

Complete Patient and Physician information (PLEASE PRINT)

STEP 1	Member Name:	Physician Name:
	Address:	Address:
	Member ID:	Phone #:
	Member DOB:	Fax #:
		Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____ Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP 2	Diagnosis	<input type="checkbox"/> Myelodysplastic syndrome <input type="checkbox"/> Multiple Myeloma	<input type="checkbox"/> Other (please state): _____ _____
	Physician Specialty	<input type="checkbox"/> Oncology <input type="checkbox"/> Hematology <input type="checkbox"/> Other (please state):	<input type="checkbox"/> Physician registered with RevAssist
	Clinical Consideration	Myelodysplastic syndrome ONLY: <input type="checkbox"/> Patient has deletion of 5q cytogenetic abnormality (low or intermediate-1 risk) <input type="checkbox"/> Transfusion dependent anemia	Multiple Myeloma ONLY: <input type="checkbox"/> Pt is receiving Dexamethasone <input type="checkbox"/> Pt has received at least 1 prior therapy
	Laboratory Consideration	<input type="checkbox"/> EPO serum level _____ mU/ml OR <input type="checkbox"/> EPO documented failure (Use of EPO for minimum of 2 months)	<input type="checkbox"/> Renal Function: SCr: _____ Date: _____
	Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required): Please attach a copy of the prescription or provide ALL of the information below: Revlimid [®] (lenalidomide) Strength _____ Sig _____ Qty _____ Refills _____ *Please note that patient, prescriber and pharmacy MUST be registered with RevAssist.	
<p>We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>			

STEP 3 I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP 4 Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/10/12

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Revlimid® (lenalidomide)

CLASSIFICATION

- Immune Modulator

DESCRIPTION

- Lenalidomide possesses immunomodulatory and antiangiogenic properties. Its exact mechanism of action is unknown but it has been shown in vitro to affect inflammatory cytokines and inhibit cell proliferation of various cell lines
- Myelodysplastic Syndrome:
 - Lenalidomide is an oral agent used in the treatment of transfusion-dependent patients with 5q deletion myelodysplastic syndrome (MDS). It has shown efficacy in an open-label single arm clinical trial and has not been evaluated in randomized clinical trials. The benefits of lenalidomide must be weighed against the risks, as it is highly myelosuppressive.
 - Lenalidomide treatment was effective in producing red blood cell (RBC) transfusion independence in patients with transfusion-dependent anemia, chromosome 5q deletion (isolated or with other cytogenetic abnormalities), and low or intermediate-1 risk MDS. Patients were treated with lenalidomide 10 mg once daily either continuously (n=102) or for 21 days every 28 days (n=46). Transfusion-dependence was defined as having received at least 2 units of RBCs within 8 weeks prior to enrollment. Patients were required to have neutrophil counts of at least 500 cells/mm³ and platelet counts of at least 50,000/mm³. Granulocyte colony-stimulating factor (G-CSF) was permitted to treat neutropenia or febrile neutropenia. Transfusion independence was defined as the absence of any RBC transfusion during any consecutive 8 weeks.
- Multiple Myeloma:
 - In 2 phase III, multicenter, randomized, double-blind, placebo-controlled studies, lenalidomide plus oral pulse high-dose dexamethasone therapy achieved greater delays in disease progression compared to dexamethasone alone in patients with multiple myeloma who had received at least one prior treatment. Study participants (n=704) were included if they had baseline multiple myeloma stages (Durie-Salmon) I, II, and III. They were excluded if they had dexamethasone-resistant disease defined as disease progression during previous high-dose dexamethasone-containing therapy (total monthly dose >200 mg).
- Lenalidomide is an analogue of thalidomide, a known human teratogen that causes severe life-threatening human birth defects.
- Prophylactic anticoagulation is recommended for patients receiving lenalidomide with dexamethasone.
- Revlimid® is only available under a restricted distribution program called RevAssist(SM).

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Revlimid® (lenalidomide) meets the definition of **medical necessity** for the following:

FDA labeled indications:

- Multiple myeloma, in combination with dexamethasone, in patients who have received at least 1 prior therapy
- Myelodysplastic syndrome, Transfusion-dependent anemia due to deletion 5q abnormality, low or intermediate-1 risk

The National Comprehensive Cancer Network (NCCN) has recommended guidelines for Revlimid use:

- Multiple Myeloma (Grade 1)
 - Palliative treatment on or off clinical trials as a single agent or in combination with dexamethasone with or without bortezomib for disease relapse or for progressive or refractory disease; induction chemotherapy for progressive solitary plasmacytoma or smoldering myeloma (asymptomatic or stage I) that has progressed beyond stage II or active myeloma (symptomatic, all stages) in combination with dexamethasone with or without bortezomib for transplant candidates or in combination with low-dose dexamethasone for nontransplant candidates.
- MDS (Grade 2A)
 - Initial treatment in lower risk patients with del(5q) chromosomal abnormalities with clinically significant cytopenia(s) and symptomatic anemia. If there is a response, continue lenalidomide treatment.
 - Initial treatment in lower risk patients with symptomatic anemia with no del(5q) and serum erythropoietin levels greater than 500 mU/mL and a low probability of response to immunosuppressive therapy
 - Treatment in lower risk patients with symptomatic anemia with no del(5q) and no response to initial treatment with epoetin alfa or darbopoetin alfa, hypomethylating agents, or immunosuppressive therapy.
- Non-Hodgkin Lymphoma (NHL) – Mantle Cell Lymphoma (Grade 2A)
 - Second-line therapy as a single agent for relapsed, refractory, or progressive disease.

