PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lenalidomide Prior Authorization Policy
- Revlimid® (lenalidomide capsules – Celgene, generic)

REVIEW DATE: 05/29/2024

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Lenalidomide, a thalidomide analog, is indicated for the following uses in adults:[1]
- **Follicular lymphoma**, previously treated, in combination with a rituximab product.
- **Mantle cell lymphoma**, in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib subcutaneous or intravenous bolus injection.
- **Marginal zone lymphoma**, previously treated, in combination with a rituximab product.
- **Multiple myeloma**, as maintenance following autologous hematopoietic stem cell transplantation.
- **Multiple myeloma**, treatment, in combination with dexamethasone.
- **Myelodysplastic syndrome**, for transfusion-dependent anemia due to low- or intermediate-risk disease, associated with a deletion 5q abnormality with or without cytogenetic abnormalities.

A limitation of use with lenalidomide is that it is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia outside of controlled clinical trials.[1]

Guidelines

Lenalidomide is incorporated into various guidelines by the National Comprehensive Cancer Network (NCCN).[2-11]

- **B-Cell Lymphomas:** NCCN guidelines for B-Cell lymphomas (version 2.2024 – April 30, 2024) discuss therapeutic options for diffuse large B-cell lymphoma (DLBCL), the most common type of other B-cell lymphoma.[2] Lenalidomide, with or without rituximab, is mentioned as a second-line therapy as "useful in certain circumstances" (category 2A). Monjuvi® (tafasitamab-cxix intravenous infusion) plus lenalidomide is recommended as a "preferred" regimen as second-line therapy (category 2A). Many examples of first-line therapies are recommended (e.g., RCHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone] {category 1}, dose-adjusted EPOCH [etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin] + rituximab [category 2A]). One example of a first-line therapy for patients with poor left ventricular function or in those who are frail is RGCVP (rituximab, gemcitabine, cyclophosphamide, vincristine, prednisone). NCCN also recommends optional first-line consolidation therapy of lenalidomide maintenance (category 2B) for patients 60 to 80 years of age. Other types of B-cell lymphomas (high grade B-cell lymphomas [not otherwise specified], post-transplant lymphoproliferative disorders, acquired immunodeficiency [AIDS]-related B-cell lymphomas, high-grade B-cell lymphomas with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma]) are also cited in the guidelines and note a place in therapy of lenalidomide. Regimens recommended in these clinical scenarios are similar to those used in DLBCL.
    - **Follicular Lymphomas:** Lenalidomide plus rituximab is a first-line recommended therapy (category 2A). Many second-line and subsequent therapies are listed, usually with or without rituximab. Lenalidomide with Gazyva® (obinutuzumab intravenous infusion) is an "other recommended regimen" in this setting (category 2A).
    - **Mantle Cell Lymphoma:** Lenalidomide, in combination with rituximab, is recommended as a preferred, less aggressive induction therapy (category 2A). Lenalidomide with rituximab is recommended as a preferred second-line and subsequent therapy (category 2A). The regimen of lenalidomide, rituximab, and Imbruvica is cited as and second-line and subsequent therapy that is "useful in certain circumstances" (category 2A).
    - **Marginal Zone Lymphoma:** Lenalidomide plus rituximab has a category 2B recommendation for first-line therapy as an "other recommended regimen" and a category 2A recommendation for second-line and subsequent therapy as a "preferred regimen". Lenalidomide + Gazyva is also recommended under "other recommended regimens" for second-line/subsequent therapy (category 2A).
- **Castleman's Disease:** NCCN guidelines (version 1.2024 – January 18, 2024) recommend lenalidomide as an option (category 2A) as second-line and subsequent therapy, with or without rituximab, for multi-centric Castleman's disease that is relapsed/refractory or progressive disease.[2]
- **Central Nervous System (CNS) Cancers:** NCCN guidelines for CNS cancers (version 1.2023 – March 24, 2023) recommend lenalidomide, with or without

rituximab (category 2A), as one of the options for patients with relapsed or refractory disease.[3]

