Use this form to apply for approval for a drug to be added to the formulary for administration in ambulatory care settings, where the drug is funded via the Pharmaceutical Benefits Scheme (PBS)

For approval to prescribe this drug outside of PBS approved indications or in non-ambulatory care settings use the [**Formulary Submission Form**](http://seslhnweb/Forms_and_Templates/Forms/Drug_Committee/SESLHDDistrictFormF021FormularySubmissionForm.docx) or [**Individual Patient Use Application Form**](http://seslhnweb/Forms_and_Templates/Forms/Drug_Committee/SESLHDDistrictFormF020IPUApplicationForm.docx)

**Product Profile**

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

PBS Listing

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

If no, complete [Formulary Submission Form](http://seslhnweb/Forms_and_Templates/Forms/Drug_Committee/SESLHDDistrictFormF021FormularySubmissionForm.docx)

# List PBS-approved indications:

**Issues Regarding Safe Handling**

|  |
| --- |
| **Product packaging and labelling**  Is product nomenclature likely to lead to confusion in selection?  Is packaging clearly labelled to facilitate safe administration?  Is appropriate Consumer Medicines Information available?  **Administration**  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 |

# Proposed prescribing protocol:

# (This section MUST be completed accurately and in full before this application will be considered)

|  |  |
| --- | --- |
| Prescribing Protocol Title |  |
| Areas where Protocol applies  *e.g. Ambulatory Care* |  |
| Areas where Protocol NOT applicable  *e.g. Inpatient settings* |  |
| Authorised Prescribers |  |
| Indication for Use  *(Specify PBS criteria)* |  |
| Clinical Conditions and Patient Selection: Inclusion criteria  *(include investigations necessary and relevant results)* |  |
| Place in Therapy  *State 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 |  |
| Monitoring Requirements:  *Safety*  *Effectiveness* |  |
| Management of Complications |  |
| Practice Points  *e.g. patient education, handling requirements* |  |
| 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

►***Forward completed form to facility pharmacy department***

Prescribing protocol checked and endorsed

***►Pharmacy to forward to*** [***Quality Use of Medicines Committee Secretariat***](mailto:SESLHD-DrugCommittee%20%3cSESLHD-DrugCommittee@health.nsw.gov.au%3e)

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

## Reference Number:

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)*  or  Reason for rejection/deferral |  |
| Approval review date  *(if applicable)* |  |
| Applicant advised of outcome  *(Date)*  *Copies to:* |  |
| Prescribing Protocol  Date published |  |

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

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_