

19 June 2024

Professor Robyn Ward AM  
Chair, Pharmaceutical Benefits Advisory Committee (PBAC)  
Australian Department of Health and Aged Care

By email to [commentspbac@health.gov.au](mailto:commentspbac@health.gov.au)

Dear Professor Ward

**Re: Application to the PBAC July 2024 Agenda for the subsidy of Lecanemab and Esketamine**

The Royal Australian New Zealand College of Psychiatrists welcomes the opportunity to give its views and feedback on items listed on the PBAC July 2024 agenda. This response concerns Spravato® (Esketamine) for treatment resistant depression and Leqembi® (Lecanemab) for Early onset Alzheimer's disease (EAD). Detailed feedback for the PBAC's consideration is provided below.

The RANZCP is responsible for the training, education and representation of psychiatrists in Australia and New Zealand. The RANZCP has more than 8400 members, including around 5900 qualified psychiatrists. This submission has been developed in consultation with the RANZCP expert committees including the Faculty of Psychiatry of Old Age (FPOA), Committee of Evidence Based Practice (CEBP), Section of Electroconvulsive Therapy and Neurostimulation (SEN).

**Consideration of subsidy Lecanemab**

The RANZCP is supportive of any reform that appropriately orients the system to positive health outcome for the ageing population. This includes consideration of potential PBS listing of evidence-based medication and treatment, which improves access to safe and quality care. The RANZCP feedback regarding the usage of Lecanemab in the diagnosis and treatment of (EAD) is:

- The advantages of Leqembi® (Lecanemab) are limited as its effectiveness is less than that of cholinesterase inhibitors for mild to moderate dementia, with current subsidised medications delivering a modest effect.
- The family/carer expectations of the effectiveness of Lecanemab should be managed appropriately, noting the resources required to deliver the medication and its efficacy.
- The consideration of potential adverse side effects of Leqembi® (Lecanemab), including brain swelling and bleeds, and the availability of essential diagnostic imaging such as PET scans and MRI, particularly in rural and remote areas may pose financial barriers for patients.

### **Consideration of subsidy Esketamine**

The RANZCP has a Clinical Memorandum (CM) on the [Use of Ketamine in Psychiatric Practice](#) (July 2022). The CM outlines the evidence, benefits, risks, and practical application of ketamine, including Esketamine, for treatment resistant depression. This highlights that the short-term efficacy of both generic and branded forms of intravenous and intranasal ketamine for adults with treatment resistant depression is established. A priority for the RANZCP is ensuring that patients have access to evidence-based treatments, and affordability is a part of that.

Ketamine is not recommended as a first-line treatment and should only be initiated after due consideration of published evidence for its use. There is currently limited guidance on translating research findings into clinical practice, with respect to treatment approaches, dosing protocols, the effectiveness and safety of long-term use, and safety monitoring. This requires due consideration by psychiatrists before expanding their scope of practice to include ketamine therapy.

There is evidence to support a role for ketamine therapy in treatment resistant depression, although there remains some uncertainty about the most appropriate position of these agents in treatment algorithms, their comparative effectiveness, safety and tolerability. Further research is needed to determine the relative benefits and risks of the different modes of administering ketamine, different formulations and how dosing should be optimised.

Accordingly, the RANZCP continues to maintain the CM to reflect current evidence-based practice. This document is continually evolving to support evidence-based practice and research.

The RANZCP welcomes further opportunities to support PBAC in the consideration of these recommendations. To discuss any of the issues raised in this submission, please contact Nicola Wright, Executive Manager, Policy, Practice, and Research via [nicola.wright@ranzcp.org](mailto:nicola.wright@ranzcp.org) or on (03) 9236 9103.

Yours sincerely



Dr Elizabeth Moore  
**President**

Ref: 4549