Reference number(s)
1662-A

SPECIALTY GUIDELINE MANAGEMENT

Mitoxantrone

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Acute nonlymphocytic leukemia (ANLL)
   Mitoxantrone in combination with other approved drug(s) is indicated in the initial therapy of ANLL in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.
2. Multiple sclerosis
   Mitoxantrone is indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (MS) (i.e., patients whose neurologic status is significantly abnormal between relapses). Mitoxantrone is not indicated in the treatment of patients with primary progressive MS.
3. Prostate cancer
   Mitoxantrone in combination with corticosteroids is indicated as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer.

B. Compendial Uses
1. Acute lymphoblastic leukemia
2. Breast cancer
3. Hodgkin lymphoma
4. Liver carcinoma
5. Non-Hodgkin's lymphoma with following subtypes
   a. AIDS-related B-cell lymphoma
   b. Diffuse large B-cell lymphoma
   c. Follicular lymphoma
   d. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
   e. T-cell prolymphocytic leukemia
   f. Post-transplant proliferative disorders
   g. High-grade B-cell lymphoma (including double/triple hit lymphoma)
   h. Malignant lymphoma, indolent
6. Ovarian cancer

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Acute lymphoblastic leukemia (ALL)

Authorization of 6 months may be granted for treatment of ALL.

B. Acute nonlymphocytic leukemia (ANLL)
Authorization of 6 months may be granted for treatment of ANLL, including acute myeloid leukemia (AML) and acute promyelocytic leukemia (APL).

C. Multiple sclerosis
Authorization of 1 dose (3 months) may be granted for treatment of multiple sclerosis.

D. Prostate cancer
Authorization of 6 months may be granted for treatment of prostate cancer.

E. Breast cancer
Authorization of 6 months may be granted for treatment of breast cancer.

F. Hodgkin lymphoma
Authorization of 6 months may be granted for treatment of Hodgkin lymphoma.

G. Liver carcinoma
Authorization of 6 months may be granted for treatment of liver carcinoma.

H. Non-Hodgkin's lymphoma (NHL)
Authorization of 6 months may be granted for treatment of one of the following subtypes of NHL:
1. AIDS-related B-cell lymphoma
2. Diffuse large B-cell lymphoma
3. Follicular lymphoma
4. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
5. T-cell prolymphocytic leukemia
6. Post-transplant proliferative disorders
7. High-grade B-cell lymphoma (including double/triple hit lymphoma)
8. Malignant indolent lymphoma (e.g., chronic lymphocytic leukemia, lymphoplasmacytic lymphoma, secondary high grade lymphoma)

I. Ovarian cancer
Authorization of 6 months may be granted for treatment of ovarian cancer.

III. CONTINUATION OF THERAPY

A. Multiple Sclerosis
Authorization of 3 months may be granted for continued treatment in members requesting reauthorization for multiple sclerosis (MS) who experienced a benefit from therapy (e.g., reduced neurologic disability, reduced frequency of clinical relapses).

B. All Other Diagnoses (Excluding Multiple Sclerosis)
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for all indications listed in Section II (excluding MS) when there is no evidence of unacceptable toxicity.

IV. REFERENCES

1. Mitoxantrone [package insert]. Lake Forest, IL: Hospira, Inc.; May 2018.

2. IBM Micromedex® DRUGDEX® System (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at https://www.micromedexsolutions.com. Accessed February 22, 2021.
3. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 1, 2021.