Tecfidera (dimethyl fumarate)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year, unless otherwise noted below

Medications	Quantity Limit
Tecfidera (dimethyl fumarate) Starter Kit – brand and generic	1 pack per fill, one time fill (30 day supply)
Tecfidera (dimethyl fumarate) 120mg delayed release capsules - brand and generic	14 capsules per fill, one time fill (starting dose, 7 day supply)
Tecfidera (dimethyl fumarate) 240mg delayed release capsules - brand and generic	2 capsules per day (maintenance dose)

APPROVAL CRITERIA

Requests for **brand and generic** Tecfidera (dimethyl fumarate) may be approved when the following criterion is met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease)

Requests for **brand** Tecfidera must also meet the following criterion, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of dimethyl fumarate (generic Tecfidera); **AND**
II. Documentation is provided that individual was unable to tolerate dimethyl fumarate (generic Tecfidera).

Tecfidera (dimethyl fumarate) may not be approved for the following:

I. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Tascenso ODT, Tysabri, Vumerity and Zeposia); **OR**
II. Individual is using to treat non-active secondary progressive multiple sclerosis.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 7, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: May 9, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 7, 2022.
6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018; 90: 777-788. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: September 7, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.