

# South Australian Medicines Evaluation Panel

## Information for clinicians on submitting a formulary application for a High Cost Medicine

Under SA Health policy, formulary applications for High Cost Medicines (HCMs) must be forwarded via the hospital Drug & Therapeutics Committee (DTC) to the South Australian Medicines Evaluation Panel (SAMEP) for evaluation of efficacy & safety, and the cost-effectiveness of the proposed medicine compared to currently available treatment options. This information sheet provides general information to assist SAMEP to complete the evaluation of the formulary application in a timely manner.

### Completion of the formulary request form

All requests for a medicine to be included on the statewide High Cost Medicines formulary must be submitted by completing an **SA Health Medicines Formulary Request Form**.

The completed and signed form must be forwarded to the executive officer of the hospital DTC. If the medicine is considered to be high cost, the DTC will forward the form to the executive officer to SAMEP.

### Additional information required

If the HCM has already been used for the proposed indication via requests for Individual Patient Use (IPU), it is expected that details of the historical use within SA Health are provided, including the clinical outcomes of patients who have already been prescribed the medicine. Non-provision of outcome data will likely delay the evaluation process. In addition, SAMEP may request other information to assist their evaluation. Information on local usage is particularly important when the indication is rare, and published data is scarce.

### Meeting with the Chair & Executive Officer to SAMEP

On receipt of a HCM formulary application, the Executive Officer to SAMEP will conduct a comprehensive literature search and will complete a summary of the application, highlighting areas of uncertainty. This summary will be forwarded to the applicant together with a meeting request to discuss issues raised and clarify areas of uncertainty prior to the SAMEP meeting.

### Consultation

The proposed formulary listing along with a draft clinical pathway or eligibility criteria will be circulated to applicable specialist clinicians with a request for expert opinion and feedback. For specialties represented by a Statewide Clinical Network, consultation will be directly via the Network. In all other cases, the heads of departments at SA public hospitals and the DTCs will be consulted. Lack of consensus among clinicians may also delay the evaluation.



## Timeline of review

SAMEP meet every two months to review formulary applications for HCMs. If a decision is possible, the recommendation of the panel will be forwarded to the South Australian Medicines Advisory Committee (SAMAC). In general, the review process will take a minimum of two months.

The progress of the review is dependent upon timely responses to consultation and the provision of any outcome data available for the indication. At any stage in the review process, the applicant may contact the Executive Officer to SAMEP for an update on the progress of the review.

SAMEP is an advisory committee to SAMAC. The role of SAMEP is to evaluate the HCM for efficacy, safety and cost-effectiveness and provide that information to SAMAC and Portfolio Executive, who make the final decisions regarding funding of the medicine within SA Health.

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## For more information

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