STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TASIMELTEON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TASIMELTEON	HETLIOZ, HETLIOZ LQ, TASIMELTEON	40927		GPI-10 (6025007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-24 hour sleep-wake disorder (N24HSWD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is light-insensitive or has total blindness
   - The patient had a trial and failure of maximally-tolerated melatonin therapy
   - The requested medication is for the Hetlioz (tasimelteon) capsules

   If yes, **approve the capsule for a lifetime by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) and meet the following criterion?
   - The patient had a trial and failure of maximally-tolerated melatonin therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The requested medication is for the brand Hetlioz capsules AND the patient is 16 years of age or older
   - The requested medication is for the Hetlioz LQ oral suspension AND the patient is 3 years to 15 years of age

   If yes, **approve the requested medication for a lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Brand Hetlioz capsules: #1 per day.**
   - **Hetlioz LQ oral suspension: #5mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TASIMELTEON

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TASIMELTEON (Hetlioz, Hetlioz LQ)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD) (type of sleep disorder where your sleep time increasingly gets delayed)
   2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS) (type of genetic disorder that causes sleeping problems)

B. **If you have non-24 hour sleep-wake disorder, approval also requires:**
   1. You are 18 years of age or older
   2. You are light-insensitive or have total blindness
   3. You have previously tried and failed maximally-tolerated melatonin therapy
   4. You are requesting the capsule

C. **If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:**
   1. You are requesting brand Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz LQ oral suspension if you are 3 to 15 years old
   3. You have previously tried and failed maximally-tolerated melatonin therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Hetlioz.

REFERENCES

- Hetlioz [Prescribing Information]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2020.
- Tasimelteon [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/13/23
Created: 03/14
Client Approval: 12/20
P&T Approval: 01/21