

Clinical Policy: Pomalidomide (Pomalyst)

Reference Number: ERX.SPA.47

Effective Date: 07.01.16

Last Review Date: 08.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Pomalidomide (Pomalyst®) is a thalidomide analogue.

FDA Approved Indication(s)

Pomalyst is indicated:

- In combination with dexamethasone, for the treatment of patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy
- For the treatment of adult patients with acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are human immunodeficiency virus (HIV)-negative*

*This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Pomalyst is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of MM;
 2. Prescribed by or in consultation with an oncologist or hematologist;
 3. Age ≥ 18 years;
 4. Failure of an immunomodulatory agent (e.g., Revlimid®, Thalomid®) and a proteasome inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®), unless clinically significant adverse effects are experienced or all are contraindicated;*
- *Prior authorization may be required for immunomodulatory agents and proteasome inhibitors*
5. Pomalyst is not prescribed concurrently with Revlimid or Thalomid;
 6. Request meets one of the following (a or b):*
 - a. Dose does not exceed 4 mg (1 capsule) per day on days 1-21 of repeated 28-day cycles;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 6 months

B. Kaposi Sarcoma (must meet all):

1. Diagnosis of KS;
2. Prescribed by or in consultation with an oncologist or immunologist;

3. Age ≥ 18 years;
4. If disease is AIDS-related, both of the following (a and b):
 - a. Pomalyst is prescribed in combination with antiretroviral therapy;
 - b. Failure of liposomal doxorubicin and paclitaxel, unless clinically significant adverse effects are experienced or both are contraindicated;
5. Pomalyst is not prescribed concurrently with Revlimid or Thalomid;
6. Request meets one of the following (a or b):*
 - a. Dose does not exceed 5 mg (2 capsules) per day on days 1-21 of repeated 28-day cycles;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 6 months

C. Systemic Light Chain Amyloidosis (off-label) (must meet all):

1. Diagnosis of systemic light chain amyloidosis;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is relapsed or refractory to prior therapy;
5. Prescribed in combination with dexamethasone;
6. Pomalyst is not prescribed concurrently with Revlimid or Thalomid;
7. Request meets one of the following (a or b):*
 - a. Dose does not exceed 4 mg (1 capsule) per day on days 1-21 of repeated 28-day cycles;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 6 months

D. Primary Central Nervous System (CNS) Lymphoma (off-label) (must meet all):

1. Diagnosis of CNS lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is relapsed or refractory to prior therapy;
5. Pomalyst is not prescribed concurrently with Revlimid or Thalomid;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 6 months

E. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Pomalyst for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

3. Pomalyst is not prescribed concurrently with Revlimid or Thalomid;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
 - a. For KS only: New dose does not exceed 5 mg (2 capsules) per day on days 1-21 of repeated 28-day cycles;
 - b. New dose does not exceed 4 mg (1 capsule) per day on days 1-21 of repeated 28-day cycles;
 - c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:

Commercial – Length of Benefit

Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AIDS: acquired immunodeficiency syndrome

CNS: central nervous system

FDA: Food and Drug Administration

HAART: highly active antiretroviral therapy

HIV: human immunodeficiency virus

KS: Kaposi sarcoma

MM: multiple myeloma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria.

The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Revlimid® (lenalidomide)	MM 25 mg PO QD days 1-21 of repeated 28 day cycles	25 mg/day
Thalomid® (thalidomide)	MM 200 mg PO QD	200 mg/day
Velcade® (bortezomib)	MM 1.3 mg/m ² /dose for 9 multi-dose treatment cycles with retreatment if indicated	1.3 mg/m ² /dose
Kyprolis® (carfilzomib)	MM • Varies	Varies
Ninlaro® (ixazomib)	MM 4 mg PO once weekly on days 1, 8, 15 of a 28-day treatment cycle	4 mg/day
First- and second-line therapies: • liposomal doxorubicin (Doxil®, Lipodox 50®) • paclitaxel	AIDS-related KS • Liposomal doxorubicin: 20 mg/m ² IV once every 21 days • Paclitaxel: 135 mg/m ² IV every 3 weeks or 100 mg/m ² every 2 weeks	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Drugs central to first-line therapy regimens: <ul style="list-style-type: none"> • bortezomib (Velcade®) • Revlimid® (lenalidomide) • melphalan (Alkeran®) 	Systemic Light Chain Amyloidosis <ul style="list-style-type: none"> • Varies 	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pregnancy, hypersensitivity
- Boxed warning(s): embryo-fetal toxicity; venous and arterial thromboembolism

