NSW Medicines Formulary Committee

Business Processes and Principles

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

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Governance

The NSW Medicines Formulary Committee (the Committee) is the peak governance committee for medicines and therapeutic agents approved for initiation in inpatients in NSW public hospitals and health services. The Committee oversees the maintenance of the NSW Medicines Formulary (the Formulary) to ensure appropriate, safe, and cost-effective use of medicines within NSW Health.

The Committee is responsible for reviewing submissions for medicines to be added to the formulary, amending/ deleting formulary listings and reviewing reports on Individual Patient Use (IPU) approvals, to determine if a formulary evaluation should be undertaken for a medicine which is not currently listed.

The key goals of the Committee are to:

- optimise clinical governance
- ensure a state-wide approach for evaluating and approving the use of medicines
- reduce clinical variation
- improve safety
- ensure a state-based approach to procurement
- improve efficiencies in decision making processes and avoid duplication of effort.

Membership consists of multidisciplinary representatives across NSW health organisations. Members have expertise in one or more areas of clinical specialty, pharmacy, clinical governance, executive leadership, or relevant district or state-wide medicines governance or safety.

Details of the core membership representation and the Committee's responsibilities are available in the Terms of Reference.

Medicines under state-wide governance

The medicines considered for inclusion on the Formulary are:

- medicines included on the Australian Register of Therapeutic Goods (ARTG) including:
    - parental oncology medicines for inpatient use
    - intravenous fluids
    - plasma derived and recombinant blood products for medicines / indications that are not available via the National Blood Agreement
    - some parenteral and enteral nutrition products, specifically:
        - Enteral products available under the Pharmaceutical Benefits Scheme (PBS).
        - Standardised base products for parenteral nutrition.
- diagnostic agents with therapeutic indications
- Special Access Scheme (SAS) and Schedule 5A (S5A) medicines are only considered when a medicine is used state-wide, such as medicines in NSW Health guidelines, on the NSW Life Saving Drugs Register or as substitutes for medicines shortages.

The medicines considered for listing on the Formulary may expand over time.

Medicines under local Drug and Therapeutic Committee governance:

The following medicines are not considered for listing on the Formulary and approval to use these items remains under local Drug and Therapeutic Committee (DTC) Governance:

- plasma derived and recombinant blood products that are available via the National Blood Agreement
- medications used in the outpatient setting
- extemporaneous products, including third party supplied compounders (such as infusors, injections, and infusions required for individual patients)
- clinical trial medications
- Medicines Access Program (MAP) medicines (for example., compassionate use, product familiarisation, and cost share programs)
- medical devices containing medicines
- gene therapies
- SAS and S5A medicines that are not listed on the Formulary
- non-core pharmacy items (refer to the Frequently Asked Questions for a list of non-core pharmacy items.

Medicines in use prior to hospital admission:

Local DTC processes apply for the continuation and supply of a patient's existing medicines. An IPU approval is not required to continue or modify a medicine in the following circumstances:

- continuation of a patient's pre-admission medicine that is not listed on the Formulary
- adjustment of a patient's pre-admission dose of a medicine that is not listed on the Formulary (for efficacy or safety reasons)
- transition of a patient's pre-admission medicine to an equivalent medicine dose or formulation where the original route of administration is unavailable and continuation with an alternative route is required.

Changes to a patient's existing therapy to a formulary listed alternative should only occur if there are no safety or clinical implications.

Formulary Listings

Formulary listings include the approved dose formulation and strength (for example 25 mg tablet). The range of dose formulations listed for a given medicine is to enable adequate titration of doses without excessive pill burden and facilitate safe and appropriate patient supply on discharge. Restrictions on the use of a medicine and additional information in a formulary note may be added to a formulary listing to support safe and appropriate use.

Restrictions

Placing restrictions on the use of a medicine may be considered by the Committee when there is:

- legislative/ specialist prescriber requirements
- safety concerns
- implications for ongoing access to supply
- cost implications

- specific population requirements
- off label use.

Medicines may be restricted by:

- indication
- prescriber/ specialty
- PBS criteria
- patient population
- monitoring requirements/ setting
- other.

