Use this form to apply for approval for use of a non-formulary medicine in an individual patient, or for use of medicine outside of the formulary restrictions.

In most circumstances, a 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**](http://sesiweb/Area%20Governance%20System/Clinical/Nursing_and_Midwifery_Services/Forms/Area-Form-F188-FormularySubmssionForm.pdf) should be used instead of this form.

**Please complete all required fields of this form electronically. Incomplete or handwritten forms will not be accepted.**

**Priority**

|  |
| --- |
| NOT URGENT: review at next Drug and Therapeutics Committee meeting ☐  URGENT: within 24 hours  within 1 to 3 working days  within 4 to 7 working days  **Please justify reason for clinical urgency:** |

**Patient details**

Patient name:       MRN:

Date of Birth:        Weight:

Location (hospital/ward/clinic):

Is this patient’s area of residence outside SESLHD?

**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

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

|  |
| --- |
|  |

Is the drug approved by the Therapeutic Goods Administration (TGA) for marketing in Australia?

**YES**  **NO**

Is this is 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):

|  |
| --- |
|  |

PBS Listing

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

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

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?

|  |
| --- |
|  |

# Outcome/date of PBAC considerations for this indication:

<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/public-summary-documents-by-product>)

|  |
| --- |
|  |

# Treatment details

|  |  |
| --- | --- |
| **Treatment details:**  Proposed dosage, route, frequency |  |
| **Concomitant therapy**: |  |
| **Previous treatment:**  Describe previous treatments used and outcomes (including non-medication treatments e.g. surgery) |  |
| **Alternative treatments:**  What alternative treatment options are available? If not appropriate, please explain why not. |  |
| **Reasons for request:**  Why do you want to use this drug and what benefit do you expect for the patient? |  |
| What are the expected outcomes from the use of the drug? | Improved quality of life  **YES**  **NO**  Prolonged survival  **YES**  **NO**  Cure  **YES**  **NO** |
| Estimated probability of the expected outcome based on literature |  |
| **Measurement of treatment outcomes:**  What objective measures will be used to monitor the outcomes of treatment e.g. pathology results. How often? |  |
| What subjective measures will be used to monitor the outcomes of treatment e.g. quality of life measures. How often? |  |
| **Treatment end point:**  Detail expected clinical outcome and anticipated length of treatment |  |

*Note: Outcome measures will be reported back to the approving authority/Committee by the applicant. Reporting frequency will be determined and communicated at the time of approval.*

# Patient goals How does the proposed treatment align with the patient’s goals, values and preferences?

|  |
| --- |
|  |

What are the potential burdens to the patient in using this drug?

Additional time in hospital

Time in outpatients

Invasive procedures

Monitoring

Requirement for the patient learn new skills

|  |
| --- |
| **Details** |

Have you informed the patient (or the person responsible) about the risks and benefits of the proposed treatment?  **YES**  **NO**

Do you agree to obtain written, signed consent to treatment if approved?

**YES**  **NO**  **N/A**

*Please enclose a draft (unsigned) copy of Consent for Exceptional Use of Medicine Form (Form SEI020.025) with this application (note: consent is not required for TGA-licenced indications)*

# Efficacy and Safety

|  |  |
| --- | --- |
| **Efficacy:**  Provide a summary of the evidence for efficacy of this drug for this indication. |  |
| Please include explanation of the following (as relevant):   * The proposed dose, frequency and route if varying from the literature |  |
| * The efficacy of this drug compared to alternative treatments |  |
| * Factors which may affect efficacy in this individual patient |  |
| Indicate level of evidence (see below) |  |
| **Safety:**  Provide a summary of the evidence for safety of this drug for this indication. |  |
| Please include explanation of the following (as relevant):   * The risks of the drug to this individual patient |  |
| * Safety compared to alternative treatments |  |
| * Factors which may affect safety in this individual patient |  |
| Indicate level of evidence (see below) |  |

# 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 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).

# Attach details of proposed protocol and/or relevant supporting documentation (published data etc).

List documentation included:

|  |
| --- |
|  |

**Financial implications:**

Proposed funding source:

Departmental budget

Medicines Access Program (MAP) e.g. Patient Familiarisation, Compassionate Access Scheme\*

Patient self-funding

Other

|  |
| --- |
| **Details** |

*\*For MAPs please attach details of the agreement to this application*

Provide an estimate of cost using the table below. **The actual cost of the medicine should be provided regardless of funding source.**

|  |  |
| --- | --- |
| a. Dose and frequency |  |
| b. Duration of treatment course |  |
| c. Total number of dosage units per treatment course |  |
| d. Cost per dosage unit | $ |
| e. Cost per treatment course *(c x d)* | $ |
| f. Additional costs *(other drugs, monitoring, etc)* | $ |
| g. Total cost of treatment course *(e + f)* | $ |
| h. Total annual cost for chronic treatment | $ |
| Total cost of current/alternative therapy | $ |
| Details of any anticipated savings or cost offsets if the treatment is successful |  |
| Any resource implications for other services?  *(eg. Infusion lounge booking, pharmacy manufacture)* |  |

**If the medicine is not being fully funded under a MAP and the cost is >$10,000 per annum or per treatment course, approval from General Manager and SESLHD Quality Use of Medicines Committee is required.**

# Third party interests

The following financial or other interests resulting from contact with pharmaceutical companies may have a bearing on this submission:

None

Gifts  Industry paid food/refreshments

Travel expenses  Honoraria

Samples  Research support

Other support (describe)

Please describe any other dualities or conflicts of interest relating to this submission:

# Requested by

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Applicant |  | | |
| Position / Appointment |  | | |
| Contact Details  (email, telephone) |  | | |
| Signature |  | Date |  |

# Endorsed by (Head of Department)

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | | |
| Position / Appointment |  | | |
| Contact Details  (email, telephone) |  | | |
| Signature |  | Date |  |

**General Manager / Budget Holder Approval** (Note: General Manager must approve if cost >$10,000)

|  |  |  |  |
| --- | --- | --- | --- |
| Comments | | | |
| Name |  | | |
| Signature |  | Date |  |

**Now complete checklist** ► **Tick**

All sections of form completed (including signatures)

Supporting data attached (relevant clinical papers, consensus guidelines, etc)

Prescribing criteria / protocol / guideline attached

Draft patient consent form attached

Details of Medicines Access Program attached

►*Forward completed form to local Pharmacy Department.*

*If >$10,000, Pharmacy will forward to SESLHD Quality Use of Medicines (QUM) Committee*

**For Drug and Therapeutics Committee Use Only**

Reference Number:

Comparative approvals (other hospitals):

Outcome of application process:

|  |  |
| --- | --- |
| **Process** | **Date / Details / Notes** |
| Application received  *By/date* |  |
| Application considered  *By/date* |  |
| Clinical benefit rating\* | High  Medium  Low |
| Cost rating\* | High  Medium  Low |
| Outcome: | Approved  Rejected  Deferred |
| Conditions of approval  *(Specify restrictions)*  or  Reason for rejection/deferral |  |
| Approval review date  *(if applicable)* |  |
| Applicant advised of outcome  *(Date)* |  |

Signed on behalf of Drug Committee:

Date:

Comments:

## \* Rating score used by QUM Committee for high cost / complex applications only