



## LENALIDOMIDE (REVLIMID®) UTILIZATION MANAGEMENT CRITERIA

<b>DRUG CLASS:</b>	<b>Immunomodulators</b>
<b>Generic (Brand) Name:</b>	Lenalidomide (Revlimid) 5mg; 10mg; 15mg; 25mg capsules

### FDA-APPROVED INDICATIONS:

- **Multiple Myeloma:** in combination with dexamethasone in patients who have received at least 1 prior therapy.
- **Myelodysplastic Syndrome (MDS):** for the treatment of patients with transfusion-dependent anemia because of low or intermediate-1-risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

### COVERAGE AUTHORIZATION CRITERIA for lenalidomide (Revlimid):

#### Lenalidomide (Revlimid) is covered for the following conditions:

- Treatment of patients with transfusion-dependent anemia due to low or intermediate-1-risk myelodysplastic syndrome with confirmation of 5-q deletion
- Treatment of patients with multiple myeloma in combination with dexamethasone
- Maintenance treatment of multiple myeloma following induction chemotherapy

### BOXED WARNING: FETAL RISK, HEMATOLOGIC TOXICITY, AND DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM

#### Fetal Risk

- Lenalidomide, a thalidomide analogue, caused limb abnormalities in a developmental monkey study similar to birth defects caused by thalidomide in humans. If lenalidomide is used during pregnancy, it may cause birth defects or death to a developing baby.
- Pregnancy must be excluded before start of treatment. Prevent pregnancy during treatment by the use of two reliable methods of contraception.
- Revlimid is available only under a restricted distribution program called "RevAssist."

#### Hematologic Toxicity

- Revlimid can cause significant neutropenia and thrombocytopenia. For patients with del 5q myelodysplastic syndromes, monitor complete blood counts weekly for the first 8 weeks and monthly thereafter.

#### Deep Vein Thrombosis and Pulmonary Embolism

- Significantly increased risk of DVT and PE in patients with multiple myeloma receiving Revlimid with dexamethasone.

### DOSAGE:

**Multiple Myeloma:** Starting dose: 25 mg/day with water orally administered as a single 25 mg capsule on days 1 through 21 of repeated 28-day cycles. Decrease dose to manage Grade 3 or

4 neutropenia or thrombocytopenia or other Grade 3 or 4 toxicity judged to be related to Revlimid.

**Myelodysplastic Syndrome:** Starting dose: 10 mg daily with water. Adjust dose according to platelet or neutrophil counts, or for renal impairment.

## **REFERENCES:**

Drug Facts and Comparisons eAnswers. Wolters Kluwer. Accessed March 2011.

Revlimid. DRUGDEX Evaluations. Micromedex 2.0. Thomson Reuters. March 2011.

Revlimid® (Lenalidomide) prescribing information. Celgene Corporation. Summit, NJ. August 2010.