Medicines Access Programs Procedure

1. Purpose

Pharmaceutical companies offer some medications via Medicines Access Programs (MAPs) that are cost subsidised or free of charge. MAPs can include Compassionately Supplied Medicines (CSM), Cost-Share Programs (CSP), Expanded Access Programs (EAP) and Product Familiarisation Programs (PFP), refer to definitions section. These programs enable greater access to medications before funding arrangements have been implemented e.g., listing on the Pharmaceutical Benefits Scheme (PBS) or for indications which may not be considered for funding.

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.

Guidance surrounding MAPs is required to enable WACHS patients, staff and hospitals expanded access to medications, whilst ensuring they are not exposed to risk of clinical, legal or financial harm resulting from use of MAPs. The resources required to manage a MAP are like that of managing a clinical trial and contracts are required to be executed between the pharmaceutical company and the organisation. Thus, having a robust governance system in place will help to ensure risks to the organisation 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 medicines and therapeutics committees (MTCs), 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 procedure 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.

2. Procedure

A MAP may be considered for a WACHS site when:

- the regional MTC 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 resources required to facilitate the MAP can be met
- a formal agreement has been made between the health service provider and the pharmaceutical company to ensure uninterrupted free supply for fully funded programs or other cost-share arrangement for as long as the prescriber considers there is a clinical benefit for the patient or until the medicine is available through a formal funding mechanism e.g., the PBS

- there is a cost or potential cost associated with the medication, financial approval is in place based on the relevant delegation authority as per WACHS Authorisation Schedule. The financial threshold relates to the value of the agreement for the anticipated duration of the MAP for all patients covered by the agreement:
  - Regional Chief Pharmacists (Tier 5) can enter into agreements up to the value of $20,000.
  - Regional Medical Directors (Tier 4) can enter into agreements up to the value of $100,000.
  - Executive Directors (regional) (Tier 3a) can enter into agreements up to the value of $500,000.

CSP is a MAP whereby the sponsor offers a medicine commercially at a reduced price and the costs are shared between a sponsor and health service provider and/or the patient. CSPs are not encouraged. The *Health Service Act 2016* (WA) limits the fee any patient may be charged for MAP according to WA Health Fees and Charges Manual. The local WACHS site may choose to fund this component following their usual review and approval processes for initiation of medication outside of the corresponding requirements of the WA Statewide Medicines Formulary (SMF) via submission on WA Individual Patient Approval System (WAIPAS).

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

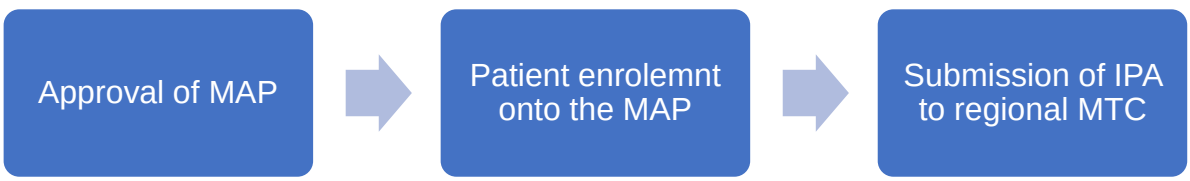
If the MAP requires aseptic preparation for administration, this is performed offsite via contracted compounder, therefore:

- 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 delivered by the pharmaceutical sponsor, prepared by compounder and delivery of the prepared product back to the region, in time for scheduled patient administration.
- If a patient is cancelled or delayed after the product has been compounded, next dose of treatment will need to be within the product expiry window or after a new supply is reissued and delivered from the pharmaceutical sponsor.

Acceptance of a MAP at a WA Health site does not commit the health service provider to add the medication to its formulary. Ongoing clinical assessment of each individual patient treated with a MAP is required to be reported by the prescriber to the MTC to ensure continued clinical appropriateness of the MAP.

2.1 Process steps

Once a MAP has been highlighted as potential for use within a WACHS site, the prescriber is to ensure the following process is followed:



Details of each step are outlined below.

