Multiple Myeloma Stakeholder Meeting (Sponsors)

Outcome Statement

Tuesday 3 February 2026

Attendees

Members of the Pharmaceutical Benefits Advisory Committee (PBAC) and representatives from pharmaceutical companies responsible for current and future Pharmaceutical Benefits Schedule (PBS) listing of therapies for the treatment of multiple myeloma (MM) and/or relapsed or refractory multiple myeloma (RRMM), and the Department of Health, Disability and Ageing were in attendance.

The discussion was focused on information available publicly and therefore there were no disclosures on confidentiality.

Purpose of meeting

This meeting followed on from the MM clinical and consumer stakeholder meeting held on Friday 25 July 2025. That meeting identified how the current treatment landscape for PBS-listed medicines for MM and/or RRMM differs from Australian and international clinical guidelines and outlined what an optimal treatment landscape might look like.

The PBAC convened this second stakeholder meeting with sponsors to respond to the issues raised in July and to discuss opportunities and challenges to moving toward this optimal and preferred treatment landscape for MM in Australia.

The following points were identified as areas for discussion:

- What is the current treatment landscape for PBS listed medicines MM and/or RRMM?
- What does the preferred treatment landscape for PBS listed medicines for MM look like with respect to:
  - moving away from lines of therapy and appetite on future state relating to patient focused approach to therapies.
  - selecting first-line PBS treatments for patients (e.g., assessing transplant eligibility. frailty);
  - optimising sequencing and treatment combinations (e.g., using three or four drugs);
- What data sources or linked data sources can be accessed to undertake a utilisation analysis to better understand treatment pathways/duration of treatment for PBS listed MM therapies?
- What are the opportunities and challenges towards moving to the preferred treatment landscape?

A member of the PBAC provided an overview of the current myeloma PBS treatment landscape, anticipated changes over the next 24 months, and a possible future PBS treatment algorithm with consideration of emerging therapies. A representative from the Department of Health, Disability and Aged Care presented findings on the utilisation and costs of PBS listed medicines for MM.

Meeting discussion

Current and preferred treatment landscape

- It was noted that clinicians and consumers prefer a more individualised approach to MM care and that current PBS treatment listings do not provide the flexibility required to support this approach. It was highlighted that achieving the ideal or preferred treatment landscape involved:
    - Exploring a shift from a line-of-therapy framework toward a model based on prior drug exposure (and or drug classes), as the existing line-based structure in some circumstances, limits clinical discretion or delays access to the most suitable regimen.
    - Removing the distinction between Autologous Stem Cell Transplant (ASCT) eligible and ineligible patients, which was described as a historical categorisation that may no longer reflect contemporary clinical decision-making. Under a more flexible approach, ASCT could remain an available option, applied at the clinician's discretion without determining the treatment line.
    - Providing broader access to generic medicines, including lenalidomide, bortezomib and thalidomide, to help support more flexible treatment combinations where clinically appropriate.
    - Looking at opportunities to simplify PBS restrictions for lenalidomide, as the current number of restrictions linked to multiple tablet strengths and phase-specific criteria can create administrative complexity.
    - Enabling clinicians to prescribe under the PBS, daratumumab + bortezomib + lenalidomide + dexamethasone as a first line for treatment naive patients and for lenalidomide to continue to be an option for maintenance. Clinicians also wanted the ability to prescribe PBS listed daratumumab for all RRMM patients.

- There was a broad discussion around the prognostic value of monitoring Minimal Residual Disease (MRD) in MM and its increasing relevance to clinical practice. It was acknowledged that MM clinical trials are increasingly incorporating MRD as an endpoint. It was noted that, in its November 2025 deliberations, the PBAC considered that sustained MRD negativity may support treatment decision-making in patients with RRMM such as when to stop treatment or to help minimise side effects. The PBAC Chair indicated she had sought further advice from MSAC on how to progress equitable access to funded MRD testing for MM within current processes.

- It was also discussed that there are numerous emerging technologies for MM and it would be expected to see submissions for multiple tri and bi specific antibody and

immunotherapies in the future, with these being guided by MRD and likely to involve dual target switching.

- Utilisation figures indicated that from 2020 onwards there has been a notable shift towards toward immunomodulatory agents (IMiDs) and daratumumab as well as a change with MM initiators therapies from proteasome inhibitors in 2019 versus IMiDs in 2022.
- It was also noted new treatment options available earlier in treatment protocols may account for longer treatment durations and an increased survival. There has been a consistent shift towards longer treatment durations in patient cohorts starting treatment from 2021 relative to those patients starting treatment in 2015.
- While expenditure on multiple myeloma listings accounted for 11% of total antineoplastic expenditure in 2024–25, the average prescription cost for MM has decreased between 2020–21 and 2024–25.

<u>Opportunities and Challenges</u>

- It was acknowledged that the ideal state should support equity of access for patients and the PBS restrictions should facilitate clinicians to use the right medicine for the right patient rather than be used as the default guidelines for MM.
- Sponsors raised that current PBS listings reflect the system in place for submissions and it was challenging within the current framework to respond to the evolving MM treatment paradigm.
- The PBAC Chair noted that the committee would welcome suggestions on how to improve flexibility in clinical decision-making while maintaining a financially sustainable, evidence-driven system that supports innovation and encourages investment.
- Sponsors expressed a willingness to work with the Department to achieve a more flexible approach. They emphasised the need for a collaborative and transparent process that recognises:

    - Future-proofing the framework is important but may be challenging, given the rapid pace of change in the treatment landscape and the need for process predictability.
    - Real-world evidence is likely to become increasingly important, particularly for emerging technologies where traditional clinical data may be limited.
    - Any changes must ensure appropriate grandfathering for current patients, with a strong preference to avoid introducing parallel or “two-track” systems.
    - MRD testing is not yet consistently used across all multiple myeloma trials, which creates variability in evidence packages for MM treatments.
    - Each company will have different global drivers and constraints which are likely to impact on the potential approach.
    - Achieving cost-effectiveness becomes more complex when multiple sponsors are involved in combination therapies and when considering drug classes rather than line of therapies.

- It was noted that a staged approach to implementing changes may be necessary given the complexity of the landscape along with the need to ensure patients have continuity to PBS medicines. However, this should not slow progress; working expeditiously should remain a core principle moving forward.

- There was interest from sponsors in gaining greater insight into clinician and patient priorities to determine what were the immediate changes that were feasible and would have a positive impact for patients.

- The PBAC Chair noted that the PBAC welcomes sponsors to continue to lodge submissions for MM therapies. It was suggested that to support a process of open dialogue sponsors should seek to have conversations with the Department on what evidence is needed to get to the optimal and preferred treatment landscape.

Conclusion

The PBAC Chair thanked stakeholders for their time in attending the meeting and the interest in working collaboratively on a way forward in aligning and managing MM listings on the PBS. The PBAC Chair proposed the Department to draw out the principles discussed from the meeting to be distributed to those in attendance for comment. The Department would then seek to involve those interested in moving forward to a future planning meeting.