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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 13, 2015
Subject:	Farydak	**Page:**	1 of 4

Last Review Date: March 12, 2021

Farydak

Description

Farydak (panobinostat)

Background
Farydak (panobinostat) is the first histone deacetylase (HDAC) inhibitor approved to treat multiple myeloma in patients who have received at least two prior standard therapies, including bortezomib and an immunomodulatory agent. Farydak is to be used in combination with bortezomib, a type of chemotherapy, and dexamethasone, an anti-inflammatory medication. Multiple myeloma causes plasma cells to rapidly multiply and crowd out other healthy blood cells from the bone marrow. When the bone marrow has too many plasma cells, the cells may move to other parts of the body. Farydak works by inhibiting the activity of enzymes, known as histone deacetylases (HDACs). The inhibition of these enzymes may slow the over development of plasma cells in multiple myeloma patients or cause these dangerous cells to die (1).

Regulatory Status
FDA-approved indication: Farydak, a histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent (2).

Farydak carries a Boxed Warning alerting patients and health care professionals that severe diarrhea and severe and fatal cardiac events, arrhythmias and electrocardiogram (ECG) changes have occurred in patients receiving Farydak. Arrhythmias may be exacerbated by electrolyte abnormalities. The most common laboratory abnormalities were low levels of

phosphorus in the blood (hypophosphatemia), low potassium levels in the blood (hypokalemia), low levels of salt in the blood (hyponatremia), increased creatinine, low platelets (thrombocytopenia), low white blood cell counts (leukopenia) and low red blood cell counts (anemia). Healthcare professionals should also inform patients of the risk of bleeding in the gastrointestinal tract and the lungs, and liver damage (hepatotoxicity) (2).

The safety and efficacy of Farydak in pediatric patients have not been established (2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Farydak may be considered **medically necessary** in patients 18 years of age or older for the treatment of patients with multiple myeloma and if the conditions indicated below are met.

Farydak may be considered **investigational** for patients that are less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Multiple myeloma

AND ALL of the following:

1. Used in combination with Velcade (bortezomib) and dexamethasone
2. Received at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent
3. Baseline monitoring of electrocardiogram (ECG) and serum electrolytes, including potassium and magnesium

a. Agreement to monitor levels prior to the start of each cycle

Prior-Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 24 capsules per 84 days

Duration 48 weeks

Prior-Approval *Renewal* Limits

None

Rationale

Summary

Farydak (panobinostat) is a histone deacetylase (HDAC) inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent. Farydak carries a Boxed Warning alerting patients and health care professionals that severe diarrhea and severe and fatal cardiac events, arrhythmias and electrocardiogram (ECG) changes have occurred in patients receiving Farydak. The safety and efficacy of Farydak in pediatric patients have not been established (2).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Farydak while maintaining optimal therapeutic outcomes.

References

1. NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 4.2021). National Comprehensive Cancer Network, Inc. December 2020.
2. Farydak [package insert]. Las Vegas, NV: Secura Bio, Inc.; September 2019.

Policy History

Date	Action
March 2015	Addition to PA
June 2015	Annual Review and addition of monitoring ECG and electrolytes prior to start of each cycle per SME
September 2015	Annual review
July 2016	Annual review and reference update Policy number change from 5.04.56 to 5.21.56
September 2016	Annual review
June 2017	Annual review and reference update Prior Approval Renewal Limits updated to indicate that there is no renewal for this drug
July 2018	Annual editorial review and reference update
June 2019	Annual review and reference update
June 2020	Annual editorial review and reference update. Addition of PA quantity limit per FEP
December 2020	Annual review
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.