UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Revlimid

Program	Prior Authorization
Medication	Revlimid® (lenalidomide)
Markets in Scope	Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, California, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Revlimid® (lenalidomide) is a thalidomide analogue indicated for the treatment of adult patients with multiple myeloma (MM), in combination with dexamethasone; MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT); transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities; mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib; previously treated follicular lymphoma (FL), in combination with a rituximab product; and previously treated marginal zone lymphoma (MZL), in combination with a rituximab product.

The National Cancer Comprehensive Network (NCCN) also recommends use of Revlimid for treatment of the following B-Cell lymphomas: histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, mantle cell lymphoma, nodal marginal zone lymphoma, follicular lymphoma (grade 1-2), nongastric MALT lymphoma (noncutaneous), Castleman's Disease, gastric MALT lymphoma, high-grade B-cell lymphoma, splenic marginal zone lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, and AIDS-related B-cell lymphomas. NCCN additionally recommends the use of Revlimid in treatment for AIDS-related Kaposi Sarcoma, primary CNS lymphoma, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), MDS/MPN overlap neoplasms, myelofibrosis, primary cutaneous CD30+ T-cell lymphoproliferative disorders, mycosis fungiodes/Sezary Syndrome, systemic light chain amyloidosis, classical Hodgkin lymphoma, and the following T-cell lymphomas: hepatosplenic gamma-delta T-cell lymphoma, peripheral T-cell lymphoma, and Adult T-cell leukemia/lymphoma.

Because of the risk of serious malformations if given during pregnancy, the manufacturer has an extensive risk management program requiring registration by patients, prescribers and dispensing pharmacies. Additional information about the Revlimid Risk Evaluation and Mitigation Strategy (REMS) [Revlimid REMS ®] program may be found at http://www.revlimidrems.com/.

Revlimid contains a black boxed warning for embryo fetal toxicity, hematologic toxicity and venous and arterial thromboembolism. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. Multiple Myeloma

1. Initial Authorization

a. Revlimid will be approved based on the following criterion:

(1) Diagnosis of multiple myeloma

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

B. Myelodysplastic Syndromes (MDS)

1. Initial Authorization

a. Revlimid will be approved based on **one** of the following criteria:

(1) Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated **with** a deletion 5q

-OR-

(2) **Both** of the following:

(a) Diagnosis of anemia due to myelodysplastic syndrome **without** deletion 5q

-AND-

(b) **One** of the following:

i. Serum erythropoetin levels > 500 mU/mL

-OR-

ii. **Both** of the following:

- **Both** of the following:
  - Serum erythropoetin levels ≤ 500 mU/mL
  - Ring sideroblasts < 15%

-AND-

- **One** of the following:
  - Revlimid therapy is in combination with an erythropoietin [e.g., Epogen, Procrit, Retacrit (epoetin alfa)]
  - History of failure, contraindication, or intolerance to erythropoietins [e.g., Epogen, Procrit, Retacrit (epoetin alfa)]

-OR-

iii. **All** of the following:

- Serum erythropoetin levels ≤ 500 mU/mL
- Ring sideroblasts ≥15%
- No response to an erythropoietin in combination with a granulocyte-colony stimulating factor (G-CSF)

-OR-

(3) **Both** of the following:

(a) Diagnosis of MDS/MPN overlap neoplasm

-AND-

(b) Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

C. B-Cell Lymphomas

1. Initial Authorization

a. Revlimid will be approved based on **one** of the following:

(1) **One** of the following diagnoses:

- Mantle cell lymphoma (MCL)
- Diffuse large B-cell lymphoma (patients 60 to 80 years old)
- Follicular lymphoma
- Gastric MALT lymphoma
- Nodal marginal zone lymphoma
- Non-gastric MALT lymphoma
- Splenic marginal zone lymphoma

-OR-

(2) **Both** of the following:

(a) **One** of the following diagnoses:

i. AIDS-related B-cell lymphoma
ii. Castleman's Disease (CD)
iii. Diffuse large B-cell lymphoma (patients who are < 60 years old)
iv. High-grade B-cell lymphoma
v. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
vi. Post-transplant lymphoproliferative disorders

-AND-

(b) **Not** used as first line therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

D. Myelofibrosis-Associated Anemia

1. Initial Authorization

a. Revlimid will be approved based on **both** of the following criteria:

(1) Diagnosis of myelofibrosis

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. Serum erythropoietin levels < 500 mU/mL

-AND-

ii. History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]

-OR-

(b) Serum erythropoietin levels ≥ 500 mU/mL

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Documentation that member has evidence of symptom improvement or reduction in spleen/liver volume while on Revlimid

Authorization will be issued for 12 months.

