PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**GILENYA**
(generic)	**(fingolimod)**
	fingolimod
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 620-A***

FDA-APPROVED INDICATION

Treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability[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

Guidelines for Approval	
Duration of Approval 12 months	
Yes to questions	**No to questions**
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. Gilenya [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; February 2016.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (GY) 09/2010
Revised:	GY 02/2011 (added IFN-β/Copaxone step); AC 04/2011, AC 09/2011, DK 09/2012 (CMS), 03/2013 (added new contraindications), 09/2013; HY 05/2014 (removed Tysabri washout period and QTc requirement), 09/2014 (CMS), PK 08/2015 (CMS), IP 04/2015, 07/2016 (CMS); KF 04/2016 (annual), 07/2017 (CMS); KF 10/2017 (added generic fingolimod)
Reviewed:	CDPR/ KP 09/2010, 03/2011, 04/2011, 05/2012, 04/2013; DNC 05/2013; LMS 05/2014, DNC 05/2015, LMS 04/2016; ME 10/2017
External Review:	10/2010, 03/2011, 06/2011, 06/2012, 06/2013, 07/2014, 06/2015, 06/2016