



Government of **Western Australia**
Department of **Health**

Individual Patient Approval (IPA) Guideline for the WA Individual Patient Approval System (WAIPAS)

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1.0 Version control

Version number	Version date	Review date	Description of change(s)	Author
0.1	22/12/2021		Initial document	Andy Campbell & Matthew Rooney
0.2	10/06/2022		Minor amendments	Scott Beattie
1.0	14/11/2023	14/11/2026	First version for publication	Matthew Rooney

2.0 Purpose

This guideline aims to support Health Service Providers (HSPs) to develop, enact and support a robust and efficient Individual Patient Approval (IPA) process. By doing so, HSPs will ensure that the initiation of medications prescribed outside of the requirements of the Statewide Medicines Formulary (SMF) is consistent, equitable, safe and accountable.

This document provides guidance on minimum standards that can be used when establishing local IPA process.

The intended audience of this guideline is any person involved with medication management working in a Western Australian (WA) public hospital, including (but not limited to) prescribers, pharmacists, and those in medication-related leadership and/or governance roles.

3.0 Background

For the purposes of this guideline, IPAs are defined as a hospital-based, patient-specific approval by the DTC/MTC or equivalent authority for a prescriber to initiate a medicine or indication not listed on the SMF, or outside the SMF specified criteria. The request must include justified clinical need with evidence or expert advice supporting use, as well as the predicted cost of treatment. IPA processes are governed by a hospital Drug and Therapeutics Committee (DTC)/Medicines and Therapeutics Committee (MTC), or an equivalent authority responsible for local medicines governance.

The IPA process involves five sequential phases as summarised by Figure 1.

