

NSW High-Cost Medicines Subcommittee



CLINICAL
EXCELLENCE
COMMISSION

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Vision

To ensure optimum clinical governance and value in medicines use, and to improve patient outcomes across NSW Health through clinical consistency and equity of access to medicines.

Definition of a High-Cost Medicine

For the purposes of this subcommittee's deliberations the definition of a high-cost medicine shall be*:

Those medicines for which the predicted expenditure is:

- ≥\$10,000 per patient per treatment course or per year; or
- ≥\$100,000 for an individual hospital per year.

Exemptions:

- medicines listed under the Pharmaceutical Benefits Scheme (section 85 or section 100) used in accordance with the PBS criteria for subsidy
- low-cost medicines which represent a high cost due to high volumes of use (e.g. sodium chloride for injection).

**this definition to be reviewed on an annual basis to assess suitability.*

Purpose of the Subcommittee

The High-Cost Medicines Subcommittee (the Subcommittee) has been established to make recommendations to the NSW Medicines Formulary Committee as to whether a high-cost medicine should be included on the NSW Medicines Formulary, thereby improving equity of allocation of resources and access to these medicines for all NSW patients.

Authority

The Subcommittee assists the NSW Medicines Formulary Committee to discharge its responsibilities in relation to high-cost medicines. The NSW Medicines Formulary Committee is accountable to the Secretary, NSW Health through the Executive Sponsor (the Sponsor) being the relevant Deputy Secretary at the Ministry of Health.

- The Subcommittee is empowered to deliberate on matters that affect NSW Health facilities and services in relation to high-cost medicines.
- Subcommittee recommendations are made by majority and are recorded in the meeting minutes.
- Any urgent decisions that can be managed as an out-of-session paper when authorised by the Chair will be recorded in a similar manner.
- Issues unable to be resolved by the Subcommittee are referred by the Chair to the NSW Medicines Formulary Committee.

Key Responsibilities

The responsibilities of the High-Cost Medicines Subcommittee are to:

- Evaluate the clinical, ethical and economic impact of high-cost medicines proposed for inclusion in the state-wide formulary and make recommendations to the NSW Medicines Formulary Committee (see Appendix 2).
- Monitor use of high-cost medicines in NSW hospitals included in the NSW Medicines Formulary.
- Review reports received of high-cost Individual Patient Use approvals and non-formulary medicine use within the LHDs/SHNs to determine if a formulary evaluation or guidance, is required.

Decision-making Principles

Evaluation of medicines should be guided by the agreed principles and an agreed decision algorithm described in the [NSW Medicines Formulary Committee Terms of Reference](#).

Additional considerations required in review of HCM for listing on the NMF should include:

- medicine utilisation and population epidemiology
- expected costs per patient, and the number of patients likely to receive treatment per year
- financial impact to LHDs/SHNs (including consideration of varying funding arrangements)
- ethical considerations for individuals or the broader community
- proposed “value” of the health outcomes.

The Subcommittee may make recommendations to the NMFC on (but not limited to) restrictions for use of HCM and outcome monitoring requirements.

Ongoing formulary management of high-cost medicines should include a systematic review process for all high-cost medicines decisions.

Membership

The High-Cost Medicines Subcommittee will be multi-disciplinary and comprise representation from clinicians, clinical governance, senior executives, and relevant state-wide advisory groups. The Subcommittee will liaise with other NSW Health committees, state-wide clinical networks, and other expert groups to seek advice, or to make recommendations on the use of high-cost medicines and the development of clinical guidelines.

Subcommittee members must be NSW Health employees. Proposed members are determined by the Chair, in consultation with the Secretariat and is based on individual expertise and commitment. Final membership is appointed by the Executive Sponsor (or nominated delegate) in consultation with the Secretariat/ Chair of the NSW Medicines Formulary Committee. Confirmation of line manager/ facility approval is required from the nominee prior to an offer of appointment.

Members will include medical practitioners and other health professionals with expertise in and a commitment to safe, cost-effective, and quality use of medicines. In the rare circumstance where the right skills and experience cannot be sourced from within NSW Health, the appointment of an external will be considered.

