

Bafiertam (monomethyl fumarate)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Multiple sclerosis (MS) is a chronic, inflammatory, demyelinating disease of the central nervous system. It typically presents in young adults with symptoms such as vision problems, muscle weakness, numbness, and difficulty with balance and coordination. The most common form is relapsing-remitting MS, characterized by acute attacks followed by periods of remission. Treatment goals include reducing relapses, slowing disability progression, and managing symptoms. Disease-modifying therapies are the primary treatment approach and include injectable medications (interferons, glatiramer acetate), oral medications (dimethyl fumarate, fingolimod, teriflunomide, etc.), and infusion therapies (natalizumab, ocrelizumab).

Bafiertam (monomethyl fumarate) is an oral fumaric acid derivative approved for the treatment of relapsing forms of MS in adults. It is the active metabolite of dimethyl fumarate (Tecfidera), another approved MS therapy. The exact mechanism of action in MS is unknown, but monomethyl fumarate is thought to have immunomodulatory and neuroprotective effects. Clinical trials with dimethyl fumarate

demonstrated efficacy in reducing relapse rates and MRI measures of disease activity compared to placebo in patients with relapsing MS. Approval of Bafiertam was based on bioequivalence to dimethyl fumarate.

Definitions

"**Bioequivalence**" refers to the absence of a significant difference in the rate and extent to which the active ingredient becomes available at the site of drug action when administered at the same molar dose under similar conditions.

"**Clinically isolated syndrome**" refers to a first episode of neurologic symptoms lasting at least 24 hours caused by inflammation or demyelination in the central nervous system.

"**Disease-modifying therapy**" is a medication that modifies the course of MS by reducing relapses and slowing disability progression.

"**Multiple sclerosis**" is a chronic autoimmune disease of the central nervous system characterized by inflammation, demyelination, and neurodegeneration.

"**Primary progressive MS**" refers to worsening neurologic function from the onset of symptoms, without early relapses or remissions.

"**Relapse**" is defined as the appearance of new symptoms or the worsening of existing symptoms lasting at least 24 hours in the absence of fever or infection.

"**Relapsing-remitting MS**" refers to a disease course characterized by clearly defined attacks of new or increasing neurologic symptoms followed by periods of partial or complete recovery.

"**Secondary progressive MS**" is a disease course following relapsing-remitting MS that is characterized by a progressive worsening of neurologic function over time with or without relapses.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Bafiertam (monomethyl fumarate)** medically necessary when recent (within the last 3 months) clinical chart documentation provided indicates the member meets **ALL** of the following:

1. Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of multiple sclerosis; **AND**
2. Is 18 years of age or older; **AND**
3. Has **ONE** of the following forms of multiple sclerosis:
 - a. relapsing-remitting (RRMS); **or**
 - b. active secondary progressive disease (SPMS); **or**
 - c. clinically isolated syndrome (CIS); **AND**
4. Is unable to use, or has tried and failed at least **TWO** of the following:
 - a. An interferon beta product (Avonex, Betaseron, Plegridy, or Rebif); **and/or**
 - b. Dimethyl Fumarate (generic Tecfidera); **and/or**
 - c. Fingolimod (generic Gilenya); **and**
 - d. Glatiramer acetate (Copaxone, Glatopa); **and/or**
 - e. Teriflunomide (generic Aubagio); **AND**
5. Bafiertam (monomethyl fumarate) will be used as monotherapy for multiple sclerosis (i.e., member is not using and will not use other disease-modifying MS therapies while on Bafiertam); **AND**
6. Bafiertam (monomethyl fumarate) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.
 - o *Initial: 95 mg orally twice daily for 7 days*
 - o *Maintenance: 190 mg orally twice daily*
 - i. *240 capsules per 30 days*

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if the member has recent (within the last 6-months) clinical documentation showing **BOTH** of the following:

1. The requested medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; **AND**
2. The member has experienced at least ONE of the following:
 - a. Improvement in at least one objective measure, such as:

- i. Reduced disease activity on MRI; **and/or**
- ii. Improved or stable disability scores; **and/or**
- iii. Reduced relapse rate; **and/or**
- iv. Improved fatigue or walking assessments; **AND/OR**
- b. Stabilization or improvement in at least one MS symptom, such as:
 - i. Motor function; **and/or**
 - ii. Fatigue; **and/or**
 - iii. Vision; **and/or**
 - iv. Bowel/bladder function; **and/or**
 - v. Spasticity; **and/or**
 - vi. Walking/gait; **and/or**
 - vii. Pain/numbness/tingling.

Experimental or Investigational / Not Medically Necessary

Bafiertam (monomethyl fumarate) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Used for the treatment of primary progressive multiple sclerosis.
- Used in combination with other disease-modifying therapies for multiple sclerosis.
- Used in members under 18 years of age.
- Used for indications other than FDA-approved relapsing forms of multiple sclerosis.

References

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Clinical Guideline Revision / History Information

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