

# Revlimid (lenalidomide)

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

Medications	Quantity Limit
Revlimid (lenalidomide)*	1 capsule per day

\*Requests for increased quantities may be approved for one (1) month, **only** when the request is for titrating doses.

## **APPROVAL CRITERIA**

Requests for Revlimid (lenalidomide) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Multiple Myeloma; **AND**
- II. Individual is using in combination with other agents for multiple myeloma; **OR**
- III. Individual is using as monotherapy for maintenance treatment (NCCN 2A);

**OR**

- IV. Individual has a diagnosis of Myelodysplastic Syndrome (MDS); **AND**
- V. Individual is using for transfusion-dependent anemia associated with low or intermediate 1-risk MDS associated with a deletion of 5q cytogenetic abnormality, with or without additional cytogenetic abnormalities (Label); **OR**
- VI. Individual is using for anemia associated with MDS/MPN with ring sideroblasts and thrombocytopenia or for symptomatic anemia in lower risk patients with or without del(5q) and with or without additional cytogenetic abnormalities (NCCN 2A);

**OR**

- VII. Individual has a diagnosis of Myelofibrosis associated anemia (NCCN 2A);

**OR**

- VIII. Individual has a diagnosis of relapsed or progressive Mantle Cell Lymphoma;

**OR**

- IX. Individual has a diagnosis of Mantle Cell Lymphoma; **AND**
- X. Individual is using as primary therapy for (NCCN 2A):
  - A. Low- or intermediate risk disease as less aggressive therapy; **OR**
  - B. High risk disease in those not eligible for transplant;

**OR**

- XI. Individual has a diagnosis of Hodgkin Lymphoma (NCCN 2A); **AND**
- XII. Individual is using as monotherapy in subsequent systemic therapy for refractory or relapsed disease (NCCN 2A); **OR**
- XIII. Individual is using as palliative therapy for relapsed/refractory disease in older adults (age > 60 years old) (NCCN 2A);

**OR**

XIV. Individual has a diagnosis of new or relapsed/refractory Systemic Light Chain Amyloidosis (NCCN 2A);

**OR**

XV. Individual has a diagnosis of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome (DrugDex B IIa, NCCN 2A);

**OR**

XVI. Individual has a diagnosis of relapsed/refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) with or without del(17p)/TP53 mutation (NCCN 2A);

**OR**

XVII. Individual has a diagnosis of relapsed or refractory T-Cell Lymphomas (which includes Peripheral T-Cell Lymphoma, Adult T-Cell Leukemia/Lymphoma, and Hepatosplenic Gamma-Delta T-cell Lymphoma) (NCCN 2A);

**OR**

XVIII. Individual has a diagnosis of B-Cell Lymphomas (NCCN 2A); **AND**

XIX. Individual is using as second-line or subsequent therapy; **AND**

A. Individual is using for nongastric or gastric MALT Lymphoma (NCCN 2A); **OR**

B. Individual is using for nodal or splenic Marginal zone Lymphoma (MZL) (NCCN 2A); **OR**

C. Individual is using for histologic transformation of MZL to diffuse Large B-cell lymphoma (NCCN 2A); **OR**

D. Individual is using for High Grade B-Cell Lymphoma or Diffuse Large B-Cell lymphoma (NCCN 2A); **OR**

E. Individual is using for AIDS-Related B-Cell lymphomas (NCCN 2A); **OR**

F. Individual is using for Post-transplant Lymphoproliferative disorders (NCCN 2A); **OR**

G. Individual is using for Castleman's Disease (NCCN 2A);

**OR**

XX. Individual has a diagnosis of Follicular lymphoma (NCCN 2A);

**OR**

XXI. Individual has a diagnosis of Primary Central Nervous System (CNS) Lymphoma (NCCN 2A); **AND**

XXII. Individual is using as induction therapy in patient unable to use high-dose methotrexate;

**OR**

XXIII. Individual has relapsed/refractory disease.

**Note:**

Revlimid (lenalidomide) has black box warnings for embryo-fetal toxicity, hematologic toxicity, and venous and arterial thromboembolism. Revlimid may cause birth defects or embryo-fetal death and should not be used during pregnancy. Exclude pregnancy before starting treatment with 2 negative pregnancy tests. Prevent pregnancy with abstinence or 2 reliable contraception methods, during and for 4 weeks after treatment. To avoid embryo-fetal exposure, Revlimid is only available through a restricted distribution program, the Revlimid REMS program. Revlimid may cause significant neutropenia and thrombocytopenia. When used in individuals with del 5q myelodysplastic syndrome, monitor blood counts weekly for 8 weeks and monthly thereafter. Risk of venous and arterial thromboembolism (DVT, pulmonary embolism, myocardial infarction, and stroke) is significantly increased in individuals with multiple myeloma who are treated with Revlimid and dexamethasone therapy. Thromboprophylaxis is recommended and should be based on underlying risks.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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: September 24, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 24, 2022.
  - a. B-Cell Lymphomas V5.2022. Revised July 12, 2022.
  - b. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma V1.2023. Revised August 30, 2022.
  - c. Hodgkin Lymphoma V1.2023. Revised September 16, 2022.
  - d. Myelodysplastic Syndromes V1.2023. Revised September 12, 2022.
  - e. Myeloproliferative Neoplasms V3.2022. Revised August 11, 2022.
  - f. T-Cell Lymphomas V2.2022. Revised March 7, 2022.
  - g. Kaposi Sarcoma V1.2022. Revised February 3, 2022.
  - h. Histiocytic Neoplasms V1.2022. Revised May 20, 2022.
  - i. Central Nervous System Cancers V1.2022. Revised June 2, 2022.
  - j. Multiple Myeloma V1.2023. Revised September 14, 2022.
  - k. Systemic Light Chain Amyloidosis V1.2023. Revised September 1, 2022.
6. Pourcher V, Desnoyer A, Assoumou L, et al. Phase II Trial of Lenalidomide in HIV-Infected Patients with Previously Treated Kaposi's Sarcoma: Results of the ANRS 154 Lenakap Trial. *AIDS Res Hum Retroviruses*. 2017;33(1):1-10. doi:10.1089/AID.2016.0069.

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