

# STATEWIDE MEDICINES FORMULARY - SUBMISSION FORM

# Non-Pharmaceutical Benefits Scheme (non-PBS) listed medications

**What is this form for?**

This form is to apply to list a new non-Pharmaceutical Benefits Scheme (non-PBS) medication, on the Statewide Medicines Formulary (SMF). Requests to amend wording of a current SMF restriction should be emailed to WADEP@health.wa.gov.au

**Who can apply?**

Submissions may be made by a senior health professional working for the WA health system (i.e. from a Health Service Provider (HSP) or contracted health entity). The SMF is applicable to all public health services.

**Application process:**

* Prior to the application being commenced, notice of intent to submit should be given to the WADEP Secretariat to ensure applications are not duplicated via WADEP@health.wa.gov.au.
* Once a submission is received, the WADEP secretariat will inform relevant Heads of Departments for open comment regarding submission content and to prevent duplication of submissions.
* The WADEP secretariat will inform local Drug and Therapeutics Committees (DTCs) or equivalent for open comment and to ensure any local executive level financial approvals are obtained. This will also help prevent duplication of submissions.
* The submission form should be completed in full.
* Applicants should garner comments from peers and/or support for the application within and across departments and other HSPs. This will strengthen the application and shorten the review process. Endorsement from relevant SMF Expert Advisory Groups, clinical committees/networks is recommended. The WADEP Secretariat can provide contacts as required.
* Applicants should consider the medicines place in therapy, particularly if treatment guidelines need to be amended or developed. High-cost or complex medicines will most likely require a treatment algorithm. Submission of an algorithm may also help to shorten the review/post-review process.
* Applicants must have the support of their line manager (e.g. Heads of Department, Clinical Service Director) for the submission after discussing cost, affordability and strategic/service delivery implications.
* The submission cannot proceed without a signed conflict of interest declaration. Electronic signatures or HE numbers are accepted in place of physical signatures
* Applicants of high-cost medications may be asked to speak to the panel to present an expert opinion on the clinical and practical use of the medication and to answer any questions relating to the submission
* Check the Formulary One Application or with the WADEP secretariat for details of upcoming WADEP meetings. Completed applications or questions may be forwarded to the WADEP secretariat; WADEP@health.wa.gov.au

# Statewide Medicine Formulary (SMF) non-PBS Submission Form

**Complete ALL relevant shaded boxes**.

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| Details of the medicine |
| General information |
| Approved (generic) name:  |  |
| Trade (brand) name(s):  |  |
| Pharmaceutical sponsor: |  |
| Dosage form(s):  |  |
| Strength(s):  |  |
| Standard dose:  |  |
| Usual duration of treatment:  |  |

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|  New non-PBS Listing Details |
| Requested non-PBS **indication**  |
|  |
| What **restrictions** are required (i.e. restricted to prescription under the direction of a specialist type)?  |
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| Population |
| All adult applications should consider if paediatric use is likely to be required; if you do not regularly work in paediatrics seek the advice of a relevant paediatrician/paediatric specialist.  |
| **A** | Adult  | [ ]  | Paediatric  | [ ]  | Both | [ ]  |
| **B** | Tertiary services  | [ ]  | Other hospital/services  | [ ]  | All  | [ ]  |
| **C** | Inpatient  | [ ]  | Outpatient  | [ ]  | Both  | [ ]  |

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| Registration details |  |  |
| Is the **medicine** registered by the TGA?  | [ ] Yes  | [ ]  No  |
| All non-TGA registered medicines will require TGA Special Access Scheme (SAS) approval for each patient treated. For further information see [TGA SAS website](http://www.tga.gov.au/form/special-access-scheme).  |
| Is the **indication requested** registered by the TGA? | [ ]  Yes  | [ ]  No  |
| All non-TGA registered indications are considered “off-label” and prescribing should be according to the CATAG Guiding Principles for the quality use of off-label medicines. Go to the CATAG document here: [CATAG Off-Label Guiding Principles](http://www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf)  |

