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. 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