## Information about this submission form

This submission form is to be used by Queensland Health clinicians to apply for an addition to or a change to a medicine listed on the statewide formulary, known as the Queensland Health List of Approved Medicines (LAM).

Submissions will be assessed by the Queensland Health Medicines Advisory Committee (QHMAC) using the [QHMAC 5 Pillars Decision Support Tool v1.0](https://qlam.com.au/File/Inline/6f6b83b6-c8e6-4838-aa9e-c09d83979355)  The five pillars are; effectiveness, safety, cost-effectiveness, equity of access and implementation & implications. Some pillars may be more relevant than others with respect to your submission.

Use the most up to date published information and in-text referencing throughout this document.

|  |
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| **Section 1 – Medicine requested** |
| ***Provide details of the medicine requested*** |
| Generic name |   |
| Trade/brand name |   |
| Form(s) |   |
| Strength(s) |   |
| Manufacturer/supplier |   |
| **Therapeutic Goods Administration (TGA) status** |
|[ ]  TGA approved for requested indication(s) |
|[ ]  TGA approved but not for requested indication(s) or patient group (off label) |
|[ ]  Not TGA approved  |
| **Pharmaceutical Benefits Scheme (PBS) status** |
|[ ]  PBS listed and intended use meets PBS eligibility criteria  |
|[ ]  PBS listed but intended use does *not* meet PBS eligibility criteria  |
|[ ]  Not PBS listed |
| **Requested access via the LAM:** |
|[ ]  Inpatient |[ ]  Day admitted |[ ]  Outpatient |[ ]  On discharge |

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| **Section 2 – Proposed LAM listing** |
| ***Propose a suitable LAM restriction for the requested item, addressing the criteria below where applicable. Has b*** |
| [ ]  | Unrestricted | [ ]  | Restricted (complete table below) |
| Requested indication(s) |   |
| Prescriber group(s)  |   |
| Patient group(s)  |   |
| Additional criteria |   |

|  |
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| **Section 3 – Key supporting literature** |
| ***List reference details for Key Supporting Literature and attach PDF copies if possible.***  |
| 1. |  |
| 2. |   |
| 3. |   |
|   |   |

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| **Section 4 – Unmet clinical need** |
| ***Describe the need for this item over other medicines/management options*** |
| In one or two sentences describe why the requested item(s) is needed over currently available LAM listed alternative(s): |
|   |
| What is the main LAM comparator or alternative? (e.g. another pharmaceutical, best supportive care, etc.) |
|   |
| Briefly describe the implications of NOT adding or amending this item as requested: |
|   |
| Which medicines, if any, could be deleted from the LAM or have their listing amended if this request is approved? (Provide detail): |
|   |

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| **Section 5 – Effectiveness** |
| ***Summarise and reference the best available evidence for the effectiveness of the medication for the requested indication. Comment on its place therapy with respect to alternatives (e.g. other pharmaceuticals, best supportive care etc.)*** |
| Main clinical benefit: *e.g. risk reduction, reduced burden of disease, disease free progression etc.* |
|   |
| Additional clinical benefits: *e.g. surgery or procedure averted, hospital admission averted, reduced length of stay, quality of life, etc.*  |
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| **Section 6 – Safety** |
| ***Summarise and reference the main safety considerations for the requested medication*** |
| Describe patient relevant safety outcomes (risks and/or benefits) of the requested medicine with respect to the alternatives: *e.g. the nature and rates of adverse events* |
|   |
| Are there any factors to consider when prescribing, dispensing or administering the requested item that may lead to medication errors? *e.g. difficult administration schedule, potential for product selection errors*  |
|   |

