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Commercial/Healthcare Exchange PA Criteria

Effective: November 11, 2020

Prior Authorization: Bafiertam

Products Affected: Bafiertam (monomethyl fumarate) delayed-release capsules

<u>Medication Description</u>: The mechanism by which monomethyl fumarate (MMF) exerts its therapeutic effect in multiple sclerosis is unknown. MMF has been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in vitro and in vivo in animals and humans. The Nrf2 pathway is involved in the cellular response to oxidative stress. MMF has been identified as a nicotinic acid receptor agonist in vitro.

Covered Uses: Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Exclusion Criteria:

- 1. Known hypersensitivity to monomethyl fumarate, dimethyl fumarate, diroximel fumarate, or to any of the excipients of Bafiertam.
- 2. Co-administration with dimethyl fumarate or diroximel fumarate

Required Medical Information:

1. Diagnosis

Age Restrictions: 18 years of age and older

<u>Prescriber Restrictions</u>: Prescribed by, or after consultation with, a neurologist or a physician who specializes in the treatment of MS

Coverage Duration: 3 years

Other Criteria:

A. Patient has a diagnosis of any of the following relapsing forms of Multiple Sclerosis:

- a. Progressive-relapsing multiple sclerosis (PRMS); OR
- b. Relapsing-remitting multiple sclerosis (RRMS); OR
- c. Secondary progressive multiple sclerosis (SPMS) with documented relapses; OR
- d. Clinically isolated syndrome

References:

1. Bafiertam[™] delayed-release capsules [prescribing information]. High Point, NC: Banner Life Sciences LLC; October 2020.

Policy Revision history



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Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/05/2020

November 2020

