

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 subtypes³
 - a. AIDS-related B-cell lymphoma
 - b. Diffuse large B-cell lymphoma
 - c. Follicular lymphoma
 - d. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
 - e. Mantle cell lymphoma
 - f. T-cell prolymphocytic leukemia
 - g. Post-transplant proliferative disorders
6. Ovarian cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Acute lymphoblastic leukemia (ALL)

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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 marginal zone lymphoma to diffuse large B-cell lymphoma
5. Mantle cell lymphoma
6. T-cell prolymphocytic leukemia
7. Post-transplant proliferative disorders

I. Ovarian cancer

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

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Mitoxantrone [package insert]. Irvine, CA: Teva Parenteral Medicines, Inc.; May 2012.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed March 26, 2018.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 22, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Hodgkin Lymphoma (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 27, 2018.
5. The NCCN Clinical Practice Guidelines in Oncology® Acute Myeloid Leukemia (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 27, 2018.

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6. The NCCN Clinical Practice Guidelines in Oncology® T-Cell Lymphomas (Version 3.2018). © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 27, 2018.
7. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 2.2018). © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 27, 2018.
8. The NCCN Clinical Practice Guidelines in Oncology® Prostate Cancer (Version 2.2018). © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 27, 2018.