Use this form to apply for:

* Approval for a new drug to be added to the formulary
* Approval for variation to an existing formulary listing
* 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**](http://sesiweb/Area%20Governance%20System/Clinical/Nursing_and_Midwifery_Services/Forms/Area-Form-F188-FormularySubmssionForm.pdf).

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

**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 this hospital?

|  |
| --- |
|       |

Is this is a TGA approved indication? **[ ]  YES [ ]  NO**

List any current or previous SESLHD formulary approvals for this product:

|  |
| --- |
|       |

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**

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?)

|  |
| --- |
|       |

# Outcome/date of PBAC considerations for this indication:

|  |
| --- |
|       |

# Reasons for request

1. Addition to the formulary **[ ]**
2. Change in formulary approved use **[ ]**
3. Other (eg familiarisation program) **[ ]**

# Explain your reasons for wanting to use this drug – include clear definition of the patient population or setting in which drug use will occur.

|  |
| --- |
|       |

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

# 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](http://www.nhmrc.gov.au/publications/_files/levels_grades05.pdf)

# Comparative Safety and Efficacy

**Comparative safety:** (include names of comparators, if necessary attach additional information as a separate document)

|  |  |  |
| --- | --- | --- |
| **Adverse effects\*** | **New drug** | **Current therapy** |
| **Common** (incidence 1% or more)**Infrequent** (incidence 0.1% to 1%)**Rare** (incidence <0.1%) |       |       |

|  |  |  |
| --- | --- | --- |
| **Safety\*** | **New drug** | **Current therapy** |
| Incidence of significant adverse events expressed as a percentage.*Specify (eg stroke, mortality, allergic reaction etc)*Level of Evidence(see page 3) |      % |      % |

**Comparative efficacy**: (include names of comparators, if necessary attach additional information as a separate document)

|  |  |  |
| --- | --- | --- |
| **Effectiveness\*** | **New drug** | **Current therapy** |
| Incidence of main effectiveness outcome expressed as a percentage.*Specify outcome measure (eg cure rate, relapse rate) and whether measure represents a surrogate marker or an actual health outcome.*Level of Evidence(see page 3) |      % |      % |

|  |  |  |
| --- | --- | --- |
| **Additional Benefits\****Specify (eg surgery or procedure averted, admission averted, reduced length of stay etc)* |      % |      % |

**\*Reference the sources used for the data above including the primary clinical trial(s)**

**Issues Regarding Safe Handling**

|  |
| --- |
| **Product packaging and labelling**e.g. Is product nomenclature likely to lead to confusion in selection?      Is packaging clearly labelled?      Is each dosing unit labelled in such a way to allow identification up to the point of administration?      Does packaging facilitate clear and practical storage?      Is appropriate Consumer Medicines Information available?      **Administration**e.g. Are physical incompatibilities likely in the administration of the product?      Are there potential adverse events associated with administration techniques?      Are there any safety implications of product preparation and/or administration requirements?     **Other**e.g. Staff education required, OH&S issues      |

**Supporting Documentation**

Supporting documentation should be attached to this application (e.g. consensus guidelines, approval by overseas agencies, published data, clinical trial data etc.)

**List documentation provided:**

|  |
| --- |
|       |

**Comparative costs of drug treatments:**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Names of comparator drugs:*** | **New** | **Current (1)** | **Current (2)** |
| a. Average dose per day |       |       |       |
| b. Average duration of treatment in days |       |       |       |
| c. Average number of dosage units per day |       |       |       |
| d. Cost per dosage unit | $      | $      | $      |
| e. Cost per standard course *(b x c x d)* | $      | $      | $      |
| f. Additional costs per patient per course *(eg additional drugs, monitoring requirements etc)* | $      | $      | $      |
| g. Total annual cost per patient *(e + f)* | $      | $      | $      |
| h. Expected number of patients per year *(indicate the basis for this estimate)* |       |       |       |
| i. Annual cost *(g x h)* | $      | $      | $      |
| j. Difference *(new cost – current cost)* | $      | $      |
| Cost offsets if the new drug were introduced:      |
| Proposed source of funding:      |

# Proposed prescribing protocol:

# (This section forms the basis of the SESLHD protocol document to be published on SESLHD intranet. This section MUST be completed accurately and in full before this application will be considered)

|  |  |
| --- | --- |
| Prescribing Protocol Title |       |
| Areas where Protocol appliese.g. District, Hospital, Clinical Area |       |
| Areas where Protocol NOT applicable |       |
| Authorised Prescribers |       |
| Indication for Use |       |
| Clinical Conditions and Patient Selection: Inclusion criteria (include investigations necessary and relevant results) |       |
| Proposed Place in TherapyState whether drug to be used as first, second or third-line. When not first line, describe therapies to be used first (consider using algorithm) |       |
| If part of combination therapy, list other drugs |       |
| Contraindications |       |
| Precautions |       |
| Dosage(include dosage adjustment for specific patient groups) |       |
| Duration of Therapy |       |
| Important Drug Interactions |       |
| Administration Instructions (For review by Pharmacy Departments) |       |
| Monitoring Requirements:SafetyEffectiveness (state objective criteria) |       |
| Management of Complications |       |
| Basis of Protocol:(including sources of evidence, references) |       |
| Consultation |       |

# Conflicts of interest

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

[ ]  Gifts [ ]  Industry paid food/refreshments

[ ]  Travel expenses [ ]  Honoraria

[ ]  Samples [ ]  Research support

[ ]  None [ ]  Other support (describe)

**Other contributors** to this submission (Names and Profession):

|  |
| --- |
|       |

# Details of applicant

# Requested by:

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

# Endorsed by:

|  |  |
| --- | --- |
| Name of Unit Head |       |
| Position / Appointment |       |
| Contact Details(Postal address, email, telephone) |       |
| Signature |       | Date |       |

**Now complete checklist** ► **Tick**

All sections of form completed [ ]

Proposed prescribing protocol completed in full [ ]

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

► ***Forward for Clinical Stream Consultation***

**Details of Clinical Stream Consultation**

|  |  |
| --- | --- |
| Clinical Stream |       |
| Peers consulted |       |
| Stream comments and recommendations | Impact on other drug utilisation:      |
| Impact on resources in other therapeutic areas:      |
| Policy implications:      |
| Overall recommendation for formulary listing:      |
| **Name** (Director/Manager) |       |
| **Signature**  |       | **Date**       |  |

►***Forward completed form to Quality Use of Medicines Committee Secretariat:***

**SESLHD-DrugCommittee**

 **For Quality Use of Medicines Committee Use Only**

## Reference Number:

## 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)

|  |
| --- |
|       |

**Clinical Stream /Service consultation required** YES ***[ ]***  NO ***[ ]***

|  |
| --- |
| Details:      |

Outcome of application process:

|  |  |
| --- | --- |
|  **Process** | **Date / Details / Notes** |
| Application received*(Date received by QUMC)* |       |
| Application considered*(QUMC meeting date**and agenda item number)* |       |
| Outcome: |  Approved Rejected Deferred |
| Conditions of approval*(Specify restrictions)*orReason for rejection/deferral |       |
| Approval review date*(if applicable)* |       |
| Applicant advised of outcome*(Date)**Copies to:* |       |
| Prescribing Protocol review and approval byAuthorQUMCDate published |       |

Signed/completed on behalf of Quality Use of Medicines Committee:

Date: