SA Health

Policy

Medicines Access Programs (MAP)

Version 4.0

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Government of South Australia

SA Health

1. Name of policy

Medicines Access Programs (MAP)

2. Policy statement

This policy provides the mandatory requirements for the governance of Medicines Access Programs (MAP) within SA Health.

MAPs provide patients and prescribers with access to medicines that may be unavailable through other usual funding mechanisms such as the Pharmaceutical Benefits Scheme (PBS). MAPs allow clinicians the opportunity, where clinically appropriate, to use, evaluate, and become familiar with a medicine without putting patients, staff, and SA Health at risk of inappropriate discontinuation of therapy or unanticipated costs at the cessation of a program.

Appropriate governance ensures equity of access and protects patients and providers from medicines access program arrangements that may unduly expose them to physical or financial risk.

3. Applicability

This policy applies to all employees and contracted staff of SA Health; that is all employees and contracted staff of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks, and SA Ambulance Service (SAAS).

This policy covers all medicines access arrangements offered by the pharmaceutical industry to facilitate deferred cost, cost-free or subsidised access to medicines for LHN and state-wide service patients before relevant funding arrangements are implemented. These include compassionate use, expanded access, product familiarisation, cost-share and all other similarly named access programs.

Out of Scope

This policy does not apply to:

- Medicines used as part of a registered clinical trial approved by the relevant Human Research Ethics Committee.
- Requirements for access to products covered under relevant SA Health procurement, consumable trials, biomedical engineering and health technology assessment processes and policies, including:
  - Approval of products or equipment for routine use (eg by the SA Health Biomedical Engineering Service and Procurement Product Standardisation Committee).
  - Approval of high risk, high-cost health technologies (by the SA Policy Advisory Committee on Technology).

4. Policy principles

SA Health's approach to medicines access programs is underpinned by the following principles:

- We will ensure appropriate governance to support safe, equitable, quality, and cost-effective use of medicines.
- We support transparency and accountability in decision making.
- We will ensure informed management of financial risk.
- We act in the public interest.

5. Policy requirements

Governance

- Drug and Therapeutics Committees (DTC) or equivalent committees within each LHN and state-wide service must ensure:
  - Appropriate governance of the management, access, and appropriate use of medicines via MAPs, and
  - Prescribers follow the approval requirements described in this policy.
- All MAPs must be approved by the LHN or state-wide service DTC and supported by the Director of Pharmacy prior to commencement. Before approving a MAP, the DTC must be satisfied that the program complies with the provisions outlined in MAP Governance Mandatory Instruction 1 (Appendix 1) and Conditions for Approval.
- Directors of Pharmacy (or delegate), LHNs and state-wide services must ensure:
  - Storage, management and dispensing of medicines accessed under a MAP occurs in accordance with procedures applicable to other medicines, including provision of information to support appropriate use.
- A clinician prescribing medicine must ensure that the patient is fully informed of the MAP, and the potential clinical and financial risk, as outlined in MAP Prescribing Mandatory Instruction 2 (Appendix 2).

Conditions for Approval

- Any MAP, including online applications, must have a formal agreement between the DTC and the sponsor to ensure uninterrupted supply, free of charge (or as otherwise approved by the DTC) until the product is made available through a formal funding mechanism, for as long as the patient's treating clinician determines that there is a clinical benefit and, the medicine remains available in Australia.
- This agreement must be documented by completing the Medicines Access Programs Pharmaceutical Company Acknowledgement Form. The form must be used as is, no amendments will be accepted. The completed form must be returned to the DTC prior to supply of medicine to the patient.
- LHN DTCs must comply with the reciprocal access agreement relating to the clinical assessment of a MAP approved by one DTC where there is appropriate service expertise within the other LHN and supports equity of access for patients.
- If requested by LHN DTC, an Individual Patient Use (IPU) Medicine application must be completed.
- If a chemotherapy medicine is being used for the treatment of cancer, the SA Health Cancer Drug Committee and the Cancer Services – State-wide Cancer Chemotherapy Policy must be considered and additional governance processes may be required.

Participating in a MAP

- Prescribers seeking to participate in a MAP must, prior to participating:
  - Complete the Medicines Access Program Prescriber Acknowledgement Form.
  - Declare any actual, potential, or perceived conflict of interest to the relevant DTC(s) for each MAP in which they are involved, and
  - Obtain approval from the relevant DTC for participation in the MAP.
- An application for a MAP must be completed by a consultant and the prescription written by the consultant or a qualified delegate.

