UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1077-10
Program	Prior Authorization/Notification
Medication	Pomalyst® (pomalidomide)
P&T Approval Date	2/2013, 7/2013, 5/2014, 5/2015, 5/2016, 5/2017, 5/2018, 5/2019, 5/2020, 5/2021
Effective Date	8/1/2021; Oxford only: 8/1/2021

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. Pomalyst is also indicated for adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative. 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.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other

Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. Patients less than 19 years of age

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

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. 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:

i. Immunomodulatory agent [e.g., Revlimid (lenalidomide)]
ii. 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.

C. 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.

D. Kaposi Sarcoma

1. Initial Authorization

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

(1) Diagnosis of HIV-negative Kaposi Sarcoma

-OR-

(2) **All** of the following:
(a) Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

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

-AND-

(c) **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.

E. 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.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Pomalyst [package insert]. Summit, NJ: Celgene Corporation; December 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed March 28, 2021.

Program	Prior Authorization/Notification - Pomalyst (pomalidomide)
Change Control	
5/2014	Annual review. Added coverage for criteria for systemic light chain amyloidosis per NCCN.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
5/2015	Updated background, coverage criteria and references. Increased authorization from 8 months to 12 months.

5/2016	Annual review. Added dexamethasone to background. Added proteasome inhibitor to Velcade in background and coverage criteria. Updated references.
5/2017	Annual review. Changed member to patient in coverage criteria. Updated formatting and references.
5/2018	Annual review. Added coverage criteria for AIDS-Related Kaposi Sarcoma per NCCN. Updated references.
5/2019	Annual review. Added coverage criteria for primary CNS lymphoma per NCCN. Updated references.
5/2020	Annual review. No changes to coverage criteria. Updated references.
5/2021	Annual review. Added coverage criteria for HIV-negative Kaposi Sarcoma per package insert. Updated references.