

Clinical Policy: Pomalidomide (Pomalyst)

Reference Number: CP.PHAR.116

Effective Date: 07.01.13

Last Review Date: 08.20

Line of Business: Commercial, HIM, 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 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.

It is the policy of health plans affiliated with Centene Corporation[®] 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;
3. Age \geq 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.*
5. 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:

Medicaid/HIM – 6 months
Commercial – Length of Benefit

B. Kaposi Sarcoma (must meet all):

1. Diagnosis of KS;
2. Prescribed by or in consultation with an oncologist or immunologist;
3. Age \geq 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. 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:

Medicaid/HIM – 6 months
Commercial – Length of Benefit

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;
3. Age \geq 18 years;
4. Disease is relapsed or refractory to prior therapy;
5. 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:

Medicaid/HIM – 6 months
Commercial – Length of Benefit

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

1. Diagnosis of primary central nervous system lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age \geq 18 years;
4. Disease is relapsed or refractory to prior therapy;
5. 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:

Medicaid/HIM – 6 months

Commercial – Length of Benefit

E. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (meets all):

1. Currently receiving medication via Centene benefit, 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. 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:

Medicaid/HIM – 12 months

Commercial – Length of Benefit

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

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

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Revlimid® (lenalidomide)	<i>MM</i> 25 mg PO QD days 1-21 of repeated 28 day cycles.	25 mg/day
Thalomid® (thalidomide)	<i>MM</i> 200 mg PO QD.	200 mg/day
bortezomib (Velcade®)	<i>MM</i> 1.3 mg/m ² /dose for 9 multi-dose treatment cycles with retreatment if indicated.	1.3 mg/m ² /dose
Kyprolis® (carfilzomib)	<i>MM</i> • Varies	Varies
Ninlaro® (ixazomib)	<i>MM</i> 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	<i>AIDS-related KS</i> • Liposomal doxorubicin: 20 mg/m ² IV every 2-3 weeks with a cumulative lifetime dose of 400-450 mg/m ² due to cardiotoxicity • Paclitaxel: 135 mg/m ² IV every 3 weeks or 100 mg/m ² every 2 weeks	Varies
Drugs central to first-line therapy regimens: • bortezomib (Velcade®) • Revlimid® (lenalidomide) • melphalan (Alkeran®)	<i>Systemic Light Chain Amyloidosis</i> • 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 2.2020): 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; May 2020. Available at <http://www.celgene.com/content/uploads/pomalyst-pi.pdf>. Accessed May 19, 2020.
2. Pomalidomide. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed May 19, 2020.
3. Multiple Myeloma (Version 2.2020). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 15, 2020.
4. AIDS-Related Kaposi Sarcoma (Version 2.2020). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed June 5, 2020.
5. Systemic Light Chain Amyloidosis (Version 1.2020). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 15, 2020.
6. 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
Background: Added age criteria, and pregnancy/renal/hepatic monitoring information; updated safety information Figure 1: Added REMS question, and questions around labs and age; edited question about previous therapy per PI – removed related appendix since was no longer necessary; edited approval periods per Centene policy. Updated references	06.15	06.15
Converted policy to new template. FDA approve use: max dose added for multiple myeloma. Age requirement removed. NCCN recommended uses added. Added REMS program and safety information to background.	05.16	06.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
For MM, added thalidomide and lenalidomide as an example of prior immunomodulatory therapy. Maximum dose added. Pregnancy contraindication removed; toxicity after dose reduction to 1 mg and dermatologic reactions removed as reasons to discontinue. Global Biopharm language added under “Other Diagnoses/Indications”. Approval durations are increased from 3/6 to 6/12 months.	05.17	06.17
2Q 2018 annual review: policies combined for Commercial and Medicaid; HIM line of business added; added age and COC; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; off-label Kaposi sarcoma and amyloidosis added; references updated.	02.13.18	05.18
2Q 2019 annual review: no significant changes; reference reviewed and updated.	01.30.19	05.19
2Q 2020 annual review: added NCCN compendium-supported indication of primary CNS lymphoma; 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

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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