Reference number(s)
2426-A

SPECIALTY GUIDELINE MANAGEMENT

HETLIOZ (tasimelteon)

POLICY

I. 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.

A. 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.

II. CRITERIA FOR INITIAL APPROVAL

Non-24-Hour Sleep-Wake Disorder
Authorization of 6 months may be granted to members who are initiating Hetlioz therapy when BOTH of the following criteria are met:
A. The member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
B. The member is NOT able to perceive light in either eye.

III. CONTINUATION OF THERAPY

Non-24-Hour Sleep-Wake Disorder
Authorization of 12 months may be granted to members who meet ALL of the following criteria:
A. The member has a diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas).
B. The member is NOT able to perceive light in either eye.
C. The member is experiencing increased total nighttime sleep and/or decreased daytime nap duration.

IV. 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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