

# Specialty Guideline Management lenalidomide-Revlimid

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Revlimid	lenalidomide

## Indications

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

### FDA-Approved Indications<sup>1,2</sup>

Revlimid is indicated for the treatment of adult patients with:

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

## Compendial Uses<sup>3-7</sup>

- Multiple myeloma
- Systemic light chain amyloidosis
- Classic Hodgkin lymphoma
- Myelodysplastic syndrome
- POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
- Plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD)
- Plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)
- Myelodysplastic/myeloproliferative neoplasm (MDS/MPN) overlap neoplasms
- T-cell Lymphomas
  - Peripheral T-Cell Lymphomas not otherwise specified
  - Angioimmunoblastic T-cell lymphoma
  - Enteropathy-associated T-cell lymphoma
  - Monomorphic epitheliotropic intestinal T-cell lymphoma
  - Nodal peripheral T-cell lymphoma with TFH phenotype
  - Follicular T-cell lymphoma
  - Adult T-cell leukemia/lymphoma
  - Hepatosplenic T-cell lymphoma
- Primary central nervous system (CNS) lymphoma
- Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
- B-Cell Lymphomas
  - HIV-related B-Cell lymphomas, including non-germinal center diffuse large B-cell lymphoma, HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HHV8+ diffuse large B-cell lymphoma, and HIV-related plasmablastic lymphoma
  - Monomorphic post-transplant lymphoproliferative disorder
  - Diffuse large B-cell lymphoma
  - Follicular lymphoma
  - Marginal zone lymphoma with any of the following subtypes: Extranodal (Nongastric/Gastric mucosa associated lymphoid tissue {MALT}), Splenic, or Nodal marginal zone lymphoma
  - High-grade B-cell lymphomas
  - Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
  - Mantle cell lymphoma
- Multicentric Castleman disease
- Kaposi Sarcoma
- Smoldering multiple myeloma
- Histiocytic Neoplasms
- Mycosis Fungoides (MF)/Sézary Syndrome (SS)

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

Reference number(s)
2232-A

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- SF3B1 mutation status, where applicable

## Coverage Criteria

### Multiple Myeloma<sup>1-3</sup>

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

### T-Cell Lymphomas<sup>3</sup>

Authorization of 12 months may be granted for treatment of T-cell lymphoma, as a single agent, with any of the following subtypes:

- Peripheral T-Cell Lymphomas not otherwise specified as initial palliative therapy or subsequent therapy.
- Angioimmunoblastic T-cell lymphoma as initial palliative therapy or subsequent therapy.
- Enteropathy-associated T-cell lymphoma as initial palliative therapy or subsequent therapy.
- Monomorphic epitheliotropic intestinal T-cell lymphoma as initial palliative therapy or subsequent therapy.
- Nodal peripheral T-cell lymphoma with TFH phenotype as initial palliative therapy or subsequent therapy.
- Follicular T-cell lymphoma as initial palliative therapy or subsequent therapy.
- Adult T-cell leukemia/lymphoma as subsequent therapy.
- Hepatosplenic T-cell lymphoma as subsequent therapy for refractory disease after treatment with two first-line therapy regimens.

### Primary Central Nervous System (CNS) Lymphoma<sup>3</sup>

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.

### Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)<sup>3</sup>

Authorization of 12 months may be granted for treatment of CLL/SLL as subsequent therapy when the requested medication is used as a single agent or in combination with rituximab after prior therapy with covalent Bruton Tyrosine Kinase inhibitor and B-cell lymphoma 2 inhibitor-containing regimens.

Reference number(s)
2232-A

## B-Cell Lymphomas<sup>1-3,7</sup>

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

- HIV-related B-Cell lymphomas, including non-germinal center diffuse large B-cell lymphoma, HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HHV8+ diffuse large B-cell lymphoma, and HIV-related plasmablastic lymphoma, as subsequent therapy.
- Monomorphic post-transplant lymphoproliferative disorder as subsequent therapy.
- Diffuse large B-cell lymphoma as subsequent therapy.
- Follicular lymphoma.
- Marginal zone lymphoma with any of the following subtypes: Extranodal (Nongastric/Gastric mucosa-associated lymphoid tissue {MALT}) or splenic, as subsequent therapy.
- Nodal marginal zone lymphoma.
- High-grade B-cell lymphomas as subsequent therapy.
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma as subsequent therapy.
- Mantle cell lymphoma.

## Multicentric Castleman Disease<sup>3</sup>

Authorization of 12 months may be granted for the treatment of multicentric Castleman disease as subsequent therapy.

## Myelodysplastic Syndrome<sup>1-3</sup>

Authorization of 12 months may be granted 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.

## Systemic Light Chain Amyloidosis<sup>3</sup>

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

## Classic Hodgkin Lymphoma<sup>3</sup>

Authorization of 12 months may be granted for treatment of classic Hodgkin lymphoma when all of the following criteria are met:

- The member has refractory disease or suspected relapse
- The member is not a candidate for high-dose therapy and autologous stem cell rescue
- The medication will be used as a single agent

Reference number(s)
2232-A

## POEMS Syndrome, plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)<sup>3,5</sup>

Authorization of 12 months may be granted for treatment of POEMS syndrome, plasma cell-related MIDD, and plasma cell-related MGRS.

## Myelodysplastic/Myeloproliferative Neoplasm (MDS/MPN) Overlap Neoplasms<sup>3</sup>

Authorization of 12 months may be granted for treatment of MDS/MPN overlap neoplasms with SF3B1 mutation and thrombocytosis, as a single agent or in combination with a hypomethylating agent.

## Kaposi Sarcoma<sup>3</sup>

Authorization of 12 months may be granted for treatment of Kaposi sarcoma, including Kaposi sarcoma associated herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS) when given in combination with rituximab.

## Smoldering Multiple Myeloma<sup>4</sup>

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

## Histiocytic Neoplasms<sup>3</sup>

Authorization of 12 months may be granted for treatment of histiocytic neoplasms, including Langerhans cell histiocytosis and Rosai-Dorfman disease, as a single agent.

## Mycosis Fungoides (MF)/Sézary Syndrome (SS)<sup>3,6</sup>

Authorization of 12 months may be granted for treatment of relapsed or refractory MF or SS to multiple prior therapies, as a single agent.

## Continuation of Therapy

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

Reference number(s)
2232-A

## References

1. Revlimid [package insert]. Princeton, NJ: Celgene Corporation; March 2023.
2. Lenalidomide [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; January 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 12, 2025.
4. Lexicomp Online®, Lexi-Drugs. Waltham, MA: UpToDate, Inc.; Updated September 24, 2025. <http://online.lexi.com> [available with subscription]. Accessed September 30, 2025.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 2.2026. [https://www.nccn.org/professionals/physician\\_gls/pdf/myeloma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf). Accessed September 25, 2025.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Cutaneous Lymphomas. Version 1.2026. [https://www.nccn.org/professionals/physician\\_gls/pdf/cutaneous\\_lymphomas.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_lymphomas.pdf). Accessed December 12, 2025.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. Version 1.2026. [https://www.nccn.org/professionals/physician\\_gls/pdf/b-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf). Accessed January 7, 2026.