

Pomalyst® (pomalidomide) (Oral)

Document Number: IC-0077

Last Review Date: 10/26/2020

Date of Origin: 03/07/2013

Dates Reviewed: 02/25/2014, 12/16/2014, 10/20/2015, 10/2016, 10/2017, 10/2018, 11/2019, 06/2020, 11/2020

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

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

B. Max Units (per dose and over time) [HCPCS Unit]:

- Multiple Myeloma/Systemic Light Chain Amyloidosis
 - 4 mg daily for 21 days per 28-day cycle
- All Other Indications
 - 5 mg daily for 21 days per 28-day cycle

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Females of reproductive potential must have two (2) negative pregnancy tests before initiation of therapy and use two (2) contraception methods starting four (4) weeks 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 (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**

- Patient will avoid coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, etc.); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**

Multiple Myeloma † Φ 1,2,4,9

- 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 either daratumumab, elotuzumab, or isatuximab; **OR**
- Patient has POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome ‡; **AND**
 - Used in combination with dexamethasone; **AND**
 - Used as induction therapy for transplant eligible patients; **OR**
 - Used for transplant ineligible patients

Primary CNS Lymphoma ‡ 4,8,10

- Used as single agent therapy for relapsed or refractory disease; **AND**
 - Patient has failed prior methotrexate-based regimen without prior radiation therapy; **OR**
 - Patient has received prior whole brain radiation therapy; **OR**
 - Patient has received prior high-dose chemotherapy with stem cell rescue; **OR**
- Used as induction therapy as a single agent; **AND**
 - Patient is unsuitable for or intolerant to high-dose methotrexate

Systemic Light Chain Amyloidosis ‡ 4-6,11

- Patient has relapsed or refractory disease; **AND**
- Used in combination with dexamethasone

Kaposi Sarcoma † Φ 1,4,7

- Patient has AIDS-related Kaposi sarcoma; **AND**
 - Used in combination with highly active antiretroviral therapy (HAART); **AND**
 - Patient has failed on at least one month of HAART; **AND**

- Patient does not have symptomatic pulmonary Kaposi Sarcoma or symptomatic visceral Kaposi Sarcoma (except for non-ulcerating disease restricted to the oral cavity); **OR**
 - Patient has relapsed or refractory advanced cutaneous, oral, visceral, or nodal disease ‡; **AND**
 - Used as subsequent therapy after failure on two lines of prior systemic therapy; **OR**
- Patient is HIV-negative; **AND**
 - Patient does not have symptomatic pulmonary Kaposi Sarcoma or symptomatic visceral Kaposi Sarcoma (except for non-ulcerating disease restricted to the oral cavity)

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

IV. **Renewal Criteria** ^{1,2,4,5-11}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by 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: hematologic toxicity (anemia, neutropenia, or thrombocytopenia), hepatotoxicity, venous or arterial thromboembolism, severe cutaneous reactions, dizziness/confusional state, neuropathy, development of second primary malignancy, tumor lysis syndrome, severe hypersensitivity (including angioedema, anaphylaxis, and anaphylactic reactions), etc.

V. **Dosage/Administration** ^{1,5,6,8,11}

Indication	Dose
Multiple Myeloma and Systemic Light Chain Amyloidosis	4 mg orally once daily on days 1 through 21 of each 28-day cycle, until disease progression or unacceptable toxicity
Primary CNS Lymphoma	Up to 5 mg orally once daily for 21 days of a 28-day cycle, until disease progression or unacceptable toxicity
Kaposi Sarcoma	5 mg orally once daily on days 1 through 21 of each 28-day cycle, until disease progression or unacceptable toxicity

VI. **Billing Code/Availability Information**

HCPCS:

- J8999 – Prescription drug, oral, chemotherapeutic, NOS

NDC:

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

VII. References

1. Pomalyst [package insert]. Summit, NJ; Celgene Corporation; May 2020. Accessed October 2020.
2. San Miguel J, Weisel K, Moreau P, et al. Pomalidomide plus low-dose dexamethasone versus high-dose dexamethasone alone for patients with relapsed and refractory multiple myeloma (MM-003): a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2013;14(11):1055-1066. doi: 10.1016/S1470-2045(13)70380-2. Epub 2013 Sep 3.
3. Dimopoulos MA, Dytfeld D, Grosicki S, et al. Elotuzumab plus pomalidomide and dexamethasone for multiple myeloma. *N Engl J Med.* 2018;379:1811-1822.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pomalidomide. National Comprehensive Cancer Network, 2020. 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 2020.
5. Dispenzieri A, Buadi F, Laumann K, et al. Activity of pomalidomide in patients with immunoglobulin light-chain amyloidosis. *Blood.* 2012;119(23):5397-5404.
6. Sanchorawala V, Shelton AC, Lo S, et al. Pomalidomide and dexamethasone in the treatment of AL amyloidosis: results of a phase 1 and 2 trial. *Blood* 2016 Aug 25; 128(8): 1059-1062.
7. 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. Epub 2016 Oct 31. Erratum in *J Clin Oncol.* 2018 Jul 1;36(19):2008.
8. Tun HW, Johnston PB, DeAngelis LM, et al. Phase 1 study of pomalidomide and dexamethasone for relapsed/refractory primary CNS or vitreoretinal lymphoma. *Blood.* 2018 Nov 22;132(21):2240-2248.
9. Richardson PG, Siegel DS, Vij R, et al. Pomalidomide alone or in combination with low-dose dexamethasone in relapsed and refractory multiple myeloma: a randomized phase 2 study. *Blood.* 2014 Mar 20;123(12):1826-32. doi: 10.1182/blood-2013-11-538835. Epub 2014 Jan 13. Erratum in: *Blood.* 2014 May 15;123(20):3208-9.
10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Central Nervous System Cancers. Version 3.2020. National Comprehensive

Cancer Network, 2020. 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 2020.

11. Palladini G, Milani P, Foli A, et al: A phase 2 trial of pomalidomide and dexamethasone rescue treatment in patients with AL amyloidosis. Blood 2017; 129(15):2120-2123.

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
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C83.80	Other non-follicular lymphoma unspecified site
C83.89	Other non-follicular lymphoma extranodal and solid organ sites
C85.89	Other specified types of non-Hodgkin lymphoma extranodal and solid organ sites
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
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
E31.9	Polyglandular dysfunction, unspecified
E85.81	Light chain (AL) amyloidosis

E85.89	Other amyloidosis
E85.9	Amyloidosis, unspecified
G62.9	Polyneuropathy, unspecified
G90.9	Disorder of the autonomic nervous system, unspecified
L98.9	Disorder of the skin and subcutaneous tissue, 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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA): 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