The maximum term of appointment of members is two years, with a maximum of three reappointments. Appointment terms are generally staggered to ensure business continuity as well as provide an opportunity for the committee to gain additional skills, knowledge, and insight from incoming members. Each year, approximately one-third of the membership will complete a term.

Members will be selected based on their individual expertise, role, or organisational affiliation. In addition, as required, experts will be invited to attend meetings to advise on areas where the Subcommittee does not have sufficient expertise.

Membership of the High-Cost Medicines Subcommittee may include:

- Clinical Pharmacology
- Drug and Therapeutics Committee Chair
- Senior medical specialists including but not limited to:
 - ✓ Immunology
 - ✓ Oncology/Haematology
 - ✓ Rheumatology
 - ✓ Neurology
 - ✓ Nephrology
 - ✓ Psychiatry/Mental Health
 - ✓ Infectious Diseases
 - ✓ Cardiology
 - ✓ Dermatology
 - ✓ Anaesthetics
 - ✓ Paediatrics
- Pharmacy (clinical and managerial)
- Nursing (clinical and managerial)
- Chief Advisor and Program Lead Medication Safety Quality and Therapeutic Optimisation, Clinical Excellence Commission
- Director of Clinical Governance
- Health economist (as required)
- Consumer Representative x 2 (as required)

Additional expertise may be called upon as required depending on the medicines being considered.

Consumer Representation

The Subcommittee will engage and seek feedback from Consumer representatives to ensure diverse voices and perspectives are included in problem solving and decision making.

Consumer input may range from one off consultations to ongoing collaboration through Committee membership.

Rural Representation

The core member positions will include individuals that work in rural or remote sites and can provide unique perspectives of rural settings in addition to the individual specialty expertise for the core member position.

Chair

The Chair will be appointed by the Ministry of Health Deputy Secretary (or nominated delegate). The Chair will be a practising clinician, with experience in Drug and Therapeutics Committees.

The maximum term of appointment of the chair is two years, after which the appointment will be reviewed for continuation. There is no limit to the number of times the chair may be reappointed, as long as each appointment is no longer than two years in duration.

The Chair of the NSW Medicines Formulary Committee will be appointed as the Deputy Chair.

If the chair is absent from a meeting or vacates the chair at a meeting, the Deputy Chair or (in that member's absence) an experienced member, who has been nominated by the Chair, may assume control of the meeting on a temporary basis (however all decisions would need to be ratified by the Chair out of session).

Member responsibilities

Responsibilities of subcommittee members are to:

1. Declare all perceived or potential conflicts of interest.
2. Consult with colleagues and relevant staff within their organisation/networks to inform the advice given to the subcommittee.
3. To advocate for the role of the subcommittee to colleagues and relevant staff within their organisation/networks and on the compliance with the NSW Medicines Formulary and its processes.
4. Identify and act on allocated actions/tasks within agreed timeframes. All documents circulated for comment will include a response deadline.

Other participants

Where agreed by the Chair, other persons may participate in subcommittee proceedings/ activities where relevant to an agenda item. However, such persons do not assume membership or participation in any decision-making processes of the subcommittee

Secretariat

Secretariat support for the High-Cost Drug Subcommittee will be provided by the Clinical Excellence Commission (CEC).

Responsibilities

The Secretariat will be responsible for:

- Providing administrative support to the High-Cost Medicines Subcommittee, including meeting co-ordination, minute taking and distribution of relevant papers.
- Providing additional information to subcommittee members to support medicines evaluations and assist in decision-making, where required.
- Maintaining a log of all subcommittee recommendations.
- Communicating subcommittee recommendations to the NSW Medicines Formulary Committee.
- Liaising closely with the Strategic Procurement Services and the state-wide clinical procurement committee.

Meeting Procedures

Frequency and Duration

A placeholder for meetings will be held on the first Tuesday of the month, however meetings will only be confirmed to take place when items have been referred to the Subcommittee by the NMFC. All meetings will be held virtually for a duration of two hours.