- Patients must be informed that the medicine or treatment is being provided under a MAP and that it is not routinely available from the LHN or state-wide service.
- Patients must be informed that if the MAP ceases and the medicine is no longer available through the LHN or state-wide service, they may be required to transfer to an alternative treatment, or to obtain ongoing private supply from another source.
    - Patients are required to agree to treatment under these conditions. The agreement must be documented in their medical record by completing the SA Health Medicines Access Programs Patient Consent Form.
    - Patient consent must be obtained and retained in the patient's medical records.
- Clinicians who have outstanding MAP outcome reports (see Reporting policy requirements) that have not been submitted to the relevant approval committee must not be granted approval for future MAP until the report(s) have been submitted.

Additional Requirements Applicable to Specific Medicines Access Program

Specific MAPs have additional requirements which must be followed, including:

- **Product Familiarisation Programs (PFP)**
    - Any applications for a PFP within the LHN or state-wide service must conform to the proposed PBS listing and any restrictions within the requested indication.
    - Individual prescribers are limited to enrolling a maximum of 10 patients into a PFP.
- **Cost-share programs (CSP)**
    - CSP must not be encouraged. It is preferable that a price reduction is negotiated with the supplier by the LHN Director of Pharmacy. Negotiations at a state-wide level are preferred to ensure equity of access for all South Australians.
    - If subsidised supply is offered, this must be via a reduced purchase price for the life of the program.
    - Any cost-share program requiring an initial purchase of product prior to the provision of cost-free or subsidised supply must not be approved.
- **Self-funding by patients**
    - There may be instances where a patient wishes to fund their own treatment under a cost-share program. Such arrangements must comply with relevant regulations and SA Health policies, including documentation of informed consent. If a patient chooses to self-fund the medicine, a risk assessment and the development and implementation of risk mitigation strategies must be conducted by the DTC to ensure no additional risks to the LHN or state-wide health service.

Supply, Administration and Storage of Medicines Approved Under a MAP

- All medicines accessed under a MAP must be used in accordance with the conditions for approval.
- MAP medicines must be stored, managed, and dispensed through LHN and state-wide service pharmacy department in accordance with procedures and legislation applicable to medicines.
- MAP medicines must be administered (where appropriate) in a SA Health facility by suitably qualified SA Health staff.
- The LHN/state-wide service CEO (or delegate) must only consider or approve alternative arrangements for the supply, administration, and storage of MAP medicines in exceptional circumstances.

- This includes (but is not limited to) engaging a private provider or an external infusion service provided outside SA Health facilities.
- The LHN/state-wide service CEO or (delegate) must only approve alternative arrangements following consideration of a risk assessment and risk management plan.

- Any decisions made for alternative arrangements must be shared between LHNs.
- Medicines provided under a MAP must not be supplied directly to the treating clinician by the sponsor company.
- Standard patient co-payments, where applicable, must be levied.

Continued Use of Medicines Accessed Under a MAP

- Ongoing patient management must not be compromised by cessation of a MAP. Medicines accessed under a MAP must not be considered part of standard care unless they have been approved by the relevant approval committee. This includes the presence of any MAP medicine on state-wide clinical guidelines or local protocols.
- Acceptance of a MAP does not commit any LHN, state-wide service or SA Health to approve any future use of that product, including formulary listing or IPU approval.
- When medicines accessed under a MAP are considered for routine use, the full price of that medicine must be considered, rather than any discounted price obtainable under a MAP.
- Reports of MAP must be used to inform decisions relating to continued supply of that product outside of the MAP.

Reporting

- Clinicians participating in a MAP must submit report(s) of the MAP to the DTC. The DTC will stipulate the timing of the reports, dependent on the duration of the MAP.
- DTCs must share reporting of MAP to promote equity of access through information sharing to provide understanding and to inform future medicine formulary considerations and promote safety and quality.
- Any agreed reporting framework between LHNs must promote safety, quality, and equity of access through information sharing.
- If an application is made for formulary listing, a report must be provided to the relevant committee (eg the SA Formulary Committee or, SA Medicines Evaluation Panel and/or the DTC). Where a clinician has outstanding reports, this must be taken into consideration by the DTC when assessing future MAP approvals.
- MAP reports must provide:
  - The number of patients participating in the MAP
  - Adverse events experienced
  - Effectiveness measures and clinical outcome of the treatment, and
  - The final report must be signed by the lead clinician or delegate.
- If as part of the MAP a report to the sponsor is required, the clinician must provide a copy of this report to the DTC before submitting to the sponsor.

