CRITERIA FOR DRUG COVERAGE

Dimethyl fumarate (Tecfidera)

**Notes:**
* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

**Initiation (new start) criteria:** Non-formulary dimethyl fumarate (Tecfidera) 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), including:
  - Non-Progressive Relapsing MS
  - Progressive Relapsing MS
  - Relapsing Remitting MS
- Patient has an allergy or intolerance* to at least one of the following:
  - Glatiramer acetate
  - Interferon beta-1a (Avonex, Rebif)
  - Interferon beta-1b (Extavia, Betaseron)
- Patient is not a candidate for rituximab per prescribing neurologist

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

- Diagnosis of Multiple Sclerosis
- Currently stable on medication
Continued use criteria for patients stable on the medication: Non-formulary dimethyl fumarate (Tecfidera) will continue to be covered on the prescription drug benefit for 24 months when the following criteria are met:

- Prescribed by a Neurologist
- Low/no new/active brain MRI lesions (no more than 1 in 1 year; or no more than 2 in 2 years, etc.)
- Patient has completed the following laboratory monitoring within the last 6 months:
  - Complete blood count with differential (CBC w/ diff)
  - Liver function test (alanine aminotransferase, ALT)
- Patient is NOT using dimethyl fumarate with another disease modifying treatment including: fingolimod, glatiramer acetate, interferon beta-1a, interferon beta-1b, natalizumab, ocrelizumab, rituximab, or teriflunomide