# SPECIALTY GUIDELINE MANAGEMENT

# TECFIDERA (dimethyl fumarate) dimethyl fumarate

# POLICY

# I. INDICATIONS

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.

# **II. 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.

# **III. 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.

## **IV. OTHER CRITERIA**

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

## V. REFERENCES

- 1. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; January 2021.
- 2. dimethyl fumarate [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; March 2021

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