

DORSET MEDICINES ADVISORY GROUP

COMMISSIONING STATEMENT ON DARIDOREXANT FOR TREATING INSOMNIA DISORDER

SUMMARY	
NHS Dorset supports the use of daridorexant for treating long-term insomnia in accordance with NICE TA922	
BACKGROUND	<p>Daridorexant is a dual orexin receptor antagonist, acting on both orexin 1 and orexin 2 receptors and equipotent on both. The orexin neuropeptides (orexin A and orexin B) act on orexin receptors to promote wakefulness. Daridorexant antagonises the activation of orexin receptors by the orexin neuropeptides and consequently decreases the wake drive, allowing sleep to occur, without altering the proportion of sleep stages (as assessed by electroencephalographic recording in rodents or polysomnography in patients with insomnia)</p> <p>The recommended dose for adults is one tablet of 50 mg once per night, taken orally in the evening within 30 minutes before going to bed.</p> <p>Daridorexant can be used as a first-line treatment option when CBTi is not available or is unsuitable. When available and suitable, CBTi should always be offered before daridorexant as per the local pathway.</p>
RELEVANT NICE GUIDANCE	<p>NICE TA922 states:</p> <p>Daridorexant is recommended for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:</p> <ul style="list-style-type: none">• cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or• CBTi is not available or is unsuitable. <p>The length of treatment should be as short as possible. Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, assess whether it is still working at regular intervals.</p>
FORMULARY STATUS	Green
NHS PAYMENT SCHEME STATUS	Included within NHSPS
COMMISSIONING IMPLICATIONS	<p>The company proposed that daridorexant would be used in primary care for long-term insomnia as:</p> <ul style="list-style-type: none">• a second-line treatment option when digital or face-to-face CBTi has been tried but not worked, or as maintenance treatment for managing longer-term symptoms• a first-line treatment option when CBTi is not available or is unsuitable.

PATIENT PATHWAY IMPLICATIONS	<p>Daridorexant is an option for patients who are eligible for it within the NICE TA who have either tried CBTi or CBTi has failed or is unavailable.</p> <p>The local pathway and guidance should be followed.</p>
PRESCRIBING INFORMATION	<p>The recommended dose for adults is one 50 mg tablet once per night, taken orally in the evening within 30 minutes before going to bed.</p> <p>The recommended dose is 25 mg once per night for those patients taking moderate CYP3A4 inhibitors (e.g., erythromycin, ciprofloxacin, cyclosporin).</p> <p>The maximum daily dose is 50 mg. Missed dose: If a patient forgets to take daridorexant at bedtime, that dose should not be taken during the night.</p> <p>The treatment duration should be as short as possible. The appropriateness of continued treatment should be assessed within 3 months and periodically thereafter. Clinical data is available for up to 12 months of continuous treatment. Treatment can be stopped without down-titration.</p>
SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS	<p>NICE states: "CBTi is the standard first treatment for people with long-term insomnia after sleep hygiene advice is offered. But access to CBTi varies across the UK, and for some people it does not work or is unsuitable. For this evaluation, the company asked for daridorexant to be considered as a first treatment when CBTi is not available or is unsuitable, and as a second treatment when CBTi has been tried but not worked. This does not include everyone who it is licensed for.</p> <p>Clinical trial evidence shows that daridorexant improves symptoms of insomnia compared with placebo for 12 months. The effects if it's taken for longer than this are unknown. A condition of the marketing authorisation is that treatment with daridorexant should be reviewed within 3 months and regularly after that. The most likely cost-effectiveness estimate is within what NICE considers an acceptable use of NHS resources. So, daridorexant is recommended for routine use in the NHS."</p>
ASSESSMENT OF COST IMPLICATIONS	<p>The list price for the 50-mg or the 25-mg dose is £1.40 per day (£42 per pack of 30 tablets; company submission).</p>
REFERENCES	<p>Daridorexant for treating long-term insomnia (NICE TA922, Overview Daridorexant for treating long-term insomnia Guidance NICE (accessed 18th October 2023)</p> <p>Summary of product characteristics - Quvivig, INN-daridorexant (europa.eu) (accessed 18th October 2023)</p> <p>Insomnia - NHS (www.nhs.uk)</p> <p>Insomnia Health topics A to Z CKS NICE</p>
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