6. Mandatory related documents

The following documents must be complied with under this Policy, to the extent that they are relevant:

- Asset Management: Biomedical Technology Maintenance Planning Policy
- Code of Ethics for the South Australian Public Sector
- Declaration and Management of Interests Policy
- *Health Care Act 2008 (SA)*
- Health Technology Assessment Policy
- Interaction between SA Health and Therapeutic Goods Industry Policy
- Medicine Samples Policy
- Probity in SA Health Procurement Policy
- *Public Sector Act 2009 (SA)*
- *Public Sector (Honesty & Accountability) Act 1995 (SA)*
- *Therapeutics Goods Act 1989 (Cth)*

7. Supporting documents

- Council of Australian Therapeutic Advisory Groups (CATAG), Managing Medicines Access Programs: *Guiding Principles for the governance of Medicines Access Programs in Australian hospitals* (June 2018)
- Medicines Australia Code of Conduct (Edition:19)

8. Definitions

- **Conflict of Interest:** means where an individual or organisation is involved in multiple interests, one of which could possibly corrupt the motivation for an act in the other. It is sometimes the perception of a conflict of interest that may be important, whether such conflict exists as such perceptions adversely affect relationships within and outside the organisation.

  Section 27 of the *Public Sector (Honesty and Accountability) Act 1995* creates a legal onus on public sector employees to disclose pecuniary or personal interests if they conflict or potentially conflict with the employee's duties. As this is a legal onus on employees, failure to do so constitutes as grounds for termination of the employee's employment in the public sector, or other disciplinary action.
- **Drug and Therapeutics Committee (DTC):** means a committee which plays an active role in the consideration and oversight of medicines issues at either a Local Health Network or state-wide service level. DTCs include Drug and Therapeutics Advisory Committees and other similarly named committees providing medicines governance.
- **South Australian Medicines Formulary (the Formulary):** means a list of core medicines which are approved for initiation of therapy within SA Public Hospitals and health services.
- **Local Health Network (LHN) and state-wide service:** means the Department for Health and Wellbeing, an incorporated hospital established under the Health Care Act 2008, SA Ambulance Service (SAAS) or any health service as defined under that Act. This includes all LHNs, their sites and the health services provided by or through them.
- **Medicine:** means a chemical substance given with the intention of preventing, diagnosing, curing, controlling, or alleviating disease, or otherwise improving the physical or mental welfare of people. Prescription, non-prescription and complementary medicines, irrespective of their administration route, are included.

- **Medicines Access Program (MAP):** means programs offered by the pharmaceutical industry to facilitate deferred cost, cost-free or subsidised access to medicines for public hospital patients prior to the implementation of relevant funding arrangements. MAP include compassionate use, expanded access, product familiarisation, cost-share programs and all other similarly named access programs:
    - **Compassionate Use Program**: where a sponsor offers to provide a medicine free of charge for indications that are not already included in a funded scheme (i.e. other MAP arrangement or eligible clinical trial). Compassionate use may be determined on an individual patient basis or as part of a wider program. Compassionate use usually involves patients with serious or life-threatening conditions or rescue treatments.
    - **Cost-Share Program**: means where a sponsor offers a medicine commercially at a reduced price. Use of the product either individually or as a program should be considered as if the drug was simply being marketed at that reduced price. This may have the effect that treatment costs are shared between a company and the Local Health Network, hospital, or health service and/or the patient. Cost-share arrangements may include deferred cost, subsidised supply of a medicine (e.g. half price) or arrangements where supply of a medicine at a reduced price is provided after the purchase of a specified (threshold) amount.

      Note: Cost Share Programs should not be encouraged. It is preferable that price reductions are negotiated with the sponsor via the appropriate procurement process. Negotiations at a system level are also preferred to ensure equity of access within the local health system. Enrolment of patients in CSP should comply with relevant regulations and policies about patients paying for their medicines.
    - **Expanded Access Program**: means the cost-free provision of an investigational product by a sponsor with access expanded after participation in a clinical trial. EAP usually involve patients with serious or life-threatening conditions. This may include patients who do not meet the enrolment criteria for a clinical trial in progress or continued supply of an investigational product to patients who have been participating in a clinical trial, following its conclusion. Medicines provided under EAP are often not yet registered with the TGA for use within Australia.
    - **Product Familiarisation Program**: means programs offered by a sponsor designed to allow the medical profession to evaluate and become familiar with a product while Pharmaceutical Benefits Scheme (PBS) listing is being sought. Products offered under a product familiarisation program must be in accordance with the TGA approved indications for the medicine and indications for which PBS listing has been sought.
- **Patient:** means a person receiving healthcare. Other terms for ‘patient’ include consumer and client. insert definition of term.
- **Pharmaceutical Company:** means organisations supplying medicines, as defined in the *Therapeutic Goods Act 1989.*
- **Sponsor:** means the pharmaceutical company or organisation supplying (exports and/or imports and/or manufactures or arranges these functions through another party) therapeutic goods for supply in Australia.
- **State-wide services:** means State-wide Clinical Support Services, Prison Health, SA Dental Service, BreastScreen SA, SA Pharmacy and any other state-wide services that fall under the governance of the Local Health Networks.

