ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Pomalyst® (pomalidomide) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Pomalyst® (pomalidomide)

Diagnosis (documentation supportive of diagnosis is required)

☐ Multiple Myeloma

☐ Other (please state): _____

Clinical Consideration (for approval, documentation supporting the following is required):

☐ Patient has received at least two prior therapies including Revlimid (lenalidomide) and Velcade (bortezomib)
☐ Patient has demonstrated disease progression on or within 60 days of completion of the last therapy
☐ Individual has an ECOG performance score of 0, 1, or 2
- ☐0
- ☐1
- ☐2

- **Approval duration is granted in 6 month intervals**
- **Renewal is granted if the patient does not show evidence of progressive disease while on Pomalyst therapy**

Physician Specialty

☐ Oncologist
☐ Pomalyst REMS certified
☐ Other (please state):_____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:
Prescriber or Authorized Signature:		Date:
Dispensing Pharmacy Name and Phone Number:		

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

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

Pomalyst® (pomalidomide)

CLASSIFICATION

- Antineoplastic Agent
- Immunomodulary Drug (IMiDs)

DESCRIPTION

- Pomalidomide is a thalidomide analogue, which exerts an immunomodulatory antineoplastic effect by the inhibition of the proliferation and induction of apoptosis of hematopoietic tumor cells. Pomalidomide also enhances T cell- and natural killer cell-mediated immunity and inhibits pro-inflammatory cytokine production (e.g. TNF-alpha and IL-6) by monocytes. Pomalidomide co-administration with dexamethasone induces tumor cell apoptosis in both lenalidomide-sensitive and lenalidomide-resistant cell lines.
- Pomalyst is indicated for patients with multiple myeloma who have received at least two prior therapies including Revlimid (lenalidomide) and Velcade (bortezomib) and have demonstrated disease progression on or within 60 days of completion of the last therapy.
- FDA approval of Pomalyst is based on response rate. Treatment with pomalidomide plus dexamethasone resulted in a higher overall response rate (ORR) compared with pomalidomide alone in patients with relapsed multiple myeloma despite prior treatment with lenalidomide and bortezomib. Clinical benefit, such as improvement in survival or symptoms, has not been verified.
- In an open-label, phase 2 study (n=221), patients with relapsed (stable disease for at least 1 cycle of treatment to at least 1 prior regimen) or refractory (progressed on or within 60 days of the last therapy) multiple myeloma were randomized to receive either pomalidomide 4 mg orally daily for 21 of 28 days (n=108) or pomalidomide + low-dose dexamethasone (n=113). Low-dose dexamethasone consisted of either 40 mg orally on days 1, 8, 15, and 22 of each 28-day cycle (≤75 years of age) or dexamethasone 20 mg orally on days 1, 8, 15, and 22 of each 28-day cycle (>75 years of age). Patients receiving pomalidomide only could receive low-dose dexamethasone when disease progression occurred. The ORR was 29.2% (95% CI: 21% to 38.5%) in the pomalidomide + dexamethasone group for a median duration of response of 7.4 months (95% CI: 5.1 to 9.2 months) compared with 7.4% (95% CI: 3.3% to 14.1%) in the pomalidomide-only group where the median response has not yet been reached. In the pomalidomide + dexamethasone group, a complete response (CR) occurred in 0.9% and a partial response (PR) in 28.3% compared with the pomalidomide-only group where a CR occurred in 0% and a PR in 7.4%.
- The most common adverse reactions occurring ≥ 30% included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper respiratory tract infections, back pain and pyrexia.
- Pomalyst REMS™ because of the risk of embryo-fetal with exposure to pomalidomide. Prescribers must be certified, patients must sign a patient-prescriber agreement form, and pharmacies must be certified. Pomalyst REMS program is available at www.celgeneriskmanagement.com or by phone at 1-888-423-5436.
- The National Comprehensive Cancer Network (NCCN) guidelines for Multiple Myeloma (version 2.2013) include Pomalyst/dexamethasone as a preferred salvage therapy regimen (category 2a recommendation).