- **Histiocytic Neoplasms:** NCCN guidelines for histiocytic neoplasms (version 1.2024 – March 15, 2024) recommend lenalidomide for Langerhans cell histiocytosis as first-line or as subsequent therapy for single system multifocal skin disease (including mucosa) and for Rosai-Dorfman disease (both category 2A).[4]
- **Hodgkin Lymphoma:** NCCN Hodgkin lymphoma guidelines (version 3.2024 – March 18, 2024) recommend lenalidomide as a subsequent option for treatment of classical Hodgkin lymphoma as a single agent for refractory or relapsed disease in patients ≥ 18 years of age (category 2A) who have tried at least three prior lines of therapy. Many other therapies are recommended as primary systemic therapy regimens before lenalidomide is recommended.[5]
- **Kaposi Sarcoma:** NCCN guidelines for Kaposi sarcoma (version 1.2024 – November 7, 2023) recommended lenalidomide as an agent "Other recommended regimens" for subsequent systemic therapy options for relapsed/refractory advanced cutaneous, oral, visceral or nodal disease that has progressed on or not responded to first-line systemic therapy and progressed on alternative first-line systemic therapy (category 2A).[9] This includes use when given alone (in patients without human immunodeficiency virus [HIV]) or with antiretroviral therapy for patients with HIV. First-line systemic therapy options include liposomal doxorubicin (preferred) and paclitaxel. Other subsequent systemic therapy options for relapsed/refractory therapy are also cited (e.g., Pomalyst® [pomalidomide capsules] {preferred}, Thalomid® [thalidomide capsules], imatinib).
- **Multiple Myeloma:** NCCN guidelines for multiple myeloma (version 4.2024 – April 26, 2024) feature lenalidomide prominently in a variety of scenarios with several category 1 recommendations (e.g., lenalidomide with dexamethasone for other recommended regimens for primary therapy, monotherapy for maintenance therapy).[6] The agent is also cited in other regimens with category 2A and 2B recommendations. Lenalidomide is also indicated for treatment in combination with dexamethasone for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome as induction therapy for transplant eligible patients and for transplant ineligible patients (category 2A).
- **Myelodysplastic Syndrome (MDS):** NCCN guidelines for MDS (version 2.2024 – May 22, 2024) recommend lenalidomide in a variety of clinical scenarios among patients with symptomatic anemia both with and without 5q deletion abnormalities (category 2A).[7]
- **Myeloproliferative Neoplasms:** NCCN has guidelines regarding myeloproliferative neoplasms (version 1.2024 – December 21, 2023) discuss myelofibrosis with related anemia.[8] Lenalidomide is recommended under "Useful in certain circumstances" in (category 2B) combination with prednisone taper for del(5q), if no symptomatic splenomegaly and/or constitutional symptoms. .
- **Systemic Light Chain Amyloidosis:** NCCN guidelines for systemic light chain amyloidosis (version 2.2024 – December 12, 2023) cite lenalidomide as a therapeutic option used in combination dexamethasone, and in some

circumstances with additional medications, in several clinical scenarios, including as primary therapy (category 2A).[10] Also, lenalidomide in combination with dexamethasone, and an additional medication recommended in some situations, is also recommended in patients with previously treated disease (category 2A).

- **T-Cell Lymphomas:** NCCN guidelines for T-cell lymphomas (version 4.2024 – May 28, 2024) make several recommendations that include lenalidomide.[11] Lenalidomide is recommended as a second-line and subsequent therapy for adult T-cell leukemia/lymphoma (category 2A). For peripheral T-cell lymphomas, lenalidomide is recommended as initial palliative-intent therapy as "other recommended regimen" (category 2A) and for second-line and subsequent therapy as"other recommended regimens" as a monotherapy (category 2A). Indications regarding peripheral T-cell lymphomas include the following: peripheral T-cell lymphoma not otherwise specified, adult T-cell leukemia/lymphoma, angioimmunoblastic T-cell lymphoma; enteropathy-associated T-cell lymphoma; monomorphic epitheliotropic intestinal T-cell lymphoma; nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype; follicular T-cell lymphoma; and hepatosplenic gamma-delta T-cell lymphomas. Other regimens are recommended as first-line or preferred in both of these clinical scenarios.

