idorsia

QUVIVIQ (daridorexant) Insurance Coverage

Navigating the denial and appeals process to support patient access

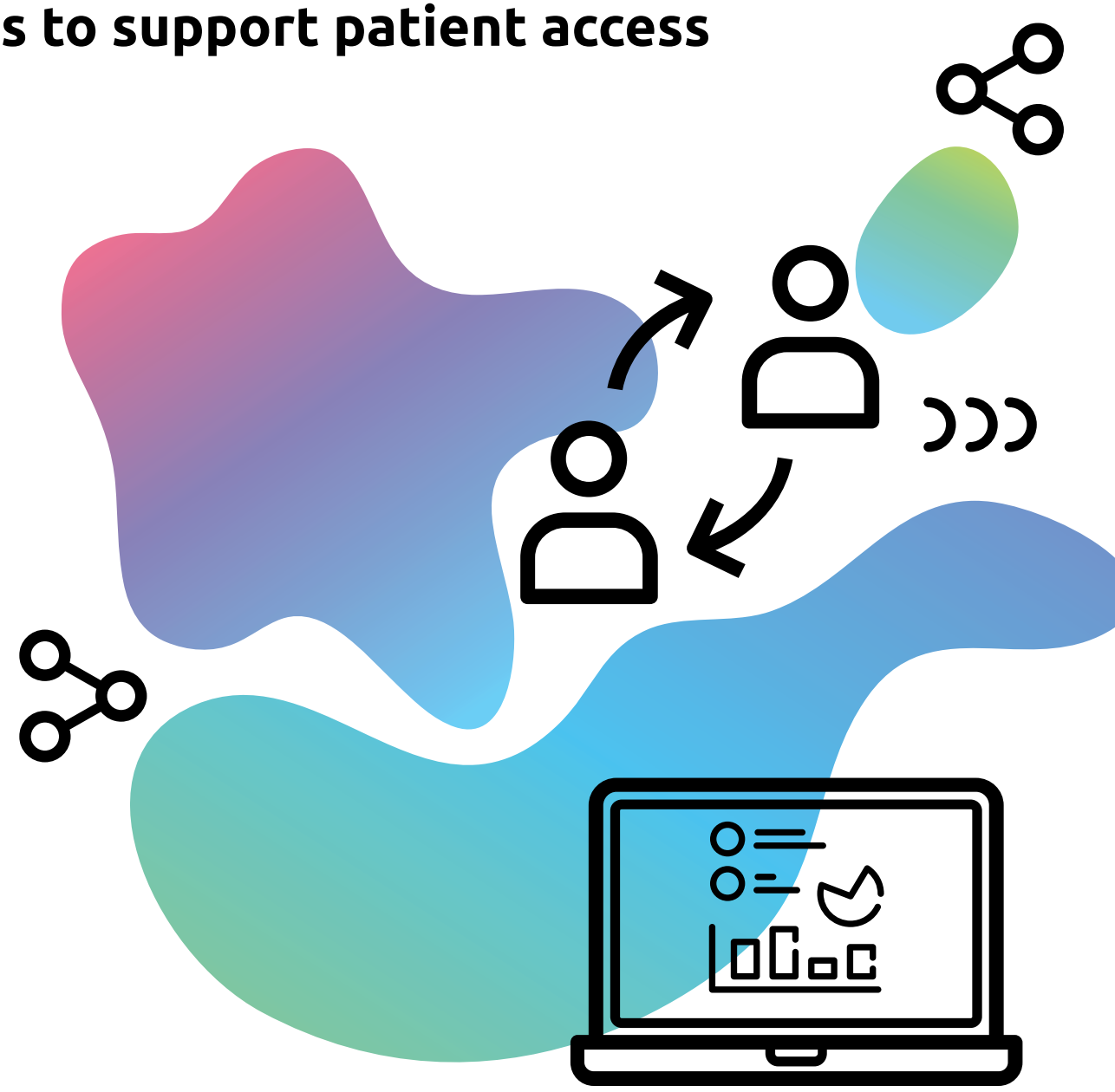

Table of Contents

Introduction

This resource is intended to help healthcare providers (HCPs) navigate potential coverage barriers for QUVIVIQ (daridorexant).

In this resource, you'll find an overview of common reasons insurers and/or health plans deny QUVIVIQ coverage.

