PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Pomalyst Prior Authorization Policy
- Pomalyst® (pomalidomide capsules – Celgene)

REVIEW DATE: 05/11/2022; selected revision 06/22/2022

OVERVIEW

Pomalyst, a thalidomide analog, is indicated for the following uses:[1]

- **Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi sarcoma** in adults after failure of highly active antiretroviral therapy (HAART) or in adults with Kaposi sarcoma who are human immunodeficiency virus (HIV)-negative.
- **Multiple myeloma**, in combination with dexamethasone, in adults who have received at least two prior therapies including lenalidomide capsules and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Disease Overview

Multiple myeloma is a cancer formed by malignant plasma cells which are found in the bone marrow.[2] Normally, B cells responding to an infection change into plasma cells that make the antibodies to help the body attack and kill pathogens. In multiple myeloma, these plasma cells grow out of control and become cancerous. Often, there are no symptoms of disease until it reaches an advanced stage. The most common signs and symptoms include: bone problems (e.g., pain, bone weakness, broken bones), decreased blood counts (e.g., anemia, leukopenia, thrombocytopenia), hypercalcemia, nervous system symptoms due to spinal cord compression, nerve damage, hyperviscosity, kidney problems, and infections. A monoclonal immunoglobulin (M protein) is produced by myeloma cells and may be found in the blood or excreted in the urine of patients with multiple myeloma. Beta-2 microglobulin is another protein made by myeloma cells, with high levels associated with more advanced disease.

Kaposi sarcoma is a multifocal malignancy that impacts endothelial cells which manifest with red or brown papules.[3] The skin is the site most commonly involved, but the oral mucosa, lymph nodes, and viscera may also be impacted.[4] The risk of Kaposi sarcoma is very high among patients who are HIV-positive but is also more common in other patient populations with altered cellular immunity (e.g., patients who have undergone transplants).[3,4] Kaposi sarcoma is usually associated with human herpes virus 8 infection.[3] In patients with Kaposi sarcoma related to HIV, HAART is the foundation of therapy.[4] For patients who do not attain an adequate response with HAART, Kaposi sarcoma-specific systemic therapies include liposomal anthracyclines (doxorubicin) and paclitaxel which have led to response rates between 46% and 76%.[4] Patients who are not HIV-positive have a less established treatment course but cytotoxics are used. Local therapies are also utilized for patients with limited disease (e.g., Panretin® [alitretinoin 0.1% gel], imiquimod 5%, intralesional chemotherapy with vinblastine).[3,4]

Clinical Efficacy

An open-label, single-center, single-arm clinical trial evaluated the efficacy of Pomalyst in patients with Kaposi sarcoma.[4] Among the 28 patients, 18 patients were HIV-positive and 10 patients were HIV-negative. Patients received Pomalyst 5 mg once daily (QD) on Days 1 through 21 of each 28-day cycle until disease progression or unacceptable toxicity. All patients who were HIV-positive continued HAART. At the time of enrollment, 75% of patients had advanced disease and 75% of patients had previously received chemotherapy. The overall response rate among all patients was 71%; overall response rates were 67% and 80% among HIV-positive and HIV-negative patients, respectively. The time to first response was approximately 2 months. The duration of response was approximately 1 year.

Guidelines

Pomalyst is addressed in guidelines from National Comprehensive Cancer Network (NCCN):[3,5-7]

- **Central Nervous System (CNS) Lymphoma:** The NCCN has guidelines regarding CNS cancers (version 2.2021 – September 8, 2021).[5] Pomalyst is listed as a recommended regimen for patients with relapsed or refractory disease for primary CNS lymphoma.
- **Kaposi Sarcoma:** The NCCN has guidelines regarding Kaposi sarcoma (version 1.2022 – February 3, 2022).[3] Pomalyst is cited as the preferred subsequent system therapy option given alone (in patients without HIV) or with antiretroviral therapy for patients with HIV for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease that has not progressed on or not responded for first-line systemic therapy and progressed on alternate first-line systemic therapy. First-line systemic therapy options include liposomal doxorubicin (preferred) and paclitaxel. Of note, the clinical trial with Pomalyst used a dose of 5 mg QD. However, Pomalyst is provided as a 4 mg dose and the NCCN Panel believed that this dose is sufficient.
- **Multiple Myeloma:** The NCCN guidelines for multiple myeloma (version 5.2022 – March 2, 2022) include Pomalyst.[6] Pomalyst is recommended in various clinical regimens after use of previous therapies in varying scenarios and with different agents among patients with multiple myeloma that has been previously treated (including as a category 1 and category 2A recommendation). It can be used as a monotherapy for patients who are steroid intolerant. Pomalyst is also indicated for treatment in combination with dexamethasone for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome as induction therapy for transplant eligible patients and for transplant ineligible patients.
- **Systemic Light Chain Amyloidosis:** The NCCN has guidelines for systemic light chain amyloidosis (version 1.2022 – June 29, 2021).[7] The guidelines list Pomalyst plus dexamethasone as one of several treatment options for patients with previously treated disease (category 2A). Many other regimens are cited as primary therapy for transplant candidates and non-transplant candidates.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Pomalyst. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pomalyst is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Kaposi Sarcoma.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i or ii):
     - **i.** Patient is Human Immunodeficiency Virus (HIV)-negative; OR
     - **ii.** Patient meets both of the following (a and b):
       - **a)** Patient is HIV-positive; AND
       - **b)** Patient continues to receive highly active antiretroviral therapy.

2. **Multiple Myeloma.** Approve for 1 year if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has received at least one other lenalidomide containing regimen.

Other Uses with Supportive Evidence

3. **Central Nervous System Lymphoma.** Approve for 1 year if the patient has relapsed or refractory disease.

4. **POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome.** Approve for 1 year if the patient meets and following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Use of Pomalyst is in combination with dexamethasone.

5. **Systemic Light Chain Amyloidosis.** Approve for 1 year if the patient meets the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Use of Pomalyst is in combination with dexamethasone; AND
   C) Patient has tried at least one other regimen.
   Note: Examples of regimens include lenalidomide plus dexamethasone; Velcade (bortezomib injection for intravenous or subcutaneous use), lenalidomide, cyclophosphamide, and dexamethasone; Velcade with or without dexamethasone; Velcade, lenalidomide, and dexamethasone; melphalan and dexamethasone; Velcade, cyclophosphamide, and dexamethasone; and Darzalex (daratumumab intravenous infusion)/Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Pomalyst is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Pomalyst® capsules [prescribing information]. Summit, NJ: Celgene; October 2021.
2. American Cancer Society. Multiple myeloma. Last updated: January 21, 2021. Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-key-statistics. Accessed on May 7, 2022.
3. The NCCN Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 1.2022 – February 3, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 3, 2022.
4. Polizzotto MN, Uldrick TS, Wyvill 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(34):4125-4131.
5. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2022 – September 8, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 9, 2022.
6. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2022.
7. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (Version 2.2022 – June 29, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2022.