RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Farydak is the first 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 has not been established (2).

Summary
Farydak is 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. Farydak carries a Boxed

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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 children 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