# NSW Medicines Formulary Frequently Asked Questions

## What is a medicines formulary?

A medicines formulary is a continually updated list of medicines and related information that has undergone a systematic, evidence-based evaluation process that considers appropriate, safe, and cost-effective medicines use.

## What is the NSW Medicines Formulary?

The NSW Medicines Formulary is a list of medicines approved for initiation in inpatients in NSW public hospitals and health services. The formulary includes the approved indication, dose formulations and prescribing restrictions for individual medicines, where applicable.

## What are the benefits of the NSW Medicines Formulary?

Establishing the NSW Medicines Formulary and the associated centralised governance arrangements aims to achieve several benefits, including:

- Equity of access to medicines for all patients in NSW.
- Consistency of medicines use, while maintaining appropriate clinician choice.
- Improving patient outcomes by supporting evidence-based use of medicines.
- Enhancing supply chain resilience.
- Using state-wide purchasing to obtain best value.
- Improving medication safety and the ability to monitor medication use and outcomes.
- Supporting clinical governance through streamlined formulary medicine decision-making and reduced duplication of effort.
- Supporting monitoring and feedback of data to clinicians and managers to enable the delivery of high-quality care.

## What medicine types are considered for listing on the NSW Medicines Formulary?

Initially, the medicines for inclusion under state-wide governance on the NSW Medicines Formulary include:

- Medicines included on the Australian Register of Therapeutic Goods (ARTG).
- Plasma derived and recombinant blood products are only considered for medicines / indications that are not available via the National Blood Agreement
- Parental oncology medications for inpatient use.
- Diagnostic agents with therapeutic indications.
- IV Fluids, excluding peritoneal dialysis solutions and perfusion fluids.
- Some parenteral and enteral nutrition products, specifically:
  - Enteral products available under the PBS.
  - Standardised base products for parenteral nutrition.
- Special Access Scheme (SAS) medicines (SAS medicines are considered on a case-by-case basis 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).
- Schedule 5A medicines are considered on a case-by-case basis



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## What medicine types are not considered for listing on the NSW Medicines Formulary?

The following medicines are not currently for consideration, their use will remain under local Drug and Therapeutics Committees (DTCs) 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 (e.g., compassionate use, product familiarisation, and cost share programs).
- Medical devices containing medicines.
- Gene therapies.
- Non-core pharmacy items.

The NSW Medicines Formulary Committee will continue to review and expand the scope of the state-wide formulary.

## What is considered a non-core pharmacy item?

Non-core pharmacy items are product lines purchased for internal use within the pharmacy department, or for specific patient use as a supplementary treatment or for non-therapeutic use.

Examples of non-core pharmacy items include:

- Diluents used in reconstitution (e.g., water for injection and sodium chloride 0.9%).
- Ingredients used in extemporaneous manufacturing, including core active ingredients and associated vehicles, excipients, and solvents.
- Nutritional and dietary supplements (e.g., Ensure).
- Irrigations and flushes, antiseptics, disinfectants, soap, soap substitutes, and washes.
- Non-medicated creams, lotions, lip balms, emollients, barrier creams, moisturising lotions, skin cleansers, and protective agents, including sunscreen.
- Dressings.
- Lubricants, substitutes, and associated products (e.g., saliva substitute, sodium chloride nasal sprays, and mouthwashes).
- Non-medicated powders and talcs.
- Inhalants, such as essential oil-based products.
- Other devices, including delivery aids, test agents and controls, and dyes and diagnostic agents, such as allergen extracts and Pathology department consumables.
- All pharmacy related consumables.

## What is the process for prescribing medicines under local governance?

The approval to prescribe medicines which are outside the scope of the NSW Medicines Formulary will remain within the remit of Local Health District (LHD)/Specialty Health Network (SHN) DTCs or equivalent, as per current processes.



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## What were the governance arrangements for the NSW Medicines Formulary during the establishment phase?

In partnership with the Ministry of Health, the Clinical Excellence Commission (CEC) has established the NSW Medicines Formulary Committee and NSW High-Cost Medicines Sub-committee. The CEC provides secretariat support to these committees.

