

Overview of Managed Access Program for PBS listing

The Managed Access Program (MAP) is a mechanism that enables the Pharmaceutical Benefits Schedule (PBS) listing of products, under special circumstances of high unmet clinical need, on terms that allow for the resolution of otherwise unacceptable clinical or economic uncertainty for the Pharmaceutical Benefits Advisory Committee (PBAC). It seeks to enhance the quality and strength of evidence provided to decision-makers in reimbursement applications.

Listing is in conjunction with, and linked to, the subsequent provision of more convincing evidence that is able to resolve specific existing areas of uncertainty as identified by the PBAC. The PBAC provides advice in relation to the initial sources of uncertainty and whether the evidence provided in the submission is sufficient to support initial listing under this program until a final review of the additional evidence is completed at a predefined point in time.

As part of the MAP submission evaluation process, the PBAC would consider the usual clinical and economic evidence available at the time of the initial consideration, and the additional information relevant to the provision of further evidence in a subsequent submission to the PBAC under the MAP framework.

The PBAC would determine if a MAP is appropriate and accordingly, may:

- make a recommendation on listing and price based on the evidence available at the time of its initial consideration;
- identify its key areas of uncertainty for decision making (which may or may not be identical to the uncertainties identified in the submission by the sponsor where provided); and
- identify the evidence it requires to resolve the areas of uncertainty, the timeframe for submission of that evidence and the potential consequences of the evidence outcomes.

In summary, a submission that would not normally be recommended for listing by the PBAC because of unacceptable clinical and/or economic uncertainty could be recommended under a MAP provided the MAP parameters are met. This would mean:

- earlier access to the drugs by patients;
- earlier access to a subsidised market for the sponsor whilst acknowledging that some form of confidential discount may be required in recognition that the initial evidence is less convincing;
- clear articulation of the evidence required to resolve the identified area of uncertainty and the consequences of potential outcomes from the additional evidence;
- agreement by the PBAC to review a submission once the additional evidence becomes available and to reconsider the listing in light of the new evidence;
- appropriate sharing of risk.