UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Pomalyst

Program	Prior Authorization
Medication	Pomalyst® (pomalidomide)
Markets in Scope	Arizona, Hawaii, Nevada, Florida-CHIP, Maryland, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island, California
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2019
Effective Date	7/2019

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. NCCN also recommends Pomalyst as a preferred subsequent systemic therapy given with antiretroviral therapy for relapsed/refractory AIDS-Related Kaposi Sarcoma that has progressed on or not responded to first-line systemic therapy, and progressed on alternate first-line systemic therapy, as well as for relapsed or refractory primary central nervous system (CNS) lymphoma.

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.

Pomalyst contains a black boxed warning for embryo fetal toxicity and venous and arterial thromboembolism. Please see full prescribing information for additional details.

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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

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.

C. AIDS-Related Kaposi Sarcoma

1. Initial Authorization

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

(1) Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

(2) Patient is currently being treated with antiretroviral therapy (ART)

-AND-

(3) **Not** used as first-line therapy

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.

D. Primary CNS Lymphoma

1. Initial Authorization

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

(1) **Both** of the following:

(a) Diagnosis of primary CNS lymphoma
(b) Used as second-line or a subsequent therapy

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.

E. NCCN Recommended Regimens

1. Initial Authorization

a. **Pomalyst** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Pomalyst therapy

Authorization will be issued for 12 months.

3. References:

1. Pomalyst [package insert]. Summit, NJ: Celgene Corporation; May 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 1, 2019.

Program	Prior Authorization - Pomalyst (pomalidomide)
Change Control	
5/2016	New program
5/2017	Annual review. Updated references.
5/2018	Added AIDS-Related Kaposi Sarcoma and NCCN recommended review criteria. Updated background and references.
5/2019	Added coverage criteria for primary CNS lymphoma per NCCN. Updated references.