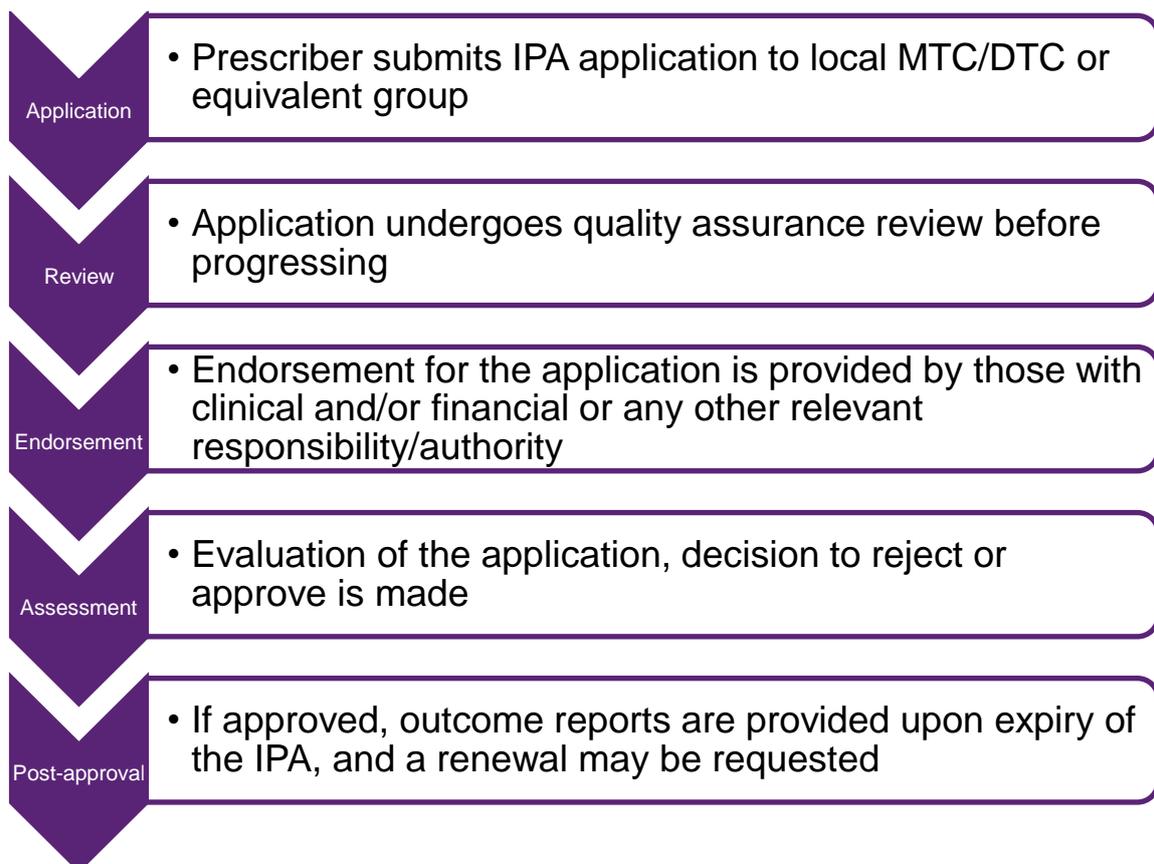


Figure 1. Phases of the IPA process

Each phase of the IPA process has specific requirements to ensure that IPAs are approved or rejected in a manner that maintains the principles of quality use of medicines, patient safety, cost-effectiveness, equity, and appropriate governance.

4.0 Scope

4.1 In scope

These guidelines support the implementation of IPA processes as per [MP0077/18 Statewide Medicines Formulary Policy](#).

For additional information about what agents are within and outside of the scope of the SMF, please see the [WA Statewide Medicines Formulary Guidelines](#).

4.2 Out of scope

The following scenarios are considered out of scope for these guidelines:

- Medications supplied for use under a Medicines Access Program (MAP)
- Investigational medicines used in a clinical trial
- Any other site-based approval for an individual patient that does not relate to the application of the SMF Policy (e.g., supply of medications to outpatients when a hospital does not have an outpatient service).

Sites may choose to adapt the principles outlined in this document for other types of individual patient approvals if deemed suitable according to the relevant site, area, and state requirements. This decision should be made in accordance with existing policies and local risk assessment practices.

5.0 Policy

This guideline supports the IPA requirements outlined in the [MP0077/18 Statewide Medicines Formulary Policy](#).

6.0 Roles and responsibilities

6.1 System Manager

6.1.1 Medicines and Technology Unit (MTU)

The MTU is the unit within the Department of Health that is responsible for overseeing medication governance across Western Australian (WA) public hospitals. This includes the maintenance and governance of the SMF in partnership with the WA Medicines Evaluation Panel (WAMEP) and the WA Therapeutic Advisory Group (WATAG).

The MTU will be responsible for:

- Providing guidance to HSPs on best-practice IPA processes
- Monitoring compliance with the SMF Policy. For further information, see the [WA Statewide Medicines Formulary Guidelines](#).

6.2 Health Service Providers

6.2.1 Chief Executives (CEs)

CEs are responsible for ensuring their HSP is compliant with the [MP0077/18 Statewide Medicines Formulary Policy](#) and all other policies and requirements associated with the IPA process.

CEs are responsible for ensuring all information related to the IPA process is accurately stored and accessed according to state, HSP and local requirements.

6.3 Hospital sites

6.3.1 Director of Clinical Services (DCS)

The DCS (or equivalent position) at a hospital is responsible for ensuring there is appropriate executive sponsorship and support for an accountable, transparent, efficient, and robust IPA process managed at a site level by the MTC/DTC or equivalent authority responsible for local medicines governance.

6.3.2 Endorsers

The Endorsers are responsible for:

- Providing review and accountability of relevant IPA applications based on the Endorser's scope of authority (e.g., financial authority as per the relevant authority delegation schedule)
- Considering the associated risks of each IPA application in the context of their role and HSP.

6.3.3 Medicines/Drugs and Therapeutics Committees (MTC/DTCs) or equivalent authority responsible for local medicines governance.

