I. Medication Description

Revlimid (lenalidomide), a thalidomide analogue, possesses immunomodulatory and antiangiogenic properties and is used in the treatment of several hematologic disorders. Since Revlimid is an analog of thalidomide, it carries similar warnings of potentially causing severe, life-threatening human birth defects. **Lenalidomide is only available under a special restricted distribution program, RevAssistSM.** Prescribers, pharmacists and patients must be registered to prescribe, dispense and receive Revlimid.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Revlimid® is provided for treatment of the following conditions:

- **Myelodysplastic Syndrome (MDS):**
  - If patient has del (5q) chromosomal abnormalities:
    - Symptomatic anemia **AND**
    - Has had 2 or more units of red blood cells in previous 8 weeks
  - If patient has no del (5q) chromosomal abnormalities:
    - Patient has serum Epo > 500 µU/ml with a low probability of response to immunosuppressive therapy or Epo ≤ 500 µU/ml with no response with erythropoietins and no response with or intolerance to immunosuppressives **AND**
    - Patient has symptomatic anemia **AND**
    - Has had 2 or more units of red blood cells in previous 8 weeks

- **Multiple Myeloma:**
  - For induction therapy or as therapy for disease relapse after 6 months following primary chemotherapy with the same regimen:
    - Used in combination with dexamethasone
      - With or without bortezomib, carfilzomib or ixazomib if a transplant candidate **OR**
      - In MPL (melphalan, prednisone, lenalidomide) in combination with bortezomib or in combination with ixazomib for nontransplant candidates
  - For maintenance therapy:
    - As a single agent
• For symptomatic myeloma responding to induction therapy OR
• For stable/responsive disease following stem cell transplant OR
• With second tandem transplant for stable or responsive disease following autologous stem cell transplant
  o For relapse or for progressive, refractory disease:
    ▪ As a single agent for steroid-intolerant patients OR
    ▪ In combination with dexamethasone with or without bortezomib, carfilzomib, or cyclophosphamide OR
    ▪ In combination with elotuzumab and dexamethasone in patients who have received one to three prior therapies OR
    ▪ In combination with bendamustine and dexamethasone OR
    ▪ In combination with ixazomib and dexamethasone in patients who have received at least one prior therapy
• Non-Hodgkin’s Lymphoma:
  o Must be second-line therapy or subsequent therapy with or without rituximab OR
  o For mycosis fungoides (MF)/Sezary syndrome (SS)- used as a single agent for stage IB – IIB MF or stage IV non-Sezary or visceral disease
• Hodgkin Lymphoma:
  o Used as additional therapy as a single agent for refractory or relapsed disease for patients ≥ 18 years of age OR
  o As palliative therapy as a single agent for patients > 60 years of age
• Systemic Light Chain Amyloidosis
  o Used as primary therapy in combination with dexamethasone with or without cyclophosphamide.

IV. Quantity Limitations

• 2.5mg, 5mg, 10mg capsules – 28 capsules covered every 21 days
• 15mg, 20mg, 25mg capsules – 21 capsules covered every 21 days

V. Coverage Duration

Coverage will be provided for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

• Absence of unacceptable toxicity from the drug AND
• Response to therapy has been noted:
  o Myelodysplastic Syndrome: member’s transfusion requirements are reduced OR
  o Multiple Myeloma/ Non-Hodgkin’s Lymphoma: positive tumor response with stabilization of disease or reduction in tumor burden.
VII. **Billing/Coding Information**

Available as 2.5mg, 5mg, 10mg, 15mg, 20mg, and 25mg oral capsules.

VIII. **Summary of Policy Changes**

- 6/15/12: Recommendations for dosage adjustment with renal function and hematologic toxicity added. Baseline platelet and ANC values added to NHL criteria for coverage.
- 6/15/13: updated quantity limits and warnings/contraindications, added additional pertinent ICD9 code information
- 12/15/13: added criteria specific to mantle cell lymphoma
- 7/21/14: coverage criteria for Hodgkin lymphoma added; criteria for mantle cell lymphoma coverage changed to reflect updated NCCN treatment guidelines
- 1/1/15: corrected platelet requirements for coverage in NHL
- 7/1/15: formulary distinctions made
- 12/15/15: addition of coverage for systemic light chain amyloidosis; quantity limits updated for 15mg and 20mg capsules; all criteria updated to conform with current NCCN treatment guidelines.
- 9/15/16: policy updated to correspond with current NCCN treatment guidelines

IX. **References**

1. UpToDate Online, retrieved February 2011
3. Facts and Comparisons Online, retrieved February 2011


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.