***Formulary Amendment Form***

***(For use with Existing Formulary-Approved Medicines Only)***

# A. Introduction

This form only applies to a medicine that is already approved for inpatient/day surgery use or has PBS approval for the new indication.

|  |  |  |
| --- | --- | --- |
| **Application type\*** | **Tick which is applicable, both may be applicable** | **Complete** |
| **Request a new formulation** of an existing formulary medicine to be added to formulary |  | Sections B, C, E, F, G, H |
| **Request to modify/add indications and/or prescribers for an existing formulary listing**  (e.g. adding PBS indications and/or changing prescriber restrictions) |  | Sections B, D, E, F, G, H |

\* If both application types, complete all Sections B-H.

For requests to add drugs approved for reimbursement under Section 100, use the relevant customised [Formulary Form](https://www.nswtag.org.au/evaluating-new-drugs/)

For all other Formulary requests, use the [Formulary Submission form](https://www.nswtag.org.au/evaluating-new-drugs/)

For approval to use this drug on an individual patient basis, use the [IPU application form](https://www.nswtag.org.au/evaluating-new-drugs/)

# B. Profile of Currently Approved Medicine

|  |  |
| --- | --- |
| **Active Ingredient Name(s)** |  |
| **Trade/Brand Name** |  |
| **Medicine Formulation(s) currently approved on formulary** |  |
| **List current formulary approval (including restrictions)** |  |
| **Is the medicine used for** | inpatients/day procedures only  outpatients only\*  both inpatients and outpatients\* |

\*If, for outpatient and not subsidised by PBS**,** use the [Formulary Submission form](https://www.nswtag.org.au/evaluating-new-drugs/)

# C. Request to add new formulation

|  |  |
| --- | --- |
| **What is the proposed new formulation?** |  |
| **Trade/Brand name** |  |
| **What is the recommended dose? Please indicate whether it is different to current formulation in use.** |  |

1. **What are the perceived advantages of the new formulation?**

|  |
| --- |
|  |

**2. Is the proposed use for the new formulation (e.g. indications, prescribers) the same as the current approved formulation?**

YES

NO If NO, also complete Section D.

**3. Is it proposed the old formulation(s) be removed from formulary?**

YES

NO

**4. If the new formulation is added to formulary, will there need to be a change in local documents e.g. guidelines, protocols, standing orders?**

YES, please provide more details below  NO  NOT KNOWN

|  |
| --- |
|  |

# D. Request to modify indications and/or prescribers

**1. What/who are the proposed new indication(s) and/or prescribers?**

|  |  |  |
| --- | --- | --- |
| **Proposed modification** | **Tick whichever is applicable (both may be applicable)** | **Detail proposed change** |
| ***Change to indications*** |  | Are the new indication(s) PBS-approved? Y / N  Is the medicine for inpatient or day procedure use only? Y / N |
| ***Change to prescribers*** |  | If applicable, do the proposed prescribers(s) meet PBS criteria? Y / N  Should any existing prescriber group(s) be removed? Y / N |

**2. What are the perceived advantages to modifying indications and/or prescribers?**

|  |
| --- |
|  |

**3. If the proposed change(s) are added to formulary, will there need to be a change in local documents e.g. guidelines, protocols, standing orders?**

YES, please provide more details below  NO  NOT KNOWN

|  |
| --- |
|  |

# E. Financial Implications

What are the comparative costs of proposed therapy changes versus current therapy)? (Current prices can be obtained from Pharmacy)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Therapy | Cost/patient/day (a) | Volume of use (patient numbers/ day) (b) | Duration (days)  (c) | **Total cost [(a x b) x c]** |
| *Proposed therapy* |  |  |  |  |
| *Current therapy* |  |  |  |  |
| *Other current therapy, if applicable* |  |  |  |  |

List any other cost implications or advantages (including drugs which may be replaced; need for training; use of other devices).

|  |
| --- |
|  |

# F. Safety Implications

List any medication safety implications, including design of packaging that may occur with proposed formulary amendment

|  |
| --- |
|  |

# G. Conflicts of Interest

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

Gifts

Travel expenses

Samples

Industry paid food/refreshments

Honoraria

Research support

Nil conflict of interest

Other support (describe below)

|  |
| --- |
|  |

# H. Approval process

**The following must be completed prior to submitting application to the DTC**

**Details of Applicant making the request**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Applicant |  | | |
| Position / Appointment |  | | |
| Signature |  | Date |  |
| E-mail address for  correspondence |  | | |
| Phone number |  | | |

**Endorsed by**

(Must be completed by Head of Unit/Manager of Department)

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Unit Head/  Manager of Department |  | | |
| Position / Appointment |  | | |
| Signature |  | Date |  |

# H. Submission

Forward completed form to the Pharmacy department with supporting data and relevant protocol/guideline (if applicable).

For questions or discussions regarding this application, the Pharmacy Department may be contacted via:

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* + *Forward completed form to the Pharmacy Department*

**For Drug and Therapeutics Committee Use Only**

# Check List (New Formulation)

Drug already on Formulary for indications requested

No significant cost implications

No significant safety implications

Inpatient use only or ongoing supply available via PBS

# Check List (New indications/prescribers)

Drug already on Formulary

New indications/prescribers approved for supply under PBS

No significant cost implications

No significant safety implications

# Outcome of application process:

|  |  |
| --- | --- |
| **Process** | **Date / Details / Notes** |
| Application received  *(Date received by DTC secretary)* |  |
| Application considered  *(DTC meeting date)* |  |
| Outcome: | Approved  Rejected  Deferred |
| Conditions of approval  *(Specify restrictions)* |  |
| Approval review date *(If applicable)* |  |
| Applicant advised of outcome *(Date)* |  |

# Approved by:

|  |  |
| --- | --- |
| Signed on behalf of  Drug and Therapeutics Committee |  |
| Name |  |
| Date |  |