

## SPECIALTY GUIDELINE MANAGEMENT

### HETLIOZ (tasimelteon)

#### POLICY

##### A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

- Hetlioz is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

All other indications are considered experimental/investigational and are not a covered benefit.

##### B. CRITERIA FOR APPROVAL

###### 1. Non-24-Hour Sleep-Wake Disorder

- a. Authorization of 3 months may be granted to members who are initiating Hetlioz therapy when BOTH of the following criteria are met:
  - i. The member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
  - ii. The member is NOT able to perceive light in either eye.

##### C. CONTINUATION OF THERAPY

###### 1. Non-24-Hour Sleep-Wake Disorder

- a. Authorization of 12 months may be granted to members who meet ALL of the following criteria:
  - i. The member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
  - ii. The member is NOT able to perceive light in either eye.
  - iii. The member is experiencing increased total nighttime sleep and/or decreased daytime nap duration.

##### D. DOSAGE AND ADMINISTRATION

###### 1. Dosing Limits<sup>1</sup>

The following dosing limit apply: 20 mg daily

##### REFERENCES

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2014.
2. Auger, Robert R, Burgess, Helen J, et al. 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: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med* 2015 Oct;11(10):1199-236.

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