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.

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
   l. 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.

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

Reference number(s)
2232-A

1. Revlimid [package insert]. Summit, NJ: Celgene Corporation; December 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 13, 2018.
3. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com (cited: 10/8/2018).
4. The Clinical NCCN Practice Guidelines in Oncology® Multiple Myeloma (Version 1.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 8, 2018.
5. The Clinical NCCN Practice Guidelines in Oncology® B-cell Lymphoma (Version 5.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed October 8, 2018.
6. The Clinical NCCN Practice Guidelines in Oncology® Myelodysplastic Syndromes (Version 1.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 8, 2018.
7. The Clinical NCCN Practice Guidelines in Oncology® Myeloproliferative Neoplasms (Version 1.2019) © 2018 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed October 8, 2018.
8. The Clinical NCCN Practice Guidelines in Oncology® Systemic Light Chain Amyloidosis (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed October 8, 2018.
9. The Clinical NCCN Practice Guidelines in Oncology® Hodgkin Lymphoma (Version 3.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed October 8, 2018.
10. The Clinical NCCN Practice Guidelines in Oncology T-cell Lymphomas (Version 5.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed October 8, 2018.