PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Farydak Prior Authorization Policy
- Farydak® (panobinostat capsules – Novartis)

REVIEW DATE: 06/12/2024

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

Farydak, a histone deacetylase inhibitor, was approved in combination with bortezomib injection and dexamethasone for the treatment of patients with **multiple myeloma** who have received at least two prior regimens, including bortezomib injection and an immunomodulatory drug (i.e., Thalomid® [thalidomide capsules], Revlimid® [lenalidomide capsules], Pomalyst® [pomalidomide capsules]).[1]

The FDA granted accelerated approval to Farydak in February 2015, based on progression free survival from a randomized, double-blind, placebo-controlled, multicenter, Phase III study. In December 2021, the manufacturer removed Farydak from the market because the required post-approval clinical studies were not feasible.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for multiple myeloma (version 3.2023 – December 8, 2022) note that due to market withdrawal, regimens containing Farydak were removed from the guideline.[2]

POLICY STATEMENT

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

- **Farydak® (panobinostat capsules – Novartis)**

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 Indication

1. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is currently receiving Farydak; AND
   B) Patient has previously tried bortezomib injection; AND
   C) Patient has tried one immunomodulatory drug (i.e., Thalomid [thalidomide capsules], lenalidomide capsules, or Pomalyst [pomalidomide capsules]); AND
   D) The medication will be taken in combination with bortezomib injection and dexamethasone.

CONDITIONS NOT COVERED

Farydak® (panobinostat capsules – Novartis)
is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Pancreatic Cancer.** A Phase II study evaluating Farydak + bortezomib injection in patients with pancreatic cancer who were progressing on gemcitabine-based therapy was discontinued early due to toxicity and a lack of response.[3]

REFERENCES

1. Farydak® capsules [prescribing information]. East Hanover, NJ: Novartis; June 2016.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 23, 2023.
3. Wang H, Cao Q, Dudek AZ. Phase II study of panobinostat and bortezomib in patients with pancreatic cancer progressing on gemcitabine-based therapy. *Anticancer Res*. 2012;32(3):1027-1031.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	05/31/2023
Annual Revision	No criteria changes	06/12/2024