CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Novantrone (mitoxantrone)
BILLING CODE	J9293 (1 unit = 5 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office, Outpatient hospital
STATUS	Prior Authorization Required

Mitoxantrone is a synthetic antineoplastic anthracenedione for intravenous use. It 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 (i.e., patients whose neurologic status is significantly abnormal between relapses). It is also used to treat certain cancers. Mitoxantrone is not indicated in the treatment of patients with primary progressive multiple sclerosis. The brand name Novantrone is no longer manufactured and the drug is only available as generic. Mitoxantrone has a black box warning for cardiotoxicity. It is seldom prescribed due to its high risk profile and frequency of severe adverse events. It should only be prescribed if the potential benefits greatly outweigh the risks.

Mitoxantrone will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, a neurologist; AND
3. Chart notes have been provided confirming diagnosis of one of the following types of MS:
   a) Secondary (chronic) progressive
   b) Progressive relapsing
   c) Worsening relapsing-remitting (i.e., member's neurologic status is significantly abnormal between relapses); AND
4. Member has had all of the baseline assessments below and does NOT have any of the following:
   a) Abnormal liver function tests
   b) LVEF less than 50%
   c) Neutrophil count less than 1500 cells/mm^3
   d) Exceeded maximum cumulative lifetime dose for mitoxantrone of 140 mg/m^2; AND
5. Member's condition continues to decline despite compliant trial and failure of at least 3 prior disease-modifying drugs indicated for MS at the max tolerated doses; AND
6. Member does NOT have primary progressive MS.
7. **Dosage allowed/Quantity limit:** 12 mg/m^2 infusion every 3 months (Maximum cumulative lifetime dose is 140 mg/m^2)
   QL: 5 units per 84 days

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must document reduced neurologic disability or reduced frequency of relapses; AND
2. Member's LVEF is being monitored prior to each dose; AND
3. Member has not exceeded the maximum cumulative lifetime dose of 140 mg/m^2.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Cancer diagnosis

Any request for oncology use must be submitted through NantHealth/Eviti portal.

CareSource considers mitoxantrone not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
07/06/2022	Transferred to new template. Updated all references. Specified and defined "worsening" relapsing-remitting disease. Added PRMS as a use and PPMS as an exclusion. Added baseline monitoring assessments. Changed step drugs from 2 to at least 3. Changed QL from per infusion to per 3 months (per label). Added reduced neurologic disability or reduced frequency of relapses to renewal criteria, split off the max cumulative dose as an additional criterion.

References:

1. Mitoxantrone. Hospira, Inc.; 2022. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/. Accessed: July 6, 2022.
2. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788
4. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed July 6, 2022.
5. Martinelli Boneschi F, Vacchi L, Rovaris M, Capra R, Comi G. Mitoxantrone for multiple sclerosis. *Cochrane Database Syst Rev*. 2013;(5):CD002127. Published 2013 May 31. doi:10.1002/14651858.CD002127.pub3
6. Scott LJ, Figgitt DP. Mitoxantrone: a review of its use in multiple sclerosis. *CNS Drugs*. 2004;18(6):379-396. doi:10.2165/00023210-200418060-00010

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