Clinical Policy: Dimethyl fumarate (Tecfidera)

Reference Number: ERX.SPMN.161
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that dimethyl fumarate (Tecfidera®) is medically necessary for the following indications:

I. Initial Approval Criteria
   A. Multiple Sclerosis (must meet all):
      1. Prescribed by or in consultation with a neurologist;
      2. Diagnosis of relapsing-remitting multiple sclerosis (RRMS) established by MRI;
      3. Prescribed dose does not exceed 240 mg twice daily;
      4. Member will not use other disease modifying therapies for MS concurrently.

          Approval duration: 6 months

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy

II. Continued Approval
   A. Multiple Sclerosis (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Responding positively to therapy;
      3. Prescribed dose does not exceed 240 mg twice daily;
      4. Member will not use other disease modifying therapies for MS concurrently.

          Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - 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
MRI: magnetic resonance imaging
MS: multiple sclerosis
Nrf2: nuclear factor-like 2
RRMS: relapsing-remitting multiple sclerosis

Reviews, Revisions, and Approvals

<table>
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<th>Policy split from USS.SPMN.36 Multiple Sclerosis (MS) Treatments and converted to new template. Added max dosing, clarified monotherapy restriction, and modified approval duration to 6 months for initial and 12 months for re-auth.</th>
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References
Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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