Pomalyst® (pomalidomide) capsules 1 · 2 · 3 · 4 mg

Bristol Myers Squibb®

Access Support®

Your patient. Our commitment.

A REFERENCE GUIDE TO

Reimbursement and Coding POMALYST® (pomalidomide) capsules

POMALYST is only available through a restricted distribution program, called the POMALYST REMS® program.

Please see Important Safety Information on pages 9–12 and US full Prescribing Information for POMALYST, including **Boxed WARNINGS**.

POMALYST Indications

POMALYST® (pomalidomide) is a thalidomide analogue indicated for the treatment of adult patients:

- in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.
- with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information for POMALYST

POMALYST Boxed WARNINGS

WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

- **POMALYST is contraindicated in pregnancy. POMALYST is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting POMALYST treatment.**
- **Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping POMALYST treatment.**

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Venous and Arterial Thromboembolism

- **Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Prophylactic antithrombotic measures were employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.**

Please see Important Safety Information on pages 9–12 and US full Prescribing Information for POMALYST, including **Boxed WARNINGS**.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Bristol Myers Squibb Is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to our medications by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that healthcare provider offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

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National Drug Code (NDC) Information for POMALYST® (pomalidomide)

The NDCs for POMALYST® are listed below.*

NDCs for POMALYST[1]

1 mg bottles of 21	1 mg bottles of 100	3 mg bottles of 21	3 mg bottles of 100
(NDC 59572-0501-21)	(NDC 59572-0501-00)	(NDC 59572-0503-21)	(NDC 59572-0503-00)
2 mg bottles of 21	2 mg bottles of 100	4 mg bottles of 21	4 mg bottles of 100
(NDC 59572-0502-21)	(NDC 59572-0502-00)	(NDC 59572-0504-21)	(NDC 59572-0504-00)

The red zero (red text) converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

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ICD-10-CM Codes

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States. This version replaces the previous version, ICD-9-CM.[2]

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters

The ICD-10-CM codes for the labeled indications for POMALYST® (pomalidomide) capsules are provided on the following pages by Bristol Myers Squibb and should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**.

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ICD-10-CM Codes for POMALYST® (pomalidomide)

ICD-10-CM Codes for Multiple Myeloma (MM)[3]	
C90.0	Multiple myeloma
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

ICD-10-CM Codes for Kaposi's Sarcoma (KS)[3]	
C46	Kaposi's sarcoma
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
C46.5	Kaposi's sarcoma of lung
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

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Dosage and Administration for POMALYST® (pomalidomide)

Recommended Dosage for Multiple Myeloma[1]

- Recommended dosage for **POMALYST is 4 mg once daily orally with or without food on Days 1–21 of each 28-day cycle** until disease progression
- Refer to US full Prescribing Information for details on dose modifications
- Give POMALYST in combination with dexamethasone (dex)
  - In the Phase 3 MM-003 trial, low-dose dex was given on Days 1, 8, 15, and 22 of a 28-day cycle
  - Dex 40 mg for patients ≤75 years
  - Dex 20 mg for patients >75 years

Important Dosing Information (MM)

- POMALYST may be taken with or without food. Inform patients not to break, chew, or open the capsules. Swallow capsules whole with water.
- Monitor CBCs every week for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification.
- Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes and evaluate. After return to baseline values, treatment at a lower dose may be considered.
- Reduce POMALYST dose to 3 mg orally daily in patients with mild to moderate hepatic impairment and to 2 mg in patients with severe hepatic impairment.
- Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg.
- Reduce POMALYST dose to 3 mg orally daily in patients with severe renal impairment requiring dialysis. Take dose of POMALYST following hemodialysis on hemodialysis days.

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Dosage and Administration for POMALYST® (pomalidomide) (cont.)

Recommended Dosage for Kaposi Sarcoma[1]

- Recommended dosage for **POMALYST is 5 mg once daily taken orally with or without food on Days 1 through 21 of each 28-day cycle** until disease progression or unacceptable toxicity. Continue HAART as HIV treatment in patients with AIDS-related Kaposi sarcoma (KS)
- Refer to US full Prescribing Information for details on dose modifications

Important Dosing Information (KS)

- POMALYST may be taken with or without food. Inform patients not to break, chew, or open the capsules. Swallow capsules whole with water.
- Monitor CBCs every 2 weeks for the first 12 weeks and monthly thereafter. Withhold, reduce the dose, or permanently discontinue POMALYST based on the severity of the reaction.
- Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes and evaluate. After return to baseline values, treatment at a lower dose may be considered.
- Reduce POMALYST dose to 3 mg orally daily in patients with mild, moderate, or severe hepatic impairment.
- Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg.
- Reduce POMALYST dose to 4 mg orally daily in patients with severe renal impairment requiring dialysis. Take dose of POMALYST following hemodialysis on hemodialysis days.

