UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Revlimid

Program	Prior Authorization
Medication	Revlimid® (lenalidomide)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2017
Effective Date	7/2017

1. Background:

Revlimid® (lenalidomide) is a thalidomide analogue indicated for the treatment of transfusion-dependent anemia due to low- or intermediate-1 risk myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. It is indicated for treatment of multiple myeloma in combination with dexamethasone, or as maintenance following autologous hematopoietic stem cell transplantation (auto-HCST). It is also indicated for treatment of mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.[1]

The National Cancer Comprehensive Network (NCCN) also recommends use of Revlimid for treatment of the following non-Hodgkin lymphoma (NHL) conditions: AIDS-related B-cell lymphoma, Castleman's disease (CD), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), diffuse large B-cell lymphoma, follicular Lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, primary cutaneous B-cell lymphoma, splenic marginal zone lymphoma, Mycosis Fungoides (MF) / Sezary Syndrome (SS), nodal marginal zone lymphoma, peripheral T-cell lymphoma, T-cell lymphoma / leukemia, and primary cutaneous CD30+ T-cell lymphoproliferative disorders.[2] NCCN additionally recommends the use of Revlimid in treatment for systemic light chain amyloidosis, and classical Hodgkin lymphoma. Additional evidence supports the use of Revlimid in myelofibrosis.[3,5-6]

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/.[4]

2. Coverage Criteria:

A. <u>Myeloma</u>

1. <u>Initial Authorization</u>

a. Revlimid will be approved based on **<u>one</u>** of 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 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 (off-label)

-AND-

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

i. Serum erythropoetin levels >500 mU/mL

-OR-

ii. **Both** of the following:

- Serum erythropoetin levels ≤ 500 mU/mL

-AND-

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

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. Non-Hodgkin's Lymphomas (NHL)

1. Initial Authorization

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

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

(a) Diagnosis of relapsed, refractory, or progressed mantle cell lymphoma (MCL)

-AND-

(b) History of failure, contraindication, or intolerance to at least one prior MCL therapies [e.g. Velcade (bortezomib), Treanda (bendamustine), cladribine, Rituxan (rituximab)]

-OR-

(2) **Both** of the following [off-label]:

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

i. AIDS-related B-cell lymphoma
ii. Castleman's Disease (CD)
iii. Chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL)
iv. Diffuse large B-cell lymphoma
v. Peripheral T-cell lymphoma
vi. Primary cutaneous CD30+ T-cell lymphoproliferative disorders
vii. T-cell leukemia / lymphoma

-AND-

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

-OR-

(3) Diagnosis of **one** of the following [off-label]:

(a) Follicular lymphoma
(b) Gastric MALT lymphoma
(c) Mycosis Fungoides (MF) / Sezary Syndrome (SS)
(d) Nodal marginal zone lymphoma
(e) Nongastric MALT lymphoma
(f) Primary cutaneous B-cell lymphoma
(g) Splenic marginal zone 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.

D. Myelofibrosis-Associated Anemia [off-label]

1. Initial Authorization

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

(1) Diagnosis of primary 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 [off-label]

1. Initial Authorization

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

(1) Diagnosis of Hodgkin 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.

F. Systemic Light Chain Amyloidosis [off-label]

1. Initial Authorization

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

(1) Diagnosis of systemic light chain amyloidosis [off-label]

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.

3. References:

1. Revlimid [package insert]. Summit, NJ: Celgene Corporation; February 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed February 28, 2017.
3. Lenalidomide. In:*DRUGDEX*® System (Micromedex 2.0) [Intranet]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Accessed February 28, 2017.
4. Revlimid REMS™. Available at http://www.revlimidrems.com/. Accessed February 28, 2017.
5. Jabbour E, Thomas D, Kantarjian H, et al. Comparison of thalidomide and lenalidomide as therapy for myelofibrosis. Blood. 2011 Jul 28;118(4):899-902.
6. Quintás-Cardama A, Kantarjian HM, Manshouri T, et al. Lenalidomide plus prednisone results in durable clinical, histopathologic, and molecular responses in patients with myelofibrosis. J Clin Oncol. 2009 Oct 1;27(28):4760-6.

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.