Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Tecfidera® (Dimethyl Fumarate)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***May 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *September 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Tecfidera® (dimethyl fumarate).

Tecfidera® (dimethyl fumarate) is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Tecfidera® (dimethyl fumarate), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a neurologist
- Must have a diagnosis of relapsing form of multiple sclerosis
- Must be age 18 years or older
- Must have recent (within 6 months) Complete Blood Count (CBC)
- Must have no evidence of active infection
- Must not be on concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

- Documentation from the provider that the member's disease course has stabilized or improved based upon the prescriber's assessment while on therapy
- Documentation that the member's lymphocyte levels are being monitored on an annual basis
- Documentation that there is no evidence of active infection
- Documentation that the member is not on concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Starter Pack	1 pack per lifetime
Capsule	60 capsules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Tecfidera [package insert]. Cambridge, MA: Biogen Idec Inc.; March 2013
2. Gold R, Kappos L, Arnold DL, et al. Placebo-controlled phase 3 study of oral BG-12 for relapsing multiple sclerosis. N Engl J Med 2012;367:1098-107
3. Fox RJ, Miller DH, Phillips JT et al. Placebo-controlled phase 3 study of oral BG-12 or glatiramer in multiple sclerosis. N Engl J Med 2012;367:1087-97

RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria Update	*09/18 (effective 1/1/19)*