AdvancedHealth
Bridging the Future of Healthcare

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Tecfidera (dimethyl fumurate) Drug Use Criteria

Created: 7/13/2021
Updated: 3/22/2024

Includes:

Brand©	*Generic*
Tecfidera©	*dimethyl fumarate 120mg and 240mg capsules*

GUIDELINE FOR USE:

Initial Request:

1. Is medication being prescribed by or in consultation with a neurologist?
    a. If yes, go to #2.
    b. If no, deny as criteria not met. Please resubmit prior authorization request with current neurology note or consult.

2. Is medication to be used to treat a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and is member 18 years of age or older?
    a. If yes, go to #3.
    b. If no, deny as criteria not met. Off-label use of medication is not a covered benefit on OHP.

3. Is member on concurrent treatment with a disease modifying drug (i.e., interferon beta-1b, glatiramer acetate, interferon beta-1a, natalizumab, ofatumumab, ocrelizumab, or mitoxantrone)?
    a. If yes, deny as criteria not met. Dimethyl fumarate is not to be used with other disease modifying drugs for multiple sclerosis.
    b. If no, go to #4.

4. Have baseline safety assessments been completed (i.e., does documentation include liver function tests and a baseline CBC with lymphocyte count greater than 500/µL)?
    a. If yes, approve for up to 6 months. Initial dose: dimethyl fumarate 120mg #14/7 day supply. Maintenance dose: dimethyl fumarate 240mg #60/30 day supply.
    b. If no, deny as criteria not met. Please resubmit request with current CBC results, including lymphocyte count and/or liver function test.

Renewal Request:

1. Has the member's condition improved as assessed by the prescribing physician and physician attests to member's improvement?
    a. If yes, approve for up to 12 months.
    b. If no, send to MD review.

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Fumarate Salts (Dimethyl Fumarate, Monomethyl Fumarate, Diroximel Fumarate) Clinical Notes:

- Fumarate salts may decrease a patient's white blood cell count. In the clinical trials the mean lymphocyte counts decreased by approximately 30% during the first year of treatment with dimethyl fumarate and then remained stable. The incidence of infections (60% vs. 58%) and serious infections (2% vs. 2%) was similar in patients treated with dimethyl fumarate or placebo, respectively. There was no increased incidence of serious infections observed in patients with lymphocyte counts <0.8 x103 cells/mm3 (equivalent to <0.8 cells/µL). A transient increase in mean eosinophil counts was seen during the first 2 months of therapy.
- Fumarate salts should be held if the WBC falls below 2 x103 cells/mm3 or the lymphocyte count is below 0.5 x103 cells/mm3 (cells/µL) and permanently discontinued if the WBC did not increase to over 2 x103 cells/mm3 or lymphocyte count increased to over 0.5 x103 cells/mm3 after 4 weeks of withholding therapy.
- Patients should have a CBC with differential monitored every 6 to 12 months.

Rationale:
To promote evidence-based treatment for MS.

FDA Approved Indications:
Dimethyl fumarate 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.

Mechanism of Action:
Dimethyl fumarate and its active metabolite, monomethyl fumarate (MMF), have been shown to activate the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway, which is involved in cellular response to oxidative stress. The mechanism by which dimethyl fumarate (DMF) exerts a therapeutic effect in MS is unknown, although it is believed to result from its anti-inflammatory and cytoprotective properties via activation of the Nrf2 pathway.

Dosing:
Oral: Initial: 120 mg twice daily; after 7 days, increase to the maintenance dose: 240 mg twice daily.

Contraindications:
Known hypersensitivity (eg, anaphylaxis, angioedema) to dimethyl fumarate or any component of the formulation.

References:

- Tecfidera Prescribing Information. Revised: 12/2023
- Oregon Medicaid FFS Drug Class List: Dimethyl fumarate. https://www.orpdl.org/durm/PA_Docs/multiple_sclerosis_oral_agents.pdf