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

Office of Pharmacy Service
Prior Authorization Criteria

Hetlioz® (tasimelteon)
Effective 4/01/2017

Prior Authorization Request Form

HETLIOZ is a melatonin receptor agonist indicated for the treatment of Non 24-Hour Sleep-Wake Disorder (Non-24).

Criteria for Approval

1) Patient must have a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels or assessment of core body temperature), or 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 showing evidence of progressively shifting sleep-wake times; **AND**

2) Patient is 18 years of age or older; **AND**

3) Documentation must be provided indicating that the patient is totally blind with absolutely **no** perception of light; **AND**

4) Patient must have documented 3-month trials* and therapy failure with all chemically unique preferred and non-preferred non-benzodiazepine sedative hypnotic agents. Quantity limits may still apply (15 tabs/30 day period), but may be waived on appeal with this specific diagnosis and documentation of at least partial efficacy; **AND**

5) Patient has a clinically documented 6-month trial* of continuous melatonin supplementation without relief of symptoms; **AND**

6) Patient must have a documented trial* and therapy failure with 6 months of ramelteon.

7) Initial prior authorization for Hetlioz will be given for 3 months. Requests for continuation of therapy shall only be considered after the patient has received 3 months of continuous therapy* with 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.

* Patient must have no significant gaps (greater than 3 days) in medication adherence in all medication trials.

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)
3.) Hetlioz package insert (12/2014)