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 ≥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.

Updated: DUR board meeting 2/16/2022 PS
DUR Board Approval: 3/08/2017

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).