MTC/DTCs are responsible for:

- Developing, maintaining and enacting robust and accountable IPA processes in the context of the local organisational structure, accountability frameworks and resourcing
- Governing the IPA processes at a site level
- Ensuring timely and reasonable review of all IPA applications
- Communicating local IPA processes and requirements with relevant stakeholders
- Supporting staff to follow local processes related to IPAs
- Working with the relevant CE to ensure all information related to IPAs is obtained, accurately stored, and accessed according to state, area, and local requirements.

6.3.4 Prescribers

Prescribers are responsible for:

- Considering the model of care and access implications of medication access via this mechanism
- Complying with site-level policy requirements associated with IPAs
- Being accountable for IPA applications and any subsequent requirements, e.g., outcome reporting
- Providing truthful and accurate information throughout the IPA process
- Declaring any conflicts of interest where applicable.

7.0 The Statewide IPA platform

The WA IPA System (WAIPAS) is the Department of Health-approved platform established in 2021 for the electronic management of IPAs.

Use of the WAIPAS will assist sites to meet the specific requirements of the [MP0077/18 Statewide Medicines Formulary Policy](#). Use of WAIPAS positively contributes to the quality use of medicines by creating a statewide repository of IPA data that has the potential to:

- Link IPAs with patient outcomes
- Provide an efficient paperless process for capturing IPA requests
- Improve data-sharing between HSPs and allow for more transparent IPA processes across the state
- Support reporting on the characteristics of IPAs from a System, HSP and local level
- Compile, store, and provide access to IPA information in a manner that complies with [MP 0015/16 Information Access, Use and Disclosure Policy](#)
- Assist with monitoring the use of non-formulary medications so that appropriate action can be taken to maintain the integrity of the SMF and ensure it reflects best practice.

8.0 Process and governance

For a visual summary of the IPA process, see [Appendix 2](#) – IPA process flowchart.

Recommendations surrounding a particular process are denoted by a box.

8.1 Application phase

8.1.1 Eligibility to apply for an IPA

As prescribers are responsible for the clinical management of their patients, they are best placed to submit IPA applications and be responsible for them.

Prescribers should be the only personnel that are eligible to apply for an IPA.

8.1.2 Restrictions on eligible applicants

Due to the clinical and financial risks involved with IPAs, sites may wish to place restrictions on the level of experience prescribers must have before they are eligible to submit IPAs.

Eligibility to submit IPA applications should be restricted to:

- Medical prescriber positions at or above a registrar level
 - Nurse practitioner and midwife prescribers
 - Other health practitioners with prescribing rights who are working within their scope of practice.

DTCs should determine if there should be additional restrictions placed on non-medical health practitioners submitting IPAs in the context of their prescribing rights and scope of practice within the relevant HSP.

If a DTC wishes to permit other staff to submit IPA applications outside of the above recommendations (e.g., intern prescribers, appropriate health practitioners requesting on behalf of senior medical staff), a risk assessment should be performed to identify and mitigate risks that may arise as a result this change.

8.1.3 Non-prescribers drafting and/or assisting with IPA applications

Depending on local resourcing, some hospital sites may permit non-prescribers with the ability to assist and/or draft IPA applications on behalf of a prescriber, who then reviews the content of

the application before formal submission to the DTC. While non-prescribers may support the creation of an IPA creation, the treating consultant maintains overall responsibility for the clinical management of their patient.

For example, pharmacists are well equipped to provide expert medication advice and may be closely involved with the patient's care by providing assistance in the development of an IPA application, where the prescriber maintains overall clinical responsibility for the patient.

If a DTC wishes to permit non-prescribers with the ability to assist/and or draft IPA applications of eligible applicants, a risk assessment should be performed to identify and mitigate risks that may arise as a result of this change.

8.1.4 Information captured by an IPA application

The information captured by an IPA application must be sufficient to enable the DTC to adequately assess the rationale, cost-efficacy, and safety for initiating the medication in question.

IPA applications should capture the information contained within [Table 1](#) at a minimum.

8.1.5 Urgent applications

There may be scenarios where an IPA application warrants immediate assessment. In these scenarios, the timely endorsement and assessment of IPA applications is imperative to minimise any delays to the commencement of treatment.

