

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Novantrone (mitoxantrone)
BILLING CODE	J9293 (1 unit = 5 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT – 5 units per infusion
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Novantrone (mitoxantrone) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis; AND
4. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug); AND
5. Member has documented Left Ventricular Ejection Fraction (LVEF) of greater than 50% in the chart notes within the last 3 months.
6. **Dosage allowed:** 12 mg/m<sup>2</sup> infusion every 3 months (Maximum cumulative lifetime dose is 140 mg/m<sup>2</sup>).

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member has documented biological response to treatment; AND
3. Member has documentation of repeated Left ventricular ejection fraction (LVEF) of greater than 50% in the chart notes (Note: Maximum cumulative lifetime dose is 140 mg/m<sup>2</sup>).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Novantrone (mitoxantrone) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Acute lymphoid leukemia
- Bone marrow transplant



- Breast cancer
- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis
- Head and neck cancer
- Liver carcinoma
- Malignant lymphoma, Indolent
- Non-Hodgkin's lymphoma
- Ovarian cancer
- Primary progressive multiple sclerosis
- Solid tumor

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Novantrone created. Not covered diagnosis added.
12/06/2017	Confirmation of diagnosis based on McDonald criteria is no longer required.

References:

1. Mitoxantrone [package insert]. Lake Zurich, IL; Fresenius Kabi USA, LLC: June, 2015.
2. Mitoxantrone. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed March 16, 2017.
3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002 Jan;58(2):169-78.
4. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. *Annals of Neurology*. 2011;69(2):292-302. doi:10.1002/ana.22366.

Effective date: 12/20/2017

Revised date: 12/06/2017