

AUSTRALIAN PATIENT ACCESS GAP TRACKER

712

Average number of days from ARTG registration to PBS listing

MEASUREMENT MATTERS

In the ninth edition of the Patient Access Gap Tracker, Amgen continues to advocate for the systematic collection, collation and publication of the performance of the Pharmaceutical Benefits Scheme (PBS) listing process. In the absence of fit-for-purpose metrics, this report plays an important role in grounding the debate in clear, evidence-based insights into Australia's reimbursement system.

Amgen's tracking of the Patient Access Gap (PAG) – the time between TGA authorisation, when a medicine is deemed clinically safe and effective for use, and PBS listing, when a patient gets subsidised access to that medicine – reinforces that innovative medical breakthroughs mean little if patients can't equitably access them.

The PAG figures (currently 712 days), while remaining relatively stable, clearly

indicate that with declining relative investment in innovative medicines¹, Australia is in an increasingly challenging position.

Australia's HTA system is at the mercy of global headwinds, and the challenges sponsors face in negotiating acceptable listing conditions are becoming more intense and time-consuming across the ecosystem.

This latest analysis coupled with that of the PBS Medicines Status website shows that:

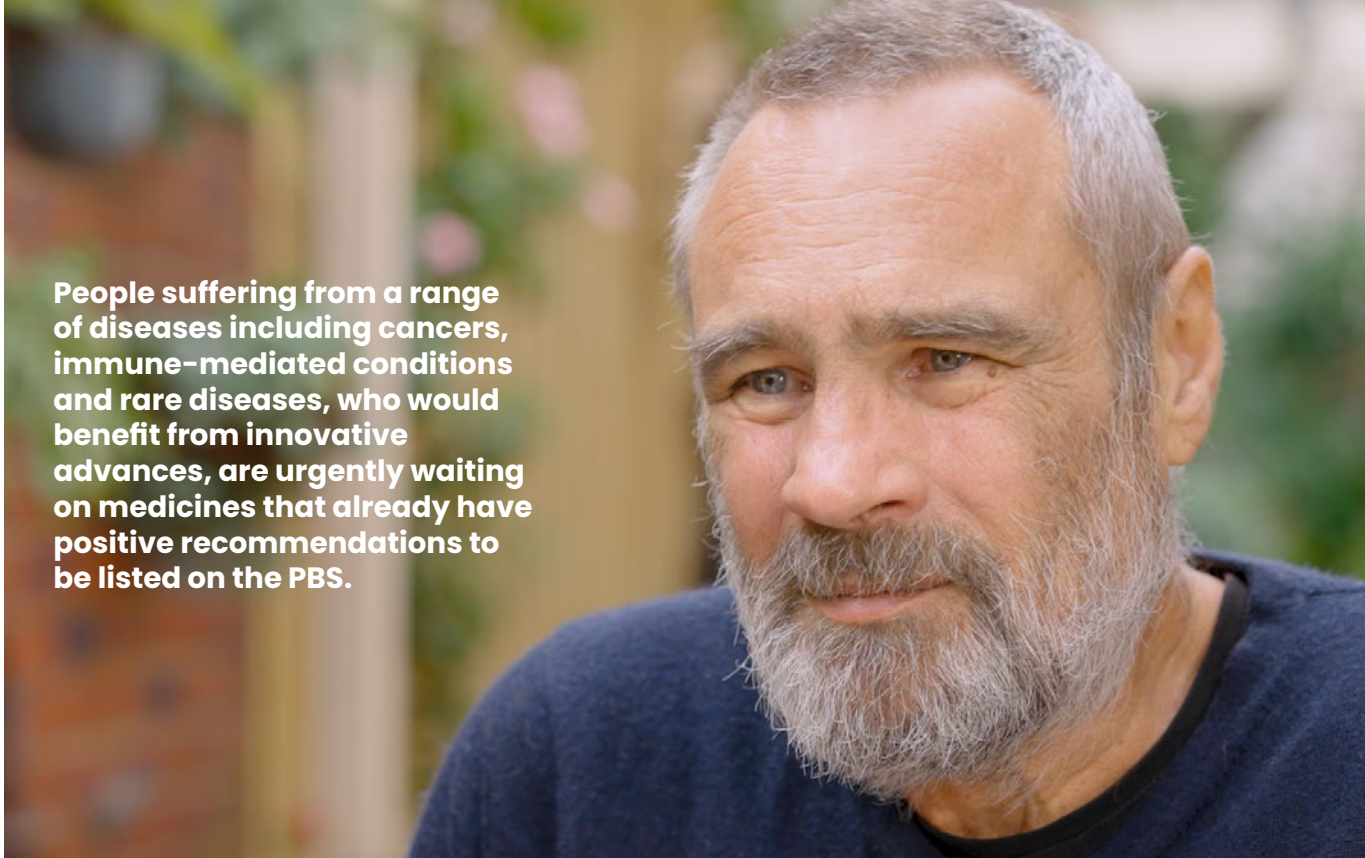
- Of the **99** medicine + population pairings that received a positive PBAC recommendation in 2025, only **50** of these pairings have progressed to PBS listing.
- **49** pairings are not yet listed.
- **20** of these are designated inactive, pricing has not been accepted and/or awaiting pharmaceutical company to proceed, leaving **27** at various stages of post PBAC processes, noting that **5** of these are back on the agenda for the July 2026 PBAC meeting.
- The number of inactive or not progressing pairings is significant to note, up from **15** in the PAG Tracker released in December 2025.