Quorum

At any meeting of the Subcommittee, a quorum will be attained when half plus one of the currently filled subcommittee positions are in attendance. A quorum is required to conduct the business of the meeting. If a quorum is not met, the following will occur:

- continuation of the meeting will be confirmed at the Chair's discretion
- if the meeting proceeds, all recommendations will be preliminary
- any preliminary recommendations will then proceed to seek an out-of-session quorum consensus.

Confidentiality

Members of the subcommittee may from time to time be in receipt of information that is regarded as 'commercial in confidence', clinically confidential or have privacy implications. Subcommittee members, the Secretariat and observers are required to sign Confidentiality Undertaking and acknowledge their responsibility to maintain confidentiality of all information that is not in the public domain.

Conflicts of interest

Subcommittee members are required to declare any real, potential or perceived pecuniary or non-pecuniary conflicts of interests relating to an agenda item at the beginning of each meeting.

The Conflicts of Interest and Gifts and Benefits Policy Directive (PD2015_045) states a conflict of interest may occur where a staff member could be influenced or perceived to be influenced by a competing interest when carrying out their public duty.

Competing interests may arise through personal or private interests, or through separate professional interests. If matters arise where there is an actual or perceived conflict of interest, they will be managed under PD2015_045 and the NSW Health Code of Conduct.

Managing and Recording Conflict of Interest

1. 'Declarations of interest' will be a standing item at the beginning of each subcommittee meeting to provide members the opportunity to declare any conflict of interest in relation to any item of agenda.
2. Conflict of interest will be recorded and reported to the Secretariat.
3. Members cannot take part in any discussion of the subcommittee relating to the interest or issue and cannot vote on the matter. This would require the member to be absent from the meeting room when any discussion or vote is taking place and to not receive any relevant subcommittee papers. This is to be recorded in the subcommittee minutes.
4. The meeting minutes are to reflect the nature of the conflict, whether it is a 'material' conflict, how the conflict is being managed in the public interest; and the times that a subcommittee member is absent from the meeting room due to the conflict.
5. In an extreme case, this may require resignation by the member from the subcommittee.

Voting and decision making

During a meeting

All members/nominated approved proxies have one vote. Decisions will be passed by the majority of members/nominated approved proxies present. Where a quorum has not been reached, endorsement will occur through out-of-session vote, or at the next scheduled meeting.

Out-of-session Consultation and Decisions

Members may be requested to provide out-of-session review and endorsement of documents, and advice on specific matters. The decision for out-of-session consultation and timeframe for feedback will be made at the discretion of the Chair and will be determined on a case-by-case basis with consideration towards the nature and urgency of advice required.

Additionally, decisions can be made out-of-session by the subcommittee. These decisions must be put forward in writing (email is sufficient) by the Chair or Deputy Chair, with members providing written approval of the position put forward.

Escalation

If a consensus regarding a recommendation for formulary listing cannot be reached, the decision will be escalated to the NSW Medicines Formulary Committee (See Appendix 2 - maintenance governance diagram).

Meeting papers

The agenda and meeting papers shall be distributed to members at least seven (7) days before the meeting date.

Apologies and Proxies

All members should advise the secretariat at least 5 days prior to the meeting if they will be an apology. If members nominate a proxy, that proxy must be equivalent in terms of expertise/credentials and will be approved by the Chair.

Due to the nature of the deliberations, proxies are generally discouraged. However, the use of a proxy may be necessary where a member expects a short-term absence from the subcommittee (e.g. annual leave). Where a member elects to nominate a proxy, this must be notified in writing to the Secretariat at least two business days prior to a meeting, who will then advise the Chair. Acceptance of the proxy is at the discretion of the Chair. The proxy must complete the relevant conflict of interest declarations. A member who nominates a proxy is expected to brief the proxy about the subcommittee and its responsibilities. Proxies accepted by the chair count towards the quorum for a meeting and are entitled to participate in subcommittee discussion and decision-making.

Reporting relationships

Formulary governance structure is in Appendix 2.

The subcommittee will provide regular reports on its activities and recommendations to:

- NSW Medicines Formulary Committee.

