Medicines Access Programs Procedure

1. Purpose

WACHS sites use and provide medicines to patients that are evidence-based and cost effective. This aligns with the National Medicines Policy and the WA Health Statewide Medicines Formulary Policy – MP 0077/18.

Access to medicines that are not listed on the Statewide Medicines Formulary is via Individual Patient Approval (IPA) processes where an assessment of need, anticipated efficacy and safety, and cost efficacy are considered for individual patients.

Pharmaceutical companies offer some medications via Medicines Access Programs (MAPs) that are subsidised or free of charge. These programs enable greater access to medications before funding arrangements have been implemented (e.g. listing on the PBS) or for indications which may not be considered for funding, however there may lack of evidence of efficacy for these medicines or indications.

Governance of MAPs is required to ensure that WACHS patients, staff and hospitals are not exposed to risk of clinical or financial harm resulting from use of these MAPs. Financial contracts are required between the pharmaceutical company and the organisation. The resources required to manage a MAP are similar to that of managing a clinical trial. Thus, having a robust governance system in place will help to ensure risks to the organisation (clinical, financial and legal) are managed, that patients have continued access to these medications and that the workload of facilitating a MAP is manageable and sustainable for the health service.

The WA Therapeutic Advisory Group (WATAG) MAPs Guidelines and Guiding Principles for the governance of Medicines Access Programs (MAPs) in Western Australian Public Hospitals assist drugs and therapeutics committees (DTCs), health professionals, consumers and pharmaceutical sponsors with the appropriate implementation, management, delegation of authority, provision of information and oversight of MAPs. These WATAG guidelines and principles are based on the national Council of Australian Therapeutic Advisory Groups (CATAG) Managing Medicines Access Programs - Guiding Principles for the Governance of Medicines Access Programs in Australian hospitals

This policy does not apply to medicines that are being used as part of a registered clinical trial that has been approved by the WACHS Human Research Ethics Committee (HREC).

2. Procedure

As per guidance by WATAG, a MAP approved by the DTC at one tertiary site should generally be accepted at other WA Health sites. Notwithstanding this, Regional Chief Pharmacists and/or regional DTC/Medication Safety Group (MSG) retain the discretion of not participating in a MAP initiated at another site.

Reasons for a WACHS site not accepting a MAP could include clinical, financial or workforce implications. For example, implementation of a MAP may not be feasible at a WACHS site, even if cost recovery has been agreed to at a larger site.

In accordance with WATAG advice, a MAP may be considered for a WACHS site when:

- approved at a WA Health tertiary site
- the regional DTC or MSG, and Regional Chief Pharmacist at the WACHS site have reviewed the MAP and are satisfied:
  - that there is a clinical or compassionate imperative for supply of a medicine
  - that the workforce requirements to facilitate the MAP can be met
- a formal agreement has been made between the Regional Chief Pharmacist and the pharmaceutical company to ensure uninterrupted free supply for fully funded programs (e.g. compassionate supply). This does not apply for compassionate access MAPs which are entered into by a tertiary hospital which then requests a WACHS site to supply/administer the medicine to the patient on its behalf
- where there is a cost or potential cost associated with the medication, financial approval is in place based on the relevant delegation authority:
  - Regional Chief Pharmacists (Tier 5) can enter into agreements up to the value of $20,000 per patient per year
  - Regional Medical Directors (Tier 4) can enter into agreements up to the value of $100,000 per patient per year
  - Regional Directors (Tier 3a) can enter into agreements up to the value of $500,000 per patient per year.

The DTC/MSG of each individual site is responsible for ensuring that the WATAG Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals are followed.

To ensure equitable access to medications, patients are not permitted to self-fund the funding component of a Cost Share Program as per the WA Health Fees and Charges Manual. The local WACHS site may choose to fund this component following their usual review and approval processes for non-PBS medicines (WACHS Request for Supply of Non-PBS Pharmaceutical or Medical Supplies – Individual Patient Approval Form).

When a MAP has been accepted by a regional DTC/MSG sufficient time must be allowed for development of a prescribing chart (if relevant), for site registration and for procurement of the medicine, as needed.

