BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.21.036

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 3, 2013
Subject:	Pomalyst	**Page:**	1 of 6

Last Review Date: June 13, 2024

Pomalyst

Description

Pomalyst (pomalidomide)

Background
Pomalyst (pomalidomide) is an analogue of thalidomide with immunomodulatory, antiangiogenic, and antineoplastic properties. Cellular activities of pomalidomide are mediated through its target cereblon, a component of a cullin ring E3 ubiquitin ligase enzyme complex. Pomalyst inhibits proliferation and induces apoptosis of hematopoietic tumor cells. Pomalyst also enhances T cell- and natural killer cell-mediated immunity and inhibits production of pro-inflammatory cytokines (1-2).

Regulatory Status
FDA-approved indications: Pomalyst is a thalidomide analogue indicated for the treatment of adult patients: (2)

- 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.
- with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative.

Pomalyst is also indicated for the treatment of adult patients with multiple myeloma in combination with Darzalex Faspro (daratumumab and hyaluronidase-fihj) and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (3).

Pomalyst is a thalidomide analogue and carries a boxed warning regarding the risk of embryo-fetal toxicity. Pomalyst is contraindicated in pregnancy. Females of reproductive potential must avoid pregnancy while taking Pomalyst and for at least 4 weeks after completing therapy. Two negative pregnancy tests must be obtained prior to initiating therapy. Pomalyst is present in the semen of male patients receiving the drug. Males must be advised of using condoms during any sexual contact with females of reproductive potential, even if they have undergone a successful vasectomy. Male patients taking Pomalyst must not donate sperm (2).

Pomalyst has an additional boxed warning regarding the risk of venous thromboembolism. Deep venous thrombosis (DVT) and pulmonary embolism (PE) may occur in patients treated with Pomalyst (2).

Patients must not donate blood during treatment with Pomalyst and for 1 month following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus must not be exposed to Pomalyst (2).

Safety and effectiveness of Pomalyst in patients below the age of 18 have not been established (2).

Because of Pomalyst's embryo-fetal risk, it is available only through the Pomalyst Risk Evaluation and Mitigation Strategy (REMS) Program. Prescribers must be certified with the Pomalyst REMS Program. Patients must sign a Patient-Physician agreement form and comply with the REMS requirements (2).

Related policies
Revlimid

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pomalyst may be considered **medically necessary** if the conditions indicated below are met.

Pomalyst may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Multiple myeloma (MM)
    a. Used in combination with dexamethasone
    b. Patient has **ONE** of the following:
        i. Patient has received at least **TWO** prior therapies for multiple myeloma including lenalidomide and a proteasome inhibitor **AND** has demonstrated disease progression on or within 60 days of completion of the last therapy for multiple myeloma
        ii. Patient has received at least **ONE** prior line of therapy including lenalidomide and a proteasome inhibitor **AND** used in combination with daratumumab and hyaluronidase-fihj
2. Kaposi sarcoma (KS) and **ONE** of the following:
    a. AIDS-related Kaposi sarcoma
        i. Patient has failed highly active antiretroviral therapy (HAART)
    b. Patient is HIV-negative

AND ALL of the following:

1. Blood counts for neutropenia, thrombocytopenia, and anemia will be monitored weekly for the first 8 weeks and monthly thereafter
2. Females of reproductive potential **only**: pregnancy has been excluded prior to initiation of therapy and patient will be advised to use 2 reliable methods of contraception during therapy and for 4 weeks after the last dose
3. Males with female partners of reproductive potential **only**: patient will be advised to use a latex or synthetic condom during therapy and for 4 weeks after the last dose, even if they have undergone a successful vasectomy
4. Physician, patient, and pharmacy are registered with the REMS program

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Multiple myeloma (MM)
2. Kaposi sarcoma (KS)

AND ALL of the following:

1. Blood counts for neutropenia, thrombocytopenia, and anemia will be monitored monthly
2. Females of reproductive potential **only**: patient will be advised to use 2 reliable methods of contraception during therapy and for 4 weeks after the last dose
3. Males with female partners of reproductive potential **only**: patient will be advised to use a latex or synthetic condom during therapy and for 4 weeks after the last dose, even if they have undergone a successful vasectomy

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Quantity
Multiple myeloma	63 capsules per 84 days **OR**
Kaposi sarcoma	126 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Pomalyst (pomalidomide) is an analogue of thalidomide with immunomodulatory, antiangiogenic, and antineoplastic properties. Cellular activities of pomalidomide are mediated through its target cereblon, a component of a cullin ring E3 ubiquitin ligase enzyme complex. Pomalyst inhibits proliferation and induces apoptosis of hematopoietic tumor cells. Pomalyst also enhances T cell- and natural killer cell-mediated immunity and inhibits production of pro-inflammatory cytokines. Pomalyst is available only through the Pomalyst Risk Evaluation and Mitigation Strategy (REMS) Program (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Pomalyst while maintaining optimal therapeutic outcomes.

References

1. NCCN Drugs & Biologics Compendium® Pomalidomide 2024. National Comprehensive Cancer Network, Inc. Accessed on April 23, 2024.
2. Pomalyst [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2023.
3. Darzalex Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2022.

Policy History

Date	Action
April 2013	Addition to PA
September 2014	Annual review and reference update
June 2015	Annual review and reference update
June 2016	Annual editorial review and reference update Addition of the requirement for combination use with dexamethasone Policy number change from 5.04.36 to 5.21.36
September 2016	Annual review
June 2017	Annual review and reference update
June 2018	Annual editorial review and reference update
June 2019	Annual review and reference update
June 2020	Annual editorial review and reference update. Addition of PA quantity limit per FEP. Addition of indication: Kaposi sarcoma and revised contraception requirements
December 2020	Annual review

August 2021	Addition of indication: multiple myeloma in combination with daratumumab and hyaluronidase-fihj (Darzalex Faspro) + dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor per Darzalex Faspro PI
September 2021	Annual review and reference update
June 2022	Annual editorial review and reference update. Revised contraception requirements to updated verbiage
March 2023	Annual review and reference update. Changed policy number to 5.21.036
December 2023	Annual review and reference update
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.