IPU Application Form

Use this form to apply for approval for hospital use of a medicine in an individual patient.

In most circumstances, a formal formulary submission will be required if a drug is used on an IPU basis in more than 3 patients. In such cases, the formulary submission form should be used instead of this form.

A. Patient details

Patient name	
MRN	
Date of Birth:	
Weight/ BSA* *For drugs dosed on a mg/kg basis or mg/m2	
Home Address	

B. Planned commencement date:

C. Product Profile

Active ingredient name(s)	
Trade / Brand Name	
Dosage Form(s) – provide full details	
Manufacturer/Supplier	
Pharmacological class and action (summary)	

D. Indication(s) for use

1. Is the drug approved by the Therapeutic Goods Administration for marketing in Australia? ☐**YES /** ☐**NO**
   a. If NO, what approval has been obtained for use?
      i. Special Access Scheme: ☐**Category A Approval |** ☐**Category B Approval |** ☐**Category C Approval |** ☐**19(5) Approval**
      ii. Clinical Trial - ☐**Attach copy of protocol and HREC approval**
      iii. Other: - ☐**Attach copy of this approval**

2. What are the proposed indication(s) for drug use in this patient?

   a. Is this is a TGA approved indication? ☐**YES /** ☐**NO**

3. Is the drug listed on the hospital formulary for other indications? ☐**YES /** ☐**NO**
   a. If YES, list current formulary approval (including restrictions):

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E. PBS Listing and Continuity of Supply

1. Has the drug been considered by the PBAC for the proposed indication for use? ☐**YES /** ☐**NO**
   a. If **YES**, are PBAC Public Summary Documents available? ☐**YES /** ☐**NO**

2. Is the proposed indication approved for subsidy under the PBS? ☐**YES /** ☐**NO**
   a. If **YES**: ☐General Benefit ☐Authority ☐Streamline Authority ☐Section 100

   b. If **NO**, explain implications for continuity of supply.
   (For example, will the drug be supplied for inpatient use, outpatient use or both? Will the hospital be required to provide ongoing therapy after discharge?)

F. Reasons for request and treatment details

1. Explain your reasons for wanting to use this drug.

2. Patient consent has been obtained and documented? ☐**YES /** ☐**NO**

3. Treatment details: Dosage, administration details, duration of treatment, concomitant therapy, etc.	
4. Treatment history: Describe previous therapy and outcomes.	
5. Alternative therapy: Describe therapy currently available for this indication (if not already described in treatment history).	
6. Monitoring requirements: Describe the objective criteria that will be used to monitor effectiveness.	

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G. Treatment Endpoints

Provide details of proposed treatment endpoints and timepoints.

H. Efficacy and Safety

- When applications are for TGA approved indications the Product Information sheet may provide some of the information below
- For drugs that have been considered by the PBAC for the proposed indication, the Public Summary Documents should be provided (*where available*)

Efficacy: Provide a summary of the evidence for efficacy of this drug for this indication. Indicate the level of evidence*****.	
Safety: Provide a summary of the evidence for safety of this drug for this indication. Indicate level of evidence*****.	

☐ **Attach relevant supporting documentation (published papers etc.)**

- *Literature references should cite the primary clinical trial(s)*

Grading for Level of Evidence*

Level I	Evidence obtained from systematic review of all relevant randomised controlled trials
Level II	Evidence obtained from one or more well-designed, randomised controlled trials
Level III	Evidence obtained from well-designed, non-randomised controlled trials, or from well designed cohort, case control or interrupted time series studies
Level IV	Case series with either post-test or pre-test/post-test outcomes

* From NHMRC additional levels of evidence and grades for recommendations for guideline developers (2009)
https://www.nhmrc.gov.au/sites/default/files/images/NHMRC%20Levels%20and%20Grades%20(2009).pdf

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I. Financial Implications

Provide an estimate of cost of the proposed treatment course using the table below

a. Average dose per day	
b. Duration of treatment in days	
c. Total number of dosage units per day	
d. Cost per dosage unit	$
e. Cost per treatment course *(b x c x d)*	$
f. Additional costs per patient per course *(e.g. additional drugs, monitoring requirements, etc.)*	$
g. Total cost of treatment course per patient *(e + f)*	**$**
h. Total annual cost of treatment per patient for chronic treatment (where applicable)	**$**
i. Total cost per course of current therapy (where applicable)	**$**

Provide an estimate of any cost savings (and details) as a result of commencing the proposed treatment

Are there any resource allocation implications for other services (e.g. Need for Infusion Lounge, manufacturing by Pharmacy)? If YES, then please obtain sign-off by relevant Service Managers.

Service Affected			
Name		Position	
Signature		Date	

J. Details of applicant

Requested by

Name of Applicant			
Position / Appointment			
Signature		Date	

Endorsed by

Name of Unit Head			
Position / Appointment			
Signature		Date	

K. Conflicts of interest

Financial or other interests resulting from contact with pharmaceutical companies, which may have a bearing on this submission:

☐ Gifts
☐ Travel expenses
☐ Samples
☐ Industry paid food/refreshments
☐ Honoraria
☐ Research support
☐ Nil conflict of interest
☐ Other support (describe)

L. Submission checklist

Tick

☐ All sections of form completed (including endorsement)
☐ Supporting data attached (relevant clinical papers, consensus guidelines, etc.)
☐ Prescribing criteria / protocol / guideline attached (if applicable).

For questions or discussions regarding this application, the Pharmacy Department may be contacted via:

Phone: _____

Email: _____

►►Forward completed form to the Pharmacy Department

For Drug and Therapeutics Committee Use Only

Comparative Approvals:

1. Has this drug been considered for formulary approval by other DTCs in NSW hospitals? ☐**YES /** ☐**NO**
   a. **If YES, list relevant DTCs and their decisions.**
   (Refer to NSW TAG or NSW TAG Decision-Making Registers http://www.nswtag.org.au/dtc-decision-making-registers/)

2. Does the product have a patient information such as a CMI suitable for use in Australia? ☐**YES** / ☐**NO**

3. Has a medication safety risk assessment been undertaken (packaging, labelling etc.)? ☐**YES /** ☐**NO**

4. Is it a hazardous substance? ☐**YES /** ☐**NO**
   a. If YES, has a risk assessment been completed? ☐**YES /** ☐**NO**

Outcome of application process:

Process	**Date / Details / Notes**
Application received *(Date received by DTC secretary)*	
Application considered *(DTC meeting date)*	
Outcome:	☐ Approved ☐ Rejected ☐ Deferred
Conditions of approval *(Specify restrictions)*	
Follow up report required	☐ **YES /** ☐ **NO**
Agreed monitoring/outcomes measures of treatment	
Follow up report due (date)	
Approval review date *(if applicable)*	
Applicant advised of outcome *(Date)*	
It is recommended that the outcome of an IPU application (including non-approval) and the supporting reason(s) is routinely documented in a consistent place that is accessible to all relevant clinicians.	

Approved by:

Signed on behalf of *Drug and Therapeutics Committee*	
Name	
Date	

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