99 medicine + population pairings received a positive PBAC recommendation in 2025

49 pairings not yet listed

20 of these pairings are either now designated inactive or pricing has not been accepted

Reforms that address critical issues regarding speed and willingness to recognise the true value of innovation in our HTA system have never been more urgent.



People suffering from a range of diseases including cancers, immune-mediated conditions and rare diseases, who would benefit from innovative advances, are urgently waiting on medicines that already have positive recommendations to be listed on the PBS.

Challenges agreeing on the conditions of the PBS listing is the likely cause of many of these 20 medicine population pairings not progressing.

In addition to delayed access, critically, only 27% of innovative medicines available globally are accessible in Australia via the PBS.¹ It is unacceptable that Australian patients are missing out on such a significant proportion of the latest treatments.

In order to maintain a world-class healthcare system, increased investment in the PBS is urgently required.

Without it, Australia will continue to face delayed or limited access to the latest innovative treatments and crucially, risk ongoing investment in local clinical trials.

PATIENT ACCESS GAP AT A GLANCE

Between Jan '21 and Apr '26, the average time to access medicine + population pairings that were recommended by the PBAC in that period was...



between registration and PBS listing.

...of 'ever CEA' medicine + population pairings in this period required multiple attempts to secure a positive PBAC recommendation.

This is a major contributor to the delay.