Safety

In a prospective randomized clinical study in the first-line treatment of patients with CLL, use of lenalidomide as a single agent increased the risk of death compared with chlorambucil given as a single agent.[1] Lenalidomide is only available through the lenalidomide Risk Evaluation Mitigation Strategy program. Males and females must follow the required reproductive precautions.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of lenalidomide. All approvals are provided for the duration noted below.

- **Revlimid® (lenalidomide capsules (Celgene, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Follicular Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii)
     - **i.** Patient is using lenalidomide in combination with rituximab; OR
     - **ii.** Patient has tried at least one other regimen.

Note: Examples include bendamustine plus Gazyva (obinutuzumab intravenous infusion) or rituximab; bendamustine plus Gazyva; CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus Gazyva or rituximab; CVP (cyclophosphamide, vincristine, prednisone) plus Gazyva or rituximab; chlorambucil with or without rituximab; cyclophosphamide with or without rituximab; rituximab; Gazyva; or Aliqopa (copanlisib intravenous infusion).

2. **Mantle Cell Lymphoma**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i or ii).
      i. Patient is using lenalidomide in combination with rituximab; OR
      ii. Patient has tried at least two other regimens.
      Note: Examples include HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine) + rituximab; the NORDIC regimen (dose-intensified induction immunochemotherapy with rituximab + cyclophosphamide, vincristine, doxorubicin, prednisone alternating with rituximab and high-dose cytarabine); RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); bendamustine injection plus rituximab; RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin); Imbruvica (ibrutinib capsules, tablets, and oral suspension) with or without rituximab; Calquence (acalabrutinib tablets and capsules); or Brukinsa (zanubrutinib capsules).

3. **Marginal Zone Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i or ii).
      i. Patient is using lenalidomide in combination with rituximab; OR
      ii. Patient has tried least one other regimen.
      Note: Examples include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab; bendamustine + rituximab; CVP (cyclophosphamide, vincristine, prednisone) + rituximab; rituximab; chlorambucil with or without rituximab; cyclophosphamide with or without rituximab; bendamustine + Gazyva (obinutuzumab intravenous infusion); Copiktra (duvelisib capsules); Aliqopa (copanlisib intravenous infusion); or Zydelig (idelalisib capsules).

4. **Multiple Myeloma.** Approve for 1 year if the patient is ≥ 18 years of age.

5. **Myelodysplastic Syndrome.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i, ii, or iii):
      i. Patient has symptomatic anemia; OR
      ii. Patient has transfusion-dependent anemia; OR

iii. Patient has anemia that is not controlled with an erythropoiesis-stimulating agent
Note: Examples include Epogen/Procrit (epoetin alfa injection), Aranesp (darbepoetin alfa injection).

Other Uses with Supportive Evidence

6. **B-Cell-Lymphomas (Other):** Approve for 1 year if the patient meets BOTH of the following (A and B):
Note: Examples include diffuse large B-cell lymphoma (DLBCL); high grade B-cell lymphomas (not otherwise specified), post-transplant lymphoproliferative disorders, AIDS-related B-cell lymphomas, high-grade B-cell lymphomas with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma).
A) Patient is ≥ 18 years of age; AND
B) Patient has tried at least one other regimen.
Note: Examples include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab; RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine); DHA (dexamethasone, cytarabine) plus platinum (carboplatin, cisplatin, oxaliplatin) ± rituximab; ICE (Ifex, carboplatin, etoposide) ± rituximab; RGCVP (rituximab, gemcitabine, cyclophosphamide, vincristine, prednisone); GDP (gemcitabine, dexamethasone, cisplatin) ± rituximab or gemcitabine, dexamethasone, carboplatin) ± rituximab; R-HyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine); or bendamustine ± rituximab.

