

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lenalidomide Prior Authorization Policy

- Revlimid® (lenalidomide capsules – Celgene, generic)

REVIEW DATE: 05/11/2022; selected revision 06/22/2022

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 Velcade® (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 (Other):** The NCCN guidelines for B-Cell lymphomas (version 3.2022 – April 25, 2022), discuss therapeutic options for diffuse large B-cell lymphoma (DLBCL), the most common type of other B-cell lymphoma (other).² Lenalidomide, with or without rituximab, is mentioned as a second-line therapy that is useful in certain circumstances (category 2A). Monjuvi® (tafasitamab-cxix intravenous infusion) plus lenalidomide is recommended as a preferred regimen in 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.
- **Castleman's Disease:** The NCCN guidelines for B-Cell lymphomas (version 3.2022 – April 25, 2022) recommend lenalidomide as an option 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) Lymphoma:** The NCCN guidelines for CNS cancers (version 2.2021 – September 8, 2021) recommend lenalidomide, with or without rituximab, as one of the options for patients with relapsed or refractory disease.³
- **Follicular Lymphomas:** The NCCN guidelines for B-Cell lymphomas (version 3.2022 – April 25, 2022) discuss agents for follicular lymphoma.² 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).
- **Histiocytic Neoplasms:** The NCCN guidelines for histiocytic neoplasms (version 2.2021 – September 8, 2021) recommend lenalidomide for Langerhans cell histiocytosis as first-line or as subsequent therapy for single system multifocal skin disease (including mucosa) and for relapsed/refractory disease (category 2A).⁴
- **Hodgkin Lymphoma:** The NCCN Hodgkin lymphoma guidelines (version 2.2022 – February 23, 2022) 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). Many other therapies are recommended as primary systemic therapy regimens before lenalidomide is recommended.⁵
- **Kaposi Sarcoma:** The NCCN guidelines for Kaposi sarcoma (version 1.2022 – February 3, 2022) recommended lenalidomide as an agent useful under certain conditions 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).
- **Mantle Cell Lymphoma:** The NCCN guidelines for B-Cell lymphomas (version 3.2022 – April 25, 2022) discuss mantle cell lymphoma.² 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). Other recommended second-line therapy regimens useful in certain circumstances include Imbruvica® (ibrutinib tablets and capsules) with or without rituximab, Calquence® (acalabrutinib capsules), Brukinsa™ (zanubrutinib capsules) [all category 2A]. The regimen of lenalidomide, rituximab, and Imbruvica is cited as a second-line and subsequent therapy that is useful in certain circumstances (category 2A). The NCCN guidelines cites many other regimens and medications for mantle cell lymphoma in various clinical scenarios.
- **Marginal Zone Lymphoma:** The NCCN guidelines for B-Cell lymphomas (version 3.2022 – April 25, 2022) discuss marginal zone lymphomas.² 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. It is also an other recommended regimen for second-line and subsequent therapy when given with Gazyva (category 2B). Many other regimens are recommended for this condition.
- **Multiple Myeloma:** The NCCN guidelines for multiple myeloma (version 6.2021 – April 12, 2021) 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):** The NCCN guidelines for MDS (version 3.2021 – January 15, 2021) recommend lenalidomide in a variety of clinical scenarios among patients with symptomatic anemia both with and without 5q deletion abnormalities (category 2A).⁷
- **Myelofibrosis:** The NCCN has guidelines regarding myeloproliferative neoplasms (version 2.2022 – April 13, 2022) discuss myelofibrosis with related anemia.⁸ Lenalidomide is recommended in the management of anemia associated with myelofibrosis (useful in certain circumstances), with or without prednisone, for a variety of clinical scenarios (category 2A) including patients with erythropoietin levels ≥ 500 mU/mL and with erythropoietin levels < 500 mU/mL and no response or loss of response to erythropoietic stimulating agents.
- **Systemic Light Chain Amyloidosis:** The NCCN guidelines for systemic light chain amyloidosis (version 1.2022 – June 29, 2021) 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:** The NCCN guidelines for T-cell lymphomas (version 2.2022 – March 7, 2022) 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 second-line and subsequent therapy (other recommended regimens) as a monotherapy (category 2A). Indications regarding peripheral T-cell lymphomas include the following: peripheral T-cell lymphoma not otherwise specified, 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 The trial was stopped for safety in July 2013. In an interim analysis, 34 deaths occurred in 210 patients in the lenalidomide treatment arm compared with 18 deaths among the 211 patients in the chlorambucil treatment arm (hazard ratio for overall survival was 1.92 [95% confidence interval: 1.08, 3.41]), which was consistent with a 92% increase in the risk of death. Also, serious adverse cardiovascular events, including atrial fibrillation, myocardial infarction, and cardiac failure, occurred more frequently in patients receiving lenalidomide. Lenalidomide has a Boxed Warning regarding embryofetal toxicity, hematologic toxicity (neutropenia and thrombocytopenia), and venous thromboembolism. Lenalidomide is only available through by restricted distribution 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of lenalidomide is recommended in those who meet the one of following criteria:

