Policy: Sedatives

Reference Number: OR.CP.PMN.1003
Effective Date: 10.01.21
Last Review Date: 02.25
Line of Business: Medicaid – Trillium Oregon Health Plan Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Goals

- Restrict use of sedatives to Oregon Health Plan (OHP) funded conditions, with individual review for individuals covered under the EPSDT program. Long-term treatment of insomnia with sedatives is not funded.
- Encourage use of cognitive behavioral therapy for insomnia.
- Prevent concomitant use of sedatives, including concomitant use with benzodiazepines or opioids.
- Limit daily zolpidem dose to the maximum recommended daily dose by the FDA.
- Permit use of melatonin in children and adolescents 18 years of age or younger.

Covered Alternatives:

- Current Trillium Preferred Drug List listed at:
  - https://www.trilliumohp.com/providers/pharmacy.html

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Trillium Community Health Plan that requested medication is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Insomnia (must meet all):

1. One of the following conditions is met (a, b, or c):
   a. Member has co-morbid depression, anxiety, panic disorder, bipolar disorder and documentation supports concurrent treatment of this condition (e.g., antidepressant, lithium, lamotrigine, anti-psychotic, or other appropriate mental health drug);
   b. Member has co-morbid sleep apnea and uses a CPAP machine;
   c. Member is eligible for EPSDT review and was born in or after the year 2004;
2. If request is for a non-preferred agent, member has failed treatment with at least two preferred drugs at maximally allowed dosing for ≥ 30 days; supported by one of the following (a, b, or c):
   a. Presence of claims in pharmacy claims history;

b. Documented contraindication(s) or clinically significant adverse effects to ALL PDL agents within the same therapeutic class or PDL drugs that are recognized as standards of care for the treatment of insomnia;
c. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;

3. If member has been treated with a different non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days one of the following must be met (a or b):
   a. Request is to switch sedative therapy due to intolerance, allergy or ineffectiveness of non-benzodiazepine sedative;
   b. Concurrent sedative therapy is part of treatment plan to taper off a long-acting benzodiazepine;
4. For melatonin requests: age ≤18 years;
5. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose and health plan approved daily quantity limit;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: Duration of request or 12 months (whichever is less)

B. Request is for member enrolled in palliative care (must meet all):
1. Member is enrolled in palliative care services (ICD-10 Z51.5)

Approval duration: Duration of request or 5 years (whichever is less)

C. Circadian Rhythm Sleep-Wake Disorders (must meet all):
1. Diagnosis of one of the following conditions (a, b, or c):
   a. People with delayed sleep-wake phase disorder;
   b. Adults with non-24 hour sleep-wake disorder
   c. Children and adolescents with neurologic disorders and irregular sleep-wake rhythm disorder;
2. Request is for a melatonin agonist* (e.g., melatonin, ramelteon, tasimelteon);
   *If request is for a different medication, refer to the drug specific coverage criteria or no coverage criteria policy CP.PMN.255 is none is available.
3. If request is for tasimelteon, failure of melatonin and remelteon, unless contraindicated or clinically significant adverse events to both are experienced;
4. For brand requests, member must use generic unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose and health plan approved daily quantity limit;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued therapy

A. Insomnia (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Request meets one of the following (a or b):
   a. Request is part of a slow taper plan;
   b. Documentation of improvement (e.g., of symptoms, function, quality of life, ect) since treatment was started and member and provider have discussed whether benefits of ongoing therapy (hospitalizations, function, quality of life) continue to outweigh risks (memory problems, dementia, cognitive impairment, daytime sedation, falls, fractures, dependency, and reduced long-term efficacy);

Approval duration: Duration of request or 12 months (whichever is less)

B. Request is for member enrolled in palliative care (must meet all):

1. Member is enrolled in palliative care services (ICD-10 Z51.5)

Approval duration: Duration of request or 5 years (whichever is less)

C. Circadian Rhythm Sleep-Wake Disorders (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. The FDA-approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;

b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence);

Approval duration: Duration of request or 3 months (whichever is less)

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Diagnoses that are not an OHP funded condition unless member is <21 years of age and EPSDT program policy requirements are met: OR.CP.PMN.234.

B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy: CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. References

1. Sedatives. Oregon Health Plan Current Drug Use Criteria. Available at: http://orpdl.org/drugs/index.php. Accessed January 17, 2025.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 17, 2025.

Reviews, Revisions, and Approvals	Date	Plan Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.18003 Sedatives.	06.15.21	07.15.21
3Q 2022 annual review: no significant changes; references reviewed and updated	06.15.22	07.07.22
3Q 2023 annual review: added limiting zolpidem to max FDA dosing, restriction of melatonin to 18 years or under and EPSDT program coverage to goals and initial approval criteria requirement sections to match FFS criteria and plan limitations, template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.	06.15.23	09.19.23
Updated initial coverage criteria per FFS criteria updates: updated policy goals; for initial approval for insomnia added conditions to	01.09.24	02.20.24

Reviews, Revisions, and Approvals	Date	Plan Approval Date
allow coverage if use of different non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days; added coverage criteria for circadian rhythm sleep-wake disorders; for insomnia continued coverage; added requirement for a taper plan or documented improvement of symptoms and risk vs benefit discussion; updated references		
Added standard YSHCN language to I.A. for new 2025 OHP program coverage.	10.16.24	11.19.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	01.17.25	02.11.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.