Where the Committee determines no restriction is required, the medicine is listed as ‘Unrestricted’. An unrestricted medicine can be used in accordance with:

A. Registered indications as per the Therapeutics Goods Administration (TGA) Product Information OR

B. Accepted off label indications included within NSW endorsed reference texts for example., Australian Medicines Handbook (AMH), Therapeutic Guidelines (eTG) and State and National Guidelines

Formulary notes

The Committee may include additional information for individual medicines with the use of a ‘formulary note’. Additional information included in a formulary note may include:

- access considerations or requirements:
    - SAS form requirements
    - informed consent
    - potential ongoing costs for medicines not available via the PBS.
- legislation information:
    - state or national prescriber authority requirements
    - monitoring programs such as Safe Script NSW
- safety information:
    - look-a-like/sound-a-like medicines
    - specific storage requirements
    - medicines that are to be prescribed by brand
    - medicine formulations/brands that are not interchangeable
    - contact information for NSW Poisons Information Centre.
- medicine availability
    - schedule 19A/SAS alternatives during supply disruptions.
- off label considerations:
    - additional supporting prescribing and administration guidance required within a DTC protocol
    - approved off label indications.

Brands

Clinical brands

For clinical or safety reasons, the Committee may approve only a specific brand(s) of medicine for listing on the Formulary. The Formulary listing will indicate the approved 'clinical brand'. Clinical brands are identified on the online platform by the use of burgundy text and additional information within the formulary note.

Biosimilars

Biologic medicines are included on the Formulary and are listed by their generic medicine name.
The Formulary does not specify a biosimilar brand for use unless there is a clinical or safety need.
The Committees position statement on biosimilars can be found on the CEC website.

Review dates

All medicines added or amended on the Formulary will have an initial review date of 24 months. The subsequent review date will be 5 years unless otherwise determined by the Committee.

The scheduled review of a formulary listing may include:

- a review of drug utilisation trends
- analysis of safety concerns and incident trends
- evaluation of new evidence
- evaluation of outcome data from a Medicines Use Evaluation (MUE)
- a review of supply and availability.

Formulary Submissions

Formulary submissions to add, amend or remove medicines listed on the Formulary may be initiated by NSW Health clinicians or by the Secretariat. Formulary submissions will not be accepted from pharmaceutical sponsors. Clinicians are required to declare any conflicts of interest (including any level of pharmaceutical sponsor involvement) when completing a submission. Where submissions have had pharmaceutical sponsor involvement, a discussion between the Chair and the applicant is required, prior to evaluation, to assess the potential conflict of interest.

Formulary submissions will be completed using the standardised submission form hosted on the online platform. Submissions require endorsement by the Local Health District (LHD) or Specialty Health Network (SHN) DTC prior to review by the NSW Medicines Formulary Committee. Further information on the Formulary submission process can be found on the NSW Medicines Formulary online platform.

The Secretariat will review the submission for completeness, accuracy, appropriateness and ensure sufficient supporting evidence has been provided. If required, the Secretariat may request advice from expert specialty groups such as the High-Cost Medicine Subcommittee, CEC speciality networks, ACI clinical advisory networks and HealthShare NSW.

The Secretariat will complete an evaluation of the submission using the Formulary Submission Framework for presentation to the Committee.

The formulary submission process is expected to take up to two months to complete from receipt of a complete formulary submission application by the Secretariat. The time frame will depend on completeness of application and/or requirement for further consultation.

Outcomes on formulary submissions will be communicated to LHD/SHN DTC's and the applicant. Formulary submissions (including outcomes) will be available to all NSW Health clinicians on the Formulary online platform for 12 months. The Secretariat will maintain a record of all submissions.

Formulary Decision-making Principles

Medicines for consideration

The Committee consider medicines based on:

- a population need that has not been met:
    - a gap of listed medicines for management of a specific medical condition*
    - a gap of listed medicines for specific patient populations*
- benefits/ risks associated with administration, prescribing, storage and dispensing
- updated evidence base.

*A clinical preference is not a gap in the formulary.

The Committee approve medicines for listing on the Formulary using the decision algorithm found in appendix 2 of the Terms of Reference and Formulary Submission Framework.