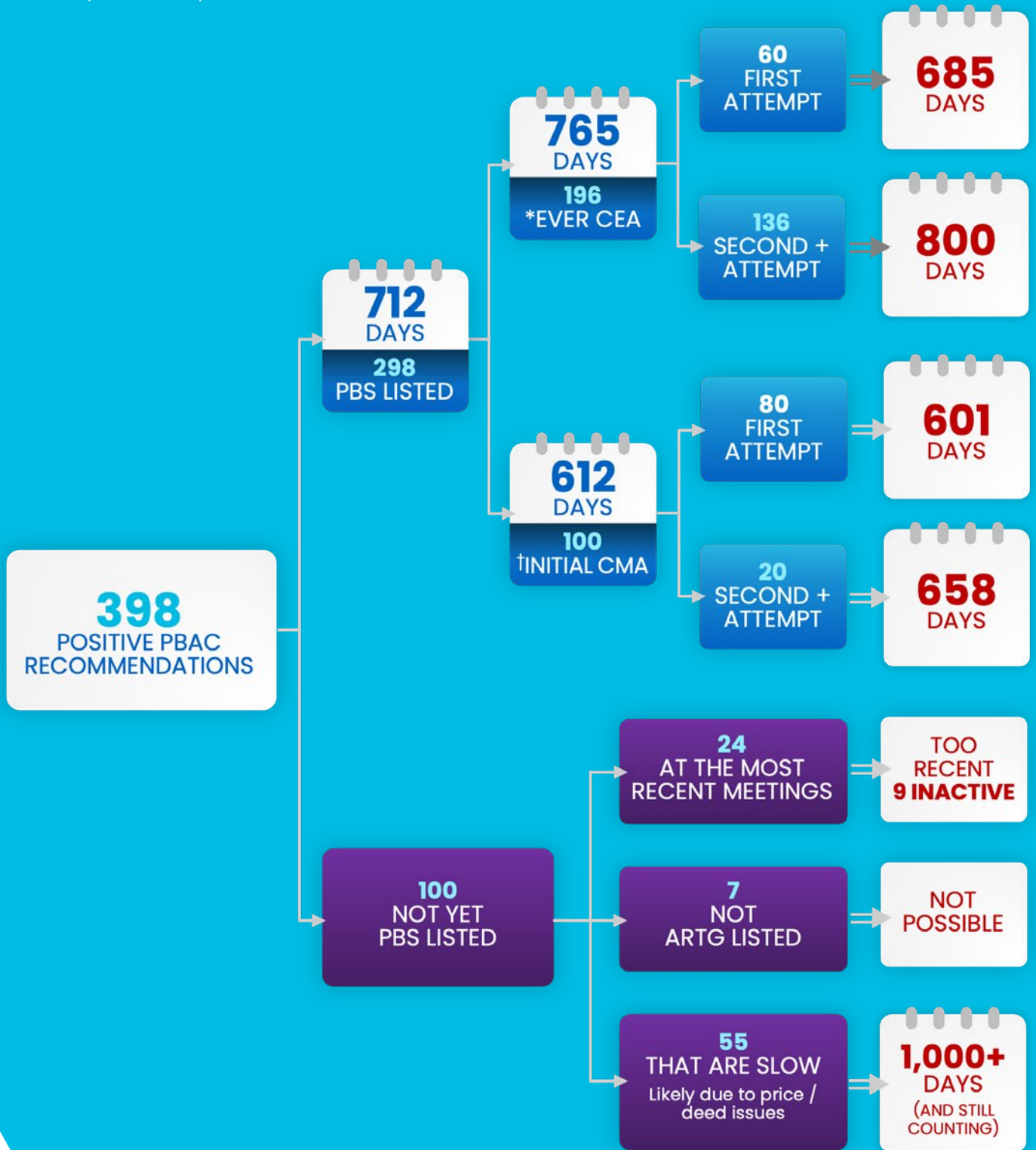
Of the **100** medicines + population pairings that received a positive PBAC recommendation but were not PBS listed in this period, **55** are particularly slow – or inactive – with an access gap that is...



...and still counting.

CONTEMPORARY TIME TO LISTING ANALYSIS

January 2021 to April 2026^{2,3}



***Ever CEA:** Ever Cost-Effective Analysis - Medicines that have a claim to clinical superiority.
 †**Initial CMA:** Initial Cost-Minimization Analysis: Medicines that have a claim to non-inferiority or equivalence.

RECOMMENDED AND LISTED WITHIN THE PERIOD



- **298 medicine + population pairings** received both a positive PBAC recommendation and a PBS listing.
 - The average time from ARTG listing to PBS listing was **712 days**.



- The average time from ARTG listing to PBS listing was **longer for medicine + population pairings where a cost-effectiveness analysis was ever the basis of the economic analysis ('ever CEA')**, compared with those where a cost-minimisation analysis was presented from the start ('initial CMA'), i.e. **765 days** vs **612 days**.



- Overall, **47% of medicine + population pairings were recommended on the first submission and subsequently listed**.
 - A first-time success is more likely for medicine + population pairings that were 'initial CMA' vs those that were 'ever CEA', i.e. **80% vs 31%**.



- **Submission "churn"**, where **multiple submissions** are required to secure a positive recommendation, is a major contributor to the PAG.
 - For recommendations made on the first submission, the time between ARTG listing to PBS listing was **685 days ('ever CEA') vs 601 days ('initial CMA')**.
 - For recommendations made on the second+ submission, the time between ARTG listing and PBS listing was **800 days ('ever CEA') vs 658 days ('initial CMA')**.



- The **average time from ARTG listing to PBS listing** for medicines + population pairings adopting the **TGA provisional pathway** was **656 days** which is shorter than the overall average of **712 days**.
 - 82% of these were in the 'ever CEA' category.



- The average time from **PBAC recommendation to PBS listing** was approximately **7.3 months**.

RECOMMENDED AND NOT LISTED WITHIN THE PERIOD



- **100** medicine + population pairings received a positive PBAC recommendation but have **not yet been PBS listed**.



