I. Medication Description

Tecfidera (studied as BG-12) is quickly metabolized in the GI-tract to the active metabolite monomethyl fumarate (MMF.) It appears to have neuro-protective and anti-inflammatory properties. Inflammation and oxidative stress are considered central factors in multiple sclerosis. It induces the nuclear factor 2 (Nrf2) antioxidant response pathway which is the primary cellular defense against cytotoxic effects of oxidative stress such as related neuronal death and damage to myelin in the CNS. It may also modulate immune cell responses affecting two distinct signaling cascades that impair production of interleukins (IL-23 and IL-12.) In addition, Tecfidera may suppress pro-inflammatory-cytokine production or directly inhibit pro-inflammatory pathways.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Tecfidera is available when the following criteria are met:

- The member has a diagnosis of a relapsing form of multiple sclerosis AND
- Medication is prescribed by or in consultation with a neurologist

IV. Quantity Limitations

- Starter pack: 1 pack per each 30 days
- 120mg tablets: up to 14 per 30 days covered to facilitate dose titration
- 240mg tablets: up to 60 per each 30 days.

V. Coverage Duration

Initial coverage is provided for 6 months and may be renewed in up to 12 month intervals.

VI. Coverage Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug
VII. Billing/Coding Information

Tecfidera is available in 120 mg and 240 mg tablets and a starter pack with #14 120mg and #46 240mg tablets.

XII. Summary of Policy Changes

- 9/15/13: new policy
- 9/15/14: no policy changes
- 11/1/14: removal of requirement for injectable agent first
- 7/1/15: formulary distinctions made
- 12/15/15: quantity limits added to starter pack
- 9/15/16: no policy changes
- 10/16/17: no policy changes

XIII. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.