Where compassionate access stock for a specific patient is provided to the regional pharmacy via an alternative process (e.g. dispensed by a tertiary hospital), the Regional Chief Pharmacist may determine if an application to the regional DTC/MSG is required (e.g. if there are additional costs involved such as for preparation of the medicine).

If the MAP requires preparation offsite with a third party compounder, e.g. Baxter, the cost of the manufacturing needs to be considered and approved by the cost centre manager. Sufficient time must be allowed to ensure the product can be prepared by the compounder as well as delivery of the medicine to the compounder, the delivery of the prepared product back to the site, in time for scheduled patient administration.

Acceptance of a MAP at a WA Health site does not guarantee that the medication will be added to the formulary.

Ongoing clinical assessment of each individual MAP is required to ensure clinical appropriateness of the MAP against formulary approved treatments.

3. Roles and Responsibilities

The regional DTC/MSG:

- are to review all MAP applications and decide to accept or decline at their site and provide justification of the decision
- are to seek further advice and input from the relevant WACHS Clinical Director and/or WACHS governance group or expert panel as required, for example the WACHS Cancer Clinical Governance Group for MAPs relating to cancer treatment
- is to liaise with the relevant Nurse Unit Manager if the medication is to be administered onsite to ensure nursing requirements, educational and supportive resources are available for staff.

The Regional Medical Director and Regional Director:

- Regional Medical Directors (Tier 4) can enter into agreements up to the value of $100,000 per patient per year.
- Regional Directors (Tier 3a) can enter into agreements up to the value of $500,000 per patient per year.
- All appeals relating to MAP decisions must be presented to the WACHS Medicines and Therapeutics Executive Sub-Committee by the Regional Director.

The Prescriber:

- is to ensure they have the agreement and support of the Regional DTC/MSG, Regional Director Nursing and Midwifery services (where nursing resources are required) and Regional Chief Pharmacist to participate in the MAP. This should be obtained by submitting a MAP Application Form to the local DTC/MSG (along with the Prescriber Agreement Form, Pharmaceutical Sponsor Agreement Form and Patient Consent Form)
- is to declare any actual, potential or perceived conflict of interest to the local DTC for each MAP
- is to inform the patient that the medicine is not routinely available at that site and that continuing of supply is dependent on the continuation of the MAP.

The Pharmacist/Pharmacy Department:

- is to identify if they have the capacity to manage handling, dispensing and arrange manufacturing (where required) of the MAP
- is to provide justification for any rejection of a MAP for that site to the DTC and prescriber
- is to ensure that all MAP medicines are stored, managed and dispensed through the hospital pharmacy in accordance with policies and procedures applicable.
- **Note:** Regional Chief Pharmacists can enter into agreements up to the value of $20,000 per patient per year.

The Pharmaceutical Company/Sponsor:

- will be subject to a formal agreement with the hospital to ensure uninterrupted supply, free of charge (unless otherwise agreed by the hospital), for as long as the patient has clinical benefit
- is to acknowledge that supply will be continued until the medicine is available through a formal funding mechanism e.g. the PBS.

All staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

4. Monitoring and Evaluation

4.1 Monitoring

Monitoring of compliance with this document is to be carried out by WACHS Chief Pharmacist or delegate on an annual basis via auditing of the completed MAP Application Forms, Patient Consent Forms and outcome reports supplied by the regional DTC/MSG.

4.2 Evaluation

Regional DTCs/MSG are to record outcomes (whether approved or not, and clinical outcomes for the patient) of Medicines Access Program (MAP) applications as per their local process e.g. record in the minutes. A copy of the completed MAP Application Form, Patient Consent Form and outcome reports (e.g. by way of DTC minutes) must be emailed to the WACHS Chief Pharmacist to be uploaded onto Records Manager (TRIM).

5. Compliance

Failure to comply with this procedure may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to Section 26 of the *Health Services Act 2016* and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies and procedures is mandatory.

6. References

1. WATAG Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals.
2. CATAG Managing Medicines Access Programs - Guiding Principles for the Governance of Medicines Access Programs in Australian hospitals.

