BlueCross BlueShield Federal Employee Program

ZOLINZA (vorinostat)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zolinza is a histone deacetylase inhibitor approved in the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma. Cutaneous T-cell lymphomas (CTCLs) are the largest group of cutaneous lymphomas, with mycosis fungoides (MF) and Sézary syndrome representing ~60% and ~5% of CTCL cases, respectively. A group of non-Hodgkin's lymphomas (1, 5), MF is characterized by primary cutaneous involvement, whereas Sézary syndrome is characterized by significant blood and lymph node involvement. Initial treatment for patients with patch/plaque disease consists of skin-directed therapies (e.g., topical corticosteroids) with the addition of systemic therapy for refractory or progressive disease (1-2).

Regulatory Status

FDA-approved indication: Zolinza is indicated for the treatment of cutaneous manifestations in patients with cutaneous T cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies (3).

The drug has the potential for serious side effects, including pulmonary embolism, deep vein thrombosis, and gastrointestinal disturbances. Zolinza may cause dose-related thrombocytopenia and anemia, which could require dose reduction or discontinuation. Patients receiving Zolinza may experience hyperglycemia, especially patients with diabetes. Zolinza requires careful monitoring of blood cell counts, electrolytes, glucose and serum creatinine. Testing should be repeated every two weeks during the first two months of therapy and monthly thereafter. Baseline and periodic ECG are also recommended since QT prolongation has been observed. Hypokalemia and hypomagnesemia should be corrected prior to starting Zolinza. It is important that adequate hydration be maintained during treatment. Any pre-existing nausea, vomiting and diarrhea should be adequately controlled before implementation of therapy (3-4).

The safety and effectiveness of Zolinza has not been established in patients less than 18 years of age (3).

Summary

Zolinza (vorinostat) is considered medically necessary for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease during or following treatment with two systemic therapies. The drug has the potential for serious side effects, including pulmonary

embolism, deep vein thrombosis, gastrointestinal disturbances, hyperglycemia, hypokalemia, hypomagnesemia, and dose-related thrombocytopenia and anemia, which could require dose reduction or discontinuation. Zolinza requires careful monitoring of blood cell counts, electrolytes, glucose, and serum creatinine. Testing should be repeated every two weeks during the first two months of therapy and monthly thereafter. It is important that adequate hydration be maintained during treatment (1-4).

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

References

1. Willemze R, Jaffe ES, Burg G, et al. WHO-EORTC classification for cutaneous lymphomas. *Blood.* May 2005; 105(10):3768-85.
2. Jaffe ES, Krenacs L, Raffeld M. Classification of cytotoxic T-cell and natural killer cell lymphomas. *Semin Hematol*. 2003; 40(3):175-84.
3. Zolinza [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; July 2022.
4. NCCN Drugs & Biologics Compendium® Vorinostat 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.