- Information included in this resource can help you **prevent** initial coverage denials where possible and can also help you **appeal** initial coverage denial decisions

- This resource includes **brief explanations of some common reasons for coverage denial**, a **checklist for information to include when appealing** specific denials, and **references to support treatment** with QUVIVIQ

- Please note that **third-party payment for medical products and services is affected by numerous factors**, and Idorsia cannot promise success in obtaining insurance payments for QUVIVIQ

QUVIVIQ is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance[1]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

QUVIVIQ is contraindicated:

- in patients with narcolepsy.
- in patients with a history of hypersensitivity to daridorexant or any components of QUVIVIQ.

Please see additional Important Safety Information on page 13 and full Prescribing Information.

Prior Authorization (PA)

PA is a utilization management tool employed by insurers and/or health plans that requires prescribers to provide documentation that patients meet specified criteria before the insurer and/or health plan will cover a prescribed medication.[2]

PA criteria for QUVIVIQ could potentially include any of the following[3,4]:

- Diagnosis of insomnia
- Trial and failure of 1 or more plan-referred sleep medications (see step therapy below)
- No history of narcolepsy
- No concurrent use with another sleep aid

Step Therapy

Step therapy is a utilization management tool employed by insurers and/or health plans that requires documentation of trial and failure of 1 or more plan-preferred medications. When insurers and/or health plans have implemented step therapy for QUVIVIQ, it may include at least 1 of the following therapies: zolpidem, eszopiclone, zaleplon, or a benzodiazepine.[2,3]

The PA Request Form Checklist can help ensure you provide sufficient documentation to prevent PA denials due to incomplete information. Prescribers may submit a PA directly to the insurer and/or health plan, or pharmacies may submit one on behalf of the prescribers.

If a PA request is denied, prescribers may submit a **PA Appeal Letter** to request approval of QUVIVIQ for the individual patient. Some plans may require a **Letter of Medical Necessity** alongside the PA Appeal Letter to support the QUVIVIQ treatment choice

The **PA Appeal Letter Checklist** and **Letter of Medical Necessity Checklist** will help ensure that pertinent patient information and clinical evidence are included to justify QUVIVIQ as the appropriate treatment choice for your patient.

Formulary Exclusion

There are 2 basic types of formularies a health plan can have:

1. An **open formulary** pharmacy benefit provides coverage at the point of sale for all medications covered under the prescription benefit, even those not listed on the formulary.[2]

2. Under a **closed formulary** pharmacy benefit, only the drugs listed on the formulary are covered at the point of sale. Non-formulary medications can only be obtained via a **formulary exception process**.[2]
   - **The formulary exception request process allows a prescriber to request that a product not on the formulary be considered for a specific patient due to medical necessity**
   - The **Formulary Exception Request Considerations** can help ensure you that you have sufficient documentation to support coverage decisions

PA Request Form Checklist

If a PA is needed, the insurer and/or health plan will have a list of criteria for the prescriber or pharmacist to include in a PA Request Form.

Be sure to fill in as much information on the form as possible. Incomplete information can lead to a PA denial.

1. **Information from the patient's medical record and chart notes**
   - **a.** Identifying information
   - **b.** Clinical diagnosis, including ICD-10 code (e.g., G47.00)
   - **c.** Detailed history of the patient's condition and physician's case notes

2. **Medication history**
   - **a.** Sleep medications tried and failed
     - **i.** Trazodone
     - **ii.** Z-drugs (e.g., zolpidem, eszopiclone)
     - **iii.** Benzodiazepines
     - **iv.** Dual Orexin Receptor Antagonists (DORAs) (include which one)
     - **v.** Others (include names)
   - **b.** Other current medications

3. **Prescriber information**
   - **a.** Name
   - **b.** National Provider Identifier (NPI) number
   - **c.** Specialty
   - **d.** Contact information

4. **Supporting documentation**
   - **a.** If requested, include the patient's medical records and any documents listed in the PA Request Form

5. **Prescriber signature**

Formulary Exception Request Considerations

If the PA includes preferred products, include the following information as applicable, clearly stating the rationale for prescribing QUVIVIQ and the reason other formulary products are not appropriate.

