AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Tecfidera			Page:	1 of 2
Effective Date:	11/1/2024			Last Review Date:	10/2024
Applies to:	☐Illinois ☒New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia		☒Florida Kids ☐Michigan ☐Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Tecfidera (dimethyl fumarate) under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Tecfidera is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Dimethyl fumarate

Policy/Guideline:

Prescriber Specialty:
This medication must be prescribed by or in consultation with a neurologist.

Criteria for Initial Approval:

A. Relapsing forms of multiple sclerosis
Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

B. Clinically isolated syndrome
Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome.

Continuation of Therapy:

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Tecfidera.

Other Criteria:
Members will not use Tecfidera concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limits:

- Dimethyl fumarate capsules 120mg: 14 capsules per 28 days
- Dimethyl fumarate capsules 240mg: 60 capsules per 30 days
- Dimethyl fumarate 30-day Starter Pack: 60 capsules per 30 days

References:

1. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
2. dimethyl fumarate [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2024.