Hetlioz (tasimelteon)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Continuation requests: 1 year

Medications	Quantity Limit
Hetlioz (tasimelteon) capsules – Brand and Generic Hetlioz (tasimelteon) oral suspension	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Hetlioz (tasimelteon) **capsules** may be approved if the following criteria is met:

I. Individual has a diagnosis of non-24-hour sleep-wake disorder (Non-24); **AND**
II. Documentation is provided that individual is totally blind as defined by the inability to perceive light; **AND**
III. Individual has had a previous trial and inadequate response to melatonin (AASM 2015 [*J Clin Sleep Med*]);

OR

IV. Documentation is provided that individual has a diagnosis of Smith-Magenis Syndrome (SMS) based on one of the following:
    A. Demonstration of a 17p11.2 deletion;
       OR
    B. Detection of mutation in *RAI1* gene; **AND**
V. Individual is 16 years of age or older; **AND**
VI. Individual is using to treat sleep disturbances related to SMS.

Continuation requests for Hetlioz (tasimelteon) capsules may be approved if the following criteria are met:

I. Documentation is provided that there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to, increase in nighttime sleep, decrease in daytime nap time, improvement in sleep quality).

Requests for **brand** Hetlioz **capsules** must meet the following, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial of one chemically equivalent generic tasimelteon capsule agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
AND
A. Generic tasimelteon capsule had inadequate response; **OR**
B. Generic tasimelteon capsule caused adverse outcome; **OR**
C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Initial requests for Hetlioz (tasimelteon) **oral suspension** may be approved if the following criteria are met:

I. Documentation is provided that individual has a diagnosis of Smith-Magenis Syndrome (SMS) based on one of the following:
A. Demonstration of a 17p11.2 deletion;
OR
B. Detection of mutation in *RAI1* gene; **AND**
II. Individual is 3 to 15 years old; **AND**
III. Individual is using to treat sleep disturbances related to SMS.

Continuation requests for Hetlioz (tasimelteon) oral suspension may be approved if the following criteria are met:

I. Documentation is provided that there is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to, increase in nighttime sleep, improvement in sleep quality).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 7, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. Auger RR, Burgess HJ, Emens JS, Deriy LV, Thomas SM, Sharkey KM. 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 sleepwake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD). An update for 2015. *J Clin Sleep Med* 2015;11(10):1199 –1236. Available from http://www.aasmnet.org/Resources/clinicalguidelines/CRSWD-intrinsic.pdf. Accessed April 7, 2023.
5. Shayota BJ, Elsea SH. Behavior and sleep disturbance in Smith-Magenis Syndrome. *Curr Opin Psychiatry*. 2019 Mar; 32(2): 73-78. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6362978/. Accessed April 7, 2023.