1. Contraindications to commonly used medications

- **a.** Trazodone[5]
  - **i.** Concomitant treatment with monoamine oxidase inhibitors (MAOIs) or use within 14 days of stopping MAOIs *(include drug name)*
- **b.** Z-drugs (e.g., zolpidem, eszopiclone)[6,7]
  - **i.** Hypersensitivity to eszopiclone
  - **ii.** Hypersensitivity to zolpidem
  - **iii.** Complex sleep behaviors after taking medication
- **c.** Hypersensitivity to benzodiazepines (e.g., temazepam)[8]
  - **i.** Pregnancy

2. Occurrence of most common adverse reactions and/or risks related to warnings and precautions of commonly used medications

- **a.** Trazodone[5]
  - **i.** Serotonin syndrome
  - **ii.** Cardiac arrhythmias
  - **iii.** Orthostatic hypotension and syncope
  - **iv.** Increased risk of bleeding
  - **v.** Priapism
  - **vi.** Activation of mania or hypomania
  - **vii.** Cognitive and motor impairment
  - **viii.** Angle-closure glaucoma
  - **ix.** Most common adverse reactions such as edema, blurred vision, syncope, drowsiness, fatigue, diarrhea, nasal congestion, and weight loss
- **b.** Z-drugs (e.g., Ambien, Lunesta)[6,7]
  - **i.** CNS depressant effects
  - **ii.** Severe anaphylactic reactions
  - **iii.** Abnormal thinking or behavioral changes
  - **iv.** Withdrawal effects
  - **v.** Worsened depression or suicidal thinking
  - **vi.** Compromised respiratory function
  - **vii.** Hepatic impairment, impaired drug metabolism, or hemodynamic responses
  - **viii.** Most common adverse reactions such as unpleasant taste, headache, somnolence, respiratory infection, dizziness, drowsiness, drugged feelings, dry mouth, rash, anxiety, hallucinations, diarrhea, and viral infections
- **c.** Benzodiazepines (e.g., Restoril)[8]
  - **i.** Concomitant treatment with opioids
  - **ii.** Abuse, misuse, and addiction
  - **iii.** Dependency and withdrawal
  - **iv.** Severe anaphylactic reactions
  - **v.** Complex behaviors (e.g., sleep-driving)
  - **vi.** Impaired renal or hepatic function or chronic pulmonary insufficiency
  - **vii.** Most common adverse reactions such as drowsiness, headache, fatigue, nervousness, lethargy, dizziness, nausea, hangover, and anxiety

3. Clinical guidelines recommending against the use of preferred agents in a population specific to the patient

Tips for Letters of Appeal

If a PA or Formulary Exception Request for QUVIVIQ is denied, the insurer and/or health plan may require a Letter of Appeal. Processes vary by insurers/health plans.

Consider the following to help prepare for a successful review in the QUVIVIQ appeal process:

1. Review the denial provided by the plan so that your Letter of Appeal can address the specific reasons for denial
2. A clinical rationale supported by medical history or publications are the most compelling, but an objective quality of life rationale may also be considered
3. Submit a letter or statement of medical necessity in writing prior to the review
4. Request a like specialist (e.g., neurologist, sleep medicine)
5. Refer to and have relevant documents and lab results available
6. Refer to supporting references and publications to support your rationale for QUVIVIQ (see **Supporting References**)
7. Discuss the results of a successful trial for QUVIVIQ, if available
8. Discuss the potential consequences for a denial for the patient
9. Discuss patient's adverse events with previous sleep medications, if appropriate
10. Be available during the call window; missing the peer-to-peer review can result in automatic denials
11. If denial is the outcome of the review, ask for the peer's name and license number to note in the chart

Tips for Letters of Medical Necessity

HCPs can use the **Letter of Medical Necessity** to provide an explanation for treatment decisions and supporting documentation for exception and appeal requests. Medical necessity letters may be required by some health plans when submitting an appeal letter.

In addition to the information listed in the PA Request Form Checklist, consider including the following items in a Letter of Medical Necessity:

1. Clearly state the rationale for your QUVIVIQ treatment recommendation and include reference support
2. Citing published trials and clinical guidelines statements can be impactful
3. Specify if the patient is already on QUVIVIQ and is clinically stable, and include specific measures of clinical benefit
4. Explain why formulary-preferred agents, if applicable, are not appropriate (e.g., contraindications, previous adverse reactions associated with sleep medications of a different class, etc.)
5. Highlight implications if the patient goes without treatment (e.g., downstream effects of uncontrolled insomnia)
6. Include the product name, duration of treatment, and reason for discontinuation for any previous sleep medications

Letter of Appeal

Click here for a sample Letter of Appeal template

Letter of Appeal Template

[Date]
[Plan Contact]
[Health plan name]
[Health plan street address]

RE: Appeal for Denial of QUVIVIQ (daridorexant) Coverage
[Insured patient name]
Date of birth: [Patient date of birth]
[Policy #]
[Group #]
[Case # (if known)]

To whom it may concern:

My name is [name, medical specialty (National Provider Identifier number)], and I am writing on behalf of [patient first name, patient last name] to appeal the denial of coverage for QUVIVIQ. [Patient name] has been in my care since [date] for the treatment of [insomnia].

