

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 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, NCCN 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 has a diagnosis of Myelofibrosis associated anemia (NCCN 2A);

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 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); **AND**

- A. Individual is using for relapsed or refractory disease after prior therapy with Bruton Tyrosine Kinase (BTK) inhibitor- and venetoclax-based regimens without del(17p)/TP53 mutation; **OR**
- B. Used for second line and subsequent therapy with del(17p)/TP53 mutation;

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 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) (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

XX. Individual has a diagnosis of Follicular lymphoma (grade 1-2) (NCCN 2A);

OR

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

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

XXIII. Individual is using as a single agent;

OR

XXIV. Individual has a diagnosis of HIV-Related Kaposi Sarcoma (KS) (NCCN 2A); **AND**

XXV. Highly active antiretroviral therapy (HAART) has failed to control disease (i.e. stable or increasing KS lesions despite HAART);

OR

XXVI. Individual has a diagnosis of Kaposi Sarcoma (Label, NCCN 2A); **AND**

XXVII. Individual is HIV-negative;

OR

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

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

OR

XXX. 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.: 2023. 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 5, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 5, 2023.
 - a. B-Cell Lymphomas V5.2023. Revised July 7, 2023.
 - b. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma V3.2023. Revised June 12, 2023.
 - c. Hodgkin Lymphoma V2.2023. Revised November 8, 2022.
 - d. Myelodysplastic Syndromes V1.2023. Revised September 12, 2022.
 - e. Myeloproliferative Neoplasms V2.2023. Revised August 29, 2023.
 - f. T-Cell Lymphomas V1.2023. Revised January 5, 2023.
 - g. Kaposi Sarcoma V2.2023. Revised October 3, 2023.
 - h. Histiocytic Neoplasms V1.2023. Revised August 11, 2023.

- i. Central Nervous System Cancers V1.2023. Revised March 24, 2023.
 - j. Multiple Myeloma V1.2024. Revised September 14, 2023.
 - k. Systemic Light Chain Amyloidosis V2.2023. Revised November 28, 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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