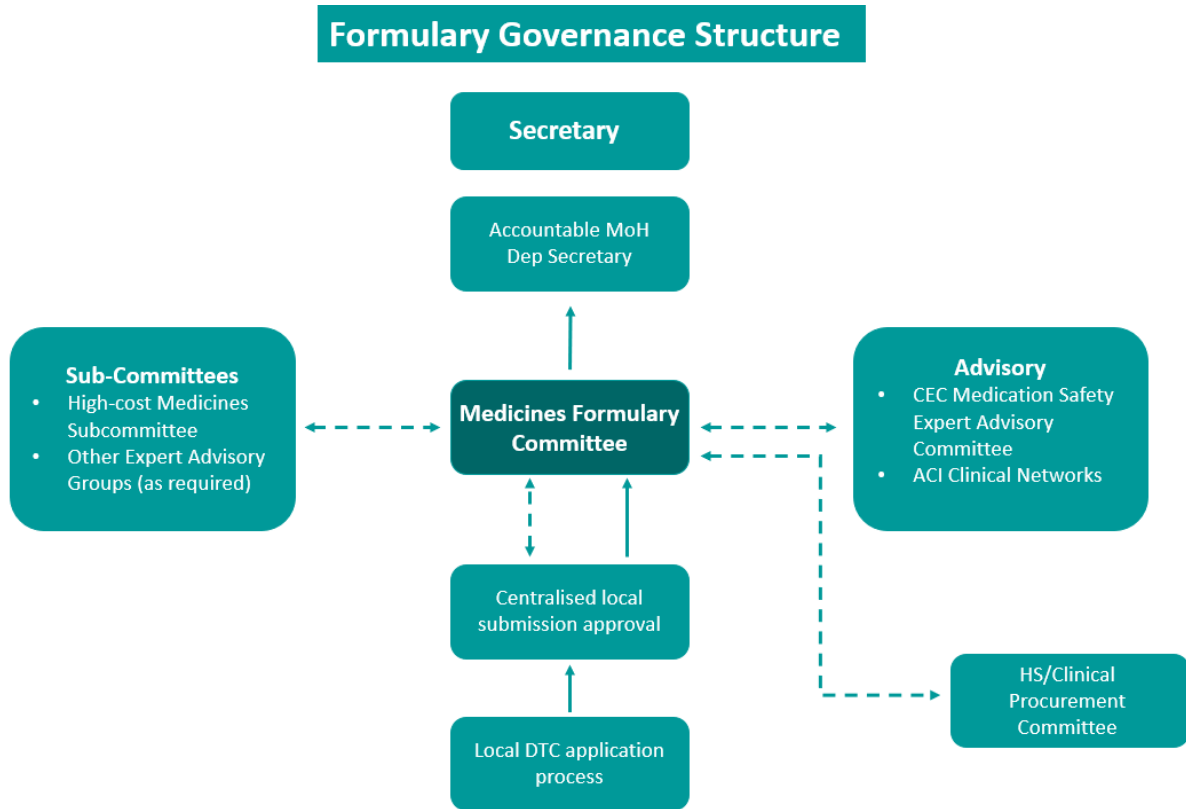
Subcommittee Evaluation

The High-Cost Medicines Subcommittee shall review its terms of reference, membership and performance annually via a self-assessment process that may involve surveys and/or interviews with various stakeholders or parties involved with the subcommittee. Member meeting attendance will be evaluated annually. It is expected that all members will attend or nominate a proxy for 75% of meetings each year.

