Commercial/Healthcare Exchange PA Criteria

Effective: January 1, 2019

Prior Authorization: Tecfidera

Products Affected: Tecfidera (dimethylfumate) oral capsule, dimethyl fumarate oral capsule

Medication Description: Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis. The mechanism by which dimethyl fumarate (DMF) exerts its therapeutic effect in multiple sclerosis is unknown. DMF and the metabolite, monomethyl fumarate (MMF), have 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: Tecfidera 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.

Exclusion Criteria: Concurrent use of Tecfidera with other disease-modifying agents used for multiple sclerosis (MS).

Required Medical Information: Diagnosis

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist or a physician that specializes in 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. TECFIDERA(R) delayed-release oral capsules, dimethyl fumarate delayed-release oral capsules. Biogen Idec, Inc, Cambridge, MA, 2013.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Update	Update	Coverage Duration: Update to 3 years	07/01/2019
3	Update	Adoption of EH policy and template; Removed from CCI MS Drug Policy	All	6/2/2020
4	Update	Added dimethyl fumarate oral capsule to Products Affected	Products Affected	9/17/2020