CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Tecfidera (dimethyl fumarate)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Tecfidera was approved by the FDA in 2013 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. It mainly exerts anti-inflammatory and cytoprotective effects through activation of the nuclear factor (erythroid-derived 2)–like 2 (Nrf2) pathway. The most common adverse effects are skin flushing and gastrointestinal disturbances. Patients should be monitored for lymphopenia.

Tecfidera (dimethyl fumarate) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of a relapsing form of MS, to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
4. The following baseline assessments have been or will be completed before starting treatment:
   a) Complete blood cell count (CBC) including lymphocyte count
   b) Liver function (ALT, AST, ALP, total bilirubin)
5. **Dosage allowed/Quantity limit:** 120 mg orally twice daily for 7 days; then 240 mg orally twice daily. QL 60 capsules per 30 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing stability or improvement in signs and symptoms of disease (e.g., fewer relapses, slowed disability progression, reduced number or volume of brain lesions).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Tecfidera (dimethyl fumarate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/07/2017	New policy for Tecfidera created. Not covered diagnosis added.
12/06/2017	Age coverage expanded. Confirmation of diagnosis based on McDonald criteria is no longer required.

07/21/2022	Transferred to new template. Updated and added references. Made correction to move CIS from exclusion to indication. Added baseline CBC, LFT. Created renewal criteria.
06/23/2025	Updated references.

References:

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4. Hauser SL, Cree BAC. Treatment of Multiple Sclerosis: A Review. *Am J Med*. 2020;133(12):1380-1390.e2. doi:10.1016/j.amjmed.2020.05.049
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6. Gold R, Arnold DL, Bar-Or A, et al. Long-term safety and efficacy of dimethyl fumarate for up to 13 years in patients with relapsing-remitting multiple sclerosis: Final ENDORSE study results. *Mult Scler*. 2022;28(5):801-816. doi:10.1177/13524585211037909
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