

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	SILDENAFIL INJECTION	
BRAND NAME (generic)	REVATIO (sildenafil intravenous solution)	
	sildenafil intravenous solution	
Status: CVS Caremark Criteria		MDC
Type: Initial Prior Authorization		Ref # 1289-A

FDA-APPROVED INDICATION¹

Revatio/sildenafil is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability and delay clinical worsening.

Studies establishing effectiveness included predominantly patients with New York Heart Association (NYHA) Functional Class II to III symptoms and etiologies of primary pulmonary hypertension (71%) or pulmonary hypertension associated with connective tissue disease (25%).

<u>CRITERIA FOR APPROVAL</u>			
1	Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1)? [If no, no further questions.]	Yes	No
2	Has pulmonary arterial hypertension (PAH) been confirmed by right heart catheterization? [If no, no further questions.]	Yes	No
3	Was the patient recently receiving the oral formulation of the requested drug and is now temporarily unable to take oral medications?	Yes	No

Guidelines for Approval	
Duration of Approval	1 month
Set 1: PAH	
Yes to question(s)	No to question(s)
1	None
2	
3	

Internal Use Only – Mapping Instructions			
		Yes	No
1.	Go to 2		Deny
2.	Go to 3		Deny
3.	Approve, 1 month		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. Revatio [package insert]. New York, NY: Pfizer Inc.; April 2015.
2. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. *J Am Coll Cardiol.* 2009;53(17):1573-1619.
3. Badesch DB, Champion HC, Gomez-Sanchez MA, et al. Diagnosis and assessment of pulmonary arterial hypertension. *J Am Coll Cardiol.* 2009;54:S55-S66.
4. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults. CHEST guideline and expert panel report. *Chest.* 2014;46(2):449-475.

DOCUMENT HISTORY:

Written: KH 05/2010 (Revatio Injection added)
Revised: TG 02/2011 (split MDC-1 PA into commercial and MDC-2 PA criteria), KH 03/2011 (Added Adcirca step), KR 04/2011, DK 04/2012, 04/2013 (removed Adcirca step), KW 05/2013; HY 05/2014, DK 03/2015 (Revatio injection-specific 1 page criteria); KF 04/2015 (annual review), KF 08/2015 (CMS), 06/2016 (CMS); ST 04/2016 (removed ped dosing limit), 03/2017 (simplification); 07/2017 (CMS)
Reviewed: CDPR/WLF/DL 05/2010; KP 03/2011, 05/2011, 05/2012, 04/2013, LCB 05/2013, DNC 06/2014, 03/2015; KRU 05/2015; DNC 04/2016; ME 03/2017
External Review: 08/2005, 06/2006, 06/2007, 7/2008, 06/2009, 07/2010, 06/2011, 06/2012, 06/2013, 07/2014, 03/2015, 06/2015, 06/2016