Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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 criteria are met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS); **AND**

A. Individual has been on Gilenya (fingolimod); **OR**
B. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following:
1. One preferred beta interferon agent:
a. Avonex (interferon beta-1-a) **OR**
b. Betaseron (interferon beta-1b); **OR**
c. Extavia (interferon beta1-1b); **OR**
d. Rebif (interferon beta-1a);

OR
2. Tecfidera (dimethyl fumarate);

OR
3. Glatopa (glatiramer) or glatiramer;

OR

II. Individual has high disease activity despite treatment with a disease modifying drug (including Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera, Tysabri, Vumerity and Zeposia) defined as the following (AAN 2018, Devonshire et al. 2012):
A. At least 1 relapse in the previous year while on therapy; **AND**
B. At least 9 T2-hyperintense lesions in cranial MRI;

OR
C. At least 1 Gadolinium-enhancing lesion;

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

OR

III. Individual is treatment naïve (no previous history of use of disease modifying drugs such as Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Betaseron, Tecfidera, Tysabri, Vumerity and Zeposia);

AND

IV. Individual has rapidly evolving severe relapsing multiple sclerosis defined as the following (Devonshire et al. 2012):
   A. Two or more disabling relapses in 1 year; **AND**
   B. One or more Gadolinium-enhancing lesions on brain MRI;

OR

V. Individual is age 10-17.

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

I. Concurrent use with other MS disease modifying agents (including Avonex, Betaseron, Copaxone/Glatiramer/ Glatopa, Extavia, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera and Tysabri); **OR**

II. 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**

III. Individual has a baseline QTc interval greater than or equal to 500 msec; **OR**

IV. 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**

V. 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**

VI. Individual has an active acute or chronic infection at the initiation of therapy.

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: April 20, 2020.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

2. Devonshire V, Havrdova E, Radue EW, et al. Relapse and disability outcomes in patients with multiple sclerosis treated with fingolimod: subgroup analyses of the double-blind, randomised, placebo-controlled FREEDOMS study. *Lancet Neurol*. 2012; 11:420-28. DOI: http://dx.doi.org/10.1016/S1474-4422(12)70056-X.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. 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: July 20, 2019.
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: June 28, 2018.

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.