Commercial/Healthcare Exchange PA Criteria
Effective: May 2016

Prior Authorization: Hetlioz

Products Affected: Hetlioz (Tasimelteon) oral capsule, Hetlioz LQ oral suspension

Medication Description:
Non-24-Hour Sleep Wake Disorder (Non-24) is a disorder that affects the normal 24-hour synchronization of circadian rhythms. In mammals, circadian rhythms are generated by the suprachiasmatic nuclei (SCN) in the hypothalamus with the day-night cycle as the primary environmental time cue that synchronizes the circadian system to the 24-hour day. People with Non-24 have circadian rhythms that are not synchronized with the 24-hour day-night cycle, either through a failure of light to reach the SCN, as in total blindness, or due to various other reasons in sighted people. The majority of blind people have some light perception and circadian rhythms that are synchronized to a 24-hour day-night cycle as in the sighted. For a totally blind individual with Non-24, their visual disorder prevents the light-dark cycle from synchronizing their internal body clock to the 24-hour day-night cycle. Non-24 is most common in totally blind individuals. Reports suggest that as many as 50% to 75% of totally blind patients have Non-24, representing approximately 65,000 to 95,000 Americans.

The precise mechanism by which Hetlioz® (tasimelteon) exerts its therapeutic effect in patients with Non-24 is not known. Hetlioz® (tasimelteon) is an agonist at melatonin MT1 and MT2 receptors. These receptors are thought to be involved in the control of circadian rhythms.

Covered Uses:
1. Non-24-Hour Sleep-Wake Disorder (Non-24)
2. Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)

Exclusion Criteria: None

Required Medical Information:
- Diagnosis

Age Restrictions: Refer to other criteria

Prescriber Restrictions: Prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders

Coverage Duration: 6 months initial, 12 months continuation of treatment

Other Criteria:
Initial –
A) diagnosis of Non-24 is confirmed by either a or b:

a. assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature)
b. if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month.

AND:

c. Patient is totally blind as defined by the inability to perceive light; AND
d. Patient has had a previous trial and inadequate response to melatonin.
e. HETLIOZ capsules are indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adult patients 18 years of age and older.

B) Diagnosis of Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)
   a. HETLIOZ capsules are indicated for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
   b. HETLIOZ LQ oral suspension is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 to 15 years of age.
   c. Patient has had a previous trial and inadequate response to melatonin OR beta-adrenergic blockers (for example acebutolol).

Continuation –

C) Approve if patient has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with Hetlioz under the guidance of a physician who specializes in the treatment of sleep disorders AND
D) has achieved adequate results with Hetlioz therapy according to the prescribing physician.
E) Patient has not experienced unacceptable toxicity from the drug.

References:

1. Hetlioz™ [package insert]. Deerfield, Illinois. Vanda Pharmaceuticals Inc. Updated December 10, 2021. Accessed March 23, 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca4a9b63-708e-49e9-8f9b-010625443b90
2. National sleep foundation. Non-24-hour Sleep Wake Disorder. http://sleepfoundation.org/non-24/treatment.html. Accessed March 21, 2016.
3. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thompson Micromedex. Updated periodically. Accessed March 2016

4. Hetlioz™. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated March 3, 2021. Accessed March 23, 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/21/2016
2	Policy update	Added new indication, new form of drug (liquid), added new age restrictions.	Covered use, age restriction, other criteria, references.	3/23/2021