Commercial/Healthcare Exchange PA Criteria

Effective: May 4, 2016

Prior Authorization: Revlimid

Products Affected: Revlimid (lenalidomide) oral capsules

Medication Description:

Revlimid, a thalidomide analog, is an immunomodulatory agent with antiangiogenic and antineoplastic properties. Revlimid inhibits proliferation and induces apoptosis of certain tumor cells including multiple myeloma, mantle cell lymphoma, and del (5q) myelodysplastic sydromes *in vitro*. The immunomodulatory properties of Revlimid include activation of T cells and natural killer (NK) cells, increased number of NKT cells, and inhibition of pro-inflammatory cytokines (TNF-α and IL-6) by monocytes. In multiple myeloma, Revlimid, in combination with dexamethasone, synergizes the inhibition of cell proliferation and the induction of apoptosis.

Revlimid is indicated, in combination with dexamethasone, for the treatment of patients with multiple myeloma.

Revlimid is also indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a 5q cytogenic abnormality with or without additional cytogenic abnormalities.

Revlimid is also indicated for the treatment of patients with mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, once of which included Velcade (bortezomib).

Revlimid is also indicated for previously treated follicular lymphoma (FL), in combination with a rituximab product.

Revlimid is also indicated for previously treated marginal zone lymphoma (MZL), in combination with a rituximab product.

Revlimid has a Black Box Warning regarding embryofetal toxicity, hematologic toxicity, and venous thromboembolism. Revlimid is only available through a restricted distribution program; Revlimid Risk Evaluation Mitigation Strategy (REMS). Both male and female patients must follow the required reproductive precautions.

Covered Uses:

1. **Mantle cell lymphoma.** Approve if the patient meets ONE of the following criteria:
   - ***a.*** Patient has tried two prior therapies or therapeutic regimens, one of which included Velcade (bortezomib)
   - ***b.*** Patient has tried one prior therapy or therapeutic regimen and has a contraindication to Velcade
2. **Multiple myeloma.** Approve if the patient is using Revlimid in combination with dexamethasone or Revlimid is being used as maintenance therapy following autologous hematopoietic stem cell transplantation
3. **Myelodysplastic syndromes.** Approve if the patient meets ONE of the following criteria:
   - ***a.*** Patient does not have 5q deletion but has symptomatic anemia; OR
   - ***b.*** Patient has low- or intermediate-risk MDS with 5q deletion and has transfusion-dependent anemia; OR
   - ***c.*** Patient has anemia that is not controlled with an erythroid stimulating agent (ESA) [e.g., Epogen/Procrit {epoetin alfa}, Aranesp {darbepoetin alfa}]
4. **Follicular Lymphoma.** Approve if patient has previously treated follicular lymphoma, in combination with a rituximab product.
5. **Marginal Zone Lymphoma.** Approve if patient has previously treated marginal zone lymphoma, in combination with a rituximab product.

Exclusion Criteria:

Revlimid has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances.

1. For Multiple myeloma: treatment naïve patients
2. For MDS: use without dexamethasone

Required Medical Information:

1. MDS: 5q deletion status
2. Multiple myeloma: in combination with dexamethasone
3. Prior therapies tried
4. Dose and frequency

Age Restrictions: None

Prescriber Restrictions: None

Coverage Duration:
Initial: 12 months
Continuation: 3 years

Other Criteria:

1. **Multiple myeloma**
   A) The patient has Multiple myeloma; AND
   B) The patient is using Revlimid in combination with dexamethasone or Revlimid is being used as maintenance therapy following autologous hematopoietic stem cell transplantation
2. **Myelodysplastic syndromes**
   A) The patient as Myelodysplastic syndromes; AND
   B) The patient has transfusion-dependent anemia and is at low- or intermediate-1 -risk with deletion 5q abnormality or patient has anemia that is not controlled with an erythroid stimulating agent (ESA)
3. **Mantle Cell Lymphoma**
   A) The patient has Mantle cell lymphoma
   B) The patient has relapsed or progressed after two prior therapies, one of which is Velcade (bortezomib)
4. **Follicular Lymphoma**
   A) The patient has previously treated follicular lymphoma
   B) Revlimid will be used in combination with a rituximab product
5. **Marginal Zone Lymphoma**
   A) The patient has previously treated marginal zone lymphoma
   B) Revlimid will be used in combination with a rituximab product

References:

1. Revlimid [prescribing information]. Summit, NJ: Celgene; March 2016.
2. NCCN Clinical Practice Guidelines in Oncology, Multiple Myeloma v.3.2015. Accessed on March 2, 2016.
3. NCCN Clinical Practice Guidelines in Oncology, Myelodysplastic Syndromes v.2.2015. Accessed on March 2, 2016.
4. NCCN Clinical Practice Guidelines in Oncology, Non-Hodgkin's Lymphomas v.1.2015. Accessed on March 2, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/02/2016
2	Addition of indication	Multiple myeloma – added use of Revlimid as maintenance therapy following autologous hematopoietic stem cell transplantation	Other criteria	11/9/2017
3	Update	Updated Indications and criteria to match FDA label (FL, MZL)	Medication Description, Covered Uses, Other Criteria	5/31/2019
4	Update	Updated Coverage duration to 3 years for continuation	Coverage Duration	7/1/2019