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| Other jurisdictions |
| Is the medicine available in other states or countries (specify where and the source of information)? |
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| Benefits and outcomes of requested medication |

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| Rationale for submission |
| Tick the box that **best** describes the rationale for this submission: |
| **Treatment need:** Prevention or treatment of medical condition inadequately covered by currently listed options | [ ]  |
| **Improved efficacy:** More effective than and as safe as currently listed options | [ ]  |
| **Improved safety:** Safer than and as effective as currently listed options | [ ]  |
| **Improved cost:** Less expensive than and as effective and safe as currently listed options  | [ ]  |
| **In your own words outline the rationale for this submission:** |  |
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| Outcomes |
| What are the **desired outcomes** of therapy from this medication (e.g. cure, relief from symptoms, relapse rate, survival, prevention of complication etc.)? |
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| What outcomes are used to measure this medicine’s efficacy in the **literature**? |
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| How is this outcome **measured**? Is this a validated test? Is this the outcome measure used in practice? |
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| Place in therapy |
| Attach any relevant guidelines or protocols for the requested indication. The below may help to inform the development/change of a guideline if required. |
| When is the new medicine to be used in therapy? |
| First – line [ ]  | Subsequent – line [ ]  | At any stage [ ]  | Preventative use [ ]  |
| What are the **starting criteria** for the medicine (i.e. failure of prior-line medications, severity of condition etc.)? |
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| What are the **stopping criteria** for the medicine (i.e. return of symptoms or failure of treatment, full recovery etc.)? |
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| Supporting evidence  |
| Complete the below for the **two** most relevant references.  |
| **Primary reference 1** **:**  |
| Randomised trial | [ ]  | Primary outcome |  |
| Non-randomised trial | [ ]  | Control |  |
| Case study with no controls | [ ]  | Absolute risk reduction c.f. control |  |
| Statistically significant P<0.05 | [ ]  | Number needed to treat |  |
| Level of evidence  | Evidence of clinical improvement | % active vs % control |
| A [ ]  | B [ ]  | C  [ ]  |

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| **Primary reference 2:**  |
| Randomised trial | [ ]  | Primary outcome |  |
| Non-randomised trial | [ ]  | Control |  |
| Case study with no controls | [ ]  | Absolute risk reduction c.f. control |  |
| Statistically significant P<0.05 | [ ]  | Number needed to treat |  |
| Level of evidence  | Evidence of clinical improvement | % active vs % control |
| [ ]  A  | [ ]  B  | [ ]  C  |
| **List all other relevant references:** |
|  |

**Level of Evidence supporting the proposed therapy**

Grade A Supported by at least one, and preferably more large randomised trials with clear-cut results and low risk of error (statistically significant results P<0.05), and the results of such studies published in peer-reviewed journals. It would be expected that the results would demonstrate substantial clinical benefit.

Grade B Supported by at least one small randomised trial with uncertain results and moderate to high risk of error (statistically) not significant P>0.05), i.e. randomised trials with positive trends but of low power due to small sample size to reach statistically significant results. It would be expected that the results would demonstrate substantial clinical benefit.

Grade C Supported by only non-randomised concurrent cohort comparisons between contemporaneous patients, or non-randomised historical cohort comparisons between current patients and former patients, or case studies with no controls. It would be expected that the results would demonstrate substantial clinical benefit.