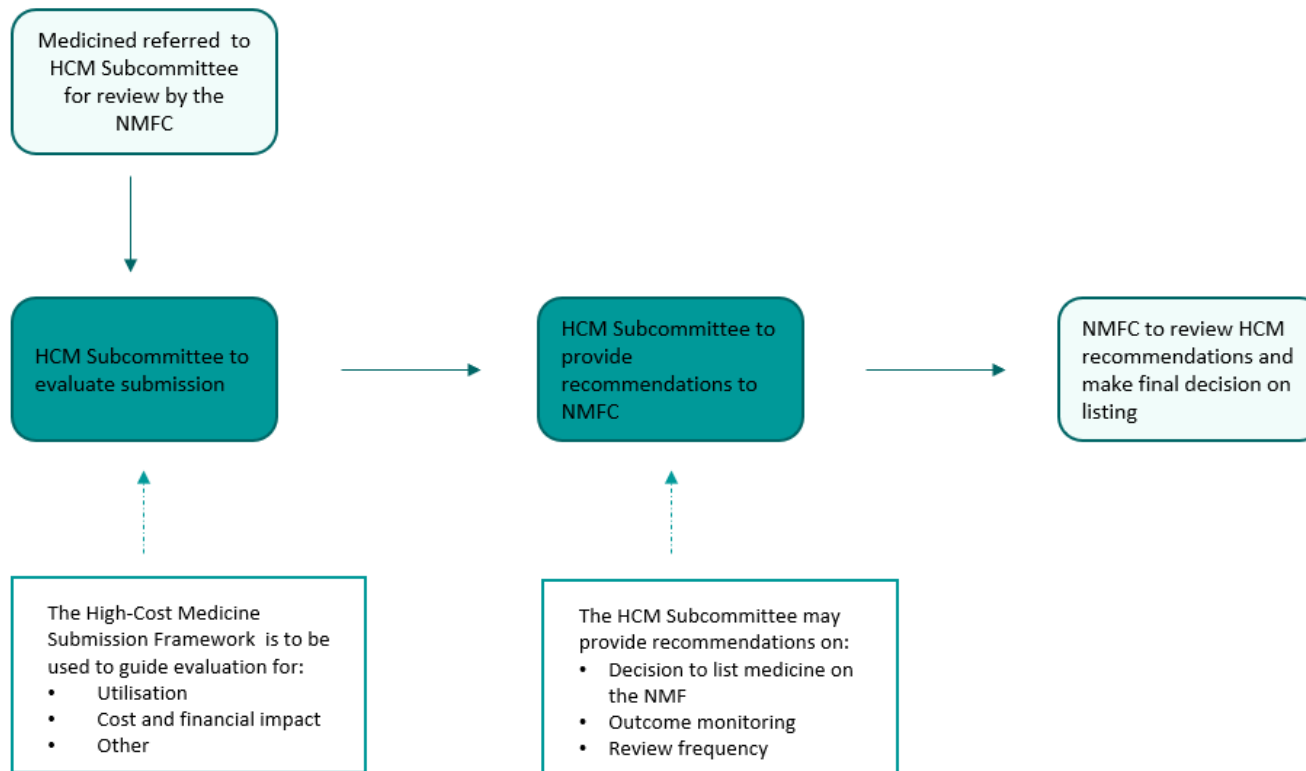
A report on this assessment will be provided to the NSW Medicines Formulary Committee.

Appendices

Appendix 1. Governance



Appendix 2. HCM Subcommittee evaluation and recommendation process



Appendix 3. Skills based matrix for Committee composition

The High-cost Medicines Subcommittee has committed to reviewing its skills matrix annually to ensure the group continues to have an appropriate mix of skills and experience. The following skills matrix presents the results of the assessment of the current membership at inauguration in September 2021.

	Previous DTC experience	Clinical Governance	Medication Safety	Rural /Regional	Critical Core Specialty	Generalist	Relevant Academic or Research interest	Financial Acumen	Health Economics	Drug Utilisation	Interstate experience	Other QUM experience or relevant committees
1	✓				✓	✓					✓	✓
2				✓			✓					✓
3					✓		✓					✓
4	✓		✓	✓								✓
5				✓	✓		✓				✓	
6					✓			✓				
7				✓		✓						
8			✓					✓		✓		
9	✓		✓					✓				✓
10				✓		✓					✓	✓
11					✓			✓				
12	✓				✓				✓	✓		
13	✓	✓						✓			✓	
14						✓	✓				✓	

15	✓	✓			✓							✓
16					✓							✓
17	✓	✓	✓			✓						
18			✓			✓						✓

No one member is expected to have every skill referenced, rather, these skills should be held collectively by the Subcommittee as a whole. The skills and experience listed demonstrate alignment of the members responsibilities in the Terms of Reference with the current mix of skills and experience on the Subcommittee. The chair believes this mix results in an appropriate set of skills, experience and expertise, and ensures a diverse range of views and perspectives for the effective governance, oversight and strategic advice of the High-Cost Medicine Subcommittee.