

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(s) (Australian Approved Name) | |
| Trade Name | |
| Dosage Form(s) – provide full details | |
| Manufacturer/Supplier | |
| Pharmacological class and action (summary) | |

D. Indication(s) for use

Is the drug approved by the Therapeutic Goods Administration for marketing in Australia? **YES / NO**

If NO, what approval has been obtained for use?

Special Access Scheme: Category A Approval | Category B Approval | Category C Approval | 19(5) Approval

Clinical Trial **Attach copy of protocol and HREC approval**

Other _____ **Attach copy of this approval**

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

Is this a TGA approved indication? **YES / NO**

Is the drug listed on the hospital formulary for other indications? **YES / NO**

If **YES**, list current formulary approval (including restrictions):

E. PBS Listing and Continuity of Supply

Has the drug been considered by the PBAC for the proposed indication for use? **YES / NO**

If **YES**, are PBAC Public Summary Documents available? **YES / NO**

Is the proposed indication approved for subsidy under the PBS? **YES / NO**

If **YES**: General Benefit Authority Streamline Authority Section 100

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

Explain your reasons for wanting to use this drug.

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

G. Treatment Endpoints

--Provide details of proposed treatment endpoints and timepoints.

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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*)

| | |
|---|--|
| <p>Efficacy:</p> <p>Provide a summary of the evidence for efficacy of this drug for this indication.</p> <p>Indicate the level of evidence*.</p> | |
| <p>Safety:</p> <p>Provide a summary of the evidence for safety of this drug for this indication.</p> <p>Indicate level of evidence*.</p> | |

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/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf

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 ($b \times c \times d$) | \$ |
| f. Additional costs per patient per course (eg 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

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| |
|--|

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 | |

Conflicts of interest

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

- | | |
|---|--|
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Industry paid food/refreshments |
| <input type="checkbox"/> Travel expenses | <input type="checkbox"/> Honoraria |
| <input type="checkbox"/> Samples | <input type="checkbox"/> Research support |
| <input type="checkbox"/> Other support (describe) | |

K. Now complete checklist ►

Tick

- | | |
|--|--------------------------|
| All sections of form completed (including endorsement) | <input type="checkbox"/> |
| Supporting data attached (relevant clinical papers, consensus guidelines, etc) | <input type="checkbox"/> |
| Prescribing criteria / protocol / guideline attached | <input type="checkbox"/> |

► **Forward completed form to the Pharmacy Department**

| |
|---|
| For Drug and Therapeutics Committee Use Only |
|---|

Comparative Approvals:

Has this drug been considered for formulary approval by other DTCs in NSW hospitals? **YES / NO**

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/>)

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

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

Is it a hazardous substance? **YES / NO**

If YES, has a risk assessment been completed **YES / NO**

J. Outcome of application process:

| Process | Date / Details / Notes |
|---|------------------------|
| Application received (<i>Date received by DTC secretary</i>) | |
| Application considered (<i>DTC meeting date</i>) | |
| Outcome: π Approved π Rejected π Deferred | |
| Conditions of approval (<i>Specify restrictions</i>) | |
| Follow up report required | YES / NO |
| <i>Agreed monitoring/outcomes measures of treatment</i> | |
| <i>Follow up report due (date)</i> | |
| Approval review date (<i>if applicable</i>) | |
| Applicant advised of outcome (<i>Date</i>) | |
| <i>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.</i> | |

Signed on behalf of Drug and Therapeutics Committee

Name

Date