# Revlimid (lenalidomide)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>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 (Label, NCCN 1, 2A); **AND**
II. Individual is using in combination with other agents for multiple myeloma, except for multiple myeloma non-transplant candidates using lenalidomide in combination with isatuximab-irfc, carfilzomib, and dexamethasone; **OR**
III. Individual is using for maintenance treatment;

**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, NCCN 1, 2A); **OR**
VI. Individual is using for anemia associated with MDS/MPN with ring sideroblasts and thrombocytopenia or for symptomatic anemia in lower risk (defined as IPSS-R (Very Low, Low, Intermediate) individuals with or without del(5q) and with or without additional cytogenetic abnormalities (NCCN 2A); **OR**
VII. Individual is using for treatment of MDS/MPN with SF3B1 mutation and thrombocytosis;

**OR**

VIII. Individual has a diagnosis of relapsed or progressive Mantle Cell Lymphoma (Label);

**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; **OR**
XIII. Individual is using after at least 3 prior lines of therapy;

**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); **AND**
- A. Individual is using for subsequent therapy as a single agent or in combination with rituximab (or rituximab biosimilars); **AND**
- B. Individual is using for relapsed or refractory disease after prior therapy with Bruton Tyrosine Kinase (BTK) inhibitor and venetoclax based regimens;

**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); **AND**

XVIII. Individual is using as a single agent;

**OR**

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

XX. Individual is using as second-line or subsequent therapy; **AND**
- A. Individual is using for Extranodal Marginal Zone Lymphoma (EMZL) of the stomach or nongastric sites (noncutaneous) (NCCN 2A); **OR**
- B. Individual is using for nodal or splenic Marginal zone Lymphoma (MZL) (Label, NCCN 2A); **OR**
- C. Individual is using for histologic transformation of indolent lymphomas 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 HIV 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**

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

**OR**

XXII. Individual has a diagnosis of Histiocytic Neoplasms (NCCN 2A); **AND**

XXIII. Individual is using for either Rosai-Dorfman disease or Langerhans Cell Histiocytosis; **AND**

XXIV. Individual is using as a single agent;

**OR**

XXV. Individual has a diagnosis of HIV-Related Kaposi Sarcoma (KS) (NCCN 2A); **AND**
XXVI. Highly active antiretroviral therapy (HAART) has failed to control disease (i.e. stable or increasing KS lesions despite HAART);

**OR**

XXVII. Individual has a diagnosis of Kaposi Sarcoma (Label, NCCN 2A); **AND**
XXVIII. Individual is HIV-negative;

**OR**

XXIX. Individual has a diagnosis of Primary Central Nervous System (CNS) Lymphoma (NCCN 2A); **AND**
XXX. Individual is using as induction therapy in patient unable to use or tolerate high-dose methotrexate; **OR**
XXXI. 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.: 2024. 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: October 7, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 7, 2024.

a. B-Cell Lymphomas V3.2024. Revised August 26, 2024.
b. Castleman Disease. V1.2024. Revised January 18, 2024.
c. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma V1.2025. Revised October 1, 2024.
d. Hodgkin Lymphoma V3.2024. Revised March 18, 2024.
e. Myelodysplastic Syndromes V3.2024. Revised July 25, 2024.
f. Myeloproliferative Neoplasms V2.2024. Revised August 8, 2024.
g. T-Cell Lymphomas V4.2024. Revised May 28, 2024.
h. Kaposi Sarcoma V1.2024. Revised November 7, 2023.
i. Histiocytic Neoplasms V2.2024. Revised July 19, 2024.
j. Central Nervous System Cancers V3.2024. Revised September 30, 2024.
k. Multiple Myeloma V1.2025. Revised September 17, 2024.
l. Systemic Light Chain Amyloidosis V1.2025. Revised September 13, 2024.

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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.