During the establishment phase, the NSW Medicines Formulary Committee was responsible for approving the initial list of medicines for inclusion on the NSW Medicines Formulary.

A list of membership positions can be provided on request via the following email address: CEC-MedicineFormulary@health.nsw.gov.au.

## How was the NSW Medicines Formulary established?

The NSW Medicines Formulary is based on a core formulary used across six rural local health districts. A comprehensive and robust process occurred to build the formulary to ensure the medicines meet the needs of both the rural and metropolitan clinicians and patients.

To determine which medicines should be considered for addition to the formulary, multidisciplinary Expert Advisory Groups (EAGs) were established based on therapeutic areas.

The NSW Ministry of Health and CEC worked with each LHD, SHN and NSW Ambulance to seek nominees for representatives to participate in these groups. Each of these groups was multidisciplinary, and included representatives from rural, regional, and metropolitan areas.

The EAGs provided expert clinical advice and applied quality use of medicines principles to make recommendations regarding the inclusion of medicines on the NSW Medicines Formulary.

Other specialty groups were consulted, including paediatrics /neonatology, geriatrics, critical care, palliative care, clinical toxicology, NSW Ambulance, and nurse practitioners where appropriate.

The NSW Medicines Formulary Committee considered these recommendations for addition or amendment of listing on the NSW Medicines Formulary.

The NSW High-Cost Medicines Sub-committee provided advice to the NSW Medicines Formulary Committee regarding which high-cost medicines should be included on the NSW Medicines Formulary.

A list of EAG membership positions can be provided on request via the following email address: CEC-MedicineFormulary@health.nsw.gov.au.

## What EAGs were formed?

Expert Advisory Groups were formed based on the following therapeutic areas:

- Allergy and Anaphylaxis
- Anaesthetics and analgesics
- Antidotes and antivenoms
- Anti-infectives
- Blood and electrolytes
- Cardiovascular drugs
- Dermatological drugs
- Ear, nose, and throat drugs



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- Endocrine drugs
- Eye drugs
- Gastrointestinal drugs
- Genitourinary drugs
- Immunomodulators and antineoplastics
- Neurological drugs
- Obstetric and gynaecological drugs
- Psychotropic drugs
- Respiratory drugs
- Rheumatological drugs
- Vaccines.

## How were clinicians involved in the establishment of the NSW Medicines Formulary?

Clinicians were directly involved in the establishment of the NSW Medicines Formulary through participation in:

- Expert Advisory groups (EAGs)
- The NSW Medicines Formulary Committee
- The High-Cost Medicines Sub-Committee.

The NSW Ministry of Health and CEC project teams worked with each LHD, SHN, and NSW Ambulance to seek nominees for representatives in these groups. Each group is multidisciplinary and includes representatives from rural, regional, and metropolitan areas.

## When will the NSW Medicines Formulary be implemented?

The establishment phase of the NSW Medicines Formulary commenced in July 2021.

The transition and implementation of the NSW Medicines Formulary and its associated governance processes commenced in September 2022.

## Where will I find the NSW Medicines Formulary?

The NSW Medicines Formulary will be hosted on a dedicated online platform.

The NSW Ministry of Health, CEC, and eHealth NSW are working together to oversee the implementation of the online platform, which will be user-friendly and easy for clinicians to access from wherever they practice. The online platform will provide clinicians with a single source of information relating to the state-wide formulary.

## What does this mean for the Rural Medicines Formulary?

A transition process has occurred across all rural LHDs from the Rural Medicines Formulary to the NSW Medicines Formulary. Minimal change is expected for rural clinicians as the medicines approved on the Rural Medicines Formulary formed the basis of the NSW Medicines Formulary. Considerations were made to add “in rural/remote settings, an appropriate specialist” as a restriction for medicines, where applicable, due to the limited availability of specialist services in these areas.