FORMULARY COVERAGE

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

COVERAGE CRITERIA

Pomalyst® (pomalidomide) meets the definition of **medical necessity** for all FDA approved indications, not otherwise excluded from Part D, including the following:

- Documentation of FDA approved indication required.
- Pomalyst is indicated for patients who have received at least 2 prior therapies including lenalidomide and bortezomib and progressed on or within 60 days of last therapy. Documentation from the patient's medical record supporting use of prior therapies and progression is required.

Approval duration is granted in 6 month intervals. Renewal is granted if the patient does not show evidence of progressive disease while on Pomalyst therapy.

- Criteria used for evidence of progressive disease is the International Myeloma Working Group Uniform Response Criteria for Disease Progression and Relapse available in the National Comprehensive Cancer Network® guidelines for Multiple Myeloma

Pomalyst® (pomalidomide) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Oncology
- Pomalyst REMS certification required

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):

- *Prior to initiating pomalidomide therapy, obtain 2 negative pregnancy tests.*
- *Do not initiate a new cycle of pomalidomide unless the neutrophil count is at least 500/mcL and the platelet count is at least 50,000/mcL.*
- Multiple Myloma: 4 mg ORALLY once daily on days 1 to 21 of repeated 28-day cycles until disease progression;
    - If ≤ 75 years: consider dexamethasone 40mg PO on days 1, 8,15, and 22 of each 28-day cycle
    - If > 75 years: consider dexamethasone 20mg PO on days 1, 8,15, and 22 of each 28-day cycle
- See prescribing information for complete prescribing and dose modification information.

PRECAUTIONS

Black Box Warning:

- Embryo-fetal toxicity: Pomalidomide is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. For females of reproductive potential: Exclude pregnancy before start of treatment. Prevent pregnancy during treatment by the use of 2 reliable methods of contraception.

- Venous thromboembolism: DVT and pulmonary embolism occur in patients with multiple myeloma treated with pomalidomide.

Precautions:

- Males sexually active with female partner must comply with mandatory contraception requirements.
- Sperm donations: do not donate during and for 28 days following therapy discontinuation
- Thromboembolism (DVT or pulmonary embolism) has been reported; monitoring recommended; consider anticoagulation prophylaxis.
- Blood donations: do not donate during treatment and for 1 month following discontinuation; pregnant women might receive the blood and expose her fetus to pomalidomide.
- Avoid concomitant use with strong CYP1A2, CYP3A, or P-glycoprotein inducers.
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- Grade 3 and 4 dizziness and confusional state have been reported.
- Increased incidence of pneumonia has been reported in geriatric (65 years or older) patients.
- Hematologic toxicity (grade 3 or 4 neutropenia, anemia, and thrombocytopenia) has been reported; monitoring recommended; dose reduction or interruption may be necessary.
- Avoid use in hepatic impairment (serum bilirubin > 2mg/dL and AST/ALT > 3 times ULN).
- Hypersensitivity to thalidomide or lenalidomide may increase risk for hypersensitivity.
- Risk of second primary malignancies (acute myelogenous leukemia) have been reported in studies outside of multiple myeloma indications.
- Neuropathy, including peripheral neuropathy, has been reported.
- Avoid use in renal impairment (serum creatinine > 3mg/dL).

Billing/Coding information

HCPCS Coding:

C9399	Unclassified drugs or biologicals (This code should only be used for drugs and biologicals that are approved by the FDA on or after January 1, 2004) (Hospital Outpatient Use ONLY)
J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

COST

- AWP (May 2013): Pomalyst 4mg oral (21): $12,534.50
- AWP (January 2014): Pomalyst 4mg oral (21): $12,910.60

COMMITTEE APPROVAL

- May 2013

GUIDELINE UPDATE INFORMATION

May 2013	Prior Authorization and Coverage Policy created
May 2014	Coverage Policy updated

REFERENCES

- DRUGDEX®, accessed 05/08/2013, 5/17/2014.
- Product Information: Pomalyst® (pomalidomide) capsules, for oral use. Celgene Corporation, Summit, NJ, 2/2013.
- Eastern Cooperative Oncology Group (ECOG). ECOG performance status. [ECOG Web site]. 07/27/06. Available at: http://www.ecog.org/general/perf_stat.html. Accessed May 9, 2013.
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology – Multiple Myeloma. V.2.2013.