UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| | |
|---|---|
| Program Number | 2025 P 2033-15 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Hetlioz®, Hetlioz LQ™ (tasimelteon) |
| P&T Approval Date | 7/2014, 5/2015, 5/2016, 5/2017, 5/2018, 5/2019, 5/2020, 5/2021, 12/2021, 12/2022, 1/2024, 3/2025 |
| Effective Date | 6/1/2025 |

**1. Background:**

Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24-hour sleep-wake disorder in adults and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older. Hetlioz LQ is an oral suspension and is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 years to 15 years of age.

Non-24-hour sleep wake disorder is also called free-running disorder, circadian rhythm sleep disorder – free running (or non-entrained) type, and hypernychthemeral syndrome.

**2. Coverage Criteria[a]:**

**A. Initial Authorization**

1. **Hetlioz** or **Hetlioz LQ** will be approved based on **all** of the following criteria:

   a. **One** of the following:

      (1) **Both** of the following:

         (a) Diagnosis of non-24-hour sleep wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome)
         (b) Patient is totally blind (has no light perception)

      **-OR-**

      (2) Diagnosis of nighttime sleep disturbances in Smith-Magenis-Syndrome (SMS)

      **-AND-**

   b. **One** of the following:

      (1) History of contraindication or intolerance to melatonin therapy

      **-OR-**

      (2) **Both** of the following:

(a) History of failure of at least 6 months[b] of continuous therapy (i.e., uninterrupted daily treatment) with melatonin

**-AND-**

(b) Continuous trial of melatonin was done under the guidance of a specialist in sleep disorders

**-AND-**

c. Prescribed by or in consultation with a specialist in sleep disorders

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Hetlioz** or **Hetlioz LQ** will be approved based on the following criterion:

   a. Documentation of positive clinical response to therapy

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] For Connecticut, Kentucky and Mississippi business, only a 30 day trial will be required.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; February 2021.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014
3. Auger RR, Burgess HJ, Emens JS, et al. Clinical Practice Guidelines for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD) *J Clin Sleep Med* 2015;11(10):1199 –1236.
4. Rajaratnam SM, Polymeropoulos MH, Fisher DM, et al. Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomised controlled multicentre trials. Lancet. 2009 Feb 7;373(9662):482-91.

| Program | Prior Authorization/Medical Necessity – Hetlioz, Hetlioz LQ (tasimelteon) |
|---|---|
| **Change Control** | |
| 7/2014 | New program. |
| 9/2014 | Administrative change - Tried/Failed exemption for State of New Jersey removed. |
| 5/2015 | Annual Review. No changes. |
| 5/2016 | Annual review. No changes to clinical intent. Updated background and references. |
| 7/2016 | Added Indiana and West Virginia coverage information. |
| 11/2016 | Administrative change. Added California coverage information. |
| 5/2017 | Annual review. Added prescriber criteria for reauthorization. Updated references. Updated state mandate reference language. |
| 5/2018 | Annual review. No changes. |
| 5/2019 | Annual review. No changes. |
| 5/2020 | Annual review. Updated references. |
| 5/2021 | Updated to allow coverage of nighttime sleep disturbances in Smith-Magenis Syndrome based on updated labeling with newly approved indication. Added Hetlioz LQ to criteria. Removed prescriber requirement from reauthorization criteria. |
| 12/2021 | Updated background and references. |
| 12/2022 | Annual review. No changes. |
| 1/2024 | Annual review. Updated step therapy mandate note to include Mississippi. |
| 3/2025 | Updated initial authorization to 12 months. |