CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Bafiertam (monomethyl fumarate)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 120 capsules per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Bafiertam (monomethyl fumarate) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** 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 MULTIPLE SCLEROSIS

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. Member has a confirmed diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS); AND
4. Member's relapse rate and/or number of lesions prior to starting treatment are documented in chart notes; AND
5. Member does NOT have concurrent use with another disease-modifying agent for MS.
6. **Dosage allowed:** 95 mg (1 capsule) twice per day orally for 7 days of titration. Maintenance dose is 190 mg (2 capsules of 95 mg) twice daily.

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. Chart notes have been provided showing stability or improvement in signs and symptoms of disease (e.g., fewer relapses, slowed disability progression, reduced number or volume of brain lesions).

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

CareSource considers Bafiertam (monomethyl fumarate) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
09/25/2020	New policy for Bafiertam created.
09/16/2021	Annual review, no changes

References:

1. Bafiertam [package insert]. High Point, NC; Banner Life Sciences LLC, April 2020.
2. Rae-Grant A, Day GS, Marrie RA, et al. Comprehensive systematic review summary: Disease-modifying therapies for adults with multiple sclerosis. *Neurology 2018*;90:789-800.
3. ClinicalTrials.gov. Identifier NCT02294058. Phase 3 study of RPC1063 in relapsing MS. Available at https://clinicaltrials.gov/ct2/show/NCT02294058.
4. ClinicalTrials.gov. Identifier NCT02047734. Efficacy and safety study of ozanimod in relapsing multiple sclerosis (Radiance study). Available at https://clinicaltrials.gov/ct2/show/NCT02047734.
5. Finkelsztejn A. Multiple sclerosis: overview of disease-modifying agents. *Perspect Medicin Chem*. 2014;6:65-72. Published 2014 Oct 5.

Effective date: 01/01/2022
Revised date: 09/16/20/21