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Self-test questions

The following statements are either true or false (answers on page 83)

7. Patients with mania are best managed in general practice.
8. In bipolar disorders, patients taking a mood stabilising drug combined with an antidepressant should be regularly reviewed for changes in their mental state.

Your questions to the PBAC

Methylphenidate

The management of adolescents who need stimulant medications is complicated by the restrictions of the Pharmaceutical Benefits Scheme (PBS). I have a patient who has benefited from using an extended-release formulation of methylphenidate. She is calmer and more relaxed than she was on intermittent doses of the immediate-release formulation. The problem is that my patient is now over 18 years old so cannot receive the extended-release formulation as a PBS prescription.

There are probably many adolescents with attention deficit hyperactivity disorder who are well managed with the extended-release formulation. Some of them will continue to need treatment after their eighteenth birthday, but the current PBS authority requirements prevent this. To continue treatment, patients will have to switch to another formulation or a different drug without an age restriction. How can this anomaly in the PBS be rectified?

George Blake
Paediatrician
Moana Medical Centre
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PBAC response:

In assessing applications and making recommendations for PBS listing, the Pharmaceutical Benefits Advisory Committee (PBAC) is required to take into account a number of criteria, including the indication for which the medicine has been approved for use in Australia. The PBAC cannot make a recommendation on a medicine for use outside its approved indication as registered with the Therapeutic Goods Administration (TGA) as this would go against evidence-based decision making.

In the case of extended-release methylphenidate, the registered TGA indication is for the treatment of attention deficit hyperactivity disorder in children and adolescents aged 6–18 years. Consequently, when considering the application to list the drug on the PBS, the PBAC was limited to making a recommendation that covered the 6–18 year old population only.

For the PBS listing to be extended to include persons over 18 years of age, the drug's sponsor would first need to have the TGA indication changed. This would most likely involve submitting data to the TGA to demonstrate safety and efficacy in this age group. Following a revised indication, the next step would be to provide a submission to the PBAC that includes an evaluation of the cost-effectiveness of extended-release methylphenidate against immediate-release methylphenidate or another appropriate comparator in the treatment of adults.

Your questions to the PBAC

Australian Prescriber readers are invited to write in with their questions about decisions of the Pharmaceutical Benefits Advisory Committee. The segment 'Your questions to the PBAC' will publish selected questions from readers, and answers from the Committee itself. Questions may address issues such as regulatory decisions, pharmaceutical benefits listings, withdrawal of a drug from the market and Authority prescriptions.

It may not be possible to reply to all individual questions. Those letters and responses selected by the Editorial Executive Committee will be published in the journal, subject to the usual editorial controls.