PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/29/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

- **Kaposi sarcoma,** Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi sarcoma in adults after failure of highly active antiretroviral therapy (HAART) or Kaposi sarcoma in adults 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.

Guidelines

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

- **Central Nervous System (CNS) Cancers:** NCCN guidelines (version 1.2023 – March 24, 2023) list Pomalyst as a recommended regimen (category 2A) for patients with relapsed or refractory disease for primary CNS lymphoma.[5]
- **Kaposi Sarcoma:** NCCN guidelines (version 1.2024 – November 7, 2023) cites Pomalyst as the "preferred" subsequent system therapy (category 2A) 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.[3] First-line systemic therapy options include liposomal doxorubicin (preferred) and paclitaxel.

- **Multiple Myeloma:** NCCN guidelines (version 4.2024 – April 26, 2024) recommend Pomalyst. 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).[6] 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:** NCCN guidelines (version 2.2024 – December 12, 2023) list Pomalyst plus dexamethasone as one of several treatment options for patients with previously treated disease (category 2A).[7] 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.

- **Pomalyst® (pomalidomide capsules (Celgene)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Kaposi Sarcoma.** Approve for 1 year if the patient meets BOTH of 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 BOTH of 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 BOTH of the 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 ALL of 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; bortezomib, lenalidomide, cyclophosphamide, and dexamethasone; bortezomib with or without dexamethasone; bortezomib, lenalidomide, and dexamethasone; melphalan and dexamethasone; bortezomib, cyclophosphamide, and dexamethasone; and Darzalex (daratumumab intravenous infusion)/Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection).

CONDITIONS NOT COVERED

- **Pomalyst® (pomalidomide capsules (Celgene)**

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Pomalyst® capsules [prescribing information]. Summit, NJ: Celgene; March 2023.
2. The NCCN Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – November 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2024.
3. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2023 – March 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 8, 2023.
4. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 4.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 21, 2024.
5. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 2.2024 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	05/10/2023
Annual Revision	No criteria changes	05/29/2024