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| **Section 7 – Cost-effectiveness** |
| ***Outline the costs or savings associated with the requested item compared with the main comparator*** |
| Dosing schedule, typical duration **for requested item**: *e.g. 500mg TDS for five days, 100mg daily ongoing, 250mg daily for 5 days each month for 6 months….etc.* |
|   |
| Specify dosing source/reference  | [ ]  | AMH | [ ]  | eMIMS |
| [ ]  | Queensland Health guideline /other: *(specify and attach)* |   |
| Dosing schedule, typical duration **for main comparator**: |
|   |
| Specify dosing source/reference  | [ ]  | AMH | [ ]  | eMIMS |
| [ ]  | Queensland Health guideline /other: *(specify and attach)* |   |
| **Estimated patient numbers requiring this therapy:** |
|  | **Number (source)** |
| At your site or hospital |   |
| Statewide (across Qld Health) if known |   |
| **Treatment costs:** |
|  | **Requested item** | **Comparator** |
| a. Dosage unit (form and strength): |   |   |
| b. Cost per dosage (indicate source) | $  | $  |
|[ ]  PBS |[ ]  Central pharmacy |[ ]  iPharmacy |[ ]  Drug company |
| c. Standard course details (provide number of dosage units, frequency, duration |   |   |
| d. Cost per standard dose | $  | $  |
|[ ]  One off course |[ ]  Continuous (per day) |[ ]  Cyclical dose |
| e. Additional costs directly associated with treatment (e.g. disposables, monitoring | $  | $  |
| f. Total estimated annual cost per patient. | $  | $  |
| **Section 7 – Cost-effectiveness (cont’)** |
| **Additional information:** |
| ***Please provide any additional information that QHMAC should know relating to how the estimated costs have been calculated:*** |
|   |
| **Other factors impacting costs to Queensland Health:** |
| ***What indirect costs or savings, if any, would you like the committee to consider?*** |
|   |

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| **Section 8 – Equity of access** |
| ***Describe any demographic, geographic, social, or economic considerations relevant to the requested item***  |
| Are there any other patient-centred benefits not already covered that you would like to list? |
|   |
| How might approving this request improve medicines access for individuals where known health disparities exist? |
|   |

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| **Section 9 – Implementation and implications** |
|  ***Consider any operational requirements associated with use of the requested medicine*** |
| Are there any significant change management issues associated with this request? |
|   |
| What impact, if any, will approving this request have on service delivery? |
|   |

## Declarations and local endorsements

Submissions will be assessed by the committee using [QHMAC’s five pillars decision support tool.](https://qlam.com.au/File/Inline/6f6b83b6-c8e6-4838-aa9e-c09d83979355) Some of the pillars may be more relevant than others with respect to your submission.

Submissions will only be accepted from Queensland Health staff. A copy of the submission may be shared with other Queensland Health clinicians.

Each applicant is required to complete the following table. A supplementary page is provided at the rear of this form there are multiple applicants.

|  |
| --- |
| **Applicant information** |
| Name |   |
| Position |   |
| Site |   |
| Email |   |
| Actual or potential conflicts of interest\* |
|[ ]  Nil known or  |[ ]  Describe below |
|   |
|  [ ]  Pharmaceutical company assistance has been involved in the preparation of this submission. |
| Signature\*\*  | Date  |

\*Conflicts of interest may include but are not limited to receipt of research funds from a sponsoring company, receipt of ex-gratia payments or consultancy fees from a sponsoring company, overseas/interstate trips funded or subsidised by a sponsoring company, personal or family shares in the company sponsoring the product(s) or competing product(s) for which application is made.

\*\* I acknowledge the information contained in this submission is based on current evidence for best practice and is reflective of my clinical opinion.

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| --- |
| **Local signoff (both required)** |
|  | Director of pharmacy | Chair of local Medicines Advisory Committee (MAC) or equivalent |
| Name |   |   |
| Position |   |   |
| Email |   |   |
| Support |[ ]  Yes |[ ]  No |[ ]  Yes |[ ]  No |
| Signature |   |   |
| Date |   |   |
| Comments |   |   |

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| **Medicines Advisory Committee (MAC) Assessment** |
| ***Please provide rationale for the MAC’s recommendation, taking into consideration QHMAC’s 5 pillars (Effectiveness, Safety, Cost Effectiveness, Equity of Access, Implementation and Implications)*** |
|   |

**Standard submission to add a medicine or make a change to the Queensland Health List of Approved medicines (LAM)**

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**For use by multiple applicants.**

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|   |
|  [ ]  Pharmaceutical company assistance has been involved in the preparation of this submission. |
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