Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Hetlioz (tasimelteon)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2014 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Hetlioz (tasimelteon).

Hetlioz (tasimelteon) is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Hetlioz (tasimelteon), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a physician who specializes in sleep medicine.
- Must have a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24) in a totally blind patient. Chart documentation describing how diagnosis was confirmed (e.g. sleep-wake logs, melatonin secretion abnormalities or progress notes, etc.) is required.
- Must submit chart documentation of a trial and failure of a prescribed sleep-wake schedule.
- Must submit chart documentation of a trial and failure of melatonin with inadequate response or significant side effects unless there is a documented contraindication.

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved as a result of treatment.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Hetlioz	30 capsules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Hetlioz [prescribing information]. Washington, DC: Vanda Pharmaceuticals; January 2014.
2. Rozerem [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals; November 2010.
3. Sack RL, Auckly RP et al. Circadian rhythm sleep disorders: part II, advanced sleep phase disorder, delayed sleep phase disorder, free-running disorder, and irregular sleep-wake rhythm. An American Academy of Sleep Medicine review. *Sleep*. 2007; 30(11):1484-501.
4. Uchiyama M, Lockley SW. Non-24-hour sleep-wake syndrome in sighted and blind patients. *Sleep Med Clin*. 2009; 4:195-221.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*