

Specialty Pharmacy Program

Revlimid® (lenalidomide)

DESCRIPTION

Revlimid is an immunomodulatory agent with antineoplastic and antiangiogenic properties. Revlimid is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Revlimid, used in combination with dexamethasone, is also indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Treatment of transfusion-dependent anemia due to low- or intermediate-1 risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality.
2. Treatment of multiple myeloma, in combination with dexamethasone, in patients who have received at least one prior therapy.

Off-Label Indication(s)

Requests for off-label use of Revlimid will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS® Drug Information, Thomson Micromedex®, National Comprehensive Cancer Network Drugs and Biologics Compendium™, and Clinical Pharmacology.