NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report: Daridorexant for treating long-term insomnia (TA922)

Published: October 2023

Summary

NICE has recommended daridorexant 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:

- cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or
- CBTi is not available or is unsuitable.

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.

We estimate that around:

- 995,000 adults with insomnia are eligible for treatment with daridorexant based on expected population growth.
- 116,600 adults will start treatment with daridorexant in 2027/28 after adjusting for expected population growth.

The estimated annual cost of implementing this guidance for the population of England based on the uptake in the resource impact assumptions is shown in table 1. Based on the assumptions used for England, this is equivalent to a cost of around £1.8m and £1m in 2027/28 for Wales and Northern Ireland respectively.

	2023/24	2024/25	2025/26	2026/27	2027/28
Uptake %	2.1	4.1	6.4	9.0	11.7
People starting treatment with daridorexant	20,018	40,182	62,554	89,516	116,612
Resource impact each year for people receiving daridorexant (£m)	£5.4	£10.9	£17.0	£24.3	£31.7

Table 1 Estimated annual cost of implementing the guidance

This report is supported by a resource impact template which may be used to calculate the resource impact of implementing the guidance by amending the variables.

This technology is commissioned by integrated care boards. Providers are NHS primary care services, expected to be mainly GPs.

1 Daridorexant

- 1.1 Long-term insomnia, also known as chronic insomnia or insomnia disorder, is defined as dissatisfaction with quantity or quality of sleep for 3 nights or more per week for at least 3 months with an effect on daytime functioning. Long-term insomnia has both night-time symptoms and an effect on daytime functioning.
- 1.2 The committee stated that long-term insomnia can substantially affect people's quality of life, and there is an unmet need for longer-term treatment options.
- 1.3 The committee highlighted that cognitive behavioural therapy for insomnia (CBTi) is the standard first-line 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.
- 1.4 Daridorexant would be used in primary care for long-term insomnia as a second-line treatment option when digital or faceto-face CBTi has been tried but not worked, or as maintenance treatment for managing longer-term symptoms. It can also be used as a first-line treatment option when CBTi is not available or is unsuitable.

2 Resource impact of the guidance

2.1 The estimated annual cost of implementing this guidance for the population of England based on the uptake in the resource impact assumptions is shown in table 1 in the summary. The cost from year 2027/28 is equivalent to around £56,000 per 100,000 population (see table 2).

Table 2 Resource impact of implementing the guidance using NICEassumptions per 100,000 population

	2023/24	2024/25	2025/26	2026/27	2027/28
Uptake %	2.1	4.1	6.4	9.0	11.7
People starting treatment with daridorexant	35	71	111	158	206
Resource impact each year for people receiving daridorexant (£k)	10	19	30	43	56

2.2 This report is supported by a resource impact template which may be used to calculate the resource impact of implementing the guidance by amending the variables.

Savings and benefits

2.3 There are no long-term treatment options available for chronic insomnia therefore addressing an unmet need.

3 Implications for commissioners and providers

- 3.1 Daridorexant is commissioned by integrated care boards.
 Providers are NHS primary care services, expected to mainly be GPs.
- 3.2 There are potential capacity savings through a reduction in GP appointments due to a positive response to treatment. However, there may be additional GP appointments required to assess whether patients are responding adequately. The local impact on capacity can be modelled in the resource impact template.

4 How we estimated the resource impact

The population

- 4.1 The National Health and Wellness Survey (NHWS) report estimates that 7.3% of the adult population in the UK are affected by insomnia disorder according to the DSM-5 criteria.
- 4.2 The IQVIA MIDAS data identified that the total standard units (SU) of prescribed insomnia treatments was 454,471,000 million in 2021. The IQVIA longitudinal patient data (LPD) estimates the annual average duration of treatment was 194 days assuming one pill per day. Based on this and assuming 84% relate to England this equates to 1.968 million people treated for insomnia each year. Of this the National Health and Wellness Survey (NHWS) 2020 report identified that 51% of respondents matched the DSM-5 criteria and self-reported as being treated with a pharmacological treatment. This estimates that approximately 1 million people are being treated with pharmacological treatment for insomnia disorder who meet the DSM-5 criteria.
- 4.3 Of those with insomnia disorder matching the DSM-5 criteria treated with pharmacological treatment it is assumed 99% have either tried cognitive behavioural therapy for insomnia (CBTi) and it has not worked, or CBTi is not available or unsuitable. This is based on the proportion of people receiving CBT from the <u>Sleepio</u> to treat insomnia and insomnia symptoms topic.
- 4.4 Table 3 shows the number of people eligible for treatment with daridorexant.

	Table 3 Number of people eligible for treatment in England	
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Population	Proportion of previous row (%)	Number of people		
Adult population forecast at 2027/28		46,263,200		
People with insomnia disorder defined as per DSM-5 criteria ¹	7.30%	3,377,214		
People with insomnia disorder defined as per DSM-5 criteria receiving treatment ^{2,1}	1,003,584			
Of those people who have tried cognitive behavioural therapy for insomnia (CBTi) but it has not worked, or CBTi it is not available or unsuitabe ³	99.16%	995,137		
¹ Company submission referencing 'The National Health and Wellness Survey (NHWS) 2020 report', (7.3% of the adult population in the UK are affected by insomnia disorder according to the DSM-5 criteria) (51% of the UK respondents matching this DSM-5 definition criteria self-reported being treated with a pharmacological treatment).				
² Company submission referencing 'IQVIA MIDAS data'. The total standard units (SU) of prescribed insomnia treatments was 454,471,000 million SU in 2021. The 'IQVIA longitudinal patient data (LPD)' estimates the annual average duration of treatment was 194 days assuming one pill per day. Assume 84% relate to England.				
³ Estimate based on proportion people receiving CBT from Sleepio to treat insomnia and insomnia symptoms & clinical opinion				

Assumptions

- 4.5 The resource impact template assumes that:
 - The recommended dose for daridorexant is one 50-mg tablet in the evening not more than 30 minutes before going to bed. The dose could be one 25-mg tablet in the evening, if your doctor considers a lower dose as appropriate.
 - No additional infrastructure is expected to be required to deliver this treatment, there are no routine blood tests required to initiate treatment.
 - There are currently no recommended drug classes indicated for long-term treatment of insomnia disorder.
 - The average duration of treatment for patients with insomnia in England is 194 days. This can be amended in the resource impact template to reflect local practice.
 - The clinical experts explained that the longer-term treatment effect is unknown because of the lack of evidence.
 - 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 longterm insomnia has not responded adequately. If treatment is
 continued, assess whether it is still working at regular intervals.
 - It is assumed daridorexant would be used for the existing patients receiving treatment who meet the DSM-5 criteria but the template allows the number of people being treated to increase.
 - Daridorexant can be used at the same time as other medicines or non-medicine treatments available in practice as they work in a different way to daridorexant.
 - No costs have been included for sleep hygiene/sleeping pills.
 We have it available for input in the resource impact template and resource impact over time if users want to enter a local cost.

About this resource impact report

This resource impact report accompanies the NICE guidance on <u>Daridorexant</u> for treating long-term insomnia and should be read with it. See <u>terms and</u> <u>conditions</u> on the NICE website.

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