BlueCross BlueShield Federal Employee Program

POMALYST (pomalidomide)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.