9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the Risk Management, Integrated Compliance and Internal Audit Policy.

Any instance of non-compliance with this policy must be reported to the Domain Custodian for the Clinical Governance, Safety and Quality Domain and the Domain Custodian for the Risk, Compliance and Audit Domain.

See further information at Appendix 3: MAP Compliance Indicators.

10. Document ownership

Policy owner: Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain

Title: Medicines Access Programs (MAP) Policy

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11. Document history

Version	Date approved	Approved by	Amendment notes
4.0	31/05/2023	A/Deputy Chief Executive, Clinical System Support and Improvement	Revised into new Policy Framework template and requirements. Additional requirements included regarding MAP assessment processes to support good practice and minimise risk to patients and SA Health.
3.0	04/03/2020	Don Frater, Deputy Chief Executive, SA Health	Formally reviewed in line with 1-5 year scheduled timeline for review.
2.1	02/07/2015	Updated version for PE approval	Formally reviewed in line with 1-5 year scheduled timeline for review.
1.0	15/12/2011	PE approved existing version	Formally reviewed in line with 1-5 year scheduled timeline for review.

12. Appendices

1: MAP Governance Mandatory Instruction

2: MAP Prescribing Mandatory Instruction

3: MAP Compliance Indicators Mandatory Instruction

Appendix 1: MAP Governance Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. Governance of MAPs

- LHNs and state-wide services must ensure that the implementation of appropriate governance and administrative arrangements, including completion of:
  - Medicines Access Programs Pharmaceutical Company Acknowledgement Form.
  - SA Health Medicines Access Programs Patient Consent Form, and
  - Medicines Access Program Prescriber Acknowledgement Form.

Appendix 2: MAP Prescribing Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. Prescribing Medicine as Part of a MAP

- A clinician prescribing medicine as part of a MAP must:
  - Inform patients that the medicine is not routinely available from the LHN or state-wide service, and that continuing supply is dependent upon continuance of the MAP at the LHN or state-wide service.
  - Counsel the patient on the medicine and advise on the MAP. This may include, where appropriate, advising the patient that the medicine is not yet registered with the Therapeutics Good Administration (TGA) for use within Australia.
  - Discuss with the patient the details of the medicine including dose, frequency, potential adverse effects, duration of treatment and matters such as potential benefits and nature and extent of monitoring (including imaging and invasive procedures).
  - Obtain the patient's written informed consent to the stated conditions of the MAP before the commencement of treatment.
  - Document the agreement with the patient in their medical record.
  - Declare any actual, potential, or perceived conflict of interest to the DTC for each MAP.
  - Limit enrolment into a Product Familiarisation Program (PFP) to a maximum of 10 patients, and as otherwise approved by the DTC for other MAPs.
  - Report all adverse drug reactions to the TGA through the Australian Adverse Drug Reaction Reporting System (the ADRS) and through the LHN or state-wide service adverse drug reaction reporting procedure.
  - Complete the forms in MAP Governance Mandatory Instruction (Appendix 1).

Appendix 3: MAP Compliance Indicators Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. SA Health-wide Compliance Indicators

> The SA Health-wide compliance indicators for this policy are set out below. These indicators are required to be met across all SA Health services. Any instance of non-compliance with this policy must be reported to the Domain Custodian for the Risk, Compliance and Audit Domain.

Indicator	Description
Governance and management of MAPs	• LHNs and state-wide services must have appropriate processes in place to ensure all MAPs are developed and managed in accordance with the SA Health Policy Medicines Access Programs (MAP)
Approvals	• All active MAPs must be assessed and approved according to the LHN or state-wide service processes. • For all approved MAPs the following forms must be completed: ○ SA Health Medicines Access Programs Pharmaceutical Company Acknowledgement Form ○ SA Health Medicines Access Programs Doctor Acknowledgement Form ○ SA Health Medicines Access Programs Patient Consent Form
Reviewing, monitoring, and reporting of MAPs	• The LHN or state-wide service Chief Executive (or equivalent executive) must establish and implement performance and reporting metrics to measure successful implementation of the policy within their organisation. • The South Australian Medicines Advisory Committee must review the policy to ensure it is relevant and up to date. • The South Australian Medicines Advisory Committee must periodically monitor implementation of the policy.