PTHB Prescribing Advice:
Daridorexant (Quviviq®) for Long-Term Insomnia

Daridorexant is licensed for the treatment of chronic insomnia in adults. It works by blocking orexin receptors, reducing the activity of the brain's wakefulness system, and helping to promote sleep.
This differs from traditional hypnotics such as benzodiazepines and Z-drugs which enhance GABA-mediated neuronal inhibition, produce more generalised central nervous system sedation, and are only licensed for short-term treatment of insomnia (up to 4 weeks). Daridorexant does not act through GABA pathways; instead, it selectively targets the orexin system, provides a more physiological and targeted approach to the treatment of insomnia (rather than inducing broad sedation), and is reserved for patients with chronic insomnia who have not had an adequate response to, or are unable to access, CBT-i (PTHB SilverCloud Online Mental Health Support).

When can daridorexant be started?

NICE TA922 (**ALL** criteria must be met)

- ☑ Adult (≥18 years)
- ☑ Chronic insomnia with symptoms:
  - Occurring **≥3 nights per week AND** lasting for **≥3 months**
- ☑ Daytime functioning is considerably affected
- ☑ CBT-i has:
  - Been tried and not worked, or
  - Is unsuitable e.g. cognitive impairment, severe mental illness, communication barriers, or other inability to engage with CBT-i

Before Prescribing Confirm

- ❖ Chronic insomnia diagnosis
- ❖ Alternative causes assessed (e.g. anxiety, depression, sleep apnoea, restless leg syndrome, substance misuse, medicines)
- ❖ Baseline sleep symptoms documented
- ❖ Any existing *hypnotic* has been **stopped**. Long-term co-prescribing with other hypnotics is not recommended (lack of evidence and increased CNS depression)
- ❖ Sleep hygiene advice provided
  - NHS sleep hygiene advice
- ❖ Daytime impairment recorded
- ❖ CBT-i status documented
  - CBT-i considered unsuccessful where the patient has *engaged with and completed* a suitable CBT-i course but still experiences persistent insomnia with significant impairment of daytime functioning.

Prescribing

- ❖ Usual dose is 50mg, taken 30 minutes before going to bed
- ❖ Avoid use when only a short sleep period is available due to the risk of next-day somnolence and impaired alertness
- ❖ Precautions for consideration – see SPC for full details
  - CNS depression and effect on alertness
  - Increased fall risk
  - Potential for worsening of depression and suicidal ideation
  - Severe COPD (FEV1 < 40% of predicted) due to lack of trial data
  - Misuse potential
- ❖ Dose reduction - consider 25mg in appropriate patients (e.g. moderate hepatic impairment or significant interactions)
- ❖ Consider interactions with co-prescribed drugs - see BNF or SPC for details
  - Strong CYP3A4 inhibitors, e.g. clarithromycin, itraconazole - are **contra-indicated**
  - Moderate CYP3A4 inhibitors, e.g. erythromycin, ciprofloxacin, ciclosporin - a reduced daridorexant dose of 25mg is recommended

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Review within 3 months of initiation

Review within 3 months is required to confirm treatment is providing benefit and is a requirement of the marketing authorisation and the NICE TA922 appraisal.

DOCUMENT:

- Improvement in insomnia symptoms
- Improvement in daytime functioning
- Adverse effects
- Ongoing need for treatment
- Patient-reported benefit

What Should Improve?

ASSESS BOTH:

1 Sleep

- Faster sleep onset
- Fewer night-time awakenings
- Longer sleep duration
- Better sleep quality

2 Daytime Functioning

- Less fatigue
- Improved alertness
- Better concentration
- Improved work/social/daily functioning

STOP Treatment If

- ☒ Inadequate response at 3 months
- ☒ No meaningful improvement in daytime functioning
- ☒ Intolerable adverse effects
- ☒ Treatment no longer providing benefit

CONTINUE Treatment If

- ☑ Clinically meaningful improvement in sleep
- ☑ Improvement in daytime functioning
- ☑ Treatment tolerated
- ☑ Ongoing benefit demonstrated at review

Ongoing Monitoring

- If continuing beyond initial 3 months ➔ review effectiveness regularly (6 monthly suggested)
- Reassess need for ongoing treatment. Treatment duration should be as short as possible
- Monitor for:
  - Daytime somnolence
  - Dizziness
  - Falls risk
  - Driving impairment
  - Drug interactions – including acute prescriptions/antibiotics
- Adverse effects
  - Daridorexant is a MHRA Black Triangle drug subject to enhanced monitoring
  - Report ALL suspected side effects via the MHRA Yellow Card Scheme
  - Direct comparative evidence between daridorexant and established hypnotics is limited but available data suggests daridorexant may be associated with lower risks of dependence, withdrawal, cognitive impairment and residual next-day sedation than benzodiazepines or Z-drugs, whilst having broadly comparable efficacy for insomnia symptoms
  - Rare orexin receptor blockade-specific adverse effects of daridorexant may include sleep paralysis, vivid dreams and hallucination-like experiences at sleep-wake transitions
- At time of writing clinical data is available only for up to 12 months of continuous treatment. All patients should be reviewed at 12 months to assess the benefits and risks of ongoing treatment and consider discontinuation.
  - If prescribing beyond 12 months, consider if a referral to specialist sleep services may be beneficial, particularly if symptoms remain uncontrolled or diagnostic uncertainty exists

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