

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Revlimid (lenalidomide)

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

Medications	Quantity Limit
Revlimid (lenalidomide)	May be subject to quantity limit; *Requests for increased quantities may be approved for 1 month only when the request is for a 5mg dose that is being titrated to 10 mg.

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 dexamethasone (with or without another agent);

OR

- III. Individual has a diagnosis of multiple myeloma; **AND**
- IV. Individual is using for maintenance treatment following autologous hematopoietic stem cell transplantation (Auto-HSCT);

OR

- V. Individual is using for maintenance treatment in a non-transplant candidate (NCCN 2A);

OR

- VI. Individual has a diagnosis of Myelodysplastic Syndrome; **AND**
- VII. Individual is using for transfusion-dependent anemia associated with low or intermediate 1-risk myelodysplastic syndromes (MDS) associated with a deletion of 5q cytogenetic abnormality (and test results are confirmed), with or without additional cytogenetic abnormalities (Label);

OR

- VIII. Individual is using for initial treatment in lower risk patients with symptomatic anemia with or without del(5q) (and test results confirmed) and with or without additional cytogenetic abnormalities (NCCN 2A);

OR

- IX. Individual has a diagnosis of Myelofibrosis(NCCN 2A);

OR

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- X. Individual has a diagnosis of Mantle Cell Lymphoma; **AND**
 XI. Individual has relapsed or progressive disease after 2 prior therapies, including bortezomib (Label, NCCN 2A);

OR

- XII. Individual has a diagnosis of Mantle Cell Lymphoma; **AND**
 XIII. 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

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

OR

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

OR

- XVIII. Individual has POEMS syndrome (DrugDex B IIa);

OR

- XIX. Individual has a diagnosis of relapsed/refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) with or without del(17p)/TP53 mutation and test results are confirmed (NCCN 2A);

OR

- XX. Individual has a diagnosis of T-Cell Lymphomas (which includes Peripheral T-Cell Lymphoma, Mycosis Fungoides/Sezary syndrome, primary cutaneous CD30+ T-Cell Lymphoproliferative disorder, Adult T-Cell Leukemia/Lymphoma, and Hepatosplenic Gamma-Delta T-cell Lymphoma) (NCCN 2A);

OR

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

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

XXIII. Individual has a diagnosis of Follicular Lymphoma (NCCN 2A);

OR

XXIV. Individual has a diagnosis of relapsed/refractory Primary Central Nervous System Lymphoma (NCCN 2A).

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:

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1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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 10, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 10, 2019.
 - a. Multiple Myeloma V2.2020. Revised October 9, 2019
 - b. B-Cell Lymphomas V5.2019. Revised September 23, 2019.
 - c. Central Nervous System Cancers V2.2019. Revised September 16, 2019.
 - d. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma V2.2020. Revised October 8, 2019.
 - e. Hodgkin Lymphoma V2.2019. Revised July 15, 2019.
 - f. Myelodysplastic Syndromes V1.2020. Revised August 27, 2019.
 - g. Myeloproliferative Neoplasms V3.2019. Revised September 4, 2019.
 - h. Primary Cutaneous Lymphomas V2.2019. Revised December 17, 2018.
 - i. Systemic Light Chain Amyloidosis V1.2019. Revised October 26, 2018.
 - j. T-Cell Lymphomas V2.2019. Revised December 17, 2018.

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