Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Fingolimod (Gilenya)

Notes:
^ Adequate trial is defined as at least 3-month treatment duration
* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
# JC virus (John Cunningham virus) positive is considered a relative contraindication to natalizumab use.
JC virus is listed as a miscellaneous lab test: Stratify JCV Antibody with Reflex to Inhibition Assay

Initiation (new start) criteria: Non-formulary fingolimod (Gilenya) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a Neurologist
- Diagnosis of Relapsing form of Multiple Sclerosis (MS) on the Problem list, including:
  - Non-Progressive Relapsing MS
  - Progressive Relapsing MS
  - Relapsing Remitting MS
- Patient has failed an adequate trial^ of, or patient has an allergy or intolerance* to, or patient is not a candidate for (per neurologist documentation) the below infusion medications:
  - Rituximab
  - Natalizumab#

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary fingolimod (Gilenya) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- See below for Continued use criteria for patients stable on the medication

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously. Non-formulary fingolimod (Gilenya) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Diagnosis of Multiple Sclerosis (MS)
- Patient is NOT using fingolimod (Gilenya) with another disease modifying treatment (i.e., glatiramer, interferon beta-1a, interferon beta-1b, natalizumab, fingolimod, teriflunomide, dimethyl fumarate, rituximab)
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CRITERIA FOR DRUG COVERAGE

Fingolimod (Gilenea)

**Continued use criteria for patients stable on the medication:** Non-formulary fingolimod (Gilenya) will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a Neurologist
- Patient has completed the following labs within the last 6 months:
  - Complete blood count with differential (CBC w/ diff)
  - Liver function test (alanine aminotransferase, ALT)
- Patient is NOT using fingolimod (Gilenya) with another disease modifying treatment (i.e., glatiramer, interferon beta-1a, interferon beta-1b, natalizumab, fingolimod, teriflunomide, dimethyl fumarate, rituximab)