7. Definitions

Term	Definition
Compassionately Supplied Medicines (CSM) Program	A pharmaceutical company (sponsor) offers to provide a medication free of charge for indications that are not part of a Product Familiarisation Program, Expanded Access Program 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 (CSP)	A program whereby the sponsor offers a medicine commercially at a reduced price. The use of the product either individually or as a program should be considered as if the medicine was simply being marketed at that reduced price. This may have the effect that treatment costs are shared between a company and the hospital / 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 following the purchase of a specified (threshold) amount. The Fees and Charges Manual limits the fee that a patient may be charged by a WA Health Site.
Drugs and Therapeutics Committee (DTC)	The multidisciplinary committee that has the primary role for the governance of the use of medicines at a regional level to ensure safe, appropriate and cost-effective use of medicines.
Expanded Access Program (EAP)	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.
Medicines Access Program (MAP)	Medicines Access Programs is a general term to mean any programs offered by pharmaceutical companies to facilitate the supply of a medicine at no charge or with a subsidised or deferred cost. MAPs may include Product Familiarisation Programs (PFP), Expanded Access Programs (EAP), Compassionately Supplied Medicines (CSM) programs and Cost Share Programs (CSP). MAPs may include non-Therapeutics Goods Administration (TGA) registered products or TGA registered medicines being used outside of TGA registered indications.
Medicines Safety Group (MSG)	At select WACHS sites this group may perform the functions of the DTC for the region.
Product Familiarisation Programs (PFP)	Programs designed to allow the medical profession to evaluate and become familiar with a product while Pharmaceutical Benefits Scheme (PBS) subsidisation is being sought. Products offered under a PFP must be in accordance with the TGA approved indications and the indication for which PBS listing is being sought.
Western Australian Therapeutics Advisory Group (WATAG)	The committee responsible for guiding the standardised use of medicines in Western Australia based on clinical efficacy, safety and cost effectiveness

8. Document Summary

Coverage	WACHS-Wide
Audience	Medical, nursing and pharmacy staff
Records Management	Records Management Policy Health Record Management Policy
Related Legislation	*Medicine and Poison Act 2014* (WA) Medicine and Poison Regulations 2016 (WA)
Related Mandatory Policies / Frameworks	Clinical Incident Management Policy 2019 – MP 0122/19 High Risk Medication Policy – MP 0131/20 Statewide Medicines Formulary Policy – MP 0077/18 Clinical Governance, Safety and Quality Policy Framework
Related WACHS Policy Documents	WACHS Anticancer Therapy Prescribing Procedure WACHS Cancer Institute NSW- Cancer Treatments Online - EviQ - Endorsed For Use In Clinical Practice Policy WACHS Systemic Anticancer Therapy Guideline WACHS Documentation Clinical Practice Standard WACHS High Risk Medication Procedure WACHS Medication Prescribing and Administration Policy WACHS Medication Handling and Accountability Policy
Other Related Documents	CATAG Managing Medicines Access Programs - Guiding Principles for the Governance of Medicines Access Programs in Australian hospitals WATAG Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals
Related Forms	WACHS Medicine Access Program (MAP) Application Form WACHS Medicines Access Program (MAP) Form B: Patient Consent to Participate in MAP WACHS Request for Supply of Non-PBS Pharmaceutical or Medical Supplies – Individual Patient Approval Form MR59A WACHS Cancer Services - Consent to Cancer Treatment
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 1961
National Safety and Quality Health Service (NSQHS) Standards	1.07, 1.08, 2.05, 2.06, 2.07, 4.01, 4.03, 4.04, 4.06, 4.07, 4.08, 4.09, 4.11, 4.12, 4.13, 6.05.
Aged Care Quality Standards	Nil
National Standards for Mental Health Services	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
1.00	2 March 2023	2 March 2023	Original document

10. Approval

Policy Owner	Executive Director Clinical Excellence
Co-approver	Executive Director Nursing and Midwifery
Contact	WACHS Chief Pharmacist
Business Unit	Pharmacy
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This document can be made available in alternative formats on request.