Protocol for Hetlioz®, Hetlioz LQ® (tasimelteon)
Approved April 2022

Background:
Non-24-hour sleep-wake disorder, formerly called free-running rhythm disorder or hypernychthemeral syndrome, refers to a condition in which the body clock becomes desynchronized from the environment.

***Hetlioz**, is a melatonin receptor agonist with high affinity for MT1 and MT2 receptors in the suprachiasmatic nucleus of the brain; MT1 and MT2 are thought to synchronize the body's melatonin and cortisol circadian rhythms with the day-night cycle in patients with non-24-hour disorder*

Criteria for approval:

Hetlioz capsules:
1. The patient has a diagnosis of non-24-hour sleep-wake disorder; **OR**
2. Patient has diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS); **AND**
3. The patient has inadequate response (at least 1 month) or has contraindication to melatonin
4. The patient is 16 years of age or older
5. Patient has no other concomitant sleep disorder (e.g., sleep apnea, insomnia)
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Hetlioz liquid:
1. The patient has a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome; **AND**
2. The patient is 3 to 15 years old

Initial Approval: 6 months
Quantity Level Limit
- Tasimelteon 20 mg capsules: 30 capsules per 30 days
- Hetlioz LQ oral suspension 4 mg/mL: 5 mL per day

Continuation of therapy:
1. Documentation of positive clinical response to treatment
2. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence.

Renewal Approval: 12 months
Quantity Level Limit
- Tasimelteon 20 mg capsules: 30 capsules per 30 days
- Hetlioz LQ oral suspension 4 mg/mL: 5 mL per day

References:

1. Hetlioz [prescribing information]. Vanda Pharmaceuticals Inc. Washington D.C. 20037. December 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Morgenthaler TI, Lee-Chiong T et al. Practice Parameters for the Clinical Evaluation and Treatment of Circadian Rhythm Sleep Disorders (An American Academy of Sleep Medicine Report). Sleep. 2007 Nov 1; 30(11): 1445–1459.
4. Coppenrath V, Daly A. Non-24-Hour Sleep-Wake Disorder: Disease Overview and Treatment Options. US Pharm. 2015;40(6):48-52
5. Abbott SM, Goldstein CA, Eichler AF. Non-24-Hour Sleep-Wake Rhythm Disorder. Waltham, MA: UpToDate. Last modified March 3, 2020. https://www.uptodate.com/contents/non-24-hour-sleep-wake-rhythm-disorder. Accessed March 10, 2022