Clinical Policy: Dimethyl fumarate (Tecfidera)

Reference Number: PA.CP.PHAR.249
Effective Date: 01/18
Last Review Date: 04/18 Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for dimethyl fumarate (Tecfidera®).

FDA Approved Indication(s)
Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Tecfidera is **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of relapsing form of multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Member will not use other disease modifying therapies for MS concurrently;
5. Dose does not exceed:
   a. Starting dose: 240 mg/day (2 capsules/day) for 7 days;
   b. Maintenance dose: 480 mg/day (2 capsules/day).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale score or reduction in relapses or magnetic resonance imaging lesions);
3. Member is not using other disease modifying therapies for MS concurrently;
4. If request is for a dose increase, new dose does not exceed 480 mg/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Dimethyl fumarate has been shown to activate the nuclear factor-like 2 (Nrf2) pathway, which is involved in the cellular response to oxidative stress. The mechanism by which dimethyl fumarate exerts its therapeutic effect in multiple sclerosis is unknown.

Formulations:

Tecfidera is provided as hard gelatin delayed-release capsules for oral administration, containing 120 mg or 240 mg of dimethyl fumarate consisting on one side and engraved with corporate logo on other side.

FDA Approved Indication(s):

Tecfidera is an Nrf2 activator/oral capsule indicated for:

- Treatment of patients with relapsing forms of multiple sclerosis.

Appendices

Appendix A: Abbreviation Key

FDA: Food and Drug Administration
MS: multiple sclerosis
Nrf2: nuclear factor-like 2

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: references reviewed and updated.	01.05.18	

References

1. Tecfidera Prescribing Information. Cambridge, MA: Biogen Inc.; January 2017. Available at http://www.tecfidera.com. Accessed January 5, 2018.
2. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. July 2016. Accessed January 5, 2018.