UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1077-13
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, 5/2022, 5/2023, 5/2024
Effective Date	8/1/2024

1. Background:

Pomalyst® (pomalidomide) is a thalidomide analogue indicated for the treatment of adult patients, 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.[1]

The National Comprehensive Cancer Network (NCCN) also recommends use of Pomalyst for the treatment of relapsed/refractory systemic light chain amyloidosis in combination with dexamethasone and for the treatment of primary central nervous system (CNS) lymphoma. Additionally, Pomalyst is recommended in NCCN for treatment of multiple myeloma in combination of dexamethasone after receiving only one prior line of therapy or for induction therapy for the management of POEMS.[2]

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.pomalystrems.com/.[3]

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]:

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) **One** of the following:

i. History of failure, contraindication, or intolerance to **one** of the following:
- Immunomodulatory agent [e.g., Revlimid (lenalidomide)]
- Proteasome inhibitor [e.g.,Velcade (bortezomib)]

-OR-

ii. Induction therapy for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome

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) **Both** of the following:

(a) Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

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

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.

F. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; March 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed March 25, 2024.
3. Pomalyst REMS®. Available at https://www.pomalystrems.com/. Accessed March 25, 2024.

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.
5/2022	Annual review. Added NCCN Recommended Regimens criteria. Updated references.
5/2023	Annual review with no changes to coverage criteria. Updated background and references. Added state mandate footnote.
5/2024	Annual review. Updated criteria for multiple myeloma and kaposi sarcoma. Updated background and references.