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Obesity

— Opinion

Price must be right to put obesity drug on the PBS

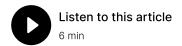
It is vital the gatekeepers of the scheme hold the line on the cost benefits of blockbuster drugs.

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Whether to fully subsidise the new generation weight loss drugs such as Mounjaro and Ozempic for obese Australians without diabetes represents one of the most unique and challenging decisions in years for the Pharmaceutical Benefits Advisory Committee (PBAC).

They are collectively known as GLP-1 agonists, and no other class of medications has gained such a foothold in the private market before being funded under the Pharmaceutical Benefits Scheme (PBS). Nor has there been such publicity and indeed controversy around how a medication should be used to treat a complex and often socially determined medical issue.



Eli Lilly's Mounjaro medication. Bloomberg

A staggering four in five older Australians are overweight or obese. One in every 15 adults aged 45-54 is classified as "morbidly obese". This is an epidemic responsible for the vast majority of lifestyle-related medical conditions. It is estimated that by 2032, obesity could cost the Australian budget a staggering \$87.7 billion.

At the same time, obesity, like so many lifestyle conditions, reflects the wider social determinants of health. There is a substantial gradient of obesity according to socio-economic status and place of residence. The corollary is that those in most need of these drugs cannot afford them on the private market.

Global pharma giant Eli Lilly has signalled that it will lodge a submission

[https://www.afr.com/companies/healthcare-and-fitness/global-pharma-giants-push-for-weight-loss-drugs-to-be-added-to-pbs-20241213-p5ky45] to have its drug Mounjaro listed on the PBS in mid-2026. Burden of disease, affordability and access as well as the UK decision to publicly fund these drugs will put significant external pressure on the PBAC to approve the submission.

However, it is essential that the relatively unknown group of medical and scientific professionals who make up the PBAC hold the line on their key metric – the costbenefit analysis of widespread and government-subsidised use of GLP-1 agonists.

PBAC holds a vital gatekeeper role for Australian patients and the taxpayer base more broadly. It considers the safety, efficacy and, most importantly, the cost-benefit of new pharmaceuticals before making a recommendation to the health minister about whether a medicine should attract a PBS subsidy.

Once those medications are on the PBS, they represent a new and permanent liability for the taxpayer until downward pressure is placed on prices when patents expire and generics enter the market. A PBAC that loosens its commitment to driving down cost and forcing global pharma giants to justify their pricing would be a nightmare for Finance and Treasury.

Chance for a new approach

PBAC and its parent, the Therapeutic Goods Administration, have been accused of excessive waiting times for novel medicines to get PBS approval, with an average of 466 days from submission to approval. But most of this time is spent in pricing negotiations, for which pharma giants need to also bear responsibility if they enter negotiations at excessively high prices.

If the pricing set by Eli Lilly for the use of Mounjaro in type 2 diabetes is any marker, the company is unlikely to do the Australian taxpayer any favours with its initial pricing bid. A protracted negotiation is likely to be accompanied by political pressure to broaden the use of Mounjaro.

This may work in favour of PBAC, with competitor drug semaglutide (Ozempic) set to come off patent within the coming years, potentially forcing a compromise position on pricing.

Meanwhile, PBAC and the TGA may take the listing of GLP-1 agonists as an opportunity for a new approach to the approval of blockbuster drugs in Australia. The funding of post-marketing studies once drugs enter the PBS is an under-used means of assessing drug effectiveness and answering important cost-benefit and side effect questions raised by the public.

Cutting through the hype to recognise that all drugs have undesirable side effects is crucial.

While the drug company-funded studies suggest a rate of gastro-intestinal side effects causing treatment cessation at 4 per cent to 7 per cent, those studies may underestimate or fail to identify side effects that emerge in the "post-marketing" phase.

As a clinician, I admit patients on Ozempic and Mounjaro with gastro-intestinal side effects relatively frequently. Author Johann Hari in his book *Magic Pill* cautioned against these drugs being seen as a panacea in the absence of long-term

data, reflecting among other things on the relapse potential once the medication ceases.

With this in mind, the TGA should insist on Eli Lilly making a funding contribution to independent post-marketing analysis of Mounjaro if it is approved for obesity on the PBS. Such an approach could provide the leverage both sides need to reach quick agreement and provide much needed financial support to Australian researchers.

Finally, the debate over PBS approval of Mounjaro must not overshadow the critical elements of Australia's 2022-2032 National Obesity Strategy – creating equity, addressing wider determinants of health and empowering personal responsibility. Though everybody agrees on the need to engage in preventive health at a whole of community level, few articulate just how far upstream we need to go to make that a reality.

Australia's obesity [https://www.afr.com/life-and-luxury/health-and-wellness/the-real-reason-men-get-belly-fat-and-how-to-get-rid-of-it-20241208-p5kwp9] crisis isn't about a magic pill. It's about how we encourage, fund and support Australians across all policy areas of government to live within a healthy weight. Now that's a challenge worth taking on in 2025.

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Nick Coatsworth was the Deputy Chief Health Office of Australia during the pandemic.