

Reference number(s)
1845-A

## 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. PRESCRIBER SPECIALTIES

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

##### III. 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 treatment of clinically isolated syndrome.

##### IV. CONTINUATION OF THERAPY

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

##### V. OTHER

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

##### VI. REFERENCES

dimethyl fumarate-Tecfidera 1845-A SGM P2024

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