Reference number(s)
2232-A

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).
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. Non-Hodgkin lymphoma (NHL) with any of the following subtypes:
   a. AIDS-related non-germinal center 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. Nodal/splenic marginal zone lymphoma
   i. Multicentric Castleman's disease
   j. Adult T-cell leukemia/lymphoma
   k. Mycosis fungoides (MF)/Sezary syndrome (SS)
   l. Angioimmunoblastic T-cell lymphoma (AITL)
   m. Peripheral T-cell lymphoma not otherwise specified (PTCL NOS)
   n. Enteropathy-associated T-cell lymphoma
   o. Monomorphic epithelotropic intestinal T-cell lymphoma
   p. Nodal peripheral T-cell lymphoma
   q. Follicular T-cell lymphoma

r. Primary cutaneous anaplastic large cell lymphoma (ALCL)
s. Hepatosplenic T-cell lymphoma
t. High-grade B-cell lymphomas
u. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
v. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma

9. AIDS-related Kaposi Sarcoma
10. Smoldering myeloma

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. Non-Hodgkin lymphoma (NHL)

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

1. Second-line or subsequent therapy for relapse of AIDS-related non-germinal center diffuse large B-cell lymphoma
2. Primary central nervous system (CNS) lymphoma as a single agent or in combination with rituximab
3. Second-line or subsequent therapy of monomorphic post-transplant lymphoproliferative disorder (non-germinal center B-cell type)
4. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
5. Second-line or subsequent therapy for histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
6. Second-line or subsequent therapy for histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma
7. Second-line or subsequent therapy for diffuse large B-cell lymphoma, not otherwise specified in non-candidates for transplant
8. Follicular lymphoma
9. Mantle cell lymphoma
10. Second-line or subsequent therapy for nongastric MALT lymphoma
11. Second-line or subsequent therapy for gastric MALT lymphoma
12. Second-line or subsequent therapy for nodal marginal zone lymphoma
13. Second-line or subsequent therapy for splenic marginal zone lymphoma
14. Relapsed, refractory or progressive multicentric Castleman's disease
15. Relapsed or refractory primary cutaneous anaplastic large cell lymphoma (ALCL) or cutaneous ALCL as a single agent
16. Second-line or subsequent therapy for adult T-cell leukemia/lymphoma (acute or lymphoma subtypes)
17. Mycosis fungoides (MF)/Sezary syndrome (SS)
18. Second line, initial palliative therapy, or subsequent therapy for angioimmunoblastic T-cell lymphoma (AITL)
19. Second-line, initial palliative therapy, or subsequent therapy for peripheral T-cell lymphoma not otherwise specified (PTCL NOS)
20. Second-line, initial palliative therapy, or subsequent therapy for enteropathy-associated T-cell lymphoma
21. Second-line, initial palliative therapy, or subsequent therapy for monomorphic epitheliotropic intestinal T-cell lymphoma
22. Second-line, initial palliative therapy, or subsequent therapy for nodal peripheral T-cell lymphoma with TFH phenotype
23. Second-line, initial palliative therapy, or subsequent therapy for follicular T-cell lymphoma
24. Second-line or subsequent therapy for refractory hepatosplenic T-cell lymphoma

25. Second line or subsequent therapy for high-grade B-cell lymphomas

C. 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.

D. 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 as a single agent or 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

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 as third-line or subsequent therapy for treatment of relapsed or refractory classical Hodgkin lymphoma as a single agent.

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

H. 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.

I. AIDS-Related Kaposi Sarcoma
Authorization of 12 months may be granted for treatment of AIDS-related Kapsoi sarcoma as subsequent therapy when given with antiretroviral therapy (ART).

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

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; May 2019.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 1, 2020.
3. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com (cited: 10/01/2020).

4. Monjuvi [package insert]. Boston, MA: Morphosys US, Inc; July 2020.
5. Lexicomp Online®, Lexi-Drugs, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com [available with subscription]. Accessed October 1, 2020.