Tecfidera® (dimethyl fumarate)

Indications:
"Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS)."[1]

Dosage Form/Strength:

- Delayed-Release Capsules: 120mg, 240mg
- Delayed-Release Capsules: 120mg and 240mg 30-Day Starter Pack

Criteria for Approval: [1]

- Patient has a diagnosis of a relapsing form of multiple sclerosis (for example: Relapsing-remitting MS, secondary-progressive MS with relapses, or progressive-relapsing MS); **AND**,
- Tecfidera is prescribed by, or in consultation with, a neurologist or a prescriber who specializes in the treatment of MS; **AND**,
- Baseline CBC with differential indicates a clinically sufficient lymphocyte count.
- Patient is ≥18 years of age; **AND**,
- Either the patient is unable to administer injections due to dexterity issues or visual impairment, OR
    - The patient has tried and failed at least one of the following: Avonex®, Copaxone®, Extavia®, or Rebif®.

Criteria for Reauthorization Approval:

- Patient meets all of the criteria for the initial authorization; **AND**,
- There is documented evidence of a positive clinical response to Tecfidera therapy, characterized by improved disease activity (i.e. improved annualized relapse rate, decreased occurrence rate of formation of gadolinium positive [GD+] lesions on MRI, or decreased rate of formation of lesions on MRI) ; **AND**,
- A current CBC with differential indicates a clinically sufficient lymphocyte count.

Criteria for Denial:

- The patient has a diagnosis of a non-relapsing form of MS (for example: primary progressive MS); **OR**,
- The patient has any diagnosis other than a relapsing form of MS; **OR**,
- Tecfidera is not prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS; **OR**,
- Patient is <18 years of age; **OR**,

- Tecfidera will be used concurrently with other MS disease-modifying agents (for example: Aubagio®, Avonex®, Betaseron®, Copaxone®, Extavia®, Gilenya®, Glatopa™, Lemtrada™, Plegridy®, Rebif®, or Tysabri®); **OR**,
- Patient does not have difficulty with dexterity or visual impairment that would preclude a trial with at least one of the following: Avonex, Rebif, Extavia, or Copaxone; **OR**,
    - The patient has not previously tried and failed at least one of the following: Avonex, Rebif, Extavia, or Copaxone.

Length of Authorization – Initial coverage:

- May be authorized for up to 1 year

Length of Authorization – Reauthorization:

- May be reauthorized for up to 1 year

Quantity Limit:

- Maximum of 2 capsules per day

Mechanism of Action:

"The mechanism by which dimethyl fumarate (DMF) exerts its therapeutic effect in multiple sclerosis is unknown. DMF and the metabolite, monomethyl fumarate (MMF), have been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in vitro and in vivo in animals and humans. The Nrf2 pathway is involved in the cellular response to oxidative stress. MMF has been identified as a nicotinic acid receptor agonist in vitro." [1]

References / Footnotes:

[1] Tecfidera® package insert: Biogen, Inc. Cambridge, MA. February 2016. http://www.tecfidera.com/pdfs/full-prescribing-info.pdf. Accessed 4/8/2016.