FDA-Approved Indications

1. **Follicular Lymphoma.** Approve for 1 year if the patient meets 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 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 and tablets) with or without rituximab; Calquence (acalabrutinib capsules); or Brukinsa (zanubrutinib capsules).
3. **Marginal Zone Lymphoma.** Approve for 1 year if the patient meets 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 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 (e.g., 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 the following criteria (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) $\pm$ rituximab; ICE (Ifex, carboplatin, etoposide) $\pm$ rituximab; RGCVP (rituximab, gemcitabine, cyclophosphamide, vincristine, prednisone); GDP (gemcitabine, dexamethasone, cisplatin) $\pm$ rituximab or gemcitabine, dexamethasone, carboplatin) $\pm$ rituximab; R-HyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine); or bendamustine $\pm$ rituximab.

7. **Kaposi Sarcoma.** Approve for 1 year if the patient meets 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.

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

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

10. **Hodgkin Lymphoma, Classical.** Approve for 1 year if the patient meets 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 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); ESHAP (etoposide, methylprednisolone, high-dose cytarabine, cisplatin); ICE (ifosfamide, carboplatin, etoposide); or GVD (gemcitabine, vinorelbine, liposomal doxorubicin).

11. **Langerhans Cell Histiocytosis:** Approve for 1 year for patients with multifocal skin disease.

12. **Myelofibrosis.** Approve for 1 year if the patient meets the following (A or B):

A) Patient meets the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. According to the prescriber the patient has anemia; AND

iii. Patient has serum erythropoietin levels ≥ 500 mU/mL.

- B)** Patient meets the following (i, ii, iii, and iv):
- i.** Patient is ≥ 18 years of age; AND
 - ii.** According to the prescriber the patient has anemia; AND
 - iii.** Patient has serum erythropoietin levels < 500 mU/mL; AND
 - iv.** Patient has experienced no response or loss of response to an erythropoiesis-stimulating agent.

13. Peripheral T-Cell Lymphomas. Approve for 1 year if the patient meets the following (A and B):

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.

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least one other regimen.

Note: Examples of regimens include Beleodaq (belinostat intravenous infusion); Adcetris (brentuximab vedotin intravenous infusion); DHAP (dexamethasone, cisplatin, cytarabine); ESHAP (etoposide, methylprednisolone, cytarabine, cisplatin); GDP (gemcitabine, dexamethasone, cisplatin); GemOX (gemcitabine, oxaliplatin); ICE (ifosfamide, carboplatin, etoposide); or Istodax (romidepsin intravenous infusion).

14. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome. Approve for 1 year if the patient meets 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 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 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 RECOMMENDED FOR APPROVAL