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Important Safety Information for POMALYST® (pomalidomide)

WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

- **POMALYST is contraindicated in pregnancy. POMALYST is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting POMALYST treatment.**
- **Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping POMALYST treatment.**

POMALYST is only available through a restricted distribution program called POMALYST REMS®.

Venous and Arterial Thromboembolism

- **Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Prophylactic antithrombotic measures were employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.**

CONTRAINDICATIONS FOR POMALYST

- **Pregnancy:** POMALYST can cause fetal harm and is contraindicated in females who are pregnant. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to a fetus.
- **Hypersensitivity:** POMALYST is contraindicated in patients who have demonstrated severe hypersensitivity (e.g., angioedema, anaphylaxis) to pomalidomide or any of the excipients.

WARNINGS AND PRECAUTIONS FOR POMALYST

- Embryo-Fetal Toxicity & Females of Reproductive Potential: See Boxed WARNINGS FOR POMALYST
  - Males: Pomalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking POMALYST and for up to 4 weeks after discontinuing POMALYST, even if they have undergone a successful vasectomy. Males must not donate sperm.
  - Blood Donation: Patients must not donate blood during treatment with POMALYST and for 4 weeks following discontinuation of POMALYST therapy because the blood might be given to a pregnant female patient whose fetus must not be exposed to POMALYST.
- POMALYST REMS Program: See Boxed WARNINGS
  - Prescribers and pharmacies must be certified with the **POMALYST REMS** program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive POMALYST. Patients must sign a Patient-Physician Agreement Form and comply with REMS requirements; female patients of reproductive potential who are not pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements.
  - Further information about the **POMALYST REMS** program is available at www.pomalystrems.com or by telephone at 1-888-423-5436.

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Important Safety Information for POMALYST® (pomalidomide) (cont.)

- **Venous and Arterial Thromboembolism: See Boxed WARNINGS FOR POMALYST.** Patients with known risk factors, including prior thrombosis, may be at greater risk, and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking). Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.
- **Increased Mortality with Pembrolizumab:** In clinical trials in patients with multiple myeloma, the addition of pembrolizumab to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.
- **Hematologic Toxicity:** In the POMALYST multiple myeloma (MM) trials, neutropenia (46%) was the most frequently reported Grade 3 or 4 adverse reaction, followed by anemia and thrombocytopenia. Monitor complete blood counts weekly for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification. In the Kaposi sarcoma (KS) trial, hematologic toxicities were the most common all Grades and Grade 3 or 4 adverse reactions. Fifty percent of patients had Grade 3 or 4 neutropenia. Monitor complete blood counts every 2 weeks for the first 12 weeks and monthly thereafter. Withhold, reduce the dose or permanently discontinue POMALYST based on the severity of the reaction.
- **Hepatotoxicity:** Hepatic failure, including fatal cases, has occurred in patients treated with POMALYST. Elevated levels of alanine aminotransferase and bilirubin have also been observed in patients treated with POMALYST. Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.
- **Severe Cutaneous Reactions:** Severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with POMALYST. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. These reactions can be fatal. Consider POMALYST interruption or discontinuation for Grade 2 or 3 skin rash. Permanently discontinue POMALYST for Grade 4 rash, exfoliative or bullous rash, or any other severe cutaneous reactions such as SJS, TEN or DRESS.
- **Dizziness and Confusional State:** In patients taking POMALYST in clinical trials, 14% experienced dizziness (1% Grade 3 or 4) and 7% a confusional state (3% Grade 3 or 4). Instruct patients to avoid situations where dizziness or confusional state may be a problem and not to take other medications that may cause dizziness or confusional state without adequate medical advice.
- **Neuropathy:** In patients taking POMALYST in the MM clinical trials, 18% experienced neuropathy (2% Grade 3 in one trial) and 12% peripheral neuropathy.
- **Second Primary Malignancies (SPMs):**
  - Cases of acute myelogenous leukemia have been reported in patients receiving POMALYST as an investigational therapy outside of multiple myeloma.
  - Monitor patients for the development of SPMs.
- **Tumor Lysis Syndrome (TLS):** TLS may occur in patients treated with POMALYST. Patients at risk are those with high tumor burden prior to treatment. These patients should be monitored closely and appropriate precautions taken.
- **Hypersensitivity:** Hypersensitivity, including angioedema, anaphylaxis, and anaphylactic reactions to POMALYST have been reported. Permanently discontinue POMALYST for angioedema or anaphylaxis.

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Important Safety Information for POMALYST® (pomalidomide) (cont.)

ADVERSE REACTIONS

POMALYST Multiple Myeloma:

The most common adverse reactions for POMALYST (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper-respiratory tract infections, back pain, and pyrexia.

