

NSW High-Cost Medicines Subcommittee HCM Submission Framework

Version 1.0

May 2023



CLINICAL
EXCELLENCE
COMMISSION

[Drug name]

Overview

Purpose

The purpose of this document is to provide a framework to assist the NSW High-Cost Medicines Subcommittee members with evaluating High-Cost Medicine (HCM) submissions for additions, amendments, or deletions to the NSW Medicines Formulary.

This framework has been developed using other decision support tools and resources including CATAG- Navigating high-cost medicines guiding principles, NSW TAG- Activity Based Funding of Medicines in Hospitals, South Australian Medicines Evaluation Panel and advice from a Health Economist.

The HCM Submission Framework is to be completed in addition to NSW Medicines Formulary Committee (NMFC) [Formulary Submission Framework](#), and includes specific considerations required when evaluating HCM for listing on the NMF.

Both the Formulary Submission Framework and the HCM Submission Framework will be completed by the NMFC Secretariat and provided to members to evaluate HCM formulary submissions.

This HCM submission framework is not a weighted scoring tool, it is intended to guide the Committee's deliberations and ensure robust discussion and decision making occurs. The framework comprises questions or considerations structured under 3 key principles, not in any order.

- Utilisation
- Cost and Financial Impact
- Other

Utilisation

1. What is the population epidemiology of the condition being treated? What is the number of patients likely to receive treatment per year?
2. Where will the patient be receiving treatment (inpatient vs. outpatient, rural/remote vs. metropolitan, under specialist care settings vs. general)?
3. Is the intended therapy for a single acute episode or ongoing chronic treatment?
4. Are there well-defined stopping criteria to indicate when treatment is no longer warranted for the patient?

Comments for Sub-Committee

Cost and Financial Impact

1. What is the expected drug cost per patient per year?
2. Are there any other expected healthcare costs required to provide the drug (e.g., administration costs, monitoring costs, adverse event costs)?
3. What is the projected financial impact on drug/hospital budgets, considering the expected utilisation of the new medicine and consequent changes to current treatments (including cost off-sets)?
4. What is the likely impact on drug budgets of LHDs/SHNs that are block funded?
5. Is there a need to consider financial delegation limits of LHDs/SHNs?
6. Compared to current practice, what are the additional health outcomes (e.g., Quality adjusted life years, survival, recurrence avoided) achieved for the additional costs associated with providing the HCM on the formulary?

Comments for Sub-Committee

Other

1. Are there any ethical considerations to be considered? (Ethical considerations should consider both the specific individual and the broader community perspective)
 - o Facilitating access where appropriate, according to due process
 - o Promoting equity, by considering valid claims for special or differential treatment based on social or economic vulnerability, or those at particular risk of discrimination
 - o Having an awareness of obligations to resource stewardship, including consideration of sustainability considering consistency in dealing with subsequent applications
 - o Considering opportunity cost, and the appropriateness of allocating resources in the high-cost medicine domain as opposed to other areas of healthcare delivery

Comments for Sub-Committee

Summary

Considering information from the Formulary Submission Framework with regards to effectiveness, safety, cost effectiveness (and financial impact), equity of access, and implementation implications AND additional considerations above:

1. Is the proposed 'value' of the health outcome thought to be proportional to the cost?

Comments for Sub-Committee

Recommendation

The Committee may determine restrictions for use or outcome monitoring requirements that include but are not limited to:

1. Chronic long-term HCM treatment to remain within ABF-funded hospitals
2. The use of a prescribing declaration to support ongoing medicines use evaluation on efficacy and safety outcomes
3. Routine review of costs to the NSW Health system

Comments for Sub-Committee

[Drug name]