## What will the ongoing governance arrangements be for the NSW Medicines Formulary?

The NSW Medicines Formulary Committee is the peak governance committee for medicines and therapeutic agents in NSW. The committee will oversee the maintenance of the NSW Medicines



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Formulary to ensure appropriate, safe, and cost-effective use of medicines within NSW Health.

The committee membership is multidisciplinary and includes representatives from clinicians, clinical governance, senior executives, and relevant state-wide advisory groups.

The responsibilities of the NSW Medicines Formulary Committee include:

- Implementing systematic, fair, and transparent process for adding, amending, removing, and reviewing medicines included in the NSW Medicines Formulary.
- Evaluating medicines for formulary inclusion with a considered and consistent approach, underpinned by evidence-based best practice and cost-effectiveness.
- Consulting with expert advisory groups and committees, and other lead clinicians and experts.
- Recommending the development of state-wide clinical guidance, protocols, or other educational resources to accompany formulary medicines.
- Ensuring effective and timely decision-making and communication of formulary matters to existing LHD and SHN DTCs and other relevant medicines-related governance committees.
- Ensuring all clinicians involved in the submission and assessment of applications for formulary listings disclose any perceived or actual conflicts of interest.
- Reviewing reports received for Individual Patient Use (IPU) approvals and non-formulary medicine use within the LHDs and SHNs to determine if a formulary evaluation is required.
- Advising the formulary secretariat regarding the need for medicines use evaluations (MUEs) to inform the review of formulary medicines.

The High-Cost Medicines Sub-committee has also been established to make recommendations to the NSW Medicines Formulary Committee about whether a high-cost medicine should be included on the NSW Medicines Formulary. This will improve the allocation of resources and access to these medicines for NSW patients.

The responsibilities of the sub-committee 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.
- Monitor use of high-cost medicines in NSW hospitals included in the NSW Medicines Formulary.
- Monitor reports received for high-cost IPU approvals and non-formulary medicine use within LHDs and SHNs to determine whether a formulary evaluation or guidance is required.

## What is the role of the Drug and Therapeutics Committee (or equivalent) in relation to the NSW Medicines Formulary?

Local and district DTCs (or equivalent) will play a vital role in implementing the NSW Medicines Formulary. Local DTCs will be responsible for reviewing submissions from local clinicians and determining whether support exists across the district or network to progress the submission to the NSW Medicines Formulary for evaluation.



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DTCs will perform functions which ensure adherence to the NSW Medicines Formulary, monitor medication use, and provide guidance to health workers in the rational use of medications and the treatment guidelines that apply in the relevant facility or facilities.

DTCs will govern medication management systems to ensure safe and appropriate use of medicines (e.g., storage, prescribing, supply, administration, and recording protocols and procedures) at facility or facilities assigned to them.

DTCs will also continue to have oversight of medication safety, including responsibility for:

- Collation and analysis of incident reports involving medications.
- Oversight of medication recall and product defect management procedures.
- Development and implementation of strategies for medication error prevention.

The relevant DTC will continue to evaluate IPU applications at a local level.

DTCs will be required to report outcomes of IPU applications for state-wide collation. They will also be responsible for communicating formulary and IPU decisions, and any related safety requirements, to relevant clinicians and medication-related governance committees.

DTCs will continue to manage medicines outside the scope of the NSW Medicines Formulary, as per current processes.

## Will a new policy be developed to support this framework?

Rather than developing a new policy, relevant existing policies were reviewed and updated to support the implementation of the NSW Medicines formulary and the associated governance arrangements. Key updated policies include PD2022)_056 Approval Process for Medicines and Their Use and PD2022_032 Medication Handling. The normal consultation processes will apply for any changes to these policies and other identified policies.

## What about patients who come into hospital on medicines that are not listed on the formulary?

Medicines included on the NSW Medicines Formulary have been approved for **initiation of therapy**.

If a patient is admitted to hospital and already taking a medicine that is not included on the formulary, existing local processes for supply of these medicines for continuation of therapy will remain. **An IPU is not required for continuation of therapy**.

