

Market Applicability				
Market	GA	MD	NJ	NY
Applicable	X	X	X	X

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	1 pack per fill, one time fill (30 day supply)
Tecfidera (dimethyl fumarate) 120mg delayed release capsules	14 capsules per fill, one time fill (starting dose, 7 day supply)
Tecfidera (dimethyl fumarate) 240mg delayed release capsules	2 capsules per day (maintenance dose)

APPROVAL CRITERIA

Requests for 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).

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, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, 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: June 6, 2021.
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.; 2021; Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: July 23, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 29, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Market	GA	MD	NJ	NY
Applicable	X	X	X	X

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: April 26, 2021.

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

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