MEDICATION POLICY

Generic Name: Lenalidomide

Therapeutic Class or Brand Name: Revlimid®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 10/5/16

GPI Code: 9939405000

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through C and must meet criteria listed under applicable diagnosis:
   A. Myelodysplastic Syndrome (MDS) and criterion 1 is met:
      1. The patient is transfusion-dependent (defined as administration of 2 or more units of red blood cells [RBCs] in the previous 8 weeks).
   B. Multiple Myeloma (MM) and criterion 1 is met:
      1. Revlimid® is being used in combination with a corticosteroid such as dexamethasone (unless used as maintenance or documentation is provided that a corticosteroid is contraindicated or is not tolerated).
   C. Mantle Cell Lymphoma (MCL) and both of criteria 1 and 2 are met:
      1. Prior treatment with bortezomib (Velcade®) was ineffective or not tolerated.
      2. Prior treatment with at least one other therapy for MCL listed in Appendix was ineffective, unless all are contraindicated or not tolerated.

II. Minimum age requirement: 18 years old.

III. Prescriber is an oncologist or a hematologist.

Exclusion Criteria:

- Chronic lymphocytic leukemia (CLL).
- Pregnancy.

Other Criteria:

- N/A

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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) or Mantle Cell Lymphoma (MCL): 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:

- CHOP/RCHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab (Rituxan®) – various regimens, including sequential and alternating
- CALGB (rituximab, methotrexate, cyclophosphamide, doxorubicin, vincristine, prednisone)
- R-HyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with rituximab plus high-dose methotrexate and cytarabine) (or modified)
- Rituximab + EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
- Modified rituximab-HyperCVAD in patients older than 65 y
- NORDIC (rituximab + cyclophosphamide, vincristine, doxorubicin, prednisone alternating with rituximab + high-dose cytarabine)
- Cladribine ± rituximab (Rituxan®)
- Bendamustine ± rituximab (Rituxan®)
- Sequential RCHOP/RICE [rituximab (Rituxan®), ifosfamide, carboplatin, etoposide]
- Alternating RCHOP/RDHAP [rituximab (Rituxan®), dexamethasone, cisplatin, cytarabine]
- VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone)

References:

1. http://blue.regence.com/trgmedpol/drugs/dru127.pdf.
2. http://www.nccn.org/professionals/physician_gls/PDF/mds.pdf.
3. http://www.nccn.org/professionals/physician_gls/PDF/myeloma.pdf.
4. https://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf.
5. Medi-Span.

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6. http://www.revlimid.com/pdf/PI.pdf.

