Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

REVLIMID (lenalidomide)

GPI CODING:

993940500001**

DESCRIPTION:

Revlimid is an immunomodulatory agent with antineoplastic and antiangiogenic properties. Revlimid is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Revlimid, used in combination with dexamethasone, is also indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.

APPROVAL DURATION:

Approval duration: 1 year

CRITERIA FOR REVLIMID

FDA-Approved Indication(s)

1. Treatment of transfusion-dependent anemia due to low- or intermediate-1 risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality
2. Treatment of multiple myeloma, in combination with dexamethasone, in patients who have received at least one prior therapy

Compendial Uses

1. Multiple myeloma, progressive solitary plasmacytoma or smoldering myeloma that has progressed to symptomatic myeloma:
    a. in combination with dexamethasone as primary induction therapy
    b. in combination with melphalan and prednisone as primary induction therapy in patients who are not candidates for an autologous stem cell transplant
    c. single agent maintenance therapy following stem cell transplant or in those responding to primary induction therapy
    d. salvage or palliative therapy
2. Systemic light chain amyloidosis, with dexamethasone as primary treatment
3. Low or INT-1 risk MDS without
    a. Serum erythropoietin level > 500 mU/mL and a low probability of response to immunosuppressive therapy OR deletion 5q cytogenetic abnormality with symptomatic anemia
    b. No response to initial treatment with epoetin alfa or darbepoetin alfa
4. Low or INT-1 risk MDS with deletion 5q cytogenetic abnormality with symptomatic anemia and clinically significant cytopenias
5. Non-Hodgkin's lymphoma (NHL), for relapsed, refractory or progressive disease as a single agent or in combination with rituximab:
    a. cutaneous B-cell lymphoma
    b. diffuse large B-cell lymphoma
    c. follicular lymphoma

   d. gastric mucosa associated lymphoid tissue (MALT) lymphoma
   e. mantle cell lymphoma
   f. nodal marginal zone lymphoma
   g. nongastric MALT lymphoma
   h. splenic marginal zone lymphoma
6. Chronic lymphocytic leukemia (CLL), for relapsed or refractory disease
7. All others if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.) A use is identified by a compendium as medically accepted if the:
   a. Indication is a Category 1 or 2A in NCCN,
   b. Indication is a Class I, Class IIa or Class IIb in DrugDex,
   c. Narrative text in AHFS or Clinical Pharmacology is supportive; or
   d. The use is supported by clinical research in 2 or more peer-reviewed medical journals

Additional Criteria

1. For female patients of childbearing potential, pregnancy was excluded by 2 negative pregnancy tests and patient was instructed on use of appropriate contraception
2. For male patients and female patients of childbearing potential, patient was instructed on the use of appropriate contraception
3. Patient will be monitored for signs and symptoms of thromboembolism
4. Complete blood count will be monitored regularly