

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	TECFIDERA	
BRAND NAME (generic)	TECFIDERA TECFIDERA STARTER PACK (dimethyl fumarate)	
Status: CVS Caremark Criteria		MDC
Type: Initial Prior Authorization		Ref # 975-A

FDA-APPROVED INDICATION

Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).¹

CRITERIA FOR APPROVAL

1	Does the patient have a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses)?	Yes	No
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Guidelines for Approval	
Duration of Approval	12 Months
Set 1	
Yes to question(s)	No to question(s)
1	None

Mapping Instructions	
Yes	No
1 Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCE

1. Tecfidera [package insert]. Cambridge, MA: Biogen Idec Inc.; January 2017.

DOCUMENT HISTORY

Written: Specialty Clinical Development (HY) 04/2013
 Revised: HY 09/2014 (CMS), IP 04/2015, PK 08/2015 (CMS), IP 07/2016; KF 04/2016 (annual), 07/2017 (CMS)
 Reviewed: CDPR/KP 04/2013; DNC 05/2013, 06/2013, 06/2014, 05/2015, LMS 04/2016
 External Review: 04/2013, 06/2013, 07/2014, 6/2015, 06/2016