MEDICAL MUTUAL®

Drug Policy

Policy:	Revlimid (lenalidomide)	Annual Review Date: 01/21/2021 Last Revised Date: 01/21/2021

OVERVIEW

Revlimid, a thalidomide analogue, is indicated in combination with dexamethasone for the treatment of patients with multiple myeloma or as maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplant. Revlimid is also indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Revlimid is also indicated for the treatment of patients with mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib injection). Revlimid has a Boxed Warning regarding embryofetal toxicity, hematologic toxicity, and venous and arterial thromboembolism. Revlimid is only available through a restricted distribution program called the Revlimid Risk Evaluation Mitigation Strategy (REMS). Males and females must follow the required reproductive precautions.

POLICY STATEMENT

This policy involves the use of Revlimid. Prior authorization is recommended for pharmacy benefit coverage of Revlimid. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Revlimid as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Revlimid be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Revlimid is recommended in those who meet the following criteria:

1. **Mantle Cell Lymphoma**
   Criteria. *Approve if the patient meets **ONE** of the following (a **or** b):*
   a) The patient has tried two prior therapies or therapeutic regimens, including Velcade (e.g., Velcade; HyperCVAD [cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine] + Rituxan; the NORDIC regimen [dose-intensified induction immunochemotherapy with Rituxan +

cyclophosphamide, vincristine, doxorubicin, prednisone alternating with Rituxan and high-dose cytarabine]; RCHOP/RICE [Rituxan, cyclophosphamide, doxorubicin, vincristine, prednisone]/[Rituxan, Ifex, carboplatin, etoposide]; Treanda plus Rituxan; Velcade ± Rituxan; cladribine + Rituxan; FC (fludarabine, cyclophosphamide) ± Rituxan; PCR [pentostatin, cyclophosphamide, Rituxan]) and Imbruvica; OR

b) The patient has tried one prior therapy or therapeutic regimen (examples listed above) and cannot take Velcade according to the prescribing physician.

2. **Multiple myeloma**
   Criteria. *Approve.*

3. **Myelodysplastic Syndrome (MDS)**
   Criteria. *Approve if the patient meets **ONE** of the following (a, b, **or** c):*
   a) The patient has symptomatic anemia; OR
   b) The patient has transfusion-dependent anemia associated with a deletion 5q abnormality; OR
   c) The patient has anemia that is not controlled with an erythroid stimulating agent (ESA) [e.g., Epogen/Procrit {epoetin alfa injection}, Aranesp {darbepoetin alfa injection}].

4. **Systemic Light Chain Amyloidosis**
   Criteria. *Approve if Revlimid will be used in combination with dexamethasone.*

5. **Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)**
   Criteria. *Approve if the patient has tried one other medication treatment regimen (e.g., R-CHOP, dose-adjusted EPOCH [etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin] + Rituxan, RCEPP [Rituxan, cyclophosphamide, etoposide, prednisone, procarbazine], DHAP [dexamethasone, cisplatin, cytarabine] ± Rituxan, ICE [Ifex, carboplatin, etoposide] ± Rituxan, and Treanda ± Rituxan) OR patient is between 60 to 80 years of age.*

6. **Follicular Lymphoma (Non-Hodgkin's Lymphoma)**
   Criteria. *Approve.*

7. **Classic Hodgkin Lymphoma**
   Criteria. *Approve if the patient meets the following criteria (a b.*
   a. The patient meets ALL the following:
      i. Patient is ≥18 years old; AND
      ii. Patient has relapsed or refractory disease; AND
      iii. Revlimid is being used as third-line or subsequent therapy as a single agent; OR
   b. Patient is receiving palliative therapy as a single agent for older adults (>60 years old).

8. **Myelofibrosis-Associated Anemia**
   Criteria. *Approve if the patient meets the following criteria (a or b):*
   a. Patient's serum EPO is ≥500 mU/mL OR
   b. Patient's with serum EPO is <500 mU/mL and no response or loss of response to erythropoietic stimulating agents

9. **T-Cell Lymphomas (including Peripheral T-Cell Lymphomas, Adult T-Cell Leukemia/Lymphoma, Heptaosplenic T-Cell Lymphoma)**
   Criteria. *Approve.*

10. **Multicentric Castleman's Disease**
    Criteria. *Approve for subsequent therapy if patient has relapsed/refractory or progressive disease.*

11. **Gastric MALT Lymphoma**
    Criteria. *Approve if used in combination with a rituximab product for recurrent or progressive disease.*

12. **Nongastric MALT Lymphoma (Non-Hodgkin's Lymphoma)**
    Criteria. *Approve if treatment as second-line or subsequent therapy for refractory or progressive disease or as first-line therapy in combination with rituximab*

13. **Nodal Marginal Zone Lymphoma**
    Criteria. *Approve.*

14. **Splenic Marginal Zone Lymphoma (Non-Hodgkin's Lymphoma)**
    Criteria. *Approve.*

15. **AIDS-Related B-Cell Lymphomas**
    Criteria. *Approve if second-line or subsequent therapy if the patient is not a candidate for transplant.*

16. **High-Grade B-Cell Lymphoma**
    Criteria. *Approve for second-line or subsequent therapy if the patient is not a candidate for transplant.*

17. **MDS/MPN Overlap Neoplasms**
    Criteria. *Approve.*

18. **Primary Central Nervous System (CNS) Lymphoma**
    Criteria. *Approve.*

19. **Histologic Transformation of Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma**
    Criteria. *Approve.*

20. **Post-Transplant Lymphoproliferative Disorders**
    Criteria. *Approve for second-line or subsequent therapy.*

21. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**
    Criteria. *Approve.*

22. **Mycosis Fungoides/Sezary Syndrome**
Criteria. *Approve.*

23. **Anaplastic Large Cell Lymphoma (ALCL)**
Criteria. *Approve for relapsed/refractory disease as a single agent.*

24. **AIDS-Related Kaposi Sarcoma**
Criteria. *Approve if patient meets the following criteria:*

A. The patient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; AND
B. The patient has progressed on or has not responded to first-line and alternative first-line systemic therapy; AND
C. The patient will continue to use antiretroviral therapy (ART)

25. **Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve*

26. **Patient has been started on Revlimid (continuation of therapy)**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Revlimid® [prescribing information]. Summit, NJ: Celgene; October 2019.
2. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 13 January 2021. Search term: lenalidomide.

3. Lenalidomide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 3 March 2020. Accessed on 13 January 2021.