I. Medication Description

Gilenya (fingolimod) is a sphingosine 1-phosphate receptor modulator. It is metabolized by sphingosine kinase to the active metabolite, fingolimod-phosphate. Fingolimod-phosphate is a sphingosine 1-phosphate receptor modulator, and binds with high affinity to sphingosine 1-phosphate receptors 1, 3, 4, and 5. Fingolimod-phosphate blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which fingolimod exerts therapeutic effects in multiple sclerosis is unknown, but may involve reduction of lymphocyte migration into the central nervous system.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request. Gilenya 0.25mg capsules do not require prior authorization (see Section VII).

III. Policy

Coverage of Gilenya is available when the following criteria are met:

- The patient has a diagnosis of a relapsing form of multiple sclerosis AND
- Medication is prescribed by or in consultation with a neurologist AND
- Member is at least 10 years of age

IV. Quantity Limitations

Gilenya 0.5mg capsules: 30 per each 30 days

V. Coverage Duration

Initial coverage is provided for 6 months and may be renewed in up to 12 month intervals.

VI. Coverage Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug
VII. Billing/Coding Information

Gilenya is available as 0.5mg oral capsules.

Note: Gilenya 0.25mg caps will not be commercially available. They will only be available only through the Gilenya Go Program (Novartis Pharmaceuticals).

VIII. Summary of Policy Changes

- 3/15/12: Renewal duration extended to 12 months, AV block risk for ECG monitoring added.
- 3/15/13: Required trial of interferon beta (Rebif®, Avonex®, Betaseron®, Extavia®) or glatiramer acetate (Copaxone®) prior to coverage of Gilenya™.
- 7/1/2013: Commercial Rx and Medicaid/Family Health Plus Rx criteria differentiated.
- 12/15/13: Removed requirement for functional arm/hand use or ability to walk/perform ADLs prior to coverage.
- 11/1/14: removal of requirement for injectable agent first
- 1/1/15: step requirement removed; baseline testing is required prior to initiation of therapy rather than prior to coverage authorization.
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 7/15/16: removal of safety monitoring parameters from policy
- 9/15/16: no policy changes
- 10/11/17: no policy changes
- 8/15/18: added minimum age to coverage criteria; added coverage notation for 0.25mg capsules
- 11/1/18: no policy changes
- 11/15/19: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.
The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.