Step 1: Approval of the MAP:

- completion of the MAP application form and submission to the Regional Chief Pharmacist for review and regional MTC endorsement
  - each MAP application is prescriber and health service provider specific
  - each prescriber is allowed to enrol a maximum of 10 patients in a PFP in accordance with the Medicines Australia Code of Conduct
- regional MTC will inform the applying prescriber of the decision of regional MTC in conjunction with the return of the MAP application form, inclusive of final comments/conditions and approval status.

Step 2: Patient enrolment onto the MAP:

- prescriber enrols patient(s) in the approved MAP via the pharmaceutical company
- in addition, WACHS requires:
  - Form B: Patient Consent to Participate in MAP
  - patient's consent on one of the below forms:
    - MR30A Patient Consent to Treatment or Investigation – Adult or Mature Minor
    - MR59A WACHS Cancer Services - Consent to Cancer Treatment
  - Form B: Patient Consent to Participate in MAP, Patient Consent Form and copy of approved MAP application form (step 1) must be retained in the patient's medical record
  - Cancer Clinical Governance Group (CCGG) recommendations are required for MAPs relating to cancer treatment.

Step 3: Submission of IPA to regional MTC:

- the prescriber to complete Individual Patient Approval (IPA) on the WAIPAS
  - Medication Access Program / Compassionate Access / Cost Share checkbox must be ticked
  - important aspect of IPA form such as applicant and patient details must be completed so it is easily trackable. Duplication of detailed information is not necessary
  - the following MUST be attached:
    - copy of the approved MAP application form
    - Form B: Patient Consent to Participate in MAP
    - CCGG recommendations for MAPs relating to cancer treatment.

IPA is then reviewed by regional pharmacy for capacity assessment and regional MTC for endorsement. The prescriber is to submit reports to the regional MTC at agreed intervals.

For enrolment of multiple patients onto an approved MAP, complete step 2 and step 3 for additional patients. Ensure that the approved MAP application form from step 1 is attached for each patient's WAIPAS application.

Patient transfer from another site:

- Where clinical governance has been transferred to another site, the MAP will need to be approved by the accepting site as per step 1, step 2 and step 3.
- Where there are issues around clinical governance or the site of governance and supply differs, advice from regional MTC or CCGG (for cancer treatment) will be required.

3. Roles and Responsibilities

The regional MTC or Medication Safety Committee (MSC) is responsible for:

- ensuring that the WATAG Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals are followed
- reviewing all MAP applications and decide to accept or decline at their site and provide justification of the decision
- seeking further advice and input from the relevant WACHS Clinical Director and/or WACHS governance group or expert panel as required
- liaising 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 Executive Director are responsible for:

- Regional Medical Directors (Tier 4) can enter into agreements up to the value of $100,000 for the anticipated duration of the MAP for all patients covered by the agreement
- Executive Directors (regional) (Tier 3a) can enter into agreements up to the value of $500,000 for the anticipated duration of the MAP for all patients covered by the agreement
- All appeals relating to MAP decisions must be presented to the WACHS MTC by the Regional Executive Director.

The Prescriber is responsible for:

- ensuring they have the agreement and support of the Regional MTC, 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 MTC
- enrolling patient in approved MAP as per procedure outline above
- declaring any actual, potential, or perceived conflict of interest to the local MTC for each MAP
- informing 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
- providing MAP information provided by the pharmaceutical company, including key contacts to the pharmacy department to facilitate supply
- submitting reports to regional MTC at agreed interval.

The Pharmacist / Pharmacy Department is responsible for:

- identifying if they have the capacity and resources to manage storage, handling, dispensing and facilitate manufacturing (where required) of the MAP
- providing justification for any rejection of a MAP for that site to the MTC and prescriber
- ensuring that all MAP medicines are stored, managed, and dispensed through the hospital pharmacy in accordance with policies and procedures applicable, including the provision of adequate information about appropriate use
- ensuring medicines accessed under MAPs are used in accordance with the approval for use within the MAP
- Regional Chief Pharmacists can enter into agreements up to the value of $20,000 for the anticipated duration of the MAP for all patients covered by the agreement.

