

Formulary Submission Form

Use this form to apply for:

- Approval for a new drug (or new presentation) to be added to the formulary, or
- Approval for variation to an existing formulary listing, or
- Approval for use of a drug under other circumstances (eg familiarisation program).

For approval to use this drug on an individual patient basis, use the [IPU application form](#).

Product Profile

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

Indication(s) for use

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

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

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

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

PBS Listing

Is the drug listed as a benefit under the Pharmaceutical Benefits Scheme? **YES / NO**

If **YES**: Section 85? **Yes / No** Section 100? **Yes / No**

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

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

Reasons for Request

- | | |
|---|---|
| <ul style="list-style-type: none"> (i) Addition to the formulary (ii) Change in formulary approved use (iii) Addition of new form or presentation of existing formulary product (iv) Other (eg familiarisation program) | <p>Tick</p> <ul style="list-style-type: none"> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
|---|---|

Explain your reasons for wanting to use this drug.

<p>Treatment details:</p> <p>Recommended dosage, administration details, duration of treatment etc</p> <p>List drugs recommended for co-administration or used in combination.</p>	
<p>Relevant comparator(s):</p> <p>Describe the therapy currently used for this indication, if any.</p> <p>If this drug is added to the formulary, which drug(s) should be deleted?</p>	
<p>Monitoring requirements:</p> <p>Describe the objective criteria that will be used to monitor effectiveness.</p>	
<p>Proposed place in therapy:</p> <p>Describe investigations necessary for patient selection and treatment.</p> <p>Which patient groups are most likely to benefit?</p> <p>Will this drug be used as first, second or third-line therapy?</p> <p>What prescribing restrictions should be in place (eg medical officers authorised to prescribe)?</p>	

Attach details of proposed prescribing criteria, guidelines and/or protocols (see [prescribing protocol template](#) for guidance about the details required).

Other supporting documentation should also be attached (eg consensus guidelines, approval by overseas agencies, published data, clinical trial data, etc).

Comparative Safety and Efficacy

Include names of comparators. If necessary, attach additional information as a separate document.

Significant side effects*	New drug:	Current therapy:
<p>Common: <i>(ie incidence of 1% or more)</i></p> <p>Infrequent: <i>(ie incidence between 0.1% and 1%)</i></p> <p>Rare: <i>(ie incidence less than 0.1%)</i></p>		

Main benefit in Safety*	New drug:	Current therapy:
<p>Incidence of main adverse event expressed as a percentage. <i>Specify (eg stroke, mortality, allergic reaction, etc).</i></p> <p>Level of evidence (see page 5)</p>	%	%

Main benefit in Effectiveness*	New:	Current:
<p>Incidence of main effectiveness outcome measure expressed as a percentage. <i>Specify outcome measure (eg cure rate, relapse rate) and whether measure represents a surrogate marker or an actual health outcome.</i></p> <p>Level of evidence (see page 5)</p>	%	%

Additional benefits*		
<p><i>Specify (eg surgery or procedure averted, admission averted, reduced length of stay, etc).</i></p>		

* Reference the sources used for above data. Literature references should cite the primary clinical trial(s).

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) | |

Now complete checklist ►

- All sections of form completed (including endorsement)
- Supporting data attached (relevant papers, consensus guidelines, etc)
- Prescribing criteria / protocol / guideline attached

Tick

-
-
-

► *Forward completed form to Pharmacy*

Grading for Level of Evidence*

- Level I Evidence obtained from systematic review of 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 interim levels of evidence 2005: www.nhmrc.gov.au/publications/_files/levels_grades05.pdf

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. (NB: Information available via NSW TAG)

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: <input type="checkbox"/> Approved <input type="checkbox"/> Rejected <input type="checkbox"/> Deferred	
Conditions of approval <i>(Specify restrictions)</i>	
Approval review date <i>(if applicable)</i>	
Applicant advised of outcome <i>(Date)</i>	

Signed on behalf of Drug and Therapeutics Committee: _____

Date: _____