DTCs should have a clearly defined mechanism to expedite urgent applications in a manner that maintains the integrity of the assessment of the IPA application and adheres to the principles of the quality use of medicines.

This pathway should be clearly communicated to the appropriate stakeholders and in local IPA procedure documents.

This pathway should maintain compliance with all applicable policies, procedures, local risk assessment practices and the recommendations of this guideline.

Table 1 Minimum information captured by an IPA application

Information category	Information
Applicant details	Name Department Professional qualification (e.g., consultant, registrar) Email address
Endorsement details	Endorsement/ No Endorsement recorded Rationale for decision (where applicable) Endorser details (name, position, email address)
Patient details	Name UMRN Date of birth Gender Hospital Location Admission status (inpatient/outpatient)
Medication product details	Generic name Brand name (if clinically appropriate) Form Strength (solid dosage forms) OR Concentration (topical, parenteral, oral solutions) Therapeutic Goods Administration registration / Special Access Scheme status Pharmaceutical Benefits Scheme status
Treatment details	Dose Frequency Duration Route of administration Urgency of treatment
Cost details	Cost per dose Cost per treatment course (for defined treatment course) Cost per cycle (for cyclical treatment) Cost per year (for ongoing treatment)
Clinical details	Indication Relevant Medical history Past treatment(s) and outcome(s) Purpose/intent of requested treatment (e.g., curative, induce remission, ongoing symptomatic control)
Rationale	Supporting evidence Outcome measures or goals of therapy Anticipated impact on prognosis
Application outcome	Approval/rejection status Reason for rejection (if applicable) Approved treatment duration Approved treatment cost for specified duration Date of approval/rejection IPA expiry

8.2 Quality assurance phase

The quality assurance phase ensures that submitted IPA applications contain information of a sufficient quality and quantity. This allows the locally delegated authority to endorse, assess and decide the outcome of an application. Quality assurance reduces the likelihood of incomplete or insufficient applications being returned to the applicant and improves the timeliness and efficiency of the IPA process.

DTCs should implement a quality assurance phase for all IPA applications.

Quality assurance should be performed by the Executive Officer/Secretariat or other member of the DTC due to their close proximity to the IPA process.

Applications that require additional information should be returned to the applicant with clear and unambiguous instructions on what action needs to be taken to allow it to progress.

Those performing quality assurance should endeavour to support applicants in developing robust IPA applications within reason.

8.3 Endorsement phase

The endorsement phase formally documents the support from one or more senior staff members for an application to proceed to the assessment phase. The endorsement phase facilitates a robust IPA process by creating additional oversight that reduces risks and assesses the clinical and financial accountability of the IPA application. This may involve (but is not limited to) consultants, Heads of Service, Executive Directors, Finance Officers, or any other personnel deemed by the DTC to have appropriate authority.

DTCs should establish clear criteria for IPA application endorsement according to local requirements and relevant authorisations and delegations schedule. These criteria should specify:

- When an endorsement is required
- Why the endorsement is required
- Who is to provide the endorsement
- The timeline for endorsements/rejections.

Where appropriate, these criteria should be communicated to applicants.

Each IPA application should receive at least one endorsement.

There should be an opportunity for an endorser to declare any conflicts of interest when providing or declining endorsement.

Where an endorser has an actual or perceived conflict of interest relating to the IPA application, DTCs should provide another means of obtaining that endorsement from an appropriate person.

If an endorser declines the endorsement of an IPA application, clear and unambiguous rationale of the reason for this decision should be provided by the endorser and communicated to the applicant. In this scenario, the application should be returned to the applicant for amendment and resubmission if appropriate.

An example framework for endorsements is provided in Table 2 Example Framework for IPA Application Endorsements . Please note that this is provided for demonstrative purposes only.