Additional principles relating to medicines for inclusion on the Formulary:

- combination medicines are considered where safety/practical/administration benefits exist OR where individual agents are not available
- the scope is not limited to commonly used medicines and includes consideration of refractory and rare conditions where evidence supports use, no alternatives exist, and the use of IPU would not add value (or be practical). Medicines are considered for formulary listing where volume of use is low when:
    - the medicine is under state-wide governance AND
    - there is evidence for its use AND
    - there are no formulary listed alternatives for the requested indication or patient population OR where complex/ refractory treatment options are needed.

Individual Patient Use (IPU) approval

The Committee may decide not to list a medicine on the Formulary if additional oversight is required for initiation of a medicine via the IPU approval process

Additional oversight may be required when:

- individual risk/ benefit assessment documentation where low levels of evidence exist
- medicine use is for refractory conditions where standard treatments are formulary listed
- to provide oversight for written informed consent
- prospective evaluation of efficacy and safety outcomes is required
- significant costs (initial and ongoing) require clinical governance oversight at the LHD/SHN level.

If a medicine/ indication is not listed on the Formulary for these reasons, the Committee is to outline the rationale for the decision and reason for additional oversight via an IPU approval process. A review of IPU approvals for this medicine/indication should occur 12 months after a decision not to list on the

Formulary, to ensure IPU approval workflow is not impractical or placing an unreasonable burden on sites for providing standard care.

Appeals Process

Appeals against decisions made by the Committee may be made on the grounds of:

- decisions based on inaccurate or incomplete information
- procedural unfairness, i.e. the published submission process has not been followed
- decisions which are expected to have high-cost, high-impact, require large practice change or pose significant risk to any LHD or facility.

A letter outlining the rationale for appeal should be addressed to the Chair of the Committee. The Chair will initiate an appeal process to ensure due diligence occurred. Upon review by the Chair, a panel of independent clinicians (e.g., a pharmacologist, a senior pharmacist, and a consultant with expertise in the area) may be consulted to review the appeal and provide recommendations to the Committee.

In the instance that the appeal cannot be resolved by the appeal process the appeal will be escalated to the accountable Deputy Secretary.

Maintenance of the formulary

Horizon scanning

Horizon scanning supports systems to stay up to date with the latest developments. It involves systematically monitoring for emerging trends, new therapies, and changes in evidence or recommendations of existing therapies.

The Secretariat will undertake routine horizon scanning to proactively initiate submissions to the Committee where there are implications for existing listings or where a new therapy should be considered for listing. This will ensure the Formulary remains current and in line with emerging evidence and safety concerns.

The following resources will be monitored monthly:

- TGA updates
- ACSQHC - On the Radar
- PBS updates
- MIMS Monthly Update
- ASQHC updates
- Ministry of Health Policy Distribution System Notifications
- ISMP Medication Safety Alerts
- Clinical Excellence Commission - Medication Safety Updates
- Australasian Neonatal Medicines Formulary
- IPU decision logs
- Therapeutic Guidelines.

Additional resources and information sources may also include correspondence from HealthShare NSW, eHealth, LHDs/SHNs, CEC-Medication Safety Quality (MSQ) team or the release of other relevant resources/publications (such as release of consensus statements or clinical practice guidelines).

Where required, the Secretariat will liaise with CEC-MSQ, HealthShare NSW, specialty networks or LHD/SHNs for advice and further input. When sufficient information has been collated, the item will be reviewed for the potential impact to determine the appropriate action(s).

Potential impact and actions may include:

- immediate impact - referred for out of session update to the formulary (e.g., critical shortage or safety information)
- impact on formulary listings, but not critical or urgent - tabled for discussion with the Chair and review by the Committee
- potential impact - discussion with Chair and other stakeholders
- no impact - noted in horizon scanning log, no action required.

IPU Decision Logs

The Secretariat will review the centrally reported IPU approvals every 6 months and present a summary to the Chair. Where multiple IPU approvals for the same medicine and indication are occurring, the Secretariat may initiate a medicine use evaluation or formulary submission, or coordinate/request a submission from a LHD/SHN.