UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1130-13
Program	Prior Authorization/Notification
Medication	Hetlioz®, Hetlioz LQ™ (tasimelteon)
P&T Approval Date	5/2014, 5/2015, 5/2016, 5/2017, 5/2018, 5/2019, 5/2020, 5/2021, 11/2021, 2/2022, 2/2023, 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. Hetlioz or **Hetlioz LQ** will be approved based on **one** of the following criteria:

1. Diagnosis of non-24-hour sleep wake disorder

-OR-

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

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.

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 and/or Medical Necessity may be in place.

4. References:

1. Hetlioz [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; February 2021.
2. International Classification of Sleep Disorders: Diagnostic & Coding Manual. 3rd ed. Westchester, 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-Wak Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD) *J Clin Sleep Med* 2015;11(10):1199 –1236.

Program	Prior Authorization/Notification – Hetlioz, Hetlioz LQ (tasimelteon)
Change Control	
5/2014	New program.
5/2015	Annual review. No changes.
5/2016	Annual review. No changes to clinical intent. Updated background and references.
5/2017	Annual review with no changes to coverage criteria. Updated references.
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.
11/2021	Removed requirement that patient is totally blind.
2/2022	Administrative changes.
2/2023	Annual review. Added state mandate language. Updated references.
1/2024	Annual review. Updated references.
3/2025	Increased authorization to 12 months.