Table 2 Example Framework for IPA Application Endorsements

Example Scenario	Suggested Endorser	Reason for Endorsement
The applicant is a registrar or nurse practitioner	<u>Inpatient</u> Consultant primarily responsible for patient’s care <u>Outpatient</u> : Consultant that the applicant reports to in the outpatient clinic.	Clinical oversight
<u>For a once-off treatment:</u> The cost of a single dose is over \$5,000	Person with appropriate authority as per relevant authorisations and delegations schedule	Financial oversight
<u>For a single course or one or more cycles:</u> The cost of a finite course or single cycle is over \$10,000	Person with appropriate authority as per relevant authorisations and delegations schedule	Financial oversight
<u>For ongoing treatment:</u> The cost of a year of treatment is over \$10,000	Person with appropriate authority as per relevant authorisations and delegations schedule	Financial oversight

8.4 Assessment Phase

The assessment phase is where the application is reviewed and a decision to approve, reject or request further information is made.

All IPAs should undergo review by a multidisciplinary DTC, with the outcome decided as per the DTC Terms of Reference. If no DTC is used (e.g., at smaller hospital sites), then at least two of the individuals responsible for IPA application decisions should discuss and decide on the outcome.

DTCs should establish procedures for the review of urgent IPAs, where it is not possible to delay review until the following DTC meeting (e.g., where delay in access to treatment can be detrimental for the patient). DTCs may adopt an out-of-session review process for urgent IPAs, where a nominated individual such as the DTC Chair, considers urgent IPAs on behalf of the DTC and decisions are tabled and minuted formally at the next DTC meeting.

DTCs should ensure that a consistent and justifiable approach is used to assess applications, that is proportional to the associated risks profile of the application.

8.4.1 Sites with limited resources and/or no DTC

Some sites may not have the ability to establish and maintain a DTC with a full complement of members due to organisation size, resourcing, or other factors. This will adversely impact on that site’s ability to oversee and assess IPA applications.

Establishment of a single HSP-wide DTC should be considered to minimise the impact of hospital resourcing (particularly at smaller hospital sites) on the ability to adhere to the recommendations of this guideline and to maximise the use of any resources allocated to this activity.

Resources proportional to the volume, urgency and relative risks associated with IPA applications should be allocated to the IPA application assessment process as to not compromise the ability for a robust review to take place.

8.4.2 Expiry dates

Expiry dates should be allocated for all IPAs to trigger a review of the use of the medication for which it was approved. Doing so ensures that the ongoing use of the medication is clinically and financially appropriate and allows DTCs to monitor for adverse events (including sentinel events) that may be associated with non-formulary prescribing.

All IPAs should be given a finite expiry date that corresponds with the clinical and financial contexts, and risk profile of the application.

The maximum expiry given to IPAs where an IPA for that medication was not previously granted should be no longer than 12 months.

8.4.3 Communication of IPA application decisions

The decision to approve or reject an application must be communicated to the appropriate personnel so that subsequent action(s) can occur.

DTCs should communicate the outcome of IPA application assessments in a timely, appropriate, and consistent manner that reaches the applicant, endorsers and any other stakeholders deemed appropriate.

Details of approved IPAs should be contained in the patient's medical record.

Details of approved IPAs should also be stored within the patient's notes section in the pharmacy dispensing software to facilitate timely medication supply using an established process for entering this information. Sites should also ensure that any information recorded in these locations (including new IPA approvals and renewals) is updated in a timely manner to guarantee that the most current information is available to stakeholders.

DTCs may consider mandating the use of templates to ensure IPA information is communicated in a consistent manner. See Appendix One for an example pharmacy dispensing software patient note template.

8.4.4 Appeals

There may be scenarios where an applicant does not agree with the decision to reject an IPA application. An appeals process provides applicants with a means of requesting that a decision is reconsidered.

There should be a means provided for applicants to appeal a decision to reject an IPA application.

DTCs should develop a robust and transparent pathway for this process which is clearly documented to maintain consistency and facilitate communication to stakeholders.

The appeal process should involve an appropriate level of independent review external to the DTC to uphold the principle of procedural fairness.