In the phase III trial, nearly all patients treated with POMALYST + low-dose dex experienced at least one adverse reaction (99%). Adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥2% higher than control) included neutropenia (51%), fatigue and asthenia (47%), upper respiratory tract infection (31%), thrombocytopenia (30%), pyrexia (27%), dyspnea (25%), diarrhea (22%), constipation (22%), back pain (20%), cough (20%), pneumonia (19%), bone pain (18%), edema peripheral (17%), peripheral neuropathy (17%), muscle spasms (15%), and nausea (15%). Grade 3 or 4 adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥1% higher than control) included neutropenia (48%), thrombocytopenia (22%), and pneumonia (16%).

POMALYST Kaposi Sarcoma:

The most common adverse reactions including laboratory abnormalities (≥30%) are decreased absolute neutrophil count or white blood cells, elevated creatinine or glucose, rash, constipation, fatigue, decreased hemoglobin, platelets, phosphate, albumin, or calcium, increased ALT, nausea, and diarrhea.

In the KS trial, adverse reactions were evaluated in 28 patients who received treatment with POMALYST. Adverse reactions (N=28) ≥20% included maculopapular rash (71%), constipation (71%), fatigue (68%), nausea (36%), diarrhea (32%), cough (29%), dyspnea (29%), peripheral edema (29%), upper respiratory tract infection (29%), muscle spasms (25%), hypothyroidism (21%), dry skin (21%), and chills (21%). Grade 3 or 4 adverse reactions included maculopapular rash (3.6%), diarrhea (3.6%) and peripheral edema (3.6%). Grade 3 or 4 laboratory abnormalities ≥5% worsening from baseline included decreased absolute neutrophil (50%), elevated glucose (7%), decreased phosphate (25%) and elevated creatine kinase (7%).

DRUG INTERACTIONS FOR POMALYST

Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg.

USE IN SPECIFIC POPULATIONS FOR POMALYST

- **Pregnancy: See Boxed WARNINGS FOR POMALYST.** If pregnancy does occur during treatment, immediately discontinue the drug and refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. There is a POMALYST pregnancy exposure registry that monitors pregnancy outcomes in females exposed to POMALYST during pregnancy as well as female partners of male patients who are exposed to POMALYST. This registry is also used to understand the root cause for the pregnancy. Report any suspected fetal exposure to POMALYST to the FDA via the MedWatch program at 1-800-FDA-1088 and also to the REMS Call Center at 1-888-423-5436.
- **Lactation:** There is no information regarding the presence of pomalidomide in human milk, the effects of POMALYST on the breastfed child, or the effects of POMALYST on milk production. Pomalidomide was excreted in the milk of lactating rats. Because many drugs are excreted in human milk and because of the potential for adverse reactions in a breastfed child from POMALYST, advise women not to breastfeed during treatment with POMALYST.

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Important Safety Information for POMALYST® (pomalidomide) (cont.)

- **Pediatric Use:** Safety and effectiveness have not been established in pediatric patients.
- **Geriatric Use:**
  - Multiple Myeloma (MM): No dosage adjustment is required for POMALYST based on age. Patients >65 years of age were more likely than patients ≤65 years of age to experience pneumonia.
  - Kaposi Sarcoma (KS): The clinical study did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.
- **Renal Impairment:** For MM patients with severe renal impairment requiring dialysis, reduce POMALYST dosage to 3 mg orally daily or for KS, reduce POMALYST dosage to 4 mg orally daily. Take dose of POMALYST following hemodialysis on hemodialysis days.
- **Hepatic Impairment:** For MM patients with mild to moderate hepatic impairment, reduce POMALYST dosage to 3 mg orally daily and to 2 mg orally daily in patients with severe hepatic impairment. For KS in patients with mild, moderate, or severe hepatic impairment, reduce POMALYST dosage to 3 mg orally daily.
- **Smoking Tobacco:** Advise patients that smoking may reduce the efficacy of POMALYST. Cigarette smoking reduces pomalidomide AUC due to CYP1A2 induction.

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References

1. POMALYST [package insert]. Princeton, NJ: Bristol-Myers Squibb Company.
2. eHealth University, Centers for Medicare & Medicaid Services. The ICD-10- transition: an introduction. Updated August 2014. Accessed May 12, 2021. https://www.cms.gov/Medicare/Coding/ICD10/Downloads/ICD10Introduction20140819.pdf
3. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Accessed December 15, 2021. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm

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Access Support®

Looking for support? We're here for you.

Coverage assistance, educational resources, and financial support options may be available through **BMS Access Support®**

Call a Patient Access Specialist at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday

Visit **www.BMSAccessSupport.com**

Scheduling a meeting with a BMS Access and Reimbursement Manager on the BMS Access Support website

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