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| Comparative evidence |
| Comparators |
| What **medicine**(s) are **currently** used for the indication requested? |
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| What **non-medicine** alternatives are **currently** used for the indication requested (i.e. surgical, blood product)?  |
|  |
| If there are no medicine or non-medicine alternatives and the **comparator is best supportive care** tick this boxand **complete section 4.2.** | [ ]  |
| **4.2 Best supportive care as the comparator** |
| What outcome is expected from best supportive care? This should be relevant to the outcome measured for the new medicine (i.e. Drug X reduces complication rates; BSC has an X% chance of complications).  |
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| Evidence for the comparator  |
| If the submission requires comparison to a current standard of therapy please provide relevant primary references for comparative analysis. **Comparator should be same as that stated in 4.1.** |
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| Comparative benefits / disbenefits |
| For all answers please specify source of information (i.e. product information, reference clinical trial etc.) |
| Comparative efficacy |
| For the outcome(s) stated in 2.2, what is the comparative effectiveness of the new medicine compared to the comparator(s) stated in 4.1? |
|  |
| Comparative safety |
| What is the comparative safety of the new medicine compared to the comparator(s) stated in 4.1 (not limited to toxicity/adverse events and may include safety of administration etc.)? |
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| Are there concerns with continuity of care and/or equity of access pertaining to this medication? |
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| Costs |
| Comparative cost / patientIt is recommended that you ask the pharmacy department for the purchase price of medications. This is the cost to the hospital for inpatient use and may differ from the PBS price. The comparator used for this section should be the same as 4.1. If a different comparator is used state the name, dose and rationale.  |
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|  | **Requested medicine (purchase price)** | **Comparator****(purchase price)** |
| Cost per standard dose (if weight based use 70 kg) | $  | $  |
| Treatment course (continuous, cyclical / intermittent, finite) |  |  |
| Average number of days of treatment / treatment course | Days |  Days |
| Average estimated cost / patient / annum | $  | $  |
| Additional costs identified (specify below) | $  |   |
|  |
| Additional savings identified (specify below) | $  |  |
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| Total cost / patient / annum  | $  | $  |
| Other relevant cost information  |
|  |
| State the source of the above information  |
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| Comparative utilisation and financial implications |
| The comparator used for this section should be the same as 4.1 or 5.1. If a different comparator is used state the name, dose and rationale. |
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|  | **Requested medicine** | **Comparator** |
| Number of patients expected to start treatment at **your hospital** per annum |  |  |
| Total number of patients expected to start treatment **across WA** per annumIt is advisable to speak with colleagues from other sites likely to treat the requested indication. The WADEP EO may be able to provide you the names of the relevant EAG.  |  |  |
| Number of patients expected to cease treatment **across WA** per annum |  |  |
| Total annual cost to the state (cost per patient x expected numbers) | $  | $  |

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| Applicant and applicant support details |
| Input from others  |
| It is highly recommended that the applicant consult with all Departments within and external to their hospital relevant to this application (including other specialties likely to prescribe the medicine). |
| Provide details of the people consulted and had input in this application.  |
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| Was a pharmaceutical company representative involved in the preparation of this submission?  | [ ]  Yes  | [ ]  No  |

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| Authorisation |
| This submission requires authorisation by the applicant’s Head of Department. Applicants that are HODs should have a peer or authority above themselves (i.e. Medical Services Director) sign-off.  |
| **HoD Name and position:**  |
| **Signature (or HE number):**  | **Date**:  |

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| Applicant details |
| **Name:**  |
| **Position**:  |
| **Clinical unit and practicing hospital(s):**  |
| **Primary email:**  |

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| Conflict of interestAll relevant potential conflicts must be declared, regardless of whether the applicant considers them to be significant, or not. Please note conflict of interests declared may not disqualify the applicant from making submissions to the SMF. The following are examples of COI: paid positions, honoraria, sponsorship of research, travel/conference funding, shares or commercial dealings, gifts, or entertainment. |
| With reference to the WA Health Code of Conduct regarding conflict of interests: |  |
| I certify that I am not aware of any potential conflict of interest which may arise in respect of this application. | [ ]  |
| OR |  |
| I may have a potential conflict of interest (complete the question below). | [ ]  |
| Briefly describe each potential conflict: |
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| Applicant declaration I declare, that to the best of my knowledge, all the information contained in this application is true and accurate. |
| **Applicant Name:**  |
| **Signature (or HE number):**  | **Date:**  |

The WADEP and the Statewide Medicines Formulary Team does not take responsibility for any delay in the application process where this form is not completed in full or to the best of the applicant’s ability. Whilst WADEP and the SMF Team will attempt to contact and assist the applicant, gaps in relevant information may hinder the process or may attribute to a negative outcome.

If you have any questions or concerns, or for advice and tips on how to complete this form please contact WADEP@health.wa.gov.au

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