Revlimid® (lenalidomide) is considered **experimental** for the following:

- Chronic lymphoid leukemia, Relapsed or refractory
- Multiple myeloma, In combination with dexamethasone, first-line therapy
- Non-Hodgkin's lymphoma, Aggressive disease, relapsed or refractory including Mantle cell lymphoma.
 - Requests for this or any other form of NHL will be individually reviewed for medical necessity

Required Provider Specialty:

- Approval is limited to Oncology or a specialty involving blood disorders
- Must register in RevAssist program

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established)

- Multiple myeloma, in combination with dexamethasone, first-line therapy: (*high-dose dexamethasone*) 25 mg ORALLY daily on days 1 to 21 of a 28-day cycle; co-administer dexamethasone 40 mg ORALLY daily on days 1 to 4, 9 to 12, and 17 to 20 of each 28-day cycle
- Multiple myeloma, in combination with dexamethasone, first-line therapy: (*low-dose dexamethasone*) 25 mg ORALLY daily on days 1 to 21 of a 28-day cycle; co-administer dexamethasone 40 mg ORALLY on days 1, 8, 15, and 22 of each 28-day cycle
- Multiple myeloma, in combination with dexamethasone, in patients who have received at least 1 prior therapy: initial, 25 mg ORALLY daily with water (as a single 25 mg capsule) on days 1 to 21 of a 28-day cycle; co-administer dexamethasone 40 mg/day ORALLY on days 1 to 4, 9 to 12, and 17 to 20 of each 28-day cycle for the first 4 cycles, then 40 mg/day ORALLY on days 1 to 4 every 28 days; continue therapy, with dose adjustments for toxicities, until disease progression
- Myelodysplastic syndrome, transfusion-dependent, deletion 5q abnormality, low or intermediate-1 risk: 10 mg ORALLY once daily with water

Dosing adjustments:

- Required for renal impairment or if either neutropenia or thrombocytopenia develop during therapy. Refer to package insert/ prescribing information.

PRECAUTIONS:

- **Black Box Warning:** May cause human birth defects, hematological toxicity (neutropenia and thrombocytopenia), deep vein thrombosis (DVT), and pulmonary embolism (PE).
- Contraindication: Pregnancy category X; high potential for birth defects; women of childbearing potential must take adequate precautions taken to prevent pregnancy; pregnancy testing required
- Hematologic toxicity (grade 3 or 4 neutropenia and thrombocytopenia) has been frequently reported; CBC monitoring recommended; dose reduction or treatment interruption may be necessary
- Males, sexually active; must comply with mandatory contraception requirements to prevent pregnancy
- Thromboembolism (DVT or PE) has been reported in patients with multiple myeloma treated with combination therapy; monitoring is recommended
- Angioedema, some cases fatal, has been reported; discontinue therapy if angioedema occurs
- Renal impairment (CrCl less than 60 mL/min); dosage adjustment recommended

- Serious skin dermatologic reactions (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis), some cases fatal, have occurred; use not recommended in patients with a history of grade 4, thalidomide-associated rash; consider therapy interruption or discontinuation if a grade 2 rash develops; discontinue therapy for serious dermatologic reactions including grade 4 rash or an exfoliative or bullous rash
- Tumor lysis syndrome may occur; monitoring recommended

Billing/Coding information

- n/a

COST

- AWP (April 2010):
 - Revlimid 10mg capsule (1): \$406.05
 - Revlimid 15mg capsule (1): \$407.70
 - Revlimid 25mg capsule (1): \$411.70
- AWP (January 2012):
 - Revlimid 5mg capsule (1): \$440.07
 - Revlimid 10mg capsule (1): \$447.62
 - Revlimid 15mg capsule (1): \$449.45
 - Revlimid 25mg capsule (1): \$453.87

COMMITTEE APPROVAL:

- March 2006

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created
September 2011	PA revised
January 2012	PA updated

REFERENCES:

- DRUGDEX®, accessed 04/06/2010, 01/06/12
- NCCN Drugs & Biologics Compendium™. Lenalidomide (Revlimid®). Copyright 2009, National Comprehensive Cancer Network (NCCN).
- Product Information: REVLIMID® oral capsules, lenalidomide oral capsules. Celgene Corporation, Summit, NJ, 2009. Revised October 2010.
- NCCN Guidelines® Myelodysplastic Syndromes. Version 1.2012, 12/6/11© National Comprehensive Cancer Network, Inc. 2011
- NCCN Guidelines® Multiple Myeloma. Version 1.2012, 07/26/11© National Comprehensive Cancer Network, Inc. 2011