PHARMACY POLICY STATEMENT **Indiana 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 **NOT** MEDICALLY NECESSARY	Click Here

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^2 infusion every 3 months (Maximum cumulative lifetime dose is 140 mg/m^2).

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^2).

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: 02/01/2018
Revised date: 12/06/2017