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:** 05/14/2018

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), Ocrevus™ (ocrelizumab), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), or Tysabri® (natalizumab).

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.

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Appendix:

N/A

References:

1. https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/tecfidera-(dimethyl-fumarate)
2. Medi-Span.
3. http://www.tecfidera.com/pdfs/full-prescribing-information.pdf.

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Historical Tracking Of Changes Made To Policy	
05/22/2018	1. **Deleted** Zinbryta™ (daclizumab) from **Exclusion criteria** 2. **Added** https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/tecfidera-(dimethyl-fumarate) and **deleted** http://blue.regence.com/trgmedpol/drugs/dru299.pdf. **under References**
11/16/2017	1. **Added** "Ocrevus™ (ocrelizumab)" **to list of drugs following the statement** "Coadministration of Tecfidera® with another disease-modifying multiple sclerosis therapy such as…" **under Exclusion Criteria**.
8/16/2016	1. **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	1. **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**. 2. **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**. 3. **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	1. **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**. 2. **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**. 3. **Changed Authorization from** "6 months" **to** "1 year" **under Approval Length**.