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
A. Breast cancer
B. Hodgkin lymphoma
C. Liver carcinoma
D. Non-Hodgkin's lymphoma with following subtypes:
   a. AIDS-related B-cell lymphoma
   b. Diffuse large B-cell lymphoma
   c. Follicular lymphoma
   d. Gastric and nongastric mucosa-associated lymphoid tissue (MALT) lymphoma
   e. Mantle cell lymphoma
   f. Primary cutaneous B-cell lymphoma
   g. Splenic marginal zone lymphoma
   h. T-cell prolymphocytic leukemia
   i. Nodal marginal zone lymphoma
E. Ovarian cancer

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

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II. CRITERIA FOR INITIAL APPROVAL

A. 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).

B. Multiple sclerosis

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

C. Prostate cancer

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

D. Breast cancer

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

E. Hodgkin lymphoma

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

F. Liver carcinoma

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

G. 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. Gastric MALT lymphoma
5. Nongastric MALT lymphoma
6. Mantle cell lymphoma
7. Primary cutaneous B-cell lymphoma
8. Splenic marginal zone lymphoma
9. T-cell prolymphocytic leukemia
10. Nodal marginal zone lymphoma

H. 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 9, 2017.

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3. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 27, 2017.

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