Effective Date **1/1/2023**
Next Review Date… **1/1/2024**
Coverage Policy Number **IP0469**

Quazepam for Individual and Family Plans

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for quazepam tablets (Doral®) for Individual and Family Plans.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Quazepam (Doral) is considered medically necessary when the following are met:

1. **Chronic Insomnia.** Individual meets **BOTH** of the following (A and B):
    A. **ONE** of the following (i or ii):
        i. Individual has a cancer diagnosis
        ii. Individual meets **ALL** of the following criteria (1, 2, 3, 4, and 5):
            (1) Individual is 18 years of age or older

(2) The individual has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, or sleep restriction therapy).
(3) Individual is not currently taking prescription stimulants (for example, methylphenidate, amphetamine products)
(4) Individual will not be taking quazepam concurrently with other sedatives, benzodiazepines, opioids, or alcohol.
(5) Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the prescriber

B. Individual meets the preferred covered alternative(s) criteria as indicated in the table below

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Individual and Family Plan Non-Covered Products and Covered Alternative(s):

Non-Covered Product	Criteria
Doral (quazepam tablets)	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **BOTH** of the following (A and B): A. **ONE** of the following: i. estazolam ii. lorazepam B. generic quazepam [prior authorization required]
Quazepam tablets	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **ONE** of the following (A or B): A. estazolam B. lorazepam

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Quazepam is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response (for example, sleep quality and quantity and/or insomnia-related daytime impairments continue to improve or remain stable), including the following:

1. Individual has been re-evaluated clinically for the appropriateness of continuation of therapy and other causes are being ruled out/addressed.

Authorization Duration

Initial approval duration: up to 8 weeks
Reauthorization approval duration: up to 8 weeks

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Quazepam is indicated for the **treatment of insomnia**.[1]

Disease Overview
Insomnia is defined in the International Classification of Sleep Disorders, Third Edition, as a complaint of trouble initiating or maintaining sleep, resulting in daytime consequences (e.g., daytime fatigue, irritability, and decreased concentration) which is not attributable to environmental circumstances or inadequate opportunity for sleep.[2] Generally, transient insomnia lasts less than 1 week, short-term (acute) insomnia lasts up to 3 months, and chronic insomnia lasts more than 3 months at a frequency of at least three times per week.[2,3] Describing insomnia by timing (difficulty falling asleep [sleep onset insomnia], difficulty staying asleep or getting back to sleep after awakening [sleep maintenance insomnia], or disrupted or non-refreshing sleep and/or early morning awakening) can be useful in the diagnosis and help to distinguish among sleep disorders. Additionally, the pattern of sleep difficulty provides a basis to match a medication based on timing of onset and duration of effect.

Guidelines
The American Academy of Sleep Medicine (AASM) published a clinical guideline for the evaluation and management of chronic insomnia in adults (2008).[4] Insomnia is primarily diagnosed by clinical evaluation through a thorough sleep history and detailed medical, substance, and psychiatric history. The evaluation and differential diagnosis of insomnia can be aided by self-administered questionnaires, at-home sleep logs, symptom checklists, psychological screening tests, and bed partner interviews. At a minimum, patients should complete a general medical/psychiatric questionnaire to identify comorbid disorders; a sleepiness assessment (e.g., Epworth Sleepiness Scale) to identify sleepy patients and comorbid disorders of sleepiness; and a 2-week sleep log to identify general patterns of sleep-wake times and day-to-day variability. A sleep diary should be maintained prior to and during the course of active treatment and in the case of relapse or reevaluation in the long-term. The primary treatment goals are to improve sleep quality and quantity and to improve insomnia related daytime impairments. Initial approaches to treatment should include at least one behavioral intervention such as stimulus control therapy or relaxation therapy, or the combination of cognitive therapy, stimulus control therapy, sleep restriction therapy with or without relaxation therapy. Patients should be instructed to keep a regular schedule; have a healthy diet, regular daytime exercise, and a quiet sleep environment; and avoid napping, caffeine, other stimulants, nicotine, alcohol, excessive fluids, or stimulating activities before bedtime. Short-term hypnotic treatment should be supplemented with behavioral and cognitive therapies when possible. Chronic hypnotic medication may be indicated for long-term use in patients with severe or refractory insomnia or chronic comorbid illness. Whenever possible, patients should receive an adequate trial of cognitive behavioral treatment during long-term pharmacotherapy. Long-term prescribing should be accompanied by regular follow-up, ongoing assessment of effectiveness, monitoring for adverse events, and evaluation for new onset or exacerbation of existing comorbid disorders. The AASM published an updated clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults (2017).[5] The recommendations are intended as a guide for choosing a specific pharmacological agent (vs. no treatment) for treatment of chronic insomnia in adults, when such treatment is indicated. The authors note that cognitive behavioral therapy for insomnia (CBT-I) is a standard of care for this condition; however, the AASM guideline does not address the relative benefits of CBT-I vs. pharmacotherapy. An AASM practice guideline regarding behavioral and psychological treatments for insomnia was also published in 2021.[8] This highlights the importance of these treatments in the management of insomnia.[8]

The American College of Physicians (ACP) developed a guideline on the management of chronic insomnia disorder in adults (2016).[6,7] Chronic insomnia can be managed with psychological therapy, pharmacologic therapy, or a combination of both. Psychological therapy options include CBT-I and other interventions, such as stimulus control, relaxation strategies, and sleep restriction. ACP recommends that all adults receive CBT-I as the initial treatment for chronic insomnia disorder (strong recommendation, moderate-quality evidence). ACP recommends that clinicians use a shared decision-making approach, including a discussion of the benefits, harms, and costs of short-term use of medications, to decide whether to prescribe a medication in adults with

chronic insomnia disorder in whom CBT-I alone was unsuccessful (weak recommendation, low-quality evidence). ACP also notes that pharmacotherapies for insomnia may cause cognitive and behavioral changes and may be associated with infrequent but serious harms.

References

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3. Brasure M, MacDonald R, Fuchs E, et al. Management of Insomnia Disorder. Comparative Effectiveness Review No. 159. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2012-00016-I). AHRQ Publication No.15(16)-EHC027-EF. Rockville, MD: Agency for Healthcare Research and Quality. December 2015. Available at: www.effectivehealthcare.ahrq.gov . Accessed on June 2, 2022.
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6. Qaseem A, Kansagara D, Forciea MA, et al. Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2016;165:125-133.
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