In a letter dated [date of denial letter], coverage for QUVIVIQ was denied due to [reason(s) for denial stated in denial letter]. I have reviewed your letter and, based on my medical expertise, believe that QUVIVIQ is the appropriate treatment for [patient name] because [high-level rationale for prescribing QUVIVIQ].

[Patient name] is a [age]-year-old [male/female] who suffers from [describe attributes of the patient's condition (such as signs, symptoms, frequency, duration, etc.)] and [ICD-10-CM diagnosis code(s), (e.g., *G47.00)*]. My current treatment plan for [patient name] includes [current treatment(s) and dosage, frequency]. [Patient name] has been on this treatment plan since [date]. My patient has previously tried [prior treatment(s), date ranges for treatment(s) (if available), and reason(s) for discontinuation (such as persistent symptoms, adverse reactions, etc.)]. [If applicable, note if your patient was referred to you by a primary care physician or if you referred your patient to a specialist].

Based upon my clinical judgment, I request that you consider approving QUVIVIQ for my patient. I have enclosed additional documentation to further support the medical necessity of QUVIVIQ for [patient name]. My office can be contacted at [phone number] or [email address] if additional information is required to overturn this decision.

Thank you in advance for your timely attention to this matter.

Sincerely,

[Physician name, medical specialty, National Provider Identifier number]
[Physician address]
[Physician phone number]
[Physician fax number]

Enclosures [suggested]:
[Relevant patient medical records]
[Letter of Medical Necessity]
[QUVIVIQ Prescribing Information]

Letter of Medical Necessity

Click here for a sample Letter of Medical Necessity template

Letter of Medical Necessity Template

[Date]
[Plan Contact]
[Health plan name]
[Health plan street address]

RE: Letter of Medical Necessity for QUVIVIQ (daridorexant)

[Insured patient name]
Date of birth: [Patient date of birth]
[Policy #]
[Group #]

To whom it may concern:

My name is [name, medical specialty (National Provider Identifier number)], and I am writing on behalf of [patient first name, patient last name] to request approval to treat [him/her] with QUVIVIQ. [Patient name] has been in my care since [date] for the treatment of [insomnia].

Based on my clinical judgment, I believe that QUVIVIQ is specifically medically necessary for [patient name]. [Patient name] is a [age]-year-old [male/female] who suffers from [describe attributes of the patient's condition (such as signs, symptoms, frequency, duration, etc.)] and [ICD-10-CM diagnosis code(s), (e.g., *G47.00)*].

If patient continues to experience uncontrolled insomnia, [describe your professional opinion of your patient's prognosis without QUVIVIQ].

My current treatment plan for [patient name] includes [current treatment(s) and dosage, frequency]. [Patient name] has been on this treatment plan since [date]. [Include information on the progress of current treatment plan].

Rationale for QUVIVIQ:

- ☐ Clinical guidelines support: _____
  [detailed description of clinical guidelines support]
- ☐ Clinical efficacy and safety profile: _____
  [detailed rationale summarizing clinical trials results relevant to the patient's diagnosis]
- ☐ Most appropriate therapy: _____
  [detailed rationale specifying why preferred agents are not the best choice for the patient, including, if applicable, adverse events likelihood, contraindications in this specific patient, previous trials and failures, and reasons for discontinuation] *Refer to the checklist in the Formulary Exceptions Request Considerations.*

[If applicable, note if your patient was referred to you by a primary care physician or if you referred your patient to a specialist].

Please promptly review the enclosed information to authorize the treatment of QUVIVIQ for [patient name]. My office can be contacted at [phone number] or [email address] if additional information is required to approve this request.

Thank you in advance for your timely attention to this matter.

