BlueCross BlueShield Federal Employee Program

HETLIOZ (tasimelteon)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Hetlioz (tasimelteon) is a melatonin receptor agonist used to treat certain sleep disorders. Hetlioz is an agonist at the melatonin MT_1 and MT_2 receptors which are thought to be involved in the control of circadian rhythms (1).

Regulatory Status

FDA-approved indications:

Hetlioz capsules are indicated for the treatment of: (1)

- Non-24-Hour Sleep-Wake Disorder (Non-24) in adults
- Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older

Hetlioz LQ oral suspension is indicated for the treatment of: (1)

- Nighttime sleep disturbances in SMS in pediatric patients 3 years to 15 years of age

Dose adjustment is not necessary in patients with mild or moderate hepatic impairment. Hetlioz has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, Hetlioz is not recommended for use in patients with severe hepatic impairment (1).

The safety and effectiveness of Hetlioz for the treatment of Non-24 in patients less than 18 years of age have not been established (1).

The safety and effectiveness of Hetlioz for the treatment of nighttime sleep disturbances in SMS have not been established in patients less than 3 years of age (1).

Summary

Hetlioz (tasimelteon) is a melatonin receptor agonist used to treat certain sleep disorders. Hetlioz is an agonist at the melatonin MT_1 and MT_2 receptors which are thought to be involved in the control of circadian rhythms. The safety and effectiveness of Hetlioz for the treatment of Non-24 in patients less than 18 years of age have not been established. The safety and effectiveness of Hetlioz for the treatment of nighttime sleep disturbances in SMS have not been

established in patients less than 3 years of age (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Hetlioz while maintaining optimal therapeutic outcomes.

References

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; January 2024.