

PRIOR AUTHORIZATION CRITERIA

BRAND NAME: HETLIOZ
(Generic) (tasimelteon)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

MDC
Ref #1125-A

FDA-APPROVED INDICATION¹

Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24-hour sleep-wake disorder.

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of non-24-hour sleep-wake disorder? [If no, no further questions.]	Yes	No
2	Does the patient have a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas)? [If no, no further questions.]	Yes	No
3	Is the patient able to perceive light in either eye? [If yes, no further questions.]	Yes	No
4	Is patient currently receiving therapy with Hetlioz? [If no, no further questions.]	Yes	No
5	Does the patient meet AT LEAST ONE of the following criteria: A) The patient is experiencing increased total nighttime sleep, OR B) The patient is experiencing decreased daytime nap duration?	Yes	No

Guidelines for Approval

Duration of Approval	3 Months	Duration of Approval	12 Months
Set 1: Initial		Set 2: Renewal	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	3	1	3
2	4	2	
		4	
		5	

Internal Use Only – Mapping Instructions

	Yes	No
1	Go to 2	Deny
2	Go to 3	Deny
3	Deny	Go to 4
4	Go to 5	Approve, 3 months
5	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. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2014.
2. Auger, Robert R, Burgess, Helen J, et al. Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders: Advanced Sleep-Wake Phase Disorder (ASWPD), Delayed Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD). An Update for 2015: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med* 2015 Oct;11(10):1199-236.

DOCUMENT HISTORY

Written: Specialty Clinical Development (KF) 03/2014
Revised: KF 09/2014 (CMS), IP 11/2014, 08/2015 (CMS), PK 12/2015, 06/2016 (CMS); JP 11/2016, 07/2017 (CMS)
Reviewed: CDPR/DNC 03/2014, SES 12/2014, 12/2015; LMS 11/2016
External Review: 03/2014, 01/2015, 01/2016, 01/2017