Louisiana Medicaid
Sedative Hypnotics

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred sedative hypnotics; **OR**
- Clinical authorization for tasimelteon (Hetlioz®, Hetlioz LQ™).

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Non-Preferred Agents

Approval Criteria for Initial and Reauthorization Requests

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- The requested medication has been prescribed for an approved diagnosis (if applicable); **AND**
- If the request is for quazepam 15mg tablet, trial of **ALL** preferred products is required. Results for each trial must be **stated on the request** and may include treatment failure, intolerable side effects, documented contraindications, and/or the preferred product(s) are inappropriate to use for the condition being treated; **OR**
- If the request is for a non-preferred product (except quazepam 15mg tablet), ~~Previous use of a preferred product –~~ **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 3 months

Tasimelteon (Hetlioz®, Hetlioz LQ™)

Approval Criteria

- The recipient has a documented diagnosis of non-24-hour sleep-wake disorder (also known as circadian rhythm sleep disorder, free-running type); **AND**
- The recipient is 18 years of age or older on date of request; **AND**
- The recipient has a documented diagnosis of being totally blind (has no light perception in either eye); **AND**
- **ONE** of the following is **true** and is **stated on the request**:
    - The recipient has had insufficient response or intolerance to other preferred medication(s) used for sleep; **OR**
    - The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a physician who specializes in the treatment of sleep disorders; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

OR

- The recipient has a documented diagnosis of Smith-Magenis Syndrome (SMS) with nighttime sleep disturbances; **AND**
- The recipient is 3 years of age or older on date of request; **AND**
- **ONE** of the following is **true** and is **stated on the request**:
    - The recipient has had insufficient response or intolerance to other preferred medication(s) used for sleep; **OR**
    - The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a physician who specializes in the treatment of sleep disorders; **AND**
- By submitting the authorization request, the prescriber attests to the following:

- The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

References

Hetlioz (tasimelteon) [Doctor Discussion Guide]. Washington, D.C.: Vanda Pharmaceutical Inc; 2014. https://hetlioz.com/assets/HETLIOZ_DoctorDiscussionGuide.pdf

Hetlioz (tasimelteon) [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc; December 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214517s000lbl.pdf

Hetlioz: Uncovering Non-24 in your patients who are totally blind. (2018, September 19). https://www.hetliozpro.com/uncovering-non-24-hour-sleep-wake-disorder/diagnostic-tools

Revision / Date	Implementation Date
Single PDL Implementation	May 2019
Separated "Select Therapeutic Classes Not Established" into individual therapeutic class documents / November 2019	January 2020
Combined sedative-hypnotic criteria and Hetlioz® clinical criteria into one document, formatting changes, updated references / July 2020	July 2020
Added criteria for Smith-Magenis Syndrome (SMS) with nighttime sleep disturbances and minimum ages to Hetlioz®, formatting changes, updated references, added Hetlioz LQ™ formulation / January 2021	July 2021
Added required trial of all preferred products for quazepam 15mg tablet / March 2026	July 2026