PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Immunomodulator) – Pomalyst Prior Authorization Policy
- Pomalyst® (pomalidomide capsules – Celgene/Bristol Myers Squibb)

REVIEW DATE: 05/14/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

The Kaposi sarcoma 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).

Guidelines

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

- **Central Nervous System (CNS) Cancers:** NCCN guidelines (version 5.2024 – March 18, 2025) list Pomalyst as "other recommended regimen" for patients with relapsed or refractory disease for primary CNS lymphoma (category 2A).[5] Pomalyst can also be used as induction therapy if the patient is unsuitable for or is intolerant to high-dose methotrexate as "useful in certain circumstances" (category 2A).
- **Kaposi Sarcoma:** NCCN guidelines (version 2.2025 – January 14, 2025) cite Pomalyst as subsequent systemic 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 progressed on or has not responded to first-line systemic therapy and progressed on alternate first-line systemic therapy (category 2A).[3] First-line systemic therapy options include liposomal doxorubicin (preferred) and paclitaxel.
- **Multiple Myeloma:** NCCN guidelines (version 2.2025 – April 11, 2025) 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 2.2025 – March 12, 2025) list Pomalyst + 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/Bristol Myers Squibb)**

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 tried at least one other regimen.
      Note: Examples of other regimens include Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection)/lenalidomide/bortezomib/dexamethasone; bortezomib/lenalidomide/dexamethasone; Kyprolis (carfilzomib intravenous infusion)/lenalidomide/dexamethasone; Sarclisa (isatuximab-irfc intravenous infusion)/bortezomib/lenalidomide/dexamethasone; Darzalex or Darzalex Faspro/lenalidomide/dexamethasone; bortezomib/cyclophosphamide/dexamethasone; Kyprolis/cyclophosphamide/dexamethasone.

Other Uses with Supportive Evidence

3. **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) The medication is used in combination with dexamethasone.

4. **Primary Central Nervous System Lymphoma.** Approve for 1 year if the patient meets ONE of the following (A, B, or C):
   A) Patient has relapsed or refractory disease; OR
   B) According to the prescriber, the patient is not a candidate for high-dose methotrexate; OR
   C) Patient has had intolerance to high-dose methotrexate.

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) The medication is used in combination with dexamethasone; AND
   C) Patient has tried at least one other regimen.
      Note: Examples of regimens include lenalidomide plus dexamethasone; melphalan and dexamethasone with or without bortezomib; bortezomib, cyclophosphamide, and dexamethasone; Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and hyaluronidase-fihj

subcutaneous injection) plus cyclophosphamide, bortezomib, and dexamethasone; or single agent Darzalex or Darzalex Faspro.

CONDITIONS NOT COVERED

- **Pomalyst® (pomalidomide capsules - Celgene/Bristol Myers Squibb) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

REFERENCES

1. Pomalyst® capsules [prescribing information]. Summit, NJ: Celgene/Bristol Myers Squibb; February 2025.
2. The NCCN Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2025.
3. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 5.2024 – March 18, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2025.
4. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 2.2025 – April 11, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2025.
5. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 2.2025 – March 12, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2025.

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
Update	04/08/2025: The policy name was changed from "Oncology – Pomalyst PA Policy" to "Oncology (Oral – Immunomodulator) – Pomalyst PA Policy".	N/A
Annual Revision	**Multiple Myeloma**: The requirement that "patient has received at least one lenalidomide-containing regimen" was revised to "patient has tried at least one other regimen." A Note was added with examples of regimens. **Primary Central Nervous System Lymphoma:** This condition of approval was previously worded as "Central Nervous System Lymphoma." The following option for approval was added, "according to the prescriber, the patient is not a candidate for high-dose methotrexate or patient has had intolerance to high-dose methotrexate." **Systemic Light Chain Amyloidosis:** The Note with examples of regimens was revised as follows: bortezomib, lenalidomide, cyclophosphamide, and dexamethasone; bortezomib with or without dexamethasone; bortezomib, lenalidomide, and dexamethasone were removed; the regimen of melphalan and dexamethasone was revised to add "with or without bortezomib" and Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and	05/14/2025

	hyaluronidase-fihj subcutaneous injection) plus cyclophosphamide, bortezomib, and dexamethasone was added.	