Sincerely,

[Physician name, medical specialty, National Provider Identifier number]
[Physician address]
[Physician phone number]
[Physician fax number]

Enclosures [suggested]:
[Relevant patient medical records]
[QUVIVIQ Prescribing Information]
[Peer-reviewed literature (e.g., treatment guidelines)]

Supporting References

Rationale to Support the Use of QUVIVIQ

Description	Citation
AASM clinical guidelines describing sleep and daytime impairment treatment goals[9]	Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med.* 2008;4(5):487-504.
Clinical practice recommendations for the pharmacologic treatment of insomnia in adults[10]	Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(2):307-349.
Patient satisfaction with current therapies and determinants for treatment-seeking[11-13]	Morin CM, LeBlanc M, Daley M, Gregoire JP, Mérette C. Epidemiology of insomnia: prevalence, self-help treatments, consultations, and determinants of help-seeking behaviors. *Sleep Med.* 2006;7(2):123-130. Bartlett DJ, Marshall NS, Williams A, Grunstein RR. Predictors of primary medical care consultation for sleep disorders. *Sleep Med.* 2008;9(8):857-864. Torrens Darder I, Argüelles-Vázquez R, Lorente-Montalvo P, Torrens-Darder MDM, Esteva M. Primary care is the frontline for help-seeking insomnia patients. *Eur J Gen Pract.* 2021;27(1):286-293.
The Phase 3 QUVIVIQ clinical trial program which assessed safety and efficacy of QUVIVIQ across both night and day end-points • *Efficacy of QUVIVIQ measured by sleep parameters of WASO, LPS, sTST, and patient-reported daytime sleepiness, as measured by IDSIQ*[14]	Mignot E, Mayleben D, Fietze I, et al. Safety and efficacy of daridorexant in patients with insomnia disorder: results from two multicentre, randomised, double-blind, placebo-controlled, phase 3 trials. *Lancet Neurol.* 2022;21(2):125-139.

Supplemental QUVIVIQ Safety Profile Data

Description	Citation
Long-term safety and tolerability of QUVIVIQ • *QUVIVIQ was evaluated in a 40-week extension safety study, for a total of 12 months of treatment*[15]	Kunz D, Dauvilliers Y, Benes H, et al. Long-term safety and tolerability of daridorexant in patients with insomnia disorder. *CNS Drugs.* 2023;37(1):93-106.

Supplemental Publications

Description	Citation
Insomnia treatment recommendations in older adults[16,17]	**The 2019 American Geriatrics Society Beers Criteria® Update Expert Panel. American Geriatrics Society 2019 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. *J Am Geriatr Soc.* 2019;67(4):674-694.** Patel D, Steinberg J, Patel P. Insomnia in the elderly: a review. *J Clin Sleep Med.* 2018;14(6):1017-1024.
Efficacy and safety analyses of QUVIVIQ in older adults[18]	Fietze I, Bassetti CLA, Mayleben DW, Pain S, Seboek Kinter D, McCall WV. Efficacy and safety of daridorexant in older and younger adults with insomnia disorder: a secondary analysis of a randomised placebo-controlled trial. *Drugs Aging.* 2022;39(10):795-810.

QUVIVIQ (daridorexant) Indication and Important Safety Information

INDICATION

QUVIVIQ (daridorexant) is indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

WARNINGS AND PRECAUTIONS

Central Nervous System (CNS) Depressant Effects and Daytime Impairment

QUVIVIQ can impair daytime wakefulness. CNS depressant effects may persist in some patients up to several days after discontinuing QUVIVIQ. Advise patients about the potential for next-day somnolence.

Driving ability was impaired in some subjects taking QUVIVIQ 50 mg. Risk of daytime impairment is increased if QUVIVIQ is taken with less than a full night of sleep or at a higher than recommended dose. If taken in these circumstances, caution patients against driving or other activities requiring complete mental alertness.

Use with other CNS depressants increases the risk of CNS depression, which can cause daytime impairment. Dosage adjustments of QUVIVIQ and CNS depressants may be necessary when administered together. Use with other insomnia drugs is not recommended. Advise patients not to consume alcohol in combination with QUVIVIQ.

Worsening of Depression/Suicidal Ideation

Patients with psychiatric disorders including insomnia are at increased risk of suicide. In primarily depressed patients treated with hypnotics, worsening of depression, suicidal thoughts and actions (including completed suicides) have been reported. Administer with caution in patients exhibiting symptoms of depression. Monitoring suicide risk and protective measures may be required.

Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-Like Symptoms

Sleep paralysis, an inability to move or speak for up to several minutes during sleep-wake transitions, and hypnagogic/hypnopompic hallucinations, including vivid and disturbing perceptions, can occur with QUVIVIQ. Explain these events to patients.

Symptoms similar to mild cataplexy have been reported with orexin receptor antagonists and can include periods of leg weakness lasting from seconds to a few minutes, can occur at night or during the day, and may not be associated with a triggering event (e.g., laughter or surprise).

