Clinical Policy: Pomalidomide (Pomalyst)

Reference Number: PA.CP.PHAR.116
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

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.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Pomalyst is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):
1. Diagnosis of multiple myeloma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of an immunomodulatory agent (e.g., lenalidomide, thalidomide) and a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib) 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: 6 months

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 ≥ 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. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 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;
3. Age ≥ 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. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Other diagnoses/indications(must meet all):

1. The following NCCN recommended use(s) meeting NCCN categories 1, 2a or 2b may be covered provided that member meets the off-label criteria defined in PA.CP.PMN.53
   a. Systemic light chain amyloidosis;
   b. Primary Central Nervous System Lymphoma that is considered relapsed or refractory.

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria, or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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. Requested new dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. 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^2/dose for 9 multi-dose treatment cycles with retreatment if indicated.	1.3 mg/m^2/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	*AIDS-related Kaposi Sarcoma* • 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
Drugs central to first-line therapy regimens: • bortezomib (Velcade) • Revlimid (lenalidomide) • melphalan (Alkeran®)	*Systemic Light Chain Amyloidosis* • 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

IV. 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

V. Product Availability

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

VI. 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. Accessed January 30, 2019.
3. Multiple myeloma (Version 2.2019). In: National Comprehensive Cancer Network Guidelines. Available at 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. Accessed January 30, 2019.
5. Systemic Light Chain Amyloidosis (Version 1.2019). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed January 30, 2019.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: 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	
2Q 2019 annual review: added ixazomib as example of proteasome inhibitor in MM criteria; references reviewed and updated	04/19	