Coverage of lenalidomide is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Revlimid® capsules [prescribing information]. Summit, NJ: Celgene; August 2021.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 3.2022 – April 25, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
3. The NCCN Central Nervous System Cancers Guidelines in Oncology (version 2.2021 – September 8, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
4. The NCCN Histiocytic Neoplasms (version 2.2021 – September 8, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
5. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 2.2022 – February 23, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
6. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 9, 2022.
7. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 3.2022 – January 13, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
8. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2022 – April 13, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
9. The NCCN Related Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 1.2022 – February 3, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
10. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 1.2022 – June 29, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.
11. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2022 – March 7, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 8, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	B-Cell Lymphoma (Other): The condition of approval was changed to delete the descriptors of “Diffuse, Large” and “Non-Hodgkin’s Lymphoma”. Examples of B-cell lymphomas were added as a Note. The requirement that the patient is ≥ 18 years of age was added. The criterion that requires that the patient try “at least one prior therapy” was changed to “at least one other regimen”. Central Nervous System Lymphoma: The condition of approval was changed to delete the descriptor of “Cancer (Primary)”. Follicular Lymphoma: The requirement that the patient is ≥ 18 years of age was added. The wording that the “patient has tried one prior therapy” was changed to “patient has tried at least one other regimen”. Hodgkin Lymphoma, Classical: The notation of “nodular sclerosis, mixed cellularity, lymphocyte depleted, and lymphocyte-rich subtypes of Hodgkin lymphoma” was deleted from the listed condition of approval. The requirements that the patient is ≥ 18 years of age and that the patient has tried at least one prior regimen were added. The examples of regimens are provided in a Note. The criterion that stated that the patient has relapsed or refractory disease was removed. Kaposi Sarcoma: The condition of approval was changed to remove “Acquired Immunodeficiency Syndrome”. The criterion that requires that the patient has “tried at least one regimen or therapy” was changed to “at least one medication”. Langerhans Cell Histiocytosis: This was added as a new condition of approval. Mantle Cell Lymphoma: The requirements were added that the patient is ≥ 18 years of age and that the patient is using Revlimid in combination with rituximab or the patient has tried at least two other regimens. The examples of regimens are provided in a Note. Marginal Zone Lymphoma: The requirements were added that the patient is ≥ 18 years of age and that the patient is using Revlimid in combination with rituximab or the patient has tried at least one other regimen. The examples of regimens are provided in a Note. Multiple Myeloma: The requirement that the patient is ≥ 18 years of age was added. Myelodysplastic Syndrome: The requirement that the patient is ≥ 18 years of age was added. Myelofibrosis: The requirement was added that the patient is ≥ 18 years of age to the previous set of criteria that the patient has anemia according to the prescriber and that serum erythropoietin levels are ≥ 500 mU/mL. An additional option of approval was added that for a patient with serum erythropoietin levels < 500 mU/mL, requirements are that the patient is ≥ 18 years of age; the patient has patient anemia according to the prescriber; and the patient has experienced no response or loss of response to an erythropoiesis-stimulating agent. Peripheral T-Cell Lymphomas: The requirement that the patient is ≥ 18 years of age was added. Also, the criterion that requires the patient to try “at least one other therapy or regimen” was changed to state “at least one other regimen.” POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome: This was added as a new condition of approval. Systemic Light Chain Amyloidosis: The requirements were added that the patient is ≥ 18 years of age and that the patient is using Revlimid in combination with dexamethasone. T-Cell Leukemia/Lymphoma: The requirement that the patient is ≥ 18 years of age was added. The criterion that requires the patient to try “at least one other therapy or regimen” was changed to state “at least one other regimen.”	04/14/2021
Update	03/15/2022: No criteria changes. Added that generic lenalidomide is now in the policy and changed related sections in the policy, including the name (changed from <i>Oncology - Revlimid PA Policy</i> to <i>Oncology - Lenalidomide PA Policy</i>), to reflect generic availability.	NA
Annual Revision	No criteria changes.	05/11/2022

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Follicular Lymphoma: Approval duration changed from 3 years to 1 year. Mantle Cell Lymphoma: Approval duration changed from 3 years to 1 year. Marginal Zone Lymphoma: Approval duration changed from 3 years to 1 year. Multiple Myeloma: Approval duration changed from 3 years to 1 year. Myelodysplastic Syndrome: Approval duration changed from 3 years to 1 year. B-Cell-Lymphomas (Other): Approval duration changed from 3 years to 1 year. Kaposi Sarcoma: Approval duration changed from 3 years to 1 year. Castleman's Disease: Approval duration changed from 3 years to 1 year. Central Nervous System Lymphoma: Approval duration changed from 3 years to 1 year. Hodgkin Lymphoma, Classical: Approval duration changed from 3 years to 1 year. Langerhans Cell Histiocytosis: Approval duration changed from 3 years to 1 year. Myelofibrosis: Approval duration changed from 3 years to 1 year. Peripheral T-Cell Lymphomas: Approval duration changed from 3 years to 1 year. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome: Approval duration changed from 3 years to 1 year. Systemic Light Chain Amyloidosis: Approval duration changed from 3 years to 1 year. T-Cell Leukemia/Lymphoma: Approval duration changed from 3 years to 1 year.	06/22/2022