Evolent Clinical Guideline 3055 for Pomalyst™ (pomalidomide)

Guideline Number: Evolent_CG_3055	**Applicable Codes**	
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STATEMENT

Purpose

To define and describe the accepted indications for Pomalyst (pomalidomide) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

AIDS-Related Kaposi Sarcoma

- The member has AIDS-related Kaposi sarcoma that has relapsed or is refractory to first line systemic therapy, including Doxil (liposomal doxorubicin) AND
- Pomalyst (pomalidomide) will be used as subsequent therapy in combination with HAART- Highly Active Anti-Retroviral Therapy.

Multiple Myeloma (MM)

- Pomalyst (pomalidomide) may be used as follows:
  - The member has relapsed or refractory multiple myeloma and has failed 2 prior therapies for myeloma including one proteasome inhibitor & one immunomodulatory agent in ANY of the following regimens:
    - In combination with dexamethasone or corticosteroid equivalent unless there is an intolerance/contraindication to a corticosteroid.
    - In combination with Darzalex (daratumumab) +/- dexamethasone
    - In combination with Cytoxan (cyclophosphamide) +/- dexamethasone

- In combination with Empliciti (elotuzumab) +/- dexamethasone
- In combination with Kyprolis (carfilzomib) +/- dexamethasone
- In combination with Ninlaro (ixazomib) +/- dexamethasone
- In combination with Velcade (bortezomib) +/- dexamethasone
- In combination with Sarclisa (isatuximab-irfc) +/- dexamethasone
- In combination with Xpovio (Selinexor) +/- dexamethasone

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Pregnancy
  - Hypersensitivity
- US Boxed Warning
  - Pomalyst (pomalidomide) is contraindicated in pregnancy. Pomalidomide is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting pomalidomide treatment. Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping Pomalyst (pomalidomide) treatment.
  - Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with Pomalyst (pomalidomide). Prophylactic antithrombotic measures were employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.

EXCLUSION CRITERIA

- Disease progression while receiving Pomalyst (pomalidomide) containing regimen.
- Dosing exceeds single dose limit of Pomalyst (pomalidomide) 4 mg for Multiple Myeloma and 5 mg for Kaposi Sarcoma.
- Treatment exceeds the maximum limit of 21 (1 mg), 21 (2 mg), 21 (3 mg), or 21 (4 mg) capsules per month.
- Investigational use of Pomalyst (pomalidomide) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately

represented in the published evidence.

- Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
- Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8999 - pomalidomide

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
April 2026	• Updated contraindications/warnings section • Updated references
April 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1239 Pomalyst (pomalidomide) • Updated references • Updated maximum dosage form quantities in exclusion criteria
April 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Polizzotto MN, et al. Pomalidomide for Symptomatic Kaposi's Sarcoma in People With and Without HIV Infection: A Phase I/II Study. *J Clin Oncol*. 2016 Dec;34(34):4125-4131. doi: 10.1200/JCO.2016.69.3812.
2. Ramaswami R, et al. Safety, Activity, and Long-term Outcomes of Pomalidomide in the Treatment of Kaposi Sarcoma among Individuals with or without HIV Infection. *Clin Cancer Res*. 2022 Mar 1;28(5):840-850. doi: 10.1158/1078-0432.CCR-21-3364.
3. Pomalyst prescribing information. Celgene Corporation. Princeton, NJ 2025.
4. Clinical Pharmacology Elsevier Gold Standard 2026.
5. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2026.
6. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2026.
7. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2026.
8. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
9. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.
10. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.