Complex Sleep Behaviors

Complex sleep behaviors, including sleep-walking, sleep-driving, and engaging in activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics, including orexin receptor antagonists, such as QUVIVIQ. These events can occur in hypnotic-naïve as well as in hypnotic-experienced persons. Patients usually do not remember these events. Complex sleep behaviors may occur following the first or any subsequent use of hypnotics, with or without the concomitant use of alcohol and other CNS depressants. Discontinue QUVIVIQ immediately if a patient experiences a complex sleep behavior.

Patients with Compromised Respiratory Function

The effects of QUVIVIQ on respiratory function should be considered for patients with compromised respiratory function. QUVIVIQ has not been studied in patients with moderate obstructive sleep apnea (OSA) requiring CPAP, severe OSA or severe chronic obstructive pulmonary disease (COPD).

Need to Evaluate for Comorbid Diagnoses

Treatment of insomnia should be initiated only after careful evaluation of the patient. Re-evaluate for comorbid conditions if insomnia fails to remit after 7 to 10 days of treatment. Worsening insomnia or new cognitive or behavioral abnormalities may be the result of an underlying psychiatric or medical disorder and can emerge during treatment with sleep-promoting drugs such as QUVIVIQ.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions (reported in ≥ 5% of patients treated with QUVIVIQ and at an incidence ≥ placebo) were headache and somnolence or fatigue.

DRUG INTERACTIONS

- **CYP3A4 Inhibitors:** The recommended dose of QUVIVIQ is 25 mg when used with a moderate CYP3A4 inhibitor. Concomitant use of QUVIVIQ with a strong inhibitor of CYP3A4 is not recommended.
- **CYP3A4 Inducers:** Concomitant use of QUVIVIQ with a strong or moderate inducer of CYP3A4 is not recommended.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

There are no available data on QUVIVIQ use in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to QUVIVIQ during pregnancy. Pregnant women exposed to QUVIVIQ and healthcare providers are encouraged to call Idorsia Pharmaceuticals at 1-833-400-9611.

There are no data on the presence of daridorexant in human milk, the effects on the breastfed infant, or the effects on milk production. Monitor infants exposed to QUVIVIQ through breastmilk for excessive sedation.

Geriatric Use

Because QUVIVIQ can increase somnolence and drowsiness, patients, particularly the elderly, are at higher risk of falls. No dosage adjustment is required in patients over the age of 65 years.

Hepatic Impairment

QUVIVIQ is not recommended in patients with severe hepatic impairment. Reduce the dose in patients with moderate hepatic impairment.

DRUG ABUSE AND DEPENDENCE

- QUVIVIQ is a Schedule IV controlled substance.
- Because individuals with a history of abuse or addiction to alcohol or other drugs may be at increased risk for abuse and addiction to QUVIVIQ, follow such patients carefully.

Please see full Prescribing Information.

References:

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3. QUVIVIQ (Daridorexant). Western Health Advantage. August 16, 2022. Accessed February 16, 2023. https://www.westernhealth.com/provider/prior-authorization-criteria/quviviq-daridorexant/
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7. Lunesta® [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; 2019.
8. Restoril® [Prescribing Information]. Webster Groves, MO: Mallinckrodt Pharmaceuticals; 2021.
9. Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med*. 2008;4(5):487-504.
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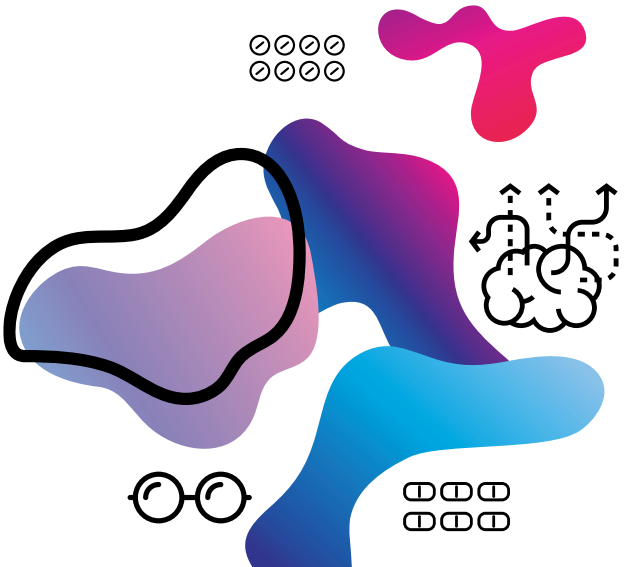

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