UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Hetlioz

Program	Prior Authorization
Medication	Hetlioz (tasimelteon)
Markets in Scope	Arizona, Hawaii, Nevada, Florida-CHIP, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island, California
Issue Date	7/2014
Pharmacy and Therapeutics Approval Date	5/2019
Effective Date	7/2019

1. Background:

Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24-hour sleep-wake disorder.[1]

Non-24-hour sleep wake disorder is also called free-running disorder,[2-3,5] circadian rhythm sleep disorder – free running (or non-entrained) type,[2-5] and hypernychthemeral syndrome.[2,4-5,7]

Per the FDA approval letter for Hetlioz, the new drug application (NDA) provides for the use of Hetlioz for non-24-hour sleep wake disorder in blind patients without light perception.[6]

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Hetlioz** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of non-24-hour sleep wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome)

   -AND-

   b. Patient is totally blind (has no light perception)

   -AND-

   c. **<u>One</u>** of the following:

(1) History of contraindication or intolerance to melatonin therapy

-OR-

(2) **Both** of the following:

(a) History of failure of at least 6 months of continuous therapy (i.e., uninterrupted daily treatment) with melatonin

-AND-

(b) Continuous trial of melatonin was done under the guidance of a specialist in sleep disorder

-AND-

d. Prescribed by or in consultation with a specialist in sleep disorders

Authorization will be issued for 12 months.

B. Reauthorization

1. **Hetlioz** will be approved based on the following criteria:

a. Documentation of positive clinical response to **Hetlioz** therapy

-AND-

b. Prescribed by or in consultation with a specialist in sleep disorders

Authorization will be issued for 12 months.

3. References:

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; December 2014.
2. *American Academy of Sleep Medicine. International Classification of Sleep Disorders.* 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
3. National Sleep Foundation. Non-24-hour Sleep Wake Disorder Facts and Prevalence. Available at: http://sleepfoundation.org/non-24/facts_prevalence.html. Accessed on March 21, 2017.

4. Circadian Sleep Disorders Network. Non-24-Hour Sleep-Wake Disorder Questions and Answers. Available at: http://www.circadiansleepdisorders.org/docs/N24-QandA.php. Accessed on March 21, 2017.
5. Food and Drug Administration Center for Drug Evaluation and Research. New Drug Approval 205677. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205677Orig1s000ltr.pdf. Accessed on April 15, 2016.
6. Rajaratnam SM, Polymeropoulos MH, Fisher DM, et al. Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomised controlled multicentre trials. Lancet. 2009 Feb 7;373(9662):482-91.

Program	Prior Authorization –Hetlioz
Change Control	
Date	Change
7/2014	New program.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
5/2015	Annual Review. No changes.
5/2016	Annual review. Updated background and references.
3/2017	Changed initial authorization duration from 6 months to 12 months.
5/2017	Added prescriber criteria for reauthorization. Updated references.
5/2018	Annual review. No changes to criteria.
5/2019	Annual review, updated reference to align with E&I.