued for 12 months.

3. References:

1. Pomalyst [package insert]. Summit, NJ: Celgene Corporation; June 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed March 29, 2017.

Program	Prior Authorization - Pomalyst (pomalidomide)
Change Control	
5/2016	New program
5/2017	Annual review. Updated references.