AUSTRALIAN PATIENT ACCESS GAP

January 2021 – April 2024

MEASUREMENT MATTERS

Throughout the HTA Review, Amgen Australia has advocated for the systematic collection, collation and publication of data on the performance of the PBS listing process.

In particular, Amgen believes that measurement of the Patient Access Gap (PAG)—the time between TGA authorisation when a medicine is deemed clinically safe and effective, and PBS listing when a patient gets effective access to that medicine—is vitally important.

Not only do Australians deserve to know how long they're waiting for equitable access to medicines, data on a well-defined set of metrics are essential to determine those elements of the current reimbursement system that are working effectively, and those that require improvement.

It was the absence of any centralised data on the PAG that first prompted Amgen Australia to conduct a **'time to listing' analysis of every TGA approved medicine** listed on the PBS for the period 2010 – 2017[1].

Completed in 2020, this analysis showed that, on average, patients had to wait **820 days** before medicines that may be considered superior to current treatment options were listed on the PBS. **The wait for many medicines, including orphan medicines, was even longer**.

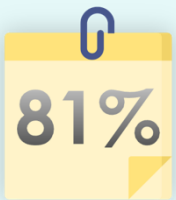
During the same period however, the access gap for the subset of medicines that had gone through the parallel **TGA-PBAC process** was smaller, at **520 days**, demonstrating the impact of intelligent reform.

Despite this improvement, the PAG remains a key issue to be addressed as part of the HTA review. To help anchor debate in facts and data about the performance of the current system, Amgen has committed to routinely undertaking contemporary time to listing analyses and making these available until appropriate metrics regarding speed of access are put in place by the Government.

PATIENT ACCESS GAP AT A GLANCE

Between Jan '21 and April '24, the average time to access innovative medicines that demonstrate superiority over existing medicines 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 43 medicine + population pairings that received a positive PBAC recommendation but were not PBS listed in this period, 22 are particularly slow with an access gap that is…

…and still counting.

AMGEN

CONTEMPORARY TIME TO LISTING ANALYSIS

January 2021 to April 2024[2]

RECOMMENDED AND LISTED WITHIN THE PERIOD

- **152 medicine + population pairings** received both a positive PBAC recommendation and a PBS listing.
  - The average time from ARTG listing to PBS listing was **591 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. **638 days** vs 488 days.

- Overall, **38% of medicine + population pairings were recommended on the first submission**.
  - A first-time success is more likely for medicine + population pairings that were 'initial CMA' vs those that were 'ever CEA', i.e. **77% vs 19%**.

- **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 **488 days ('ever CEA') vs 462 days ('initial CMA')**.
  - For recommendations made on the second+ submission, the time between ARTG listing and PBS listing was **674 days ('ever CEA') vs 573 days ('initial CMA')**.

- The **average time from ARTG listing to PBS listing** for medicines + population pairings adopting the **TGA provisional pathway** was **580 days** which is similar to the overall average of **591 days**.
  - 75% of these were in the 'ever CEA' category.

- The average time from **PBAC recommendation to PBS listing** was approximately **6.6 months**.

RECOMMENDED AND NOT LISTED WITHIN THE PERIOD

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

- **15** recommendations were within the second half of 2023, so feasibly have **not had sufficient time** to be listed.

- **6** were **not yet ARTG listed**.

- **22 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 April 2024, the gap for these medicine + population pairings is **1,149 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 2024 (21 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 will build 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). 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.

2). Analysis by Wonder Drug Consulting Pty Ltd using the MAESTrO Database. April 2024.

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