8.4.5 Minuting and ratification of decisions made

All IPA decisions should be minuted and ratified at a formal meeting of the DTC, with de-identified details available to other health professionals to view within the organisation, or at other hospital sites. Increased visibility of IPA decisions ensures that the governance of the IPA process and any decisions made are transparent. It also helps support other sites, where similar requests might be made by sharing information.

8.5 Post-approval phase

The post-approval phase refers to activities that occur from the date of IPA approval, including modifications to existing IPAs, outcome reporting requirements, and IPA renewals if ongoing therapy is required.

8.5.1 Modifications to an approved IPA

There may be instances where a prescriber wishes to modify the conditions of an IPA. This may include changes in the dose, frequency, or duration of treatment. Modifying any of these factors will influence the safety, cost, and evidenced-based nature of the treatment with the medication in question.

Any IPA modification that has potential to affect the safety, cost, or evidence-based nature of treatment with the medication in question, should undergo re-assessment by the DTC via the submission of a new IPA.

IPA applications that have resulted from a modification should undergo the same process as per the recommendations of this guideline.

8.5.2 Outcome reports

Outcome reports provide DTCs with a formal update on patient outcomes resulting from the use of an IPA-approved medication. It also provides justification for renewing an IPA for continued therapy, if required.

Outcome reports allow a repository of clinical evidence to be gathered that links IPAs with patient outcomes. As a result, DTCs and clinicians are better equipped to adequately assess the risks and benefits associated with the use of IPA-approved medications in past, present and future contexts.

The absence of outcome reports may put patients at risk of inappropriate treatment by withholding information pertaining to safety and efficacy that could justify the approval or rejection of future IPAs in similar clinical scenarios. Outcome reports may also provide additional real-world data to support the application and review of existing SMF restrictions by WAMEP.

Outcome reports should be provided at or before the expiry of all IPAs, regardless of whether treatment with the IPA-approved medication achieved the desired outcome(s).

Outcome reports should, at a minimum, contain sufficient detail on:

- Patient outcomes with specific reference to the outcome measures stated in the IPA application
- Any side effects or adverse events experienced by the patient that were confirmed or suspected to be caused by the IPA-approved medication
- Whether treatment should continue or cease.

MTC/DTCs should clearly specify the format in which outcome reports are to be presented and when these are to be provided.

MTCs/DTCs should develop processes for obtaining outcome reports in a timely manner.

8.5.3 IPA renewals

Applicants may wish to continue prescribing an IPA application after an IPA has expired. Before this occurs, an assessment should be conducted to ascertain if it is appropriate to continue treatment with the medication in question in the context of the justification provided in the initial approval and the resulting outcomes of treatment.

If an applicant wishes to renew an IPA, an outcome report should be provided before the request is considered.

Renewal of an IPA should be via submission of a new IPA to allow for ongoing assessment of the use of the relevant medication that considers potential differences in cost and availability of new evidence.

8.5.4 Supply of a medication where an IPA has expired

There may be instances where an IPA has expired, but there is a request to supply the corresponding medication. In these scenarios the safety and wellbeing of the patient must be maintained whilst balancing the need to consider outcomes in the context of the original IPA approval.

MTCs/DTCs should create a procedure for these scenarios that maintain the safety and wellbeing of the patient, consider the recommendations of this guideline, and complies with all applicable policies, procedures, and local risk assessment practices.

A single point of contact within the MTC/DTC should be established to allow staff to query these scenarios and obtain advice on how to proceed in a timely manner.

These instances should be recorded by the MTC/DTC or equivalent authority responsible for local medicines governance in a central register for quality improvement purposes.

These instances should be documented in the patient's notes within the pharmacy dispensing software to ensure there is a clear record of what occurred and assist with future dispensing.

Prescribers should be notified of these scenarios and requested to forward an outcome report and/or IPA renewal as soon as practicable.

Affected patients and/or carers should be included in conversations around these events if appropriate.

9.0 Management of IPA information

All information relating to IPAs is considered sensitive and should be treated appropriately.

