NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Zuranolone for treating postnatal depression [ID6431]

Final scope

Remit/evaluation objective

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

Background

Postnatal depression (PND) is a form of depression that can affect people 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, and situational factors such as support from close friends or family, navigating a difficult relationship with a partner, recent significant life events such as bereavement, and physical or psychological stress. However, people can also develop PND in the absence of any of these factors.

PND typically begins within the first six weeks after childbirth but can emerge up to a year later. Symptoms may also begin before birth (perinatal or antenatal depression). PND often improves within a few months, though about 30% of people continue to experience symptoms after the first year. Common symptoms include feeling consistently low in mood, anxiety, 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 can result in poor outcomes for the child, including cognitive delay, emotional disorders, and behavioural problems.

PND affects over 10% of people within a year after childbirth.[1] A UK study from 2000 to 2013 found that 11% of 206,517 women experienced depression symptoms or had a diagnosis post-birth.[2] A further study found that the UK prevalence of PND increased from 10.3% in 2014 to 23.9% in 2020.[3] In 2022, with 577,046 births in England, there would have been an estimated 63,000 (11%) to 138,000 (23.9%) cases of PND.[4]

There are currently no treatments specifically approved for PND. NICE guideline: antenatal and postnatal mental health [CG192] recommends facilitated self-help for people with mild to moderate depression. For people with a history of severe depression who initially present with mild depression, antidepressants should be considered. For people with moderate to severe depression, the guideline recommends high-intensity psychological therapy, such as cognitive behavioural therapy (CBT). Antidepressants such as a tricyclic antidepressant, a selective serotonin reuptake inhibitor (SSRI), or a serotonin noradrenaline reuptake inhibitor (SNRI) can be considered if preferred or if psychological therapy alone is insufficient. Combination treatment with a high-intensity psychological intervention and an antidepressant can be considered if there is no response or limited response to either of these treatments alone. For very severe PND that remains unresponsive to treatment, 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 (in combination with established clinical management) compared with placebo (in combination with established clinical management) in adults with severe PND.

Intervention(s)	Zuranolone with established clinical management
Population(s)	Adults with postnatal depression
Subgroups	If the evidence allows, the following subgroups may be considered: • Previous history of depression • Severity of postnatal depression

Comparators	Established clinical management without zuranolone which may include:
	• Psychological therapies (e.g. cognitive behavioural therapy (CBT); facilitated self-help)
	• Antidepressant treatments:
	  ○ Tricyclic antidepressants
	  ○ Selective serotonin reuptake inhibitors (SSRIs)
	  ○ Serotonin noradrenaline reuptake inhibitors (SNRIs)
	  ○ Atypical antidepressants (e.g. mirtazapine)
	• High-intensity psychological intervention combined with antidepressant treatments
	• Augmentation with additional antidepressants, antipsychotics, or electroconvulsive therapy
	• Best supportive care

Outcomes	The outcome measures to be considered include: • depressive symptoms including relapse and remission rates • severity of depression • cognitive function • anxiety • sleep quality • hospitalisation • mortality • child health-related outcomes • adverse effects of treatment (including adverse effects of treatment discontinuation) • health-related quality of life

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	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.
Related NICE recommendations	**Related NICE guidelines:** Depression in adults: treatment and management (2022) NICE guideline 222. Postnatal care (2021) NICE guideline 194. Antenatal and postnatal mental health: clinical management and service guidance (2014; updated 2020) NICE guideline 192. **Related health technology evaluations:** Digitally enabled therapies for adults with depression: early value assessment (2023; updated 2024) NICE health technology evaluation 8. **Related interventional procedures:** Implanted vagus nerve stimulation for treatment-resistant depression (2020) NICE interventional procedures guidance 679. Review date April 2026 **Related quality standards:** Antenatal and postnatal mental health (2016) NICE quality standard 115 Postnatal care (2023; updated 2022) NICE quality standard 37 Depression in adults (2011; updated 2023) NICE quality standard 8

Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2016) Specialised Perinatal Mental Health Services (In-Patient Mother and Baby Unit and Linked Outreach Teams) Service Specification C06/S/a. NHS England (2023) Prescribed specialised services manual (version 6) Chapter 124. NHS England (2019) Postnatal Depression: Don't reinvent the wheel NHS England (2019) Peer support for mothers with postnatal depression: A pilot study NHS England (2018: updated 2024) NHS Talking Therapies for anxiety and depression Manual NHS England (2018) One to one antenatal and postnatal support for mental health Department of Health and Social Care (2016) NHS outcomes framework 2016 to 2017 NHS Digital (2022) NHS Outcomes Framework England, March 2022 Annual Publication

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. Harrison S, Quigley MA, Fellmeth G et al. (2023) The impact of the Covid-19 pandemic on postnatal depression: analysis of three population-based national maternity surveys in England (2014-2020). Lancet Reg Health Eur. Available from: https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(23)00073-X/fulltext [Accessed October 2024]
4. Office for National Statistics (2024) Births in England and Wales. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthsummarytables [Accessed: October 2024]