

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Zuranolone for treating severe postnatal depression ID6431

Draft scope

**Draft remit/evaluation objective**

To appraise the clinical and cost effectiveness of zuranolone within its marketing authorisation for treating severe postnatal depression.

**Background**

Postnatal depression (PND) is a commonly experienced form of depression that can affect women after childbirth. While the exact causes are not fully understood, several factors may increase the likelihood of developing this condition. These include a previous history of mental health issues or mental health challenges during pregnancy. They could also include situational factors such as the amount of support from close friends or family, navigating a difficult relationship with a partner, recent significant life events such as bereavement, and experiences of physical or psychological stress.

PND typically begins within the first six weeks after childbirth but can also emerge up to a year later. Symptoms may also emerge before birth (perinatal or antenatal depression). This condition often improves within a few months, though about 30% of women may continue to experience symptoms after the first year. Common symptoms include feeling consistently low in mood, heightened irritability towards a partner, baby, or other children, persistent fatigue, difficulty sleeping at night, challenges with concentration or decision-making, changes in appetite, recurring negative thoughts, feelings of guilt, concerns about the baby's well-being, and difficulties with bonding or finding enjoyment in time spent with the baby.

PND affects over 10% of women within a year after childbirth.<sup>1</sup> A UK study from 2000 to 2013 found that 11% of 206,517 women experienced depression symptoms or a diagnosis post-birth.<sup>2</sup> In 2021, with 694,684 births in the UK, there would have been an estimated 69,468 cases of PND.<sup>3</sup>

[NICE guidance: antenatal and postnatal mental health \[CG192\]](#) recommends psychological therapies, such as cognitive behavioural therapy (CBT) for managing moderate to severe depression during pregnancy or after childbirth. Alternatively, antidepressants such as a tricyclic antidepressant, an SSRI, or an SNRI would be considered if preferred or if therapy alone is insufficient. . Additionally, if depression does not improve with either therapy or medication alone, a combination of both high-intensity psychological therapy and medication is recommended For cases of very severe PND that remain unresponsive to these treatments, a referral to a specialist community perinatal mental health team is advised.

### **The technology**

Zuranolone (Zurzuvae, Biogen) does not currently have a marketing authorisation in the UK for PND. It has been studied in clinical trials compared with placebo in adults with severe PND.

Intervention(s)	Zuranolone

<b>Population(s)</b>	Adults with severe postnatal depression
----------------------	---

<b>Comparators</b>	<p>Established clinical management without zuranolone which may include:</p> <ul style="list-style-type: none"><li>• Psychological therapies (e.g. cognitive behavioural therapy (CBT))</li><li>• Antidepressant treatments:<ul style="list-style-type: none"><li>○ Tricyclic antidepressant</li><li>○ Selective serotonin reuptake inhibitors (SSRIs)</li><li>○ Serotonin noradrenaline reuptake inhibitors (SNRIs)</li></ul></li><li>• High-intensity psychological intervention combined with antidepressant treatments</li><li>• Best supportive care</li></ul>
--------------------	---

<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"><li>• remission of depressive symptoms</li><li>• severity of depression</li><li>• cognitive dysfunction</li><li>• anxiety</li><li>• sleep quality</li><li>• hospitalisation</li><li>• functioning and associated disability</li><li>• mortality</li><li>• adverse effects of treatment (including adverse effects of treatment discontinuation)</li><li>• health-related quality of life</li></ul>
-----------------	--

<p><b>Economic analysis</b></p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<p><b>Other considerations</b></p>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p><b>Related NICE recommendations</b></p>	<p><b>Related technology appraisals:</b></p> <p><a href="#">Esketamine nasal spray for treatment-resistant depression</a> (2022) NICE technology appraisal guidance 854.</p> <p><a href="#">Vortioxetine for treating major depressive episodes</a> (2015; reviewed 2018) NICE technology appraisal guidance 367.</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Depression in adults: treatment and management</a> (2022) NICE guideline 222.</p> <p><a href="#">Postnatal care</a> (2021) NICE guideline 194.</p> <p><a href="#">Antenatal and postnatal mental health: clinical management and service guidance</a> (2014; updated 2020) NICE guideline 192.</p> <p><a href="#">Depression in adults with a chronic physical health problem: recognition and management</a> (2009) NICE guideline 91.</p> <p><b>Related interventional procedures:</b></p> <p><a href="#">Digitally enabled therapies for adults with depression: early value assessment</a> (2023; updated 2024) NICE health technology evaluation 8.</p>

	<p><a href="#">Implanted vagus nerve stimulation for treatment-resistant depression</a> (2020) NICE interventional procedures guidance 679. Review date April 2026</p> <p><b>Related quality standards:</b></p> <p><a href="#">Antenatal and postnatal mental health</a> (2016) NICE quality standard 115</p> <p><a href="#">Postnatal care</a> (2023; updated 2022) NICE quality standard 37</p> <p><a href="#">Depression in adults</a> (2011; updated 2023) NICE quality standard 8</p>
<p><b>Related National Policy</b></p>	<p>The NHS Long Term Plan (2019) <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2016) <a href="#">Specialised Perinatal Mental Health Services (In-Patient Mother and Baby Unit and Linked Outreach Teams)</a> Service Specification C06/S/a.</p> <p>NHS England (2023) <a href="#">Prescribed specialised services manual (version 6)</a> Chapter 124.</p> <p>NHS England (2019) <a href="#">Postnatal Depression: Don't reinvent the wheel</a></p> <p>NHS England (2019) <a href="#">Peer support for mothers with postnatal depression: A pilot study</a></p> <p>NHS England (2018: updated 2024) <a href="#">NHS Talking Therapies for anxiety and depression Manual</a></p> <p>NHS England (2018) <a href="#">One to one antenatal and postnatal support for mental health</a></p> <p>Department of Health and Social Care (2016) <a href="#">NHS outcomes framework 2016 to 2017</a></p> <p>NHS Digital (2022) <a href="#">NHS Outcomes Framework England, March 2022 Annual Publication</a></p>

### Questions for consultation

Where do you consider zuranolone will fit into the existing care pathway for postnatal depression?

Please select from the following, will zuranolone be:

- A. Prescribed in primary care with routine follow-up in primary care
- B. Prescribed in secondary care with routine follow-up in primary care
- C. Prescribed in secondary care with routine follow-up in secondary care
- D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would zuranolone be a candidate for managed access?



Do you consider that the use of zuranolone can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which zuranolone will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation>).

### References:

1. National Health Service. Overview - Postnatal depression. 2022. Available from: <https://www.nhs.uk/mental-health/conditions/post-natal-depression/overview/> [Accessed: August 2024]
2. Petersen I, Peltola T, Kaski S, Walters KR, Hardoon S. Depression, depressive symptoms and treatments in women who have recently given birth: UK cohort study *BMJ Open*. 2018;8(10):e022152. Available from: <https://doi.org/10.1136/bmjopen-2018-022152> [Accessed: August 2024]
3. Statista. Number of live births in the United Kingdom from 1887 to 2021. 2023. Available from: <https://www.statista.com/statistics/281981/live-births-in-the-united-kingdom-uk/> [Accessed: August 2024]