Appendix D: General Information

- The NCCN recommends Pomalyst as a preferred 4th line therapy for AIDS-related KS, following HAART, liposomal doxorubicin, and paclitaxel. In Pomalyst's pivotal KS trial, 61% (11/18) of HIV-positive patients received prior chemotherapy.
- The 2019 European consensus-based interdisciplinary KS guideline (European Dermatology Forum [EDF], the European Association of Dermato-Oncology [EADO] and the European Organisation for Research and Treatment of Cancer [EORTC]) recommends liposomal doxorubicin and paclitaxel as first-line agents for all KS types.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	4 mg PO QD on days 1-21 of repeated 28-day cycles	4 mg/day
KS	5 mg PO QD on days 1-21 of repeated 28-day cycles* Continue HAART as HIV treatment in patients with AIDS-related KS	5 mg/day

*NCCN AIDS-related KS guidelines (version 1.2021): The NCCN recommends either 4 or 5 mg/day. Although the clinical trial used a dose of 5 mg/day, the NCCN Panel believes that 4 mg is a sufficient dose.

VI. Product Availability

Capsules: 1 mg, 2 mg, 3 mg, 4 mg

VII. References

1. Pomalyst Prescribing Information. Summit, NJ: Celgene Corporation; December 2020. Available at <http://www.celgene.com/content/uploads/pomalyst-pi.pdf>. Accessed June 29, 2021.
2. Pomalidomide. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 19, 2021.
3. AIDS-Related Kaposi Sarcoma (Version 1.2021). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 19, 2021.
4. Systemic Light Chain Amyloidosis (Version 2.2021). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 19, 2021.
5. Lebbe C, Garbe C, Stratigos AJ, et al. Diagnosis and treatment of Kaposi's sarcoma: European consensus-based interdisciplinary guideline (EDF/EADO/EORTC). European Journal of Cancer. 2019; 114: 117-127.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Increased approval durations from 3/6 months to 6/12 months. Updated off-label NCCN recommendation for MM. Split NCCN off-label use into its own criteria set per updated template.	04.17	05.17
2Q 2018 annual review: age and COC added; NCCN and FDA approved uses summarized for improved clarity; specialist involvement in care added; off-label Kaposi sarcoma and amyloidosis added; approval durations increased to length of benefit; references updated.	02.13.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	01.30.19	05.19
2Q 2020 annual review: added NCCN compendium-supported indication of primary CNS lymphoma; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	02.14.20	05.20
RT2: Criteria revised for newly FDA approved indication of KS: allowed use in non-AIDS-related disease; added immunologist as a prescriber option per specialist feedback; for AIDS-related disease, added requirement that Pomalyst must be prescribed in combination with HAART and modified requirement from failure of 2 agents to specify first line doxorubicin and paclitaxel per NCCN and European consensus guidelines; modified max daily dose from 4 mg/day to 5 mg/day per FDA labeling.	06.30.20	08.20
2Q 2021 annual review: added hematology specialist option to MM and amyloidosis indications; for systemic light chain amyloidosis, added requirement for combination with dexamethasone per NCCN; references reviewed and updated.	02.19.21	05.21
Added requirement for no concurrent use with Revlimid or Thalomid since all are thalidomide analogs.	06.29.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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