CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Bafiertam (monomethyl fumarate)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Bafiertam is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. It has been shown to activate the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway, which is involved in the cellular response to oxidative stress.
Unlike the other fumarates, Tecfidera and Vumerity, which are prodrugs, Bafiertam directly provides the active metabolite monomethyl fumarate (MMF) without requiring metabolic conversion in the gastrointestinal (GI) tract. Subsequently, a lower dose is needed to produce a bioequivalent effect in comparison with Tecfidera or Vumerity. Thus, like Vumerity, Bafiertam may have GI tolerability advantages over Tecfidera, however the comparative study by the manufacturer did not meet its primary endpoint and had numerous limitations despite positive outcomes of exploratory analyses.

Bafiertam (monomethyl fumarate) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of a relapsing form of MS, to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
4. The member has tried generic Tecfidera but experiences intolerable gastrointestinal side effects; AND
5. The following baseline assessments have been or will be completed before starting treatment:
   a) Complete blood cell count (CBC) including lymphocyte count
   b) Liver function (ALT, AST, ALP, total bilirubin)
6. **Dosage allowed/Quantity limit:** 95 mg (1 capsule) twice daily, orally, for 7 days, followed by maintenance dose of 190 mg (2 capsules of 95 mg) twice daily.
   QL: 120 capsules per 30 days

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

For **reauthorization**:
1. 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 all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Bafiertam (monomethyl fumarate) 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
09/25/2020	New policy for Bafiertam created.
07/22/2022	Transferred to new template. Updated and added references. Removed clinical baseline measures. Added trial of generic Tecfidera. Added baseline monitoring.
06/23/2025	Updated references.

References:

1. Bafiertam [prescribing information]. Banner Life Sciences LLC; 2024.
2. Wynn D, Lategan TW, Sprague TN, Rousseau FS, Fox EJ. Monomethyl fumarate has better gastrointestinal tolerability profile compared with dimethyl fumarate. *Mult Scler Relat Disord*. 2020;45:102335. doi:10.1016/j.msard.2020.102335
3. 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.
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://cdn.sanity.io/files/y936aps5/production/76159995e7f4c6c0c2e6de5c4ba6a5881ab368f7.pdf. Accessed June 23, 2025.
5. Hauser SL, Cree BAC. Treatment of Multiple Sclerosis: A Review. *Am J Med*. 2020;133(12):1380-1390.e2. doi:10.1016/j.amjmed.2020.05.049

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