ALASKA MEDICAID
Prior Authorization Criteria

Orexin Receptor Antagonists
Belsomera®, Dayvigo™, Quviviq™

FDA INDICATIONS AND USAGE[1,2,5]

Orexin receptor antagonists are indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

APPROVAL CRITERIA[1,2,3,4,5]

1. Patient has a diagnosis of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance **AND;**
2. Patient is 18 years of age or older **AND;**
3. Other causes of sleep disturbance, such as a physical or psychiatric disorder, have been ruled out **AND;**
4. A diagnosis of sleep disturbance caused by a medication has been considered and addressed as clinically appropriate by one of the following:
    a. Medication-induced sleep disturbance has been ruled out, **OR**
    b. Medications which are causing sleep disturbance have been discontinued as clinically appropriate, **OR**
    c. Medications which are causing sleep disturbance have been adjusted to minimize the effects on sleep (for example, dosing the medication earlier in the day, or decreasing the medication dosage) as clinically appropriate **AND;**
5. There is documentation that the patient has tried and failed two prescription sleep aids **AND;**
6. The patient has had a documented trial of cognitive behavior therapy (CBT) which must include education on sleep hygiene improvements and common misconceptions about sleep/insomnia.

DENIAL CRITERIA[1,2,3]

1. Failure to meet approval criteria **OR;**
2. Patient has a narcolepsy diagnosis **OR**;
3. Patient is taking another sedative hypnotic agent concurrently

CAUTIONS[1,2]

- May impair alertness and motor coordination including morning impairment.
- May worsen depression or suicidal ideation.
- Sleep-walking, sleep-driving, and engaging in other activities while not fully awake has been observed.
- Sleep Paralysis, Hypnogogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms may occur.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 6 months

QUANTITY LIMITS

- Belsomra® - 30 tablets per 30 days of all strengths (5mg, 10mg, 15mg, 20mg)
- Dayvigo™ - 30 tablets per 30 days of all strengths (5mg, 10mg)
- Quviviq™ - 30 tablets per 30 days of all strengths (25mg, 50mg)

REFERENCES / FOOTNOTES:

1. Belsomra® [Prescribing Information] Whitehouse Station, NJ: Merck & Co, Inc.; May 2016.
2. Dayvigo™ [Prescribing Information] Woodcliff Lake, NJ: Eisai Inc.; December 2019.
3. Trauer JM, Qian MY, Doyle JS, Rajaratnam SM, Cunnington D. Cognitive Behavioral Therapy for Chronic Insomnia: A Systematic Review and Meta-analysis. Ann Intern Med. 2015;163:191-204. doi:10.7326/M14-2841.
4. Mayo Clinic Staff. "Insomnia treatment: Cognitive behavioral therapy instead of sleeping pills." February 11th, 2014. http://www.mayoclinic.org/diseases-conditions/insomnia/in-depth/insomnia-treatment/ART-20046677. Accessed 03/18/20.
5. Quviviq™ [Prescribing Information] Radnor, PA: Idorsia Pharmaceuticals US Inc.; April 2022.