Pomalyst® (pomalidomide)
(Oral)

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I. Length of Authorization

Coverage will be provided for 6 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
- Primary CNS Lymphoma & Kaposi Sarcoma
  - 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**
- Females of reproductive potential have two (2) negative pregnancy tests before initiation of therapy; **AND**

Universal Criteria [1]

- Females of reproductive potential will undergo regular (i.e., monthly or biweekly) pregnancy testing while on therapy; **AND**
- Females of reproductive potential will either abstain continuously from heterosexual sexual intercourse or use two (2) contraception methods starting four (4) weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**

- Male patients will use effective forms of contraception during sexual contact with females of reproductive potential while on therapy and for up to 4 weeks after discontinuation of therapy (even if they have undergone a successful vasectomy); **AND**
- Male patients will not donate sperm; **AND**
- Patients will avoid donating blood while on therapy and for 4 weeks following discontinuation of therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient will avoid concomitant therapy with all of the following:
    - Coadministration with programmed death (PD-1/PD-L1)-targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab, dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, toripalimab, etc.)
    - Coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

Multiple Myeloma † Φ [1,2,4,9]

- Patient has previously treated relapsed or progressive disease; **AND**
    - Used in combination with dexamethasone and carfilzomib; **OR**
    - Used in combination with dexamethasone and either elotuzumab or bortezomib; **AND**
        - Patient has lenalidomide-refractory disease; **OR**
    - Used in combination with dexamethasone and daratumumab; **AND**
        - Patient received prior therapy including lenalidomide and a proteasome inhibitor*; **OR**
    - Used in combination with dexamethasone and isatuximab-irfc; **AND**
        - Patient received at least two (2) prior therapies, including lenalidomide and a proteasome inhibitor*; **OR**
    - Used in combination with dexamethasone with or without one of the following: ixazomib, cyclophosphamide, or selinexor; **AND**
        - Patient received at least two (2) prior therapies, including an immunomodulatory agent and a proteasome inhibitor*; **AND**
        - Patient has demonstrated disease progression on or within 60 days of completion of last therapy; **OR**
    - Used as a single agent; **AND**
        - Patient is steroid-intolerant; **AND**

        - Patient received at least two (2) prior therapies, including an immunomodulatory agent and a proteasome inhibitor*; **AND**
        - Patient has demonstrated disease progression on or within 60 days of completion of last therapy; **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

**Examples of proteasome inhibitors include: bortezomib, carfilzomib, and ixazomib; Examples of immunomodulatory agents include: lenalidomide and thalidomide.*

Primary CNS Lymphoma ‡ [4,8,10]

- Used as single-agent therapy; **AND**
    - Used for relapsed or refractory disease; **AND**
        - Patient has received a prior high-dose methotrexate-based regimen without prior radiation therapy; **OR**
        - Patient has received prior whole brain radiation therapy; **OR**
        - Used in combination with radiation therapy in patients who had either no response or a short response (< 12 month duration) to a prior high-dose methotrexate-based regimen without prior radiation therapy; **OR**
        - Patient has received prior high-dose systemic therapy with stem cell rescue; **OR**
    - Used as induction therapy; **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**
    - Used after failure of HAART; **OR**
- Patient is HIV-negative; **AND**
    - Used as a single agent

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based on the following criteria:

- Patient continues to meet the 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 (e.g., 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	Administer 4 mg orally once daily on days 1 through 21 of each 28-day cycle, until disease progression or unacceptable toxicity
Primary CNS Lymphoma	Administer up to 5 mg orally once daily for 21 days of a 28-day cycle, until disease progression or unacceptable toxicity
Kaposi Sarcoma	Administer 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 Code:

- J8999 – Prescription drug, oral, chemotherapeutic, NOS

NDC(s):

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

VII. References

1. Pomalyst [package insert]. Princeton, NJ; Celgene Corporation; March 2023. Accessed April 2024.
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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.

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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.
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10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Central Nervous System Cancers. Version 1.2023. National Comprehensive Cancer Network, 2024. 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 April 2024.
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
C85.99	Non-Hodgkin lymphoma, unspecified, 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
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
E31.9	Polyglandular dysfunction, unspecified
E85.3	Secondary systemic amyloidosis
E85.4	Organ-limited amyloidosis
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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