A subset of medicines for **continuation of therapy** have been included in the NSW Medicines Formulary to facilitate easy access to high volume medicines commonly used in the community. Medicines in this subset may be kept on imprest in clinical areas for inpatient use, for continuation of therapy only.

It is encouraged that patient's non-formulary medicines are reviewed on admission to consider the safety, efficacy, and cost-effectiveness of treatment. Consider switching to the preferred or first-line alternative medicine listed on the formulary where appropriate. Prescribers should discuss these decisions with the patient and/or their carer, and the initiating prescriber if relevant.



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Where the patient's medicine is stable and there are no clinical reasons for change, treatment may be continued. This may be through procurement of non-formulary medicines through the local hospital Pharmacy Department or utilisation of patient's own medicines if immediate access is required.

### What happens if a prescriber wants to initiate a medication which is not on the formulary?

If a prescriber is seeking to **initiate a medication** which is not on the NSW Medicines Formulary, the prescriber will need to follow local medicines governance processes to obtain approval to prescribe the medicine. This will typically require an approval for Individual Patient Use (IPU) from the local DTC. The local hospital Pharmacy Department should be contacted for further advice on IPU application processes.

### Do hospitals have to keep all medicines listed on the NSW Medicines Formulary?

No. Individual facilities will decide which medicines will be routinely stocked according to local needs. Facilities may choose not to stock certain formulary medicines for local reasons. However, to support equity of access, these medicines should be made available in a timely manner when prescribed under the formulary criteria and where clinically appropriate.

### What happens if there is a shortage or recall of medicines listing on the NSW Medicines Formulary?

If medicine shortages or recalls occur, the NSW Medicines Formulary Committee will have a process in place to facilitate the rapid assessment and approval of an alternative medicine. The CEC has existing mechanisms to coordinate the response to system-level shortages. The procurement reforms being implemented as part of the broader Pharmaceutical Procurement Review will also result in enhanced supply chain resilience, which will improve the management of medicine shortages and reduce risk to supply.

### How can a medicine be added to the NSW Medicines Formulary?

Clinicians (with endorsement of their local DTC) can request to add or amend medicines included on the NSW Medicines Formulary. Clinicians should contact their local DTC for advice on how to proceed with a submission.

Applicants can utilise their local formulary application forms for submission until a standardised submission application is available through the online platform. Formulary submissions will not be accepted from pharmaceutical sponsors.

The NSW Medicines Formulary Committee secretariat will also conduct regular horizon scans to assess Pharmaceutical Benefits Scheme updates, medicines shortages, discontinuations, safety notices, and therapeutic information updates. Based on the findings of these environmental scans, the secretariat may request that the NSW Medicines Formulary Committee considers amending the NSW Medicines Formulary accordingly.

### Can a medicine be removed from the NSW Medicines Formulary?

Yes. A medicine may be removed from the NSW Medicines Formulary in the following circumstances:



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- Following the regular formulary review process. The NSW Medicines Formulary will be reviewed regularly, with each medicine allocated a review date at the time of approval by the NSW Medicines Formulary Committee. For example, the review will consider whether a newer, safer, or more cost-effective alternative medicine is available.
- Where a new formulary submission has prompted a review of current approved medicines within the same class or indication.
- If new evidence arises (e.g., additional side effects or contraindications). In these situations, clinicians or local DTCs (or both) can apply to have a medicine removed or restrictions amended.
- Where there is evidence of infrequent use of a particular medicine, which may prompt a review of its inclusion in the NSW Medicines Formulary.

### Will high-cost medicines be included on the NSW Medicines Formulary?

High-cost medicines will be considered for listing on the NSW Medicines Formulary. However, the evaluation process for these medicines will require an additional level of assessment by the High-cost Medicines Sub-committee.

### What does this mean for the Justice Health and Forensic Mental Health Network?

The approval to initiate medicines in inpatient settings within Justice Health and Forensic Mental Health Network (JHMHN) falls within state-wide governance of the NSW Medicines Formulary. The approval to initiate medicines in non-inpatient settings remains under local governance, as per current processes.



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