- **24** recommendations were at the most recent PBAC meetings (November and December), so feasibly have **not had sufficient time** to be listed. Critically **9** have been designated as inactive.



- **7** were not **ARTG listed**.



- **55 are slow** where recommendations are needing to be reconsidered by the PBAC and/or the PBAC recommendation has additional price and risk share conditions (e.g. PBAC stipulating use of lowest cost comparator, and/or seeking further price reduction).
 - As at 1 March 2026, the gap for these medicine + population pairings is **1,000+ days... and counting**.
 - Many of these are important products for serious and/or rare diseases where **patients can't afford to wait this long**.

ABOUT THE ANALYSIS

Time Period

The analysis looks at all positive PBAC recommendations in the public domain from the start of 2021 to 1 April 2026 (33 meetings in total).

- This period was selected because it is after the changes to the PBAC/PBS listing process that were implemented from the 2017 strategic agreement.
- Subsequent analyses have built on this starting point.

Scope

The analysis covers all submissions for medicines across all therapeutic areas and diseases / conditions considered by the PBAC during the specified period.

- The only medicines excluded were those that were not considered informative for the purposes of calculating the PAG, for example medicines which are treated as 'alternate brands' of an already listed medicine, including so-called generics and biosimilars.
- The report also excludes new formulations of existing medicines that make no claim of clinical superiority, fixed dose combinations of existing listed products, and nutritional products.

Sources

All the data used for the purposes of conducting this analysis were sourced from the public domain.

- Information from disparate government websites and documents—including the TGA, the Department of Health, PBAC Public Summary Documents and PBAC agendas—were collated by MAESTrO into a single database format that permits analysis.
- The results are therefore verifiable and replicable.



Medicine + Population Pairings

Medicines in Australia are typically listed on the PBS for specific uses. These can be indications (for example metastatic HER2+ breast cancer) and/or a sub-population within an indication (for example third-line treatment of metastatic HER2+ breast cancer).

- The ultimate PBS listing will almost always be consistent with the use authorised by the TGA but will commonly be narrower or more restricted.
- It is not unusual for a sponsor to initially seek PBS listing for only a 'part' of the TGA authorised use, and then seek to expand the reimbursed use later. Likewise, the PBAC may recommend funding for only a subset of the population the sponsor seeks.
- It is important to note that not all TGA authorised medicine + population pairings ultimately receive a PBS listing. The PAG figures however reflect only those medicine + population pairings that receive a positive PBAC recommendation and a PBS listing within the time period.
 - As such, **the analysis underestimates the true PAG in Australia.**
- A separate analysis for those medicine + population pairings that receive a positive PBAC recommendation but are not PBS listed within the time period is also included.
 - While the PAG for this cohort is still open-ended, the analysis provides important information about how lengthy the delay for some medicines can be.

'Ever CEA' vs 'Initial CMA'

The Australian PBS listing process allows sponsors to adopt different strategies for establishing value for money with the PBAC.

- The two most common are cost-effectiveness analysis (CEA) and cost-minimisation analysis (CMA).
- For the purpose of calculating the PAG, medicines have been divided into two mutually exclusive cohorts: 'ever CEA' and 'initial CMA'.
 - The 'ever CEA' cohort contains those medicine + population pairings for

which the sponsor has made at least one submission based on a CEA, while the 'initial CMA' group contains those medicine + population pairings for which the initial claim lodged by the sponsor was based on a CMA approach.

- This delineation provides an objective way of considering how well the system manages those medicines which claim clinical superiority compared to an existing funded treatment, versus those that claim non-inferiority or equivalence.

A Final Note

- **The perspective taken in this analysis is that of the patient who needs a medicine.**
- **The analysis does not point the finger of blame at any party but simply seeks to quantify the effects of the system for the patient, as it currently operates.**

For further information about the analysis, please contact:

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REFERENCES

1. Medicines Australia 2026-27 Pre-Budget Submission.
2. Analysis of PBAC submissions and their related outcomes and timelines. Report prepared for Amgen by Wonder Drug Consulting Pty Ltd using the MAESTRO Database. December 2020.
3. Analysis by Wonder Drug Consulting Pty Ltd using the MAESTRO Database. March 2026.