PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/22/2015
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HETLIOZ® (tasimelteon) oral capsule
HETLIOZ LQ™ (tasimelteon) oral suspension

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

HETLIOZ® (tasimelteon) oral capsule
HETLIOZ LQ™ (tasimelteon) oral suspension

Criteria:

- **Criteria for initial therapy:** Hetlioz (tasimelteon) capsule and Hetlioz LQ (tasimelteon) suspension is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Specialist in Sleep Disorders

  2. Individual is **ONE** of the following:
     a. Hetlioz **capsule** for an individual 18 years of age or older with a confirmed diagnosis of Non-24-hour sleep wake disorder in an individual who is totally blind with no light perception

     b. Hetlioz **capsule** for an individual 16 years of age or older with a confirmed diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

     c. Hetlioz LQ **suspension** for an individual 3 years to 15 years of age with a confirmed diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

  3. Diagnosis is supported by **ONE** of the following:
     a. For Non-24-hour sleep wake disorder
        i. Measurement of urinary melatonin levels
        ii. Actigraphy performed for ≥ 1 week plus evaluation of sleep logs recorded for ≥ 1 month

     b. For Smith-Magenis Syndrome
        i. Confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or *RAI1* gene mutation is identified

  4. Individual has failure, contraindication or intolerance to **ALL** the following preferred step therapy agents:
     a. For Non-24-hour sleep wake disorder
        i. Preferred step therapy agents include: (used nightly at same time, not on an as needed basis)
           1. Timed melatonin
           2. Timed Rozerem (ramelteon)

     b. For Smith-Magenis Syndrome
        i. Co-administration of acebutolol in the morning and melatonin at bedtime

  5. Individual does not have severe hepatic impairment (Child-Pugh Class C)

  Initial approval duration: 6 months

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- **Criteria for continuation of coverage (renewal request):** Hetlioz (tasimelteon) capsule and Hetlioz LQ (tasimelteon) suspension is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Specialist in Sleep Disorders

  2. Individual's condition responded while on therapy
     a. Response is defined as **ONE** of the following:
        i. For Non-24-hour sleep wake disorder, **BOTH** of the following:
           1. 45-minute increase in nighttime sleep and 45 minute decrease in daytime sleep
           2. Entrainment to a 24-hour cycle has been achieved
        ii. For Smith-Magenis Syndrome, **BOTH** of the following:
           1. Improvement in sleep quality
           2. Increase in nighttime sleep time

  3. Individual has been adherent with the medication, there must not be any gaps in usage

  4. There are no significant interacting drugs

  Renewal duration: 12 months

Description:

Hetlioz (tasimelteon) capsules are indicated for the treatment of Non-24-hour Sleep-Wake Disorder (Non-24) in adults and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older.

Hetlioz (tasimelteon) LQ oral suspension is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 to 15 years of age.

Tasimelteon is an agonist of melatonin receptors MT1 and MT2; it has greater affinity for the MT2 receptor than the MT1 receptor. Stimulation of MT1 receptors is thought to preferentially induce sleepiness, while MT2 receptor activation preferentially influences regulation of circadian rhythms. Because of individual differences in circadian rhythms the effect of tasimelteon may not be seen for weeks or months.

Definitions:

Diagnostic criteria for non-24-hour sleep-wake rhythm disorder - American Academy of Sleep Medicine. International Classification of Sleep Disorders

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Diagnostic criteria A-D must be met:	
A	There is a history of insomnia, excessive daytime sleepiness, or both, which alternate with asymptomatic episodes, due to misalignment between the 24-hour light-dark cycle and the non-entrained endogenous circadian rhythm of sleep-wake propensity.
B	Symptoms persist over the course of at least three months.
C	Daily sleep logs and actigraphy for at least 14 days, preferably longer for blind persons, demonstrate a pattern of sleep and wake times that typically delay each day, with a circadian period that is usually longer than 24 hours.
D	The sleep disturbance is not better explained by another current sleep disorder, medical or neurological disorder, mental disorder, medication use, or substance use disorder.

Resources:

Hellioz (tasimelteon) product information, revised by Vanda Pharmaceuticals, Inc. 12-2020, at DailyMed http://dailymed.nlm.nih.gov accessed January 12, 2021.

Wyatt JK. Overview of circadian sleep-wake rhythm disorders. In: UpToDate, Goldstein CA, Eichler AF (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on January 12, 2021.

Abbott SM. Non-24-hour sleep-wake rhythm disorder. In: UpToDate, Goldstein CA, Eichler AF (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on January 12, 2021.

Bacino CA. Microdeletion syndromes (chromosomes 12 to 22). In: UpToDate, Firth HV, TePas E (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on January 12, 2021.

Elsea SH, Girirajan S. Smith-Magenis syndrome. Eur J Human Genetics 2008; 16: 412–421; doi:10.1038/sj.ejhg.5202009; published online 30 January 2008. Accessed January 13, 2021.