Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

tasimelteon (Hetlioz®)

**Initial approval criteria:** Non-formulary *tasimelteon (Hetlioz®)* will be covered for 3 months on the prescription drug benefit when the following criteria are met:

- Prescriber is a Sleep Specialist
- Diagnosis of Non-24-Hour Sleep-Wake Disorder
- Patient has tried oral melatonin for at least 2 months
- Patient has tried oral ramelteon for at least 2 months
- Patient has used non-pharmacologic sleep entrainment (*alignment of the internal biological clock rhythm to external time cues, such as the natural dark-light cycles*) including: bright light therapy (in patients with light perception) and/or optimizing sleep hygiene
- Patient is already stable on the drug
- Dose Change Only: Patient previously met criteria and is already taking the drug

**Continued use criteria:** Non-formulary *tasimelteon (Hetlioz®)* will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Documentation of positive clinical response of at least a 45-minute gain in nighttime sleep AND a 45-minute decrease in daytime sleep (napping) during the worst part of the cycle.