



MEDICATION POLICY

Generic Name: Dimethyl Fumarate

Therapeutic Class or Brand Name: Tecfidera®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 9/5/14

Date Last Reviewed/Revised: 8/16/2016

GPI Code: 6240552500

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

- I. Documented diagnosis of a relapsing form of multiple sclerosis.
- II. Minimum age requirement: 18 years old.
- III. Prescribing physician must be a neurologist or a multiple sclerosis physician specialist.
- IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

Exclusion Criteria:

- Coadministration of Tecfidera® with another disease-modifying multiple sclerosis therapy such as Aubagio® (teriflunomide), Avonex® (interferon beta-1a), Betaseron® (interferon beta-1b), Copaxone® (glatiramer), Extavia® (interferon beta-1b), Gilenya® (fingolimod), Glatopa™ (glatiramer), Lemtrada® (alemtuzumab), Novantrone® (mitoxantrone), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), Tysabri® (natalizumab), or Zinbryta™ (daclizumab).

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 60 capsules per 30 days.

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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Appendix:

N/A

References:

1. <http://blue.regence.com/trgmedpol/drugs/dru299.pdf>.
2. [Medi-Span](#).
3. <http://www.tecfidera.com/pdfs/full-prescribing-information.pdf>.

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Historical Tracking Of Changes Made To Policy	
8/16/2016	<ol style="list-style-type: none"> Changed “IV. Refer to plan document for the list of preferred products. If Tecfidera® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to two preferred products” to “IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s)” under Prior Authorization Criteria.
5/28/2016	<ol style="list-style-type: none"> Changed “I. Documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting or secondary progressive multiple sclerosis)” to “I. Documented diagnosis of a relapsing form of multiple sclerosis” under Prior Authorization Criteria. Changed “IV. Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (refer to plan document for the list of preferred products)” to “IV. Refer to plan document for the list of preferred products. If Tecfidera® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to two preferred products” under Prior Authorization Criteria. Changed “Tecfidera® is considered investigational when used concomitantly with other disease-modifying multiple sclerosis therapies [i.e. Alemtuzumab (Lemtrada™), Fingolimod (Gilenya®), Glatiramer acetate (Copaxone®), Interferon beta-1a (Avonex®, Rebif®), Interferon beta-1b (Betaseron®, Extavia®), Mitoxantrone (Novantrone®), Natalizumab (Tysabri®), Peginterferon beta-1a (Plegridy™), Teriflunomide (Aubagio®)]” to “Coadministration of Tecfidera® with another disease-modifying multiple sclerosis therapy such as Aubagio® (teriflunomide), Avonex® (interferon beta-1a), Betaseron® (interferon beta-1b), Copaxone® (glatiramer), Extavia® (interferon beta-1b), Gilenya® (fingolimod), Glatopa™ (glatiramer), Lemtrada® (alemtuzumab), Novantrone® (mitoxantrone), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), Tysabri® (natalizumab), or Zinbryta™ (daclizumab)” under Exclusion Criteria.
3/30/2015	<ol style="list-style-type: none"> Changed “Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (Avonex®, Copaxone®, and/or Betaseron®)” to “Documented trial and failure of, intolerance to, or contraindication to two preferred MS Biologics (refer to plan document for the list of preferred products)” under Prior Authorization Criteria. Added “Alemtuzumab (Lemtrada™)” and “Peginterferon beta-1a (Plegridy™)” to list of examples following “Tecfidera® is considered investigational when used concomitantly with other disease-modifying multiple sclerosis therapies” under Exclusion Criteria. Changed Authorization from “6 months” to “1 year” under Approval Length.

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