MTCs/DTCs should ensure that IPA information is stored, accessed and disclosed in a manner that is compliant with [MP 0015/16 Information Access, Use and Disclosure Policy](#) and any relevant area or local policies, procedures or guidelines.

MTCs/DTCs should ensure that sufficient quality assurance processes are in place to facilitate the accurate capture of information relating to IPAs.

10.0 Reporting

10.1 State level

DTCs may be requested to provide the System Manager with data pertaining to IPAs where this information is not available via other legitimate means, as per [MP0077/18 Statewide Medicines Formulary Policy](#) and the [WA Statewide Medicines Formulary Guidelines](#).

MTCs/DTCs should establish processes for the timely supply of accurate IPA data to System Manager when requested.

MTCs/DTCs should be transparent in communicating any limitations in the provided data to the System Manager, within a reasonable time.

10.2 HSP/local-level reporting

Reporting on IPAs may be required at a HSP or local level. The requirement to report on IPAs may differ between HSPs and hospital sites.

MTCs/DTCs should establish processes that allow for the timely supply of accurate IPA data for HSP or local level reporting purposes.

MTCs/DTCs should endeavour to ensure that any reports provided to HSP/local personnel are accompanied by an appropriate level of commentary that explains the limitations of the data, if applicable. Doing so assists in mitigating the risk of data misinterpretation.

11.0 Definitions

Term	Definition
Clinical trial	Research investigations to test new treatments, interventions, or tests as a means to prevent, detect, treat or manage various diseases or medical conditions.
Drugs and Therapeutics Committee (DTC)	<p>A multidisciplinary committee with a commitment to the overall governance of the medicines management system in their health service organisation to ensure the judicious, appropriate, safe, effective and cost-effective use of medicines. DTCs/MTCs or an equivalent authority own the primary governance role in relation to the use of medicines at a local hospital or regional level.</p> <p>May also be known as the Medicines and Therapeutics Committee (MTC).</p> <p>For the purposes of this documents, DTC also refers to the delegated persons responsible for the relevant medicines management system where no DTC is present, e.g., in secondary metropolitan or regional hospitals.</p>
Endorsers	A person that provides support for (or “endorses”) an IPA application. This could be clinical or financial in nature. Endorsers are usually accountable for the nature of support they provide, e.g., financial endorsement being provided by a person with the appropriate authority to do so as per the relevant authorisations and delegation schedule for the projected value of an IPA.
Medication Access Program (MAP)	A collective term which describes initiatives offered by the pharmaceutical industry to facilitate deferred cost, cost-free or subsidised access to medicines. Such programs include Product Familiarisation Programs, Expanded Access Programs, Compassionately Supplied Medicines and Cost Share Programs.
Medicines and Technology Unit (MTU)	The Unit within the Patient Safety and Clinical Quality Directorate, Clinical Excellence Division of the Department of Health responsible for promoting the quality use of medicines and custodian of the Statewide Medicines Formulary policy.
Statewide Medicines Formulary (SMF)	The SMF is a list of approved medicines which can be initiated across the WA health system. The formulary includes details on the prescribing restrictions and requirements where applicable, available formulations and strengths, safety alerts and other relevant information for the medicine.
Western Australian Medicines Evaluation Panel (WAMEP)	The group who is responsible for developing and maintaining the SMF as per the MP0077/18 Statewide Medicines Formulary Policy .