All staff are required to comply with the directions in WACHS policies and procedures as per their roles and responsibilities. Guidelines are the recommended course of action for WACHS and staff are expected to use this information to guide practice. If staff are unsure which policies procedures and guidelines apply to their role or scope of practice, and/or are unsure of the application of directions they should consult their manager in the first instance.

4. Monitoring and Evaluation

Monitoring of compliance with this document is to be carried out by regional MTCs (via the Regional Chief Pharmacist or delegate) on an annual basis via auditing of the completed MAP Application Forms, Patient Consent Forms and outcome reports.

Regional MTCs are to record whether MAPs are approved or not, and clinical outcomes for enrolled patient via outcome reports as per their local process e.g. record in the minutes.

6. References

Government of Western Australia Department of Health [Internet]. Perth (AU): Western Australian Therapeutics Advisory Group (WATAG); Medicines Access Programs (MAPS) Guidelines [2019 December; cited 2024 Aug 26]. Available from: https://www.health.wa.gov.au/~/media/Files/Corporate/general-documents/WATAG/Medicines-Access-Programs-MAP-Guidelines.pdf.

Government of Western Australia Department of Health [Internet]. Perth (AU): Western Australian Therapeutics Advisory Group (WATAG); Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals [2019 November; cited 2024 Aug 26]. Available from: https://www.health.wa.gov.au/~/media/Files/Corporate/general-documents/WATAG/Medicines-Access-Programs-Guiding-Principles.pdf

Council of Australian Therapeutic Advisory Groups (CATAG) [Internet]. Darlinghurst (AU): Managing Medicines Access Programs - Guiding Principles for the Governance of Medicines Access Programs in Australian hospitals [2018 June 1; cited 2024 Aug 26]. Available from https://catag.org.au/resource/managing-medicines-access-programs/

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.
Medicines and Therapeutics Committee (MTC)	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.
Medication Safety Committee (MSC)	At select WACHS sites this group may perform the functions of the MTC 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	Non Clinical: Corporate Recordkeeping Compliance Policy Clinical: Health Record Management Policy
Related Legislation	*Health Services Act 2016* (WA) *Medicine and Poison Act 2014* (WA) Medicine and Poison Regulations 2016 (WA)
Related Mandatory Policies / Frameworks	• MP 0122/19 Clinical Incident Management Policy 2019 • MP 0131/20 High Risk Medication Policy • MP 0077/18 Statewide Medicines Formulary Policy • Clinical Governance, Safety and Quality Policy Framework
Related WACHS Policy Documents	• Anticancer Therapy Prescribing Procedure • Cancer Institute NSW- Cancer Treatments Online - EviQ - Endorsed For Use In Clinical Practice Policy • Systemic Anticancer Therapy Guideline • Documentation Clinical Practice Standard • High Risk Medication Procedure • Medication Prescribing and Administration Policy • 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 • WA Country Health Service Authorisation Schedule • WATAG Guiding Principles for the governance of Medicines Access Programs in Western Australian Public Hospitals • WATAG Medicines Access Programs (MAPs) Guidelines
Related Forms	• WACHS Medicine Access Program (MAP) Application Form • WACHS Medicines Access Program (MAP) Form B: Patient Consent to Participate in MAP • MR30A Patient Consent to Treatment or Investigation – Adult or Mature Minor • MR59A WACHS Cancer Services - Consent to Cancer Treatment • WA Individual Patient Approval System
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 3041
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
Chief Psychiatrist's Standards for Clinical Care	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
1.00	2 March 2023	2 March 2023	Original document
2.0	30 September 2024	2 March 2023	• removed requirement for MAP to be approved at a WA Health tertiary site before it may be considered for a WACHS site • detailed process of MAP application is listed • added clarity regarding the process of patient transfer from another site • clarified the financial approval based on the relevant delegation authority as per WACHS Authorisation Schedule.

10. Approval

Policy Owner	Executive Director Clinical Excellence
Co-approver	Executive Director Nursing and Midwifery
Contact	WACHS Chief Pharmacist
Business Unit	Pharmacy
EDRMS #	ED-CO-21-234540

This document can be made available in alternative formats on request.