# SPECIALTY GUIDELINE MANAGEMENT

# **REVLIMID** (lenalidomide)

#### **POLICY**

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## A. FDA-Approved Indications

- 1. Multiple myeloma in combination with dexamethasone.
- 2. Multiple myeloma, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).
- Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
- Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

## B. Compendial Uses

- 1. Multiple myeloma
- 2. Systemic light chain amyloidosis
- 3. Classical Hodgkin lymphoma
- 4. Myelodysplastic syndrome without the 5q deletion cytogenetic abnormality
- 5. Myelofibrosis-associated anemia
- 6. POEMS Syndrome
- 7. Non-Hodgkin lymphoma (NHL) with any of the following subtypes:
  - a. AIDS-related diffuse large B-cell lymphoma
  - b. Primary central nervous system (CNS) lymphoma
  - c. Monomorphic post-transplant lymphoproliferative disorder
  - d. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
  - e. Diffuse large B-cell lymphoma
  - f. Follicular lymphoma
  - g. Nongastric/Gastric mucosa associated lymphoid tissue (MALT) lymphoma
  - h. Primary cutaneous B-cell lymphoma
  - i. Nodal/splenic marginal zone lymphoma
  - j. Multicentric Castleman's disease
  - k. Adult T-cell leukemia/lymphoma
  - I. Mycosis fungoides (MF)/Sezary syndrome (SS)
  - m. Angioimmunoblastic T-cell lymphoma (AITL)
  - n. Peripheral T-cell lymphoma not otherwise specified (PTCL NOS)
  - o. Enteropathy-associated T-cell lymphoma
  - p. Monomorphic epithelotropic intestinal T-cell lymphoma
  - q. Nodal peripheral T-cell lymphoma
  - r. Follicular T-cell lymphoma
  - s. Primary cutaneous anaplastic large cell lymphoma (ALCL)

All other indications are considered experimental/investigational and are not covered benefits.

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## II. CRITERIA FOR INITIAL APPROVAL

## A. Multiple myeloma

Authorization of 12 months may be granted for treatment of multiple myeloma.

## B. Non-Hodgkin lymphoma (NHL)

Authorization of 12 months may be granted for treatment of NHL with any of the following subtypes:

- 1. AIDS-related diffuse large B-cell lymphoma
- 2. Primary central nervous system (CNS) lymphoma
- 3. Monomorphic post-transplant lymphoproliferative disorder
- 2. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
- 3. Diffuse large B-cell lymphoma
- 4. Follicular lymphoma
- 5. Mantle cell lymphoma
- 6. Nongastric/Gastric MALT lymphoma
- 7. Primary cutaneous B-cell lymphoma
- 8. Nodal/splenic marginal zone lymphoma
- 9. Multicentric Castleman's disease
- 10. Primary cutaneous anaplastic large cell lymphoma (ALCL) (monotherapy only)
- 11. Adult T-cell leukemia/lymphoma
- 12. Mycosis fungoides (MF)/Sezary syndrome (SS)
- 13. Angioimmunoblastic T-cell lymphoma (AITL)
- 14. Peripheral T-cell lymphoma not otherwise specified (PTCL NOS)
- 15. Enteropathy-associated T-cell lymphoma
- 16. Monomorphic epitheliotropic intestinal T-cell lymphoma
- 17. Nodal peripheral T-cell lymphoma
- 18. Follicular T-cell lymphoma

#### C. Myelodysplastic syndrome

Authorization of 12 months may be granted for treatment of low- to intermediate-1 risk myelodysplastic syndrome for those with symptomatic anemia.

## D. Myelofibrosis-associated anemia

Authorization of 12 months may be granted for treatment of myelofibrosis-associated anemia.

### E. Systemic light chain amyloidosis

Authorization of 12 months may be granted for treatment of systemic light chain amyloidosis.

### F. Classical Hodgkin lymphoma

Authorization of 12 months may be granted for treatment of classical Hodgkin lymphoma.

#### G. POEMS Syndrome

Authorization of 12 months may be granted for treatment of POEMS syndrome.

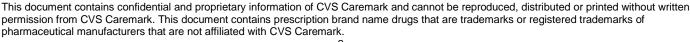
#### **III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

#### IV. REFERENCES

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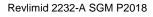
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