



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** Lenalidomide

**Brand Name:** Revlimid

**Medication Class:** Immunomodulator

**FDA Approved Uses:**

- Transfusion dependent anemia due to low or intermediate risk **myelodysplastic syndromes (MDS)** associated with deletion 5q cytogenetic abnormality with or without additional chromosomal abnormalities.
- In combination with dexamethasone for the treatment of **multiple myeloma (MM)** who have received at least one prior therapy.

**Available Dosage Forms:** 5mg, 10mg, 15mg, and 25mg capsules

**Usual Dose:**

- MDS: 10mg daily for 21 days out of 28 days or 10mg daily.
- MM: 25 mg daily for 21 days out of 28 days along with dexamethasone 40mg/day on days 1-4, 9-12, and 17-20.

**Duration of Therapy:** Depends on response to therapy

**Approximate monthly cost** (based on AWP 200): \$8,652.00 for 10mg daily for 28 days  
\$10,612.00 for 25 mg daily for 28 days

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

Myelodysplastic Syndromes (MDS):

- Prescribed by an oncologist or a hematologist.
- Clinically diagnosed low to intermediate risk MDS associated with deletion 5q cytogenetic abnormality with or without additional chromosomal abnormalities.
- Transfusion dependent anemia (2 or more units of RBC every 8 weeks).

Or

- Symptomatic anemia with hgb less than 10g/dl
- Absolute neutrophil count (ANC) of at least 500/ml.
- Platelet count of at least 50,000/ml.
- Serum creatinine  $\leq$  2.5 mg/dl.

Multiple Myeloma (MM):

- Prescribed by an oncologist or a hematologist.
- Clinically diagnosed MM
- Failed or intolerant to at least on prior treatment
- Must be receiving concurrent treatment with dexamethasone.
- Absolute neutrophil count (ANC) of at least 500/ml.
- Platelet count of at least 50,000/ml.



- Serum creatinine  $\leq$  2.5 mg/dl.

**Criteria for Continuation of Therapy:**

Myelodysplastic Syndromes (MDS):

(will be approved for 3 months at a time and the following information must be provided for continuation of therapy)

- Transfusion independence or decrease in need.
- Cytogenic response. (50% or greater reduction in abnormal metaphases)

Multiple Myeloma (MM):

- Response to therapy without disease progression.

**Cautions:**

- Neutropenia and thrombocytopenia have been reported with lenalidomide therapy. If either occurs, the next dose should be decreased or delayed.

**Monitoring** (refer to table):

- Hematologic parameters (white blood cell counts and platelet counts) should be closely monitored weekly for the first 8 weeks and then monthly thereafter.

**Contraindications:**

- History of hypersensitivity to lenalidomide or any of the other ingredients in the product formulation.

**Not Approved if:**

- Patient has any contraindications to the use of lenalidomide.
- Patient does not meet the above stated criteria.

**Special Considerations:**

-in one MDS study approximately 80% of patients required dosage reductions or dose delays because of adverse reactions.

- The dose of lenalidomide was reduced or interrupted at least once due to an adverse event in 118 (79.7%) of the 148 MDS patients.

-lenalidomide (Revlimid) is related to thalidomide

-Lacks the neurotoxic and teratogenic effects of thalidomide.

-It's role in treating other subtypes of MDS is under investigation.

-Revlimid is only available through the RevAssist program and specialty pharmacy vendors.



**Dose adjustments for Myelodysplastic Syndromes (MDS):**

**Platelet Counts**

**If thrombocytopenia develops WITHIN 4 weeks of starting treatment at 10 mg daily**

<i>Platelets</i>	<i>Recommended Course</i>
Fall to <50,000/mcl	Interrupt Revlimid treatment
Return to $\geq$ 50,000/mcl	Resume Revlimid at 5mg daily
Fall to 50% of baseline value	Interrupt Revlimid treatment
If baseline $\geq$ 60,000/mcl and returns to $\geq$ 50,000/mcl	Resume Revlimid at 5mg daily
If baseline < 60,000/mcl and returns to $\geq$ 30,000/mcl	Resume Revlimid at 5mg daily

**If thrombocytopenia develops AFTER 4 weeks of starting treatment at 10 mg daily**

<i>Platelets</i>	<i>Recommended Course</i>
< 30,000/mcl or < 50,000/mcl and platelet transfusions	Interrupt Revlimid treatment
return to $\geq$ 30,000/mcl (without hemostatic failure)	Resume Revlimid at 5mg daily

**If thrombocytopenia develops DURING treatment at 5 mg daily**

<i>Platelets</i>	<i>Recommended Course</i>
< 30,000/mcl or < 50,000/mcl and platelet transfusions	Interrupt Revlimid treatment
return to $\geq$ 30,000/mcl (without hemostatic failure)	Resume Revlimid at 5mg daily

**Absolute Neutrophil Counts (ANC)**

**If neutropenia develops WITHIN 4 weeks of starting treatment at 10 mg daily**

<i>Neutrophils</i>	<i>Recommended Course</i>
Fall to < 750/mcl	Interrupt Revlimid treatment
Return to $\geq$ 1,000/mcl	Resume Revlimid at 5mg daily
Fall to < 500/mcl	Interrupt Revlimid treatment
Return to $\geq$ 500/mcl	Resume Revlimid at 5mg daily

**If neutropenia develops AFTER 4 weeks of starting treatment at 10 mg daily**

<i>Neutrophils</i>	<i>Recommended Course</i>
< 500mcl/mcl for $\geq$ 7 days or < 500/mcl associated with fever ( $\geq$ 38.5 C)	Interrupt Revlimid treatment
Return to $\geq$ 500/mcl	Resume Revlimid at 5mg daily

**If neutropenia develops DURING treatment at 5 mg daily**

<i>Neutrophils</i>	<i>Recommended Course</i>
< 500mcl/mcl for $\geq$ 7 days or < 500/mcl associated with fever ( $\geq$ 38.5 C)	Interrupt Revlimid treatment
Return to $\geq$ 500/mcl	Resume Revlimid at 5mg daily



**Dose adjustments for Multiple Myeloma (MM):**

**Platelet Counts**

Dose modification guidelines, as summarized are recommended to manage Grade 3 or 4 neutropenia or thrombocytopenia or other Grade 3 or 4 toxicity judged to be related to lenalidomide.

<i>Platelets</i>	<i>Recommended Course</i>
Fall to <30,000/mcl	Interrupt Revlimid treatment, follow CBC weekly
Return to $\geq$ 30,000/mcl	Restart Revlimid at 15mg daily
For each subsequent drop < 30,000/mcl	Interrupt revlimid treatment
For each subsequent return to $\geq$ 30,000/mcl	Restart Revlimid at 15mg daily

**Neutrophil counts (ANC)**

<i>Neutrophils</i>	<i>Recommended Course</i>
Fall to <1,000/mcl	Interrupt Revlimid treatment, add G-CSF, follow CBC weekly
Return to $\geq$ 1,000/mcl and neutropenia is the only toxicity	Restart Revlimid at 25mg daily
Return to $\geq$ 1,000/mcl and if other toxicity	Restart Revlimid at 15mg daily
For each subsequent drop < 1,000/mcl	Interrupt Revlimid treatment
For each subsequent return to $\geq$ 1,000/mcl	Restart Revlimid at 5mg less than the previous dose. Do not dose below 5 mg daily

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_