NC Medicaid **Effective Date: January 14, 2022**
Outpatient Pharmacy
Prior Approval Criteria
Hetlioz (tasimelteon) **Amended Date: January 05, 2026**

Therapeutic Class Code: H8B
Therapeutic Class Description: Hypnotics, Melatonin MT1/MT2 Receptor Agonists

Medication
Hetlioz
Hetlioz LQ

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.

b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Criteria for Hetlioz:

- **Beneficiary has a documented diagnosis of Non-24 sleep-wake disorder.**
    - The diagnosis of Non-24 is confirmed by meeting ONE of the following conditions:
        - **i.** Assessment of at least one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset [as measured in blood or saliva], assessment of core body temperature);
        OR
        - **ii.** If assessment of at least one physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for ≥ 1 week plus evaluation of sleep logs recorded for ≥ 1 month.
    AND
    - Beneficiary must be 18 years of age or older.
    AND
    - Beneficiary has had an insufficient response or intolerance to at least two (2) other medications for sleep. (can be over-the-counter or prescription)
    AND
    - The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders.

OR

- **Beneficiary has a documented diagnosis of Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)**
AND
    - Beneficiary must be 16 years of age or older
    AND
    - Beneficiary has had an insufficient response or intolerance to at least two (2) other medications for sleep (can be over-the-counter or prescription)
    AND
    - The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders.

Criteria for Helioz LQ:

- **Beneficiary has a documented diagnosis of Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)**
  AND
  - Beneficiary must be 3 years to 15 years of age
    AND
  - Beneficiary has had an insufficient response or intolerance to at least two (2) other medications for sleep
    AND
  - The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders.

Procedures:

- Coverage is limited to a maximum of 30 capsules per 30 days or 158 mL per 30 days
- Initial approval is limited to a period of 3 months.
- For continuation of therapy, beneficiary's use of Hetlioz or Hetlioz LQ must be continuous without gaps in treatment and the prescriber must provide an objective evaluation of the beneficiary's sleep quality, including documentation of an improvement in overall sleep quality while taking Hetlioz or Hetlioz LQ.
- Continuation approvals may be up to a period of 6 months.

References

1. Prescriber Information-Hetlioz ® (tasimelton) Vanda Pharmaceuticals Inc. Washington DC 20037, January 2014. Updated December 2020. Updated January 2024.

Criteria Change Log

03/16/2015	Criteria effective date
10/01/2021	Added Hetlioz LQ Added Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) as an approvable indication for Hetlioz
01/14/2022	Removed blindness
01/05/2026	Criteria reviewed and no changes made.