Generic Name: Lenalidomide

Therapeutic Class or Brand Name: Revlimid®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: Lenalidomide (generic)

Non-preferred: Revlimid

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 9/17/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A through E and must meet criteria listed under applicable diagnosis:

   A. Myelodysplastic Syndrome (MDS) and criterion 1 is met:

      1. Documentation of transfusion-dependent anemia (defined as administration of 2 or more units of red blood cells [RBCs] in the previous 8 weeks) due to low- or intermediate-1-risk MDS associated with a deletion 5q (del 5q) cytogenetic abnormality with or without additional cytogenetic abnormalities.

   B. Multiple Myeloma (MM) and criterion 1 OR 2 is met:

      1. Revlimid® is used in combination with dexamethasone or documented intolerance or contraindication to a corticosteroid.
      2. Revlimid® is used as maintenance therapy following autologous hematopoietic stem cell transplantation.

   C. Mantle Cell Lymphoma (MCL) and criterion 1 is met:

      1. Documentation of disease progression, relapse, or intolerance to at least 2 other MCL therapies, one of which included bortezomib (Velcade®). See Appendix for first-line therapy options for MCL.

   D. Follicular Lymphoma (FL) and criteria 1 and 2 are met:

      1. Documentation of disease progression, relapse, or intolerance to at least 1 other FL regimen. See Appendix for first-line therapy options for FL.
      2. Revlimid® is used in combination with a rituximab product.

   E. Marginal Zone Lymphoma (MZL) and criteria 1 and 2 are met:

      1. Documentation of disease progression, relapse, or intolerance to at least 1 other MZL therapy. See Appendix for first-line therapy options for MZL.
      2. Revlimid® is used in combination with a rituximab product.

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Pregnancy.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 30 capsules (any combination of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, or 25 mg dosage strengths) per 30 days.

APPROVAL LENGTH

- **Authorization:**
  - Myelodysplastic Syndrome (MDS): 3 months.
  - Multiple Myeloma (MM), Mantle Cell Lymphoma (MCL), Follicular Lymphoma (FL), or Marginal Zone Lymphoma (MZL): 1 year.
- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective (for MDS, medication must be shown to be effective in significantly decreasing the number of red blood cell transfusions required).

APPENDIX

First-line therapy options for Mantle Cell Lymphoma:

- LyMA regimen: RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) x 4 cycles followed by RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)
- NORDIC regimen: Dose-intensified induction immunochemotherapy with rituximab + cyclophosphamide, vincristine, doxorubicin, prednisone (maxi-CHOP) alternating with rituximab+ high-dose cytarabine
- Rituximab, bendamustine followed by rituximab, high dose cytarabine
- TRIANGLE regimen: Alternating RCHOP + covalent BTKi/RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) (category 2A for ibrutinib; category 2B for acalabrutinib or zanubrutinib)
- HyperCVAD: (cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine) + rituximab
- Bendamustine + rituximab

- VR-CAP: (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone)
- RCHOP: (cyclophosphamide, doxorubicin, vincristine, prednisone + rituximab)
- Lenalidomide (continuous) + rituximab
- RBAC 500: (rituximab, bendamustine, cytarabine)

First-line therapy options for Follicular Lymphoma:

- Bendamustine+ obinutuzumab or rituximab
- CHOP: (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab
- CVP: (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab
- Rituximab (375 mg/m^2 weekly for 4 doses)[a]
- Chlorambucil ± rituximab[a]
- Cyclophosphamide ± rituximab[a]

First-line therapy options for Marginal Zone Lymphoma:

- Bendamustine + rituximab
- CHOP: (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab
- CVP: (cyclophosphamide, vincristine, prednisone) + rituximab
- Chlorambucil ± rituximab[a]
- Cyclophosphamide ± rituximab[a]
- Rituximab (375 mg/m^2 weekly for 4 doses)[a]

[a] First-line therapy for elderly or infirm (if none of the above are expected to be tolerable in the opinion of treating physician).

REFERENCES

1. NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes V.1.2023. Updated September 12, 2022. Accessed September 8, 2023. http://www.nccn.org/professionals/physician_gls/PDF/mds.pdf.
2. NCCN Clinical Practice Guidelines in Oncology. Multiple Myeloma V.4.2023. Updated August 25, 2023. Accessed September 8, 2023. https://www.nccn.org/professionals/physician_gls/PDF/myeloma.pdf.
3. Revlimid. Prescribing information. Celgene Corporation. 2023. Accessed August 8, 2023. https://packageinserts.bms.com/pi/pi_revlimid.pdf.
4. NCCN Clinical Practice Guidelines in Oncology. B-Cell Lymphomas V.5.2023. Updated July 7, 2023. Accessed August 16, 2023. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.