Hetlioz (tasimelteon)

Coverage Criteria:

1. Patient has been diagnosed with one of the following:
    a. Smith-Magenis Syndrome (SMS), confirmed with microdeletions (17p11.2) or mutations of RAI1 with nighttime sleep disturbances. Medical documentation, confirming secondary causes of nighttime sleep disturbances have been evaluated and ruled out, is required; or
    b. Non-24 hour sleep wake disorder with total blindness without light perception; and,
2. Patient is experiencing functional impairment, documented in the medical record; and
3. Timed melatonin administration has been failed, after a trial of at least 12 weeks; and
4. At least three prescription medications used for sleep have failed (or are medically contraindicated), after a trial of at least 12 weeks for each medication (such as zolpidem, eszopiclone, zaleplon, trazodone for adults; antihistamines (e.g. hydroxyzine), clonidine, guanfacine for children (less than 18 years of age)); and
5. Prescribed within the FDA-approved dosing regimen (A current weight is required for pediatric patients).

Prescriber Restriction:

Patients with a diagnosis of SMS must be followed by a sleep specialist

Coverage Duration:

Initial approvals will be provided for 12 weeks.

Other Criteria:

Medical chart notes must be submitted, with documentation affirming that all coverage criteria are met prior to approval.

Renewal Criteria:

Re-authorization requires documentation of improved sleep function and improvement in functional impairment. Chart notes documenting sleep function and functional impairment prior to starting Hetlioz and improvement while on Hetlioz are required. Re-authorization is limited to 6 months.