Gilenya (fingolimod)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Gilenya (fingolimod)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Gilenya (fingolimod) 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** Gilenya must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has failed an adequate trial of one chemically equivalent generic fingolimod agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
AND
   A. Generic fingolimod had inadequate response; **OR**
   B. Generic fingolimod caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Gilenya (fingolimod) may not be approved for the following:

I. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/Glatiramer/Glatopa, Extavia, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Tecfidera, Tysabri, Vumerity and Zeposia); **OR**
II. Use in combination with another fingolimod agent; **OR**
III. Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block or sick sinus syndrome, unless individual has a functioning pacemaker; **OR**
IV. Individual has a baseline QTc interval greater than or equal to 500 msec; **OR**
V. Individual is being treated with Class Ia (such as quinidine, procainamide, or disopyramide) or Class III [such as amiodarone, Multaq (dronedarone), Tikosyn (dofetilide), or sotalol] anti-arrhythmic drugs; **OR**
VI. Individual has had a recent (within the past 6 months) occurrence of one of the following:
   A. Myocardial infarction; **OR**
   B. Unstable angina; **OR**

C. Stroke; **OR**
D. Transient ischemic attack (TIA); **OR**
E. Decompensated heart failure requiring hospitalization; **OR**
F. Class III/IV heart failure; **OR**

VII. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
VIII. 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: October 27, 2023.
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. Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: August 30, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 19, 2023.
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: October 27, 2023.