VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Pomalyst® (pomalidomide capsules – Celgene)

DATE REVIEWED: 04/01/2020; selected revision 05/27/2020

OVERVIEW

Pomalyst, a thalidomide analogue, is indicated for the treatment of multiple myeloma in combination with dexamethasone in adults who have received at least two prior therapies including Revlimid® (lenalidomide capsules) and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.[1] Pomalyst is also indicated for the treatment of Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi sarcoma in adults after failure of highly active antiretroviral therapy (HAART) or in patients with Kaposi sarcoma who are Human Immunodeficiency Virus (HIV)-negative.

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's 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's 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's sarcoma is usually associated with human herpes virus 8 (HHV-8) infection.[3] In patients with Kaposi's sarcoma related to HIV, HAART is the foundation of therapy.[4] For patients who do not attain an adequate response with HAART, Kaposi's sarcoma-specific systemic therapies include liposomal anthracyclines (doxorubicin) and paclitaxel which have led to response rates between 46% to 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 gel 0.1%], 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

The National Comprehensive Cancer Network (NCCN) guidelines on multiple myeloma (version 3.2020 – March 10, 2020) include Pomalyst.[5] Pomalyst is recommended in various clinical regimens in varying scenarios and with different agents among patients with multiple myeloma that has been previously treated. It can be used as a monotherapy for patients who are steroid-intolerant.

The NCCN has guidelines regarding AIDS-related Kaposi Sarcoma (version 1.2020 – February 12, 2020).[3] Pomalyst is cited as the preferred subsequent system therapy option for relapsed/refractory 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.

The NCCN has guidelines regarding Central Nervous System (CNS) Cancers (version 1.2020 – March 10, 2020).[6] Pomalyst is listed as a recommended regimen for patients with relapsed or refractory disease.

The NCCN has guidelines for systemic light chain amyloidosis (version 1.2020 – December 6, 2019).[7] The guidelines list Pomalyst plus dexamethasone as one of several treatment options for patients with previously treated disease.

Safety

Pomalyst has a Boxed Warning regarding embryofetal toxicity and venous arterial thromboembolism.[1] The availability of Pomalyst is through a restricted program called Pomalyst Risk Evaluation and Mitigation Strategy (REMS). Warnings and Precautions include hematologic toxicity, hepatotoxicity, hypersensitivity reactions, and tumor lysis syndrome.

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 the following criteria:

FDA-Approved Indications

1. **Multiple Myeloma.** Approve for 3 years.

2. **Kaposi Sarcoma.** Approve for 3 years if the patient meets both of the following (A and B):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient meets one of the following (i or ii):
     - **i.** The patient is Human Immunodeficiency Virus (HIV)-negative; OR
     - **ii.** The patient meets both of the following (a and b):

a) The patient is Human Immunodeficiency Virus (HIV)-positive; AND
b) The patient continues to receive highly active antiretroviral therapy (HAART).

Other Uses with Supportive Evidence

3. Central Nervous System (CNS) Lymphoma. Approve for 3 years if the patient has relapsed or refractory disease.

4. Systemic Light Chain Amyloidosis. Approve for 3 years.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Pomalyst has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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; May 2020.
2. American Cancer Society. Multiple myeloma. Last updated: February 28, 2018. Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-key-statistics. Accessed on May 16, 2020.
3. The NCCN AIDS-Related Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 1.2020 – February 12, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 15, 2020.
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 Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 3.2020 – March 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 13, 2020.
6. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2020 – March 13, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 13, 2020.
7. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (Version 1.2020 – December 6, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 13, 2020.