7. **Castleman's Disease.** Approve for 1 year in patients with relapsed/refractory or progressive disease.

8. **Central Nervous System Lymphoma.** Approve for 1 year if according to the prescriber the patient has relapsed or refractory disease.

9. **Histiocytic Neoplasms.** Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. Patient has Langerhans cell histiocytosis with single-system multifocal skin disease; OR
ii. Patient has Rosai-Dorfman disease.

10. **Hodgkin Lymphoma, Classical.** Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) Patient has tried at least three other regimens.
Note: Examples include ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine); BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone); Adcetris

(brentuximab vedotin intravenous infusion); Adcetris + AVD (doxorubicin, vinblastine, and dacarbazine); DHAP (dexamethasone, cisplatin, high-dose cytarabine); ICE (ifosfamide, carboplatin, etoposide); or GVD (gemcitabine, vinorelbine, liposomal doxorubicin).

11. Kaposi Sarcoma. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient has relapsed or refractory disease; AND

B) Patient has tried at least one other medication; AND

Note: Examples include liposomal doxorubicin, paclitaxel, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules), and imatinib.

12. Myelofibrosis. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) According to the prescriber the patient has anemia with presence of del(5q); AND

C) The medication is used in combination with prednisone.

13. Peripheral T-Cell Lymphomas. Approve for 1 year if the patient is ≥ 18 years of age.

Note: Indications regarding peripheral T-cell lymphomas include peripheral T-cell lymphoma not otherwise specified (PTCL-NOS), angioimmunoblastic T-cell lymphoma (AITL); enteropathy-associated T-cell lymphoma (EATL); monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL); nodal peripheral T-cell lymphoma (nodal PTCL) with T-follicular helper (TFH) phenotype; follicular T-cell lymphoma (FTCL); and hepatosplenic gamma-delta T-cell lymphomas.

14. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome. Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) Use of lenalidomide is in combination with dexamethasone.

15. Systemic Light Chain Amyloidosis. Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) Use of lenalidomide is in combination with dexamethasone.

16. T-Cell Leukemia/Lymphoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) Patient has tried at least one other regimen.
Note: Examples include Adcetris (brentuximab vedotin intravenous infusion) plus CHP (cyclophosphamide, doxorubicin, and prednisone); CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone); CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, and prednisone); dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin); HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) alternating with high-dose methotrexate and cytarabine; or Beleodaq (belinostat intravenous infusion).

CONDITIONS NOT COVERED

Revlimid® (lenalidomide capsules (Celgene, generic) is(are) considered experimental, investigational or unproven for ANY other use(s)

REFERENCES

1. Revlimid® capsules [prescribing information]. Summit, NJ: Celgene; March 2023.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2024.
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7. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 4.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2024.

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9. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 27, 2024.
10. The NCCN Related Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – November 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2024.
11. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 2.2024 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2024.
12. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Myelodysplastic Syndrome:** Examples of regimens are provided in a Note. **Hodgkin Lymphoma, Classical:** Criterion has been updated to state patient has tried at least "three" other regimens, as per guidelines. Previously it said one other regimen. ESHAP (etoposide, methylprednisolone, high-dose cytarabine, cisplatin) was removed from the list of examples in Note.	05/10/2023
Annual Revision	**Histiocytic Neoplasms:** Added new condition of approval and criteria. **Langerhans Cell Histiocytosis:** Deleted approval condition and criteria since it is now addressed under "Histiocytic Neoplasm". **Myelofibrosis:** Deleted criteria referring to serum erythropoietin levels and response to erythropoiesis-stimulating agents. New criteria added requiring combination use with prednisone. In criteria verifying presence of anemia, added qualifier that is for del(5q) mutation. **Peripheral T-Cell Lymphoma:** Deleted criterion "patient has tried at least one other regimen", since lenalidomide can be used for initial palliative intent therapy or subsequent therapy.	05/29/2024