

PHARMACY POLICY STATEMENT Kentucky Medicaid	
DRUG NAME	Tecfidera (dimethyl fumarate)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT – 60 per 30 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Tecfidera (dimethyl fumarate) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS, SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS

For **initial** authorization:

1. Member must be between 18 and 65 years of age; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Chart notes have been provided confirming diagnosis of Multiple Sclerosis based on McDonald Diagnostic Criteria.
4. **Dosage allowed:** 120 mg orally twice daily for 7 days; then 240 mg orally twice daily.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Tecfidera (dimethyl fumarate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis

DATE	ACTION/DESCRIPTION
06/07/2017	New policy for Tecfidera created. Not covered diagnosis added.

References:

1. Tecfidera [package insert]. Cambridge, MA; Biogen, Inc. January, 2017.



2. Tecfidera. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed March 16, 2017.
3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002 Jan;58(2):169-78.
4. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. *Annals of Neurology*. 2011;69(2):292-302. doi:10.1002/ana.22366.

Effective date: 08/09/2017

Revised date: 06/07/2017