Clinical Pharmacy Program Guidelines for Revlimid

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<td>Approval Date</td>
<td>5/2016</td>
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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, and 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), 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, progressive solitary plasmacytoma, smoldering myeloma, 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. **Myeloma**

1. **Initial Authorization**

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

(1) Multiple myeloma
(2) Progressive solitary plasmacytoma [off-label]  
(3) Smoldering myeloma [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.**

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. **All** of the following:
   
   • Serum erythropoetin levels ≤ 500 mU/mL
   -AND-

   • History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]
   -AND-
History of failure, contraindication, or intolerance to initial treatment with immunosuppressive therapy [e.g., antithymocyte globulin [ATG], Neoral/Sandimmune/Gengraf (cyclosporine)]

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. bortezomib, bendamustine, cladribine, rituximab)

      -OR-

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

      (a) One of the following diagnoses:

         i. AIDS-related B-cell lymphoma
         ii. Diffuse large B-cell lymphoma
         iii. Chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL)
         iv. Follicular lymphoma
         v. Gastric MALT lymphoma
         vi. Nongastric MALT lymphoma
vii. Primary cutaneous B-cell lymphoma
viii. Splenic marginal zone lymphoma
ix. Castleman’s Disease (CD)
x. T-cell leukemia / lymphoma
xi. Peripheral T-cell lymphoma
xii. Mycosis fungoides (MF) / Sezary Syndrome (SS)

-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 [off-label]

1. Initial Authorization

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

(1) Diagnosis of myelofibrosis

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 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:**


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