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Historical Tracking Of Changes Made To Policy	
10/5/2016	1. **Changed** "I. A. Myelodysplastic Syndrome (MDS) and criteria 1 through 3 are met: 1. The patient is transfusion-dependent (defined as administration of 2 or more units of red blood cells [RBCs] in the previous 8 weeks); 2. The patient has an absolute neutrophil count (ANC) of at least 500 cells/mm3; 3. The patient has a platelet count of at least 50,000/mm3" **to** "I. A. Myelodysplastic Syndrome (MDS) and criterion 1 is met: 1. The patient is transfusion-dependent (defined as administration of 2 or more units of red blood cells [RBCs] in the previous 8 weeks)" **under Prior Authorization Criteria**. 2. **Changed** "I. B. Multiple Myeloma (MM) and criteria 1 through 3 are met: 1. Revlimid® is being used in combination with a corticosteroid such as dexamethasone (unless used as maintenance or documentation is provided that a corticosteroid is contraindicated or is not tolerated); 2. The patient has an absolute neutrophil count (ANC) of at least 1,000 cells/mm3; 3. The patient has a platelet count of at least 30,000/mm3" **to** "I. B. Multiple Myeloma (MM) and criterion 1 is met: 1. Revlimid® is being used in combination with a corticosteroid such as dexamethasone (unless used as maintenance or documentation is provided that a corticosteroid is contraindicated or is not tolerated)" **under Prior Authorization Criteria**. 3. **Changed** "I. C. Mantle Cell Lymphoma (MCL) and criteria 1 through 4 are met: 1. Prior treatment with bortezomib (Velcade®) was ineffective or not tolerated; 2. Prior treatment with at least one other therapy for MCL listed in Appendix has been ineffective, unless all are contraindicated or not tolerated; 3. The patient has an absolute neutrophil count (ANC) of at least 500 cells/mm3; 4. The patient has a platelet count of at least 50,000/mm3" **to** "I. C. Mantle Cell Lymphoma (MCL) and both of criteria 1 and 2 are met: 1. Prior treatment with bortezomib (Velcade®) was ineffective or not tolerated; 2. Prior treatment with at least one other therapy for MCL listed in Appendix was ineffective, unless all are contraindicated or not tolerated" **under Prior Authorization Criteria**. 4. **Added** "Modified rituximab-HyperCVAD in patients older than 65 y" **and** "VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone)" below "First-line therapy options for Mantle Cell Lymphoma" **under Appendix**. 5. **Added** "– various regimens, including sequential and alternating" **following** "CHOP/RCHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab (Rituxan®)" **and** "(or modified)" **following** "R-HyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with rituximab plus high-dose methotrexate and cytarabine)" below "First-line therapy options for Mantle Cell Lymphoma" **under Appendix**. 6. **Removed** "CVP (cyclophosphamide, vincristine, prednisone) + rituximab (Rituxan®)" **and** "Modified HyperCVAD with rituximab (Rituxan®) maintenance" below "First-line therapy options for Mantle Cell Lymphoma" **under Appendix**. 7. **Added** "https://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf" **under References**.
4/14/2015	1. **Removed** "Revlimid® is being used in combination with bortezomib (Velcade®) or carfilzomib (Kyprolis®)" **from Exclusion Criteria**. 2. **Added** "2.5 mg" and "20 mg" to list of dosage strengths **under Quantity/Days Supply Restrictions**. 3. **Changed** "CHOP/RCHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab (Rituxan®)" **to** "CHOP/RCHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab (Rituxan®)"**,** "Cladribine + rituximab (Rituxan®)" **to** "Cladribine ± rituximab (Rituxan®)"**, and** "Bendamustine + rituximab (Rituxan®)" **to** "Bendamustine ± rituximab (Rituxan®)"**under Appendix**. 4. **Added** "http://www.nccn.org/professionals/physician_gls/PDF/mds.pdf" **and** "http://www.nccn.org/professionals/physician_gls/PDF/myeloma.pdf" **under References**.
12/26/2013	1. **Adapted policy to new format.** 2. **Added GPI code**. 3. **Added** "Mantle Cell Lymphoma (MCL) and criteria 1 through 4 are met: 1. Prior treatment with bortezomib (Velcade®) was ineffective or not tolerated; 2. Prior treatment with at least one other therapy for MCL listed in Appendix has been ineffective, unless all are contraindicated or not tolerated;

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Historical Tracking Of Changes Made To Policy	
	3. The patient has an absolute neutrophil count (ANC) of at least 500 cells/mm^3; 4. The patient has a platelet count of at least 50,000/mm^3" **to list of diagnoses included under Prior Authorization Criteria**. 4. **Added** Chronic lymphocytic leukemia (CLL) **to Exclusion Criteria**. 5. **Added** Pregnancy **to Exclusion Criteria**. 6. **Assigned 1 year Approval Length to Mantle Cell Lymphoma (MCL) diagnosis under Authorization.** 7. **Changed Quantity/Days Supply Restrictions from** "30 capsules (any combination of 5 mg, 10 mg, 15 mg, or 25 mg dosage strengths) per 30 days" **to** "Quantities of up to 30 capsules (any combination of 5 mg, 10 mg, 15 mg, or 25 mg dosage strengths) per 30 days". 8. **Updated references** to include Medi-Span and updated website address for package insert.