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 goalsHow 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