Pomalyst (pomalidomide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limits
Pomalyst (pomalidomide)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Pomalyst (pomalidomide) may be approved if the following criteria are met:

I. Individual has a diagnosis of relapsed/refractory Multiple Myeloma; **AND**
II. Individual is using in combination with dexamethasone (with or without a proteasome inhibitor or cyclophosphamide); **AND**
III. Individual has demonstrated disease progression on or within 60 days of completion of the last therapy; **AND**
IV. Individual has had a trial of at least two prior therapies, including an immunomodulatory agent (such as lenalidomide and proteasome inhibitor) (Label, NCCN 2A);

OR

V. Individual has a diagnosis of relapsed/refractory Multiple Myeloma; **AND**
VI. Individual has had a trial of at least two prior therapies, including an immunomodulatory agent (such as lenalidomide) and a proteasome inhibitor; **AND**
VII. Individual is using in combination with dexamethasone and one of the following (NCCN 1, 2A):
    A. Elotuzumab; **OR**
    B. Isatuximab-irfc;

OR

VIII. Individual has a diagnosis of relapsed/refractory Multiple Myeloma; **AND**
IX. Individual has had a trial of at least one prior line of therapy including lenalidomide and a proteasome inhibitor; **AND**
X. Individual is using in combination with dexamethasone and Daratumumab (Darzalex or Darzalex Faspro);

OR

XI. Individual has a diagnosis of systemic light chain amyloidosis and is using in combination with dexamethasone (NCCN 2A);

OR

XII. Individual has a diagnosis of AIDS-Related Kaposi Sarcoma (KS); **AND**

XIII. Highly active antiretroviral therapy (HAART) has failed to control disease (i.e., stable or increasing KS lesions despite HAART);

OR

XIV. Individual has a diagnosis of Kaposi Sarcoma; **AND**
XV. Individual is HIV-negative;

OR

XVI. Individual has a diagnosis of Primary Central Nervous System (CNS) Lymphoma (NCCN 2A); **AND**
XVII. Individual is using as a single agent; **AND**
XVIII. Individual is using as induction therapy in patient unable to use high-dose methotrexate; **OR**
XIX. Individual has relapsed/refractory disease;

OR

XX. Individual has a diagnosis of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome (NCCN 2A); **AND**
XXI. Individual is using in combination with dexamethasone.

Note:
Pomalyst (pomalidomide) has black box warnings for embryo-fetal toxicity and venous and arterial thromboembolism. Pomalyst, as a thalidomide analogue, is contraindicated in pregnancy. Thalidomide is a known human teratogen causing severe life-threatening birth defects. Exclude pregnancy with 2 negative pregnancy tests before starting treatment and prevent pregnancy with 2 reliable contraception methods, during and for 4 weeks after treatment. To avoid embryo-fetal exposure, Pomalyst is only available through a restricted distribution program, the POMALYST REMS program. In addition, deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke have occurred in patients with MM treated with Pomalyst. Thromboprophylaxis is recommended and should be based on underlying risks.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 4, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Tun HW, Johnston PB, DeAngelis LM, et al. Phase 1 study of pomalidomide and dexamethasone for relapsed/refractory primary CNS or vitreoretinal lymphoma. Blood 2018;132:2240-2248.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 3, 2023.
    a. Kaposi Sarcoma V2.2023. Revised October 3, 2023.

b. Central Nervous System Cancers V1.2023. Revised March 24, 2023.
c. Multiple Myeloma V1.2024. Revised September 22, 2023.
d. Systemic Light Chain Amyloidosis V2.2023. Revised November 28, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.