E. Hodgkin Lymphoma

1. Initial Authorization

a. Revlimid will be approved based on **all** of the following criterion:

(1) Diagnosis of Hodgkin lymphoma

-AND-

(2) Disease is **one** of the following:

(a) Relapsed
(b) Refractory

-AND-

(3) Used as third-line or subsequent therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

F. Systemic Light Chain Amyloidosis

1. Initial Authorization

a. Revlimid will be approved based on the following criterion:

(1) Diagnosis of systemic light chain amyloidosis

-AND-

(2) **One** of the following:

(a) Used in combination with dexamethasone
(b) Used in combination with dexamethasone and cyclophosphamide

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

G. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

1. Initial Authorization

a. Revlimid will be approved based on the following criteria:

(1) **Both** of the following:

(a) Diagnosis of chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL)

-AND-

(b) **One** of the following:

i. Used post first-line chemoimmunotherapy maintenance therapy
ii. Used post second-line maintenance therapy
iii. Used for relapsed or refractory disease

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

H. Primary Cutaneous Lymphomas

1. Initial Authorization

a. Revlimid will be approved based on **one** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Mycosis Fungoides (MF) / Sezary Syndrome (SS)

(b) Primary cutaneous CD30+ T-cell lymphoproliferative disorders

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

I. T-Cell Lymphomas

1. Initial Authorization

a. Revlimid will be approved based on the following criteria:

(1) **Both** of the following:

(a) **One** of the following diagnoses:

(1) Peripheral T-cell lymphoma
(2) T-cell leukemia / lymphoma
(3) Hepatosplenic gamma-delta T-cell lymphoma

-AND-

(b) **Not** used as first line therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

J. Central Nervous System Cancers – Primary CNS Lymphomas

1. Initial Authorization

a. Revlimid will be approved based on the following criterion:

(1) Diagnosis of primary central nervous system lymphoma

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

K. AIDS-Related Kaposi Sarcoma

1. Initial Authorization

a. Revlimid will be approved based on the following criterion:

(1) Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

(2) Patient is currently being treated with antiretroviral therapy (ART)

-AND-

(3) **Not** used as first line therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Revlimid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Revlimid therapy

Authorization will be issued for 12 months.

L. NCCN Recommended Regimens

1. Initial Authorization

a. **Revlimid** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Revlimid** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Revlimid therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Revlimid [package insert]. Summit, NJ: Celgene Corporation; October 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 15, 2020.

Program	Prior Authorization - Revlimid (lenalidomide)
Change Control	
Date	Change
5/2016	New program.
5/2017	Removed try/fail of immunosuppressants from MDS. Added criteria to MF associated anemia per NCCN guidelines. Removed progressive solitary plasmacytoma and smoldering myeloma, added nodal marginal zone lymphoma per NCCN. Reordered NHL diagnoses to separate second line use and first line use. Updated background and references.
5/2018	Revised criteria for NHL, added criteria for histological transformation of marginal zone lymphoma to diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, and primary CNS lymphoma. Added NCCN recommended regimen language. Updated background and references.
5/2019	Reformatted coverage criteria indications to align with NCCN guidelines. Revised criteria for myelodysplastic syndromes. Added criteria for high-grade B-cell lymphoma and gamma-delta

	T-cell lymphoma. Updated background and references.
5/2020	Annual review. Reformatted coverage criteria indications to align with NCCN guidelines. Added criteria for AIDs related Kaposi Sarcoma and MDS/MPN overlap neoplasm according to NCCN guidelines. Clarified criteria for CLL/SLL, T-cell lymphoma, and primary CNS lymphoma according to NCCN guidelines.