

Prior Authorization DRUG Guidelines

POMALYST (pomalidomide)

Effective Date: 10/20/14

Date Developed: 10/14/14

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Description: POMALYST, an analogue of thalidomide, is an immunomodulatory antineoplastic agent that enhances T cell- and natural killer (NK) cell-mediated immunity and inhibits production of pro-inflammatory cytokines (e.g., TNF- α and IL-6) by monocytes. It has also demonstrated anti-angiogenic activity.

Authorization Criteria: Patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy. ANC should be ≥ 500 cells/mm³ and platelets $\geq 50,000$ cells/mm³ prior to initiating new cycles of therapy.

Dosing: 4 mg once daily without food for 21 days; may repeat after seven days

How Supplied: Capsules 1, 2, 3, 4 mg

Contraindications/Warnings: Contraindicated in pregnancy; **Pomalyst** is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called “POMALYST REMS.” (1-888-423-5436)

Major Adverse Reactions: Neutropenia, anemia, thrombocytopenia; peripheral neuropathy; tumor lysis syndrome

Major Drug Interactions: CYP1A2 Inducers (e.g. omeprazole, cruciferous vegetables, insulin) decrease serum concentration; CYP1A2 inhibitors (e.g. fluoroquinolones, calcium channel blockers, INH, cimetidine, grapefruit) may increase serum concentration; enhancement of other immune modulators

REFERENCES

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3. Richardson PG, Siegel D, Baz R, et al, "Phase I Study of Pomalidomide MTD, Safety and Efficacy in Patients With Refractory Multiple Myeloma Who Have Received Lenalidomide and Bortezomib," *Blood*, 2013, 121(11):1961-7.
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5. Pomalyst (pomalidomide) [prescribing information]. Summit, NJ: Celgene Corporation; March 2014.
6. www.uptodate.com: Pomalidomide: Drug Guidelines

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