PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Hetlioz and Hetlioz LQ (tasimelteon)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Hetlioz is a melatonin receptor agonist that was originally FDA approved in 2014 for the treatment of Non-24-Hour Sleep-Wake Disorder (non-24), and later approved in 2020 for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS). It acts upon MT1 and MT2 receptors to entrain circadian sleep phase timing.
Non-24 is a type of circadian rhythm sleep-wake disorder that is often present in blind individuals due to the inability to perceive light, causing the hypothalamic circadian pacemaker to fail to entrain (synchronize) with the 24-hour day. This results in nighttime insomnia and excessive daytime sleepiness.
SMS is a rare genetic neurodevelopmental disorder that affects multiple organ systems and is characterized by cognitive impairment, behavioral problems, and sleep disturbances. The sleep disturbances are caused by an inverted circadian rhythm with abnormal timing of melatonin release.

Hetlioz (tasimelteon) will be considered for coverage when the following criteria are met:

Non-24-Hour Sleep -Wake Disorder (Non-24)

For initial authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a sleep specialist; AND
3. Member has a diagnosis of non-24 confirmed by at least one of the following:
   a) Daily sleep logs and/or actigraphy for at least 14 days
   b) Measurements of at least one circadian biomarker (e.g., 6-sulf9Treasons

Smith -Magenis Syndrome (SMS)

For initial authorization:

1. Member is at least 3 years of age; AND
2. Medication is prescribed by or in consultation with a sleep specialist, geneticist, or neurologist; AND
3. Member has documentation of nighttime sleep disturbance with diagnosis of SMS; AND
4. Molecular genetic testing confirms one of the following:
   a) Chromosome 17p11.2 microdeletion (encompasses the RAI1 gene)
   b) Pathogenic variant in the RAI1 gene; AND
5. Member has had at least a 4-6 week trial and failure of melatonin.
6. Dosage allowed/Quantity limit:
   Age 16 years and older: 20 mg (1 capsule) one hour before bedtime, at the same time every night. (QL: 30 capsules per 30 days)
   Age 3 to 15 years: Hetlioz LQ oral suspension, based on body weight:

   (QL: 3 bottles per 30 days for the 48 mL bottle; 1 bottle per 30 days for the 158 mL bottle)

If all the above requirements are met, the medication will be approved for 3 months.

For reauthorization:

1. Chart notes must document improved nighttime sleep disturbances compared to baseline, such as improved sleep quality.

7. Quera Salva MA, Hartley S, Léger D, Dauvilliers YA. Non-24-Hour Sleep-Wake Rhythm Disorder in the Totally Blind: Diagnosis and Management.