



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Services  
Prior Authorization Criteria

Hetlioz® (tasimelteon)  
**Effective 2/16/2022**

Prior Authorization Request Form

**Hetlioz (tasimelteon)** is a melatonin receptor agonist. **Hetlioz capsules** are indicated for the treatment of Non 24-Hour Sleep-Wake Disorder (Non-24) in adults and **for the treatment of nighttime sleep disturbances in Smith-Magenis syndrome patients  $\geq 16$  years of age.** **Hetlioz LQ oral suspension** is indicated for treatment of nighttime sleep disturbances in Smith-Magenis syndrome patients 3 to 15 years of age.

**CRITERIA FOR APPROVAL:**

1. Patient must have a diagnosis of either of the following:
  - a. Non-24-Hour Sleep-Wake Disorder (Non-24) as confirmed by:
    - 1- An assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels; or an assessment of core body temperature); **or**
    - 2- If an 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 showing evidence of progressively shifting sleep-wake times; **AND**
    - 3- Symptoms are not related to sleep hygiene, substance, or medication use, or other neurological or mental disorders.
  - b. Nighttime sleep disturbances in Smith-Magenis syndrome with a confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is identified; **AND**
2. The patient is within the age range as recommended by the FDA label; **AND**
3. Hetlioz is prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders; **AND**
4. Patient has a clinically documented 6-month trial of continuous melatonin supplementation without relief of symptoms; **AND**
5. Patient must have a documented trial and therapy failure with 6 months of ramelteon.



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**Approval Duration:**

Initial approval will be for 3 months.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; **AND**
2. Documentation indicating that the patient has achieved adequate results with Hetlioz, such as entrainment, significant increases in nighttime sleep, and/or significant decreases in daytime sleep has been provided.

**Continuation of therapy will be granted for 12 months.**

**References:**

1. 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 [J Clin Sleep Med](#). 2015 Oct 15; 11(10): 1199–1236.  
(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4582061/>)
2. Lexi-Comp drug monograph for Hetlioz -Reviewed 2/27/2017, 2/2022
3. Hetlioz package insert dated 12/2014, 12/2020
4. Richardson GS, Zee PC, Wang-Weigand S, Rodriguez L, Peng X. Circadian phase-shifting effects of repeated ramelteon administration in healthy adults. *J Clin Sleep Med* 2008;4:456–61.
5. UpToDate article: Non-24-Hour sleep-wake rhythm disorder (reviewed 2/2022).