

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	REBIF	
BRAND NAME (generic)	REBIF REBIF TITRATION PACK (interferon beta-1a)	
Status: CVS Caremark Criteria		MDC
Type: Initial Prior Authorization		Ref # 542-A

FDA-APPROVED INDICATION

Rebif is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability.¹

Compendial Use

Treatment of the first clinical episode or demyelinating event with MRI features consistent with MS.^{2,3}

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses)? [If yes, no further questions.]	Yes	No
2	Is Rebif prescribed for the first clinical episode of MS?	Yes	No

Guidelines for Approval

Duration of Approval		12 months	
Set 1: Relapsing form of MS		Set 2: First clinical episode	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	2	1

Mapping Instructions

	Yes	No
1	Approve, 12 months	Go to 2
2	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.

REFERENCES

1. Rebif [package insert]. Rockland, MA: EMD Serono, Inc., November 2015.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed April 25, 2016.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed April 25, 2016.

DOCUMENT HISTORY

Written: JG 03/2002

Revised: MG 02/2003, 03/2004; NB 04/2005; MG 03/2006; MY/MG 03/2007; HN 06/2008; TG 04/2009, 08/2009; GY 04/2010; AC 04/2011, 10/2011, DK 09/2012 (CMS), 09/2013; HY 09/2014 (CMS), IP 04/2015, PK 08/2015 (CMS), IP 07/2016 (CMS); KF 04/2016 (annual), KF 03/2017 (2018 simplification), 07/2017 (CMS)

Reviewed: CRC: 3/2002, 02/2003, 03/2004; CDPR: 04/2005, 03/2006, 03/2007, 06/2008, 05/2009; KP 05/2010, 04/2011, 05/2012, DNC 05/2013, 06/2014, 05/2015, LMS 04/2016, AN 03/2017

External Review: 05/2002, 02/2003, 04/2004, 05/2005, 05/2006, 07/2007, 07/2008, 06/2009, 06/2010, 06/2011, 06/2012, 06/2013, 07/2014, 6/2015, 06/2016