Criteria Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
dimethyl fumarate (Tecfidera®)

Initial approval criteria: Non-formulary dimethyl fumarate (Tecfidera®) will be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Prescriber is a Neurologist
-AND-
- Diagnosis of Relapsing form of Multiple Sclerosis (MS), including:
  - Non-Progressive Relapsing MS
  - Progressive Relapsing MS
-AND-
- Adequate trial and failure of glatiramer acetate OR interferon beta-1a or interferon beta-1b, unless contraindication, intolerance, or allergy
-AND-
- Patient is not a candidate for rituximab per prescribing neurologist
-OR-
- Patient is already stable on the drug
-OR-
- Dose Change Only: Patient previously met criteria and is already taking the drug

Continued use criteria: Non-formulary dimethyl fumarate (Tecfidera®) will continue to be covered for 24 months on the prescription drug benefit when the following criteria are met:

- Patient does NOT have Progressive Non-Relapsing MS diagnosis
-AND-
- Low/no new/active brain MRI lesions (no more than 1 in 1 year; or no more than 2 in 2 years, etc.)
-AND-
- 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
-AND-
- Complete blood count (CBC) with differential monitored within the last 12 months
-AND-
- If JC virus* negative: lymphocytes greater than or equal to 0.5 x 10^9/L OR
  if JC virus positive: lymphocytes greater than or equal to 1 x 10^9/L

Note:
* JC virus listed as miscellaneous lab test: “Stratify JCV Antibody with Reflex to Inhibition Assay”