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, Revlimid REMS®.** 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 of Revlimid is available when the following criteria have been met:

- Member is at least 18 years of age **AND**
- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

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:
Drug Therapy Guidelines  
Revlimid® (lenalidomide)  
Last Review Date: 9/2017

- Myelodysplastic Syndrome: member’s transfusion requirements are reduced OR
- 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
- 10/16/17: coverage criteria updated to allow use as supported by current NCCN guidelines; RevAssistSM changed to current Revlimid REMS® program

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.

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 medication 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.