Reference number(s)
2232-A

SPECIALTY GUIDELINE MANAGEMENT

REVLIMID (lenalidomide)
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).
3. 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.
4. Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.
5. Previously treated follicular lymphoma, in combination with a rituximab product
6. Previously treated marginal zone lymphoma, in combination with a rituximab product

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 (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
7. Myelodysplastic syndrome/myeloproliferative neoplasms
8. T-cell Lymphomas
    a. Peripheral T-Cell Lymphomas not otherwise specified
    b. Angioimmunoblastic T-cell lymphoma (AITL)
    c. Enteropathy-associated T-cell lymphoma
    d. Monomorphic epitheliotropic intestinal T-cell lymphoma
    e. Nodal peripheral T-cell lymphoma
    f. Follicular T-cell lymphoma
    g. Adult T-cell leukemia/lymphoma
    h. Hepatosplenic T-cell lymphoma
9. Primary central nervous system (CNS) lymphoma
10. Primary Cutaneous Lymphomas
    a. Mycosis fungoides (MF)/Sezary syndrome (SS)
    b. Primary cutaneous anaplastic large cell lymphoma (ALCL)
11. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
12. B-Cell Lymphomas

a. AIDS-related non-germinal center diffuse large B-cell lymphoma
b. Monomorphic post-transplant lymphoproliferative disorder
c. Diffuse large B-cell lymphoma
d. Follicular lymphoma
e. Marginal zone lymphoma with any of the following subtypes: Nongastric/Gastric mucosa associated lymphoid tissue (MALT) lymphoma, splenic/nodal marginal zone lymphoma
f. Multicentric Castleman's disease
g. High-grade B-cell lymphomas
h. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
i. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma

13. Kaposi Sarcoma
14. Smoldering myeloma
15. Langerhans cell histiocytosis

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple myeloma

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

B. T-cell Lymphomas

Authorization of 12 months may be granted for treatment of T-cell lymphoma with any of the following subtypes:

1. Peripheral T-Cell Lymphomas not otherwise specified second line, initial palliative therapy, or subsequent therapy.
2. Angioimmunoblastic T-cell lymphoma (AITL), second line, initial palliative therapy, or subsequent therapy.
3. Enteropathy-associated T-cell lymphoma second line, initial palliative therapy, or subsequent therapy.
4. Monomorphic epitheliotropic intestinal T-cell lymphoma second line, initial palliative therapy, or subsequent therapy.
5. Nodal peripheral T-cell lymphoma second line, initial palliative therapy, or subsequent therapy.
6. Follicular T-cell lymphoma second line, initial palliative therapy, or subsequent therapy.
7. Adult T-cell leukemia/lymphoma, second-line or subsequent therapy.
8. Hepatosplenic T-cell lymphoma, second-line or subsequent therapy.

C. Primary central nervous system (CNS) lymphoma

Authorization of 12 months may be granted for treatment of primary central nervous system (CNS) lymphoma as a single agent or in combination with rituximab.

D. Primary Cutaneous Lymphomas

Authorization of 12 months may be granted for treatment of primary cutaneous lymphoma with any of the following subtypes:

1. Mycosis fungoides (MF)/Sezary syndrome (SS)
2. Primary cutaneous anaplastic large cell lymphoma (ALCL), relapsed or refractory as a single agent.

E. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

Authorization of 12 months may be granted for treatment of CLL/ SLL.

F. B-Cell Lymphomas

Authorization of 12 months may be granted for treatment of B-cell lymphoma with any of the following subtypes:

1. AIDS-related non-germinal center diffuse large B-cell lymphoma, second-line or subsequent therapy.
2. Monomorphic post-transplant lymphoproliferative disorder, second-line or subsequent therapy.
3. Diffuse large B-cell lymphoma, second-line or subsequent therapy.
4. Follicular lymphoma.
5. Marginal zone lymphoma with any of the following subtypes: Nongastric/Gastric mucosa associated lymphoid tissue (MALT) lymphoma, splenic/nodal marginal zone lymphoma, second-line or subsequent therapy.
6. Multicentric Castleman's disease, relapsed, refractory or progressive disease.
7. High-grade B-cell lymphomas, second-line or subsequent therapy.
8. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, second-line or subsequent therapy.
9. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma, second-line or subsequent therapy.
10. Mantle cell lymphoma.

G. Myelodysplastic syndrome

Authorization of 12 months may be granted as a single agent for treatment of lower risk myelodysplastic syndrome (defined as Revised International Prognostic Scoring System (IPSS-R) (Very Low, Low, Intermediate), International Prognostic Scoring System (IPSS) (Low/Intermediate-1), WHO classification-based Prognostic Scoring System (WPSS) (Very Low, Low, Intermediate)) for those with symptomatic anemia.

H. Myelofibrosis-associated anemia

Authorization of 12 months may be granted for treatment of myelofibrosis-associated anemia when all of the following criteria are met:

1. The requested medication will be given in combination with prednisone.
2. The member has serum erythropoietin levels of either of the following:
   a. 500 mU/mL or greater
   b. Less than 500 mU/mL and no response or loss of response to erythropoietin stimulating agents

I. Systemic light chain amyloidosis

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

J. Classical Hodgkin lymphoma

Authorization of 12 months may be granted as third-line or subsequent therapy for treatment of relapsed or refractory classical Hodgkin lymphoma as a single agent.

K. POEMS Syndrome

Authorization of 12 months may be granted for treatment of POEMS syndrome in combination with dexamethasone.

L. Myelodysplastic/myeloproliferative neoplasms

Authorization of 12 months may be granted for treatment of myelodysplastic/myeloproliferative neoplasms with ring sideroblasts and thrombocytosis as a single agent or in combination with a hypomethylating agent.

M. Kaposi Sarcoma

Authorization of 12 months may be granted for treatment of Kapsoi sarcoma as subsequent therapy.

N. Smoldering Myeloma

Authorization of 12 months may be granted for treatment of asymptomatic high-risk smoldering myeloma.

O. Langerhans Cell Histiocytosis
Authorization of 12 months may be granted for treatment of Langerhans cell histiocytosis as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Revlimid [package insert]. Summit, NJ: Celgene Corporation; August 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 4, 2021.
3. Lexicomp Online®, Lexi-Drugs, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com [available with subscription]. Accessed October 4, 2021.