Pomalyst® (pomalidomide)
(Oral)

Document Number: IC-0077

Last Review Date: 10/30/2018
Date of Origin: 03/07/2013
Dates Reviewed: 02/25/2014, 12/16/2014, 10/20/2015, 10/2016, 10/2017, 10/2018

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 1 mg capsule: 21 capsules per 28 days
- 2 mg capsule: 21 capsules per 28 days
- 3 mg capsule: 21 capsules per 28 days
- 4 mg capsule: 21 capsules per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Females of reproductive potential must have negative pregnancy testing and use contraception methods prior to initiation, during and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST REMS program; **AND**
- Patient will not receive in combination with PD-1 or PD-L1 targeted therapy; **AND**

Multiple Myeloma†

- Patient has relapsed or progressive disease and received at least two (2) prior therapies, including an immunomodulatory agent [i.e. lenalidomide or thalidomide] and a proteasome inhibitor [i.e. bortezomib, carfilzomib, ixazomib, etc]; **AND**
    - Patient has demonstrated disease progression on or within 60 days of completion of last therapy; **AND**

- Used in combination with dexamethasone with or without one of the following: bortezomib, carfilzomib, ixazomib, or cyclophosphamide; **OR**
- Used as a single agent if patient is steroid-intolerant; **OR**

- Used in combination with dexamethasone and daratumumab.

Systemic Light Chain Amyloidosis ‡

- Must be used for relapsed or refractory disease; **AND**
- Must be used in combination with dexamethasone

AIDS-Related Kaposi Sarcoma ‡

- Patient has relapsed or refractory disease; **AND**
- Patient has advanced cutaneous, oral, visceral or nodal disease; **AND**
- Used as subsequent therapy in combination with antiretroviral therapy (ART) after failure to two lines of systemic therapy

† FDA Approved Indication(s); ‡ Compendia recommended indication

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hematologic toxicity (anemia, neutropenia, or thrombocytopenia); hepatotoxicity, venous or arterial embolism; severe cutaneous hypersensitivity reactions; severe dizziness/confusion; severe neuropathy; development of second primary malignancy; tumor lysis syndrome; etc.

V. Dosage/Administration

Indication	Dose
Multiple myeloma and Systemic Light Chain Amyloidosis	4 mg orally once daily for 21 days of a 28-day cycle, until disease progression or unacceptable toxicity
AIDS-Related Kaposi Sarcoma	Up to 5 mg orally once daily for 21 days of a 28-day cycle, until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS:

J8999 – Prescription drug, oral, chemotherapeutic, NOS

C9399 – Unclassified drugs or biologicals (Hospital outpatient use only)

NDC:

- 1 mg capsule: 59572-0501-xx
- 2 mg capsule: 59572-0502-xx
- 3 mg capsule: 59572-0503-xx
- 4 mg capsule: 59572-0504-xx

VII. References

1. Pomalyst [package insert]. Summit, NJ; Celgene Corporation; May 2018. Accessed October 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pomalidomide. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2018.
3. Dispenzieri A, Buadi F, Laumann K, et al. Activity of pomalidomide in patients with immunoglobulin light-chain amyloidosis. *Blood*. 2012;119(23):5397-5404.
4. Sanchorawala V, Shelton AC, Lo S, et al. (2016). Pomalidomide and dexamethasone in the treatment of AL amyloidosis: results of a phase 1 and 2 trial. Blood, 128(8), 1059-1062.
5. Polizzotto MN, Uldrick TS, Kyvill KM, et al. Pomalidomide for symptomatic Kaposi's sarcoma in people with and without HIV infection; a phase I/II study. J Clin Oncol 2016;34:4125-4131.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
C46.9	Kaposi's sarcoma, unspecified
C90.00	Multiple myeloma not having achieved remission

C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis
E85.9	Amyloidosis, unspecified
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC