Principles of broad (multi-cancer) listings for programmed cell death-1/programmed death ligand-1 (PD-(L)1) inhibitors

This document is intended to outline the guiding principles for sponsors who may be seeking a broad (multi-cancer) listing for PD-(L)1 inhibitors.

Sponsors of PD-L(1) medicines are not required to seek a broad listing. Sponsors retain the ability to lodge submissions seeking PBS listings for specific indications in accordance with the Procedure guidance[1] for listing medicines on the PBS and PBAC Guidelines[2].

Sponsors seeking a broad listing for their PD-(L)1 inhibitor would need to have previously demonstrated efficacy, safety and cost-effectiveness in the advanced and metastatic settings resulting in PBS listings in a range of indications across different tumour types. An application for a broad listing would then be suitable for PBAC consideration.

Sponsors are requested to provide their summarised clinical evidence to PBAC@health.gov.au prior to submitting a formal submission. The Department will progress the summarised clinical evidence to the PBAC to review at the next available meeting. If the PBAC determines it is confident there is sufficient clinical evidence to substantiate use in a broad listing setting, the Department will work with individual sponsors to facilitate submission of economic and financial evidence information via a formal submission.

General expectations

- Sponsors are encouraged to engage with consumers and relevant consumer organisations. This approach is consistent with findings from the Health Technology Assessment (HTA) Policy and Methods Review[3] and Enhance HTA[4] reports, which emphasise the value of early and meaningful engagement with consumers and patient organisations to inform outcomes and access decisions.
- The broad listing is intended to replace all existing and future advanced and metastatic PBS listings for the product.
- There is a reasonable expectation that a product seeking broad listing should be likely to replace existing treatments.
- There is an expectation that sponsors will share published and unpublished trial data on EviQ (or alternative site), using the format adopted by other sponsors[5].
- Sponsors are expected to participate in any review of broad listings for PD-(L)1 inhibitors.

Clinical expectations

- The PBAC does not consider class effect assumptions are appropriate to support a broad listing submission. Evidence that directly supports their product should have previously been considered by the PBAC.

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[1] https://pbac.pbs.gov.au/
[2] https://www.pbs.gov.au/pbs/industry/listing/listing-steps
[3] https://www.health.gov.au/resources/publications/health-technology-assessment-policy-and-methods-review-final-report
[4] https://www.health.gov.au/resources/publications/enhance-hta-an-enhanced-consumer-engagement-process-in-australian-health-technology-assessment-a-report-of-recommendations
[5] https://www.eviq.org.au/medical-oncology/tumour-agnostic/4660-tumour-agnostic-advanced-or-metastatic-ipilim#evidence

- Sponsors are expected to provide information on all current and anticipated future Therapeutic Goods Administration (TGA) indications for the product in the advanced/metastatic setting. This includes indications that are already TGA registered (with or without PBS subsidy), as well as indications where TGA registration is expected or may be sought in future.
- Sponsors should provide a summarised list of clinical trials demonstrating use in a broad setting. This should include positive studies, negative studies, and aborted trials. It is not expected that the individual clinical trial data is provided for broad listing submissions.
- Sponsors may use *Table 2: Summarised clinical evidence* to present this information.

Economic and financial expectations

- Sponsors should anticipate that a weighted price will be required to give effect to a broad listing.
- Sponsors should not expect a pricing advantage above those prices established for existing medicines with a broad listing.
- Broad listing utilisation estimates should comprise two components: utilisation under the existing PBS-listed market and utilisation associated with future indications.
- Sponsors are encouraged to consider the risk-sharing arrangements (RSA) considered by the PBAC in the PSD for nivolumab and ipilimumab[6].
- Medicines seeking broad listing should be added to the existing RSA for advanced and metastatic cancers and be subject to the same pricing structure.
- Following receipt of the table of clinical evidence and upon agreement from PBAC that the drug is suitable for consideration for a broad listing, sponsors are encouraged to use the following checklist when generating a formal submission for PBAC consideration of the economic and financial implications.
- The Department will provide advice to individual sponsors regarding the appropriate submission category once the PBAC has reviewed the summarised clinical evidence and provided its advice on broad listing suitability.

Table 1: Checklist table for economic and financial evidence required for PBAC broad listing submissions.

Pricing	
☐	Proposal includes an acknowledgement that the sponsor is willing to join the existing RSA for advanced and metastatic cancers.
☐	Proposal uses a weighted price based on current PBS listings. Advice will be provided by the PBAC and the pricing branch to sponsors regarding cost-effective pricing to ensure no price advantages over comparators).
Financial impact	
☐	Demonstrates no net cost increase to Government.
Utilisation	
☐	Clearly describes intended use of the product, including whether it is a substitution, sequencing option or add on therapy.
☐	Clearly specifies all inputs and assumptions used to generate utilisation and financial outputs, presented in a structured format (e.g. flowchart and/or table).
☐	Outputs are transparent and verifiable; all formulas used are explicitly documented to allow replication and adjustment during PBAC consideration.
☐	Documents impact on (if any): patient population, treatment pathway, dosing, duration of treatment and services required.

[6] nivolumab-plus-ipilimumab-psd-july-2025.pdf

Sponsors should provide their summarised clinical evidence to PBAC@health.gov.au prior to submitting a formal submission. The Department will progress the summarised clinical evidence to the PBAC to review at the next available meeting. If the PBAC determines it is confident there is sufficient clinical evidence to substantiate use in a broad listing setting, the Department will work with individual sponsors to facilitate submission of economic and financial evidence information via a formal submission.

Table 2: Summarised clinical evidence

Population	Clinical trial details	Clinical trial outcomes	Summary of results	Other comments	TGA status	Previous PBAC consideration
Population #1	This section should include: - Tumour type - Trial name/ID - Description of the study - Phase, design, number of patients etc - Population, setting, including duration of study/follow up period - Intervention	This section should include: - Endpoints for each trial - primary and secondary - A link to published studies (or provide the document where the study is not freely available or not published)	Sponsors should include a brief summary of the clinical results and outcomes of the study	This section should include the sponsors assessment of any biases/limitations of the trial, and the anticipated place in clinical practice	This section should indicate: - If the indication has been approved by the TGA and the date of ARTG registration. - If the indication is currently under consideration by the TGA or the sponsor is intending to seek TGA approval for the indication. - If the indication has not been approved by the TGA.	This section should indicate: - If the population has been recommended by PBAC, at which meeting, and date listed on the PBS. - The circumstances and the comparator under which the PBAC recommendation was based (i.e. accepted under a cost-minimised basis, cost-effectiveness analysis etc.). - If the indication has been previously considered by PBAC and not recommended for PBS listing - If the indication has not been considered by PBAC
	Clinical trial #1					
	Clinical trial #2					
	Clinical trial #3					
	Clinical trial #4					
Population #2	etc.					
Population #3	etc.					
Population #4	etc.					
Population #5	etc.					