

## **Clinical Policy: Pomalidomide (Pomalyst)**

Reference Number: CP.PHAR.116

Effective Date: 07.01.13

Last Review Date: 05.19

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<sup>®</sup>) 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.

### **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<sup>®</sup> 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<sup>®\*</sup>, Thalomid<sup>®\*</sup>) and a proteasome inhibitor (e.g., bortezomib<sup>\*</sup>, Kyprolis<sup>®\*</sup>, Ninlaro<sup>®\*</sup>) unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization is (or may be) required.*
5. Request meets one of the following (a or b):
  - a. Dose does not exceed 4 mg/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*).

##### **Approval duration:**

**Medicaid/HIM** - 6 months

**Commercial** - Length of Benefit

##### **B. AIDS-Related Kaposi Sarcoma (off-label) (must meet all):**

1. Diagnosis of AIDS-related Kaposi sarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;

4. Failure of at least two prior therapies;
5. Request meets one of the following (a or b):
  - a. Dose does not exceed 4 mg/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*).

**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/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*).

**Approval duration:**

**Medicaid/HIM** - 6 months

**Commercial** - Length of Benefit

**D. 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 or b):
  - a. New dose does not exceed 4 mg/day on days 1-21 of repeated 28-day cycles;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**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*

FDA: Food and Drug Administration

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)	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
bortezomib (Velcade®)	MM 1.3 mg/m <sup>2</sup> /dose for 9 multi-dose treatment cycles with retreatment if indicated.	1.3 mg/m <sup>2</sup> /dose
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	<i>AIDS-related Kaposi Sarcoma</i> • Liposomal doxorubicin: 20 mg/m <sup>2</sup> IV once every 21 days • Paclitaxel: 135 mg/m <sup>2</sup> IV every 3 weeks <b>or</b> 100 mg/m <sup>2</sup> 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
- Boxed warning(s): embryo-fetal toxicity; venous and arterial thromboembolism

**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

**VI. Product Availability**

Capsule: 1 mg, 2 mg, 3 mg, 4 mg

**VII. References**

1. Pomalyst Prescribing Information. Summit, NJ: Celgene Corporation; March 2018. Available at <http://www.celgene.com/content/uploads/pomalyst-pi.pdf>. Accessed January 30, 2019.
2. Pomalidomide. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [www.nccn.org](http://www.nccn.org). Accessed January 30, 2019.
3. Multiple myeloma (Version 2.2019). In: National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed January 30, 2019.
4. AIDS-Related Kaposi Sarcoma (Version 2.2019). In: National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed January 30, 2019.
5. Systemic Light Chain Amyloidosis (Version 1.2019). In: National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed January 30, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Updated background information; added Appendix A and B; reviewed and added references	07.14	07.14
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
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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

**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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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