12.0 Appendices

12.1 Appendix 1 – Template for pharmacy dispensing software patient note to document approved IPAs

Date: **[date of note]**

This patient has an IPA for: **[drug name and strength(s)]**

Dose: **[dose, frequency duration]**

Indication: **[indication]**

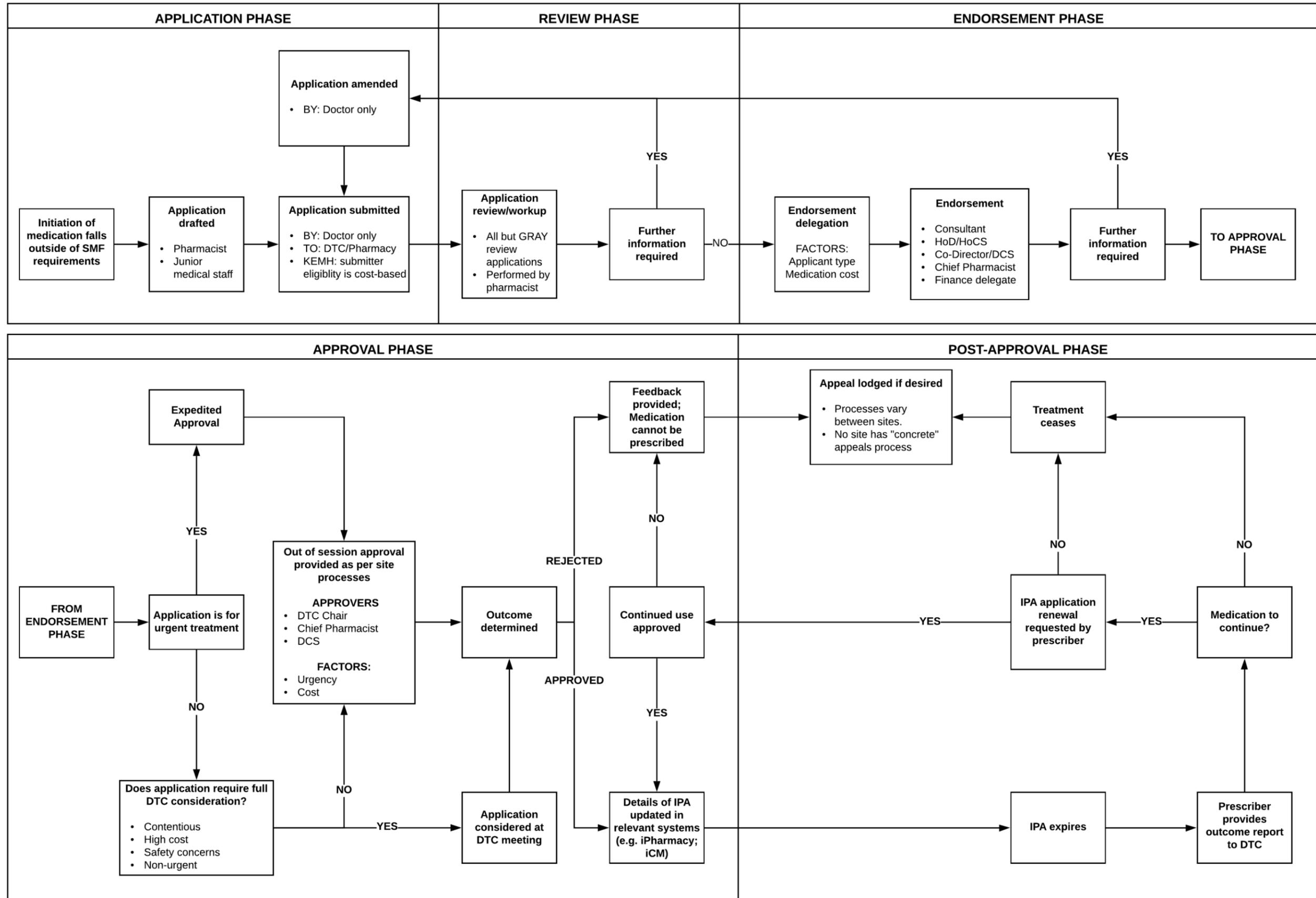
Prescriber: **[name of IPA applicant]**

Expiry Date: **[IPA expiry date]**

[Hospital/care group] DTC **[initials of author]**

For queries regarding this IPA contact **[DTC contact name]** on **[contact number and/or email]**

12.2 Appendix 2 – IPA Process Flowchart



**This document can be made available in alternative formats
on request for a person with disability.**

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