BlueCross BlueShield Federal Employee Program

VYXEOS
(daunorubicin and cytarabine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Vyxeos is a cancer agent that is a liposomal combination of daunorubicin, an anthracycline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor. Vyxeos is indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) which is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow. Therapy-related acute myeloid leukemia (t-AML) occurs as a complication of chemotherapy or radiation AML-MRC is characterized by a history of certain blood disorders and other significant mutations within cancer cells (1).

Regulatory Status

FDA-approved indication: Vyxeos is a liposomal combination of daunorubicin, an anthracycline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor, that is indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older (1).

Vyxeos has a boxed warning for not interchanging with other daunorubicin and/or cytarabine containing products (1).

Vyxeos contains the anthracycline daunorubicin, which has a known risk of cardiotoxicity. Prior therapy with anthracyclines, pre-existing cardiac disease, previous radiotherapy to the mediastinum, or concomitant use of cardiotoxic drugs may increase the risk of daunorubicin induced cardiac toxicity. Prior to administering Vyxeos, obtain an electrocardiogram (ECG) and assess cardiac function by multi-gated radionuclide angiography (MUGA) scan or echocardiography (ECHO) (1).

Reconstituted Vyxeos contains 5 mg/mL copper gluconate, of which 14% is elemental copper. The maximum theoretical total exposure of copper under the recommended Vyxeos dosing regimen is 106 mg/m^2. Monitor total serum copper, serum non-ceruloplasmin bound copper, 24-hour urine copper levels and serial neuropsychological examinations (1).

The safety and effectiveness of Vyxeos in pediatric patients less than 1 year of age have not been

established (1).

Summary

Vyxeos is indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) which is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow. The safety and effectiveness of Vyxeos in pediatric patients less than 1 year of age have not been established (1).

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

References

1. Vyxeos [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; September 2022.
2. NCCN Drugs & Biologics Compendium® Daunorubicin/Cytarabine 2023. National Comprehensive Cancer Network, Inc. Accessed on October 2, 2023.