Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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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-remitting multiple sclerosis (RRMS); **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
      2. Tecfidera (dimethyl fumarate); **OR**
      3. Copaxone/Glatopa (glatiramer);

OR

II. Individual has high disease activity despite treatment with a disease modifying drug (Aubagio, Avonex, Plegridy, Rebif, Betaseron, Extavia, Copaxone/Glatopa, Tecfidera) defined as the following (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;

OR

III. Individual is treatment naïve (no previous history of use of disease modifying drugs such as Aubagio, Avonex, Plegridy, Rebif, Betaseron, Extavia, Copaxone/Glatopa, Tecfidera); **AND**

IV. Individual has rapidly evolving severe relapsing multiple sclerosis defined as the following (Devonshire et al. 2012):
   A. 2 or more disabling relapses in 1 year; **AND**
   B. 1 or more Gadolinium-enhancing lesions on brain MRI

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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

I. Individual is not concurrently using with other MS disease modifying agents (such as Aubagio, Tecfidera, Tysabri, Lemtrada, Zinbryta); **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 ms; **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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.