SESLHD POLICY COVER SHEET

NAME OF DOCUMENT	Medicine: Medicine Formulary Policy
TYPE OF DOCUMENT	Policy
DOCUMENT NUMBER	SESLHDPD/183
DATE OF PUBLICATION	August 2023
RISK RATING	Medium
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 1 – Clinical Governance Standard 4 – Medication Safety
REVIEW DATE	August 2026
FORMER REFERENCE(S)	SESIAHS PD 178
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, Clinical Governance and Medical Services
AUTHOR	SESLHD Change Lead Pharmacist- NSW Medicines Formulary (Temporary position) seslhd-drugcommittee@health.nsw.gov.au
POSITION RESPONSIBLE FOR THE DOCUMENT	SESLHD Quality Use of Medicines, Lead Pharmacist seslhd-drugcommittee@health.nsw.gov.au
FUNCTIONAL GROUP(S)	Medicine
KEY TERMS	Medicine, formulary, individual patient use (IPU), special access scheme (SAS), medicine access program, prescriber, pharmacy, medicines use evaluation (MUE).
SUMMARY	This document describes the ongoing management of the SESLHD Medicines Formulary including processes for addition and amendments. It outlines the process for access to non-formulary medicines via SESLHD facility pharmacies. It outlines access to approved outpatient medicines via SESLHD facility pharmacies and associated patient charges.

Feedback about this document can be sent to SESLHD-Policy@health.nsw.gov.au

1. POLICY STATEMENT

This policy describes the ongoing management of the SESLHD Medicines Formulary (MF). SESLHD has a comprehensive Formulary which is informed by the NSW MF and governed by the SESLHD Drug and Therapeutics Committee (DTC). The SESLHD MF informs prescribing by authorised clinicians across all SESLHD sites and services, in both inpatient and outpatient settings.

This policy outlines the governance structure for medicines use and approval, including, processes for addition and amendment to the SESLHD MF and processes for Individual Patient Use (IPU) requests.

This policy also defines the access to outpatient medicines via SESLHD Pharmacy services and associated patient charges.

2. AIMS

- To maintain a SESLHD MF to regulate the medicines available for initiation in inpatients in facilities within SESLHD.
- To maintain a SESLHD MF which includes Formulary Categories to guide clinicians on how to manage medicines based on their specific category.
- To support equity of access to medicines for patients and improve patient outcomes from evidence- based use of medicines.
- To detail a standard framework of processes for SESLHD MF amendments.
- To detail a standard framework of processes for evaluation of requests to use non-formulary medicines or to use medicines in circumstances where the formulary restrictions are not met.
- To define outpatient eligibility to access supply of outpatient medicines via SESLHD Pharmacy services.
- To define patient charges for supply of ALL outpatient medicines to ensure consistency across SESLHD Pharmacy services.

3. TARGET AUDIENCE

The policy is applicable to all public hospital and community health facilities in SESLHD.

4. RESPONSIBILITIES

SESLHD Drug and Therapeutics Committee (DTC)

- Review and endorse SESLHD Medicines Formulary policy and associated procedures.
- Ensure formulary management is in accordance with NSW Ministry of Health Policy Directive PD2022_056 - Approval Process of Medicines and Their Use and support local adoption of the NSW MF.
- Timely review and assessment of formulary according to approved procedures. Escalation of formulary applications to the NSW Medicines Formulary Committee (MFC) if applicable and appropriate.
- Ensure clear and effective communication of all formulary decisions.
- Monitor implementation of, and compliance with the NSW Medicines Formulary.

- Review usage of formulary items as determined by the SESLHD DTC and if associated with medication incidents or adverse events.
- Undertake Individual Patient Use (IPU) evaluations using the decision framework of this policy Appendix C and monitor decisions.
- Maintain a register of IPU decisions and report to Clinical Excellence Commission (CEC).

Medicines Advisory Subcommittee of the SESLHD DTC

- Provide advice on Pharmacy-related matters to, and at the request of the SESLHD DTC.

SESLHD Clinical Streams

- Coordinate and ensure relevant clinical consultation and review of SESLHD Formulary Applications at the request of the SESLHD DTC.
- Provide recommendations to the SESLHD DTC regarding Formulary applications via the Service Director/ Manager.

Site/service Medication Safety Committees

- Monitor implementation and compliance with the SESLHD MF, locally or as directed by the SESLHD DTC.
- Escalate Formulary and IPU issues to the SESLHD DTC.

Clinical Staff

- Ensure medication use is consistent with the SESLHD MF and associated procedures.
- Request additions or amendment to the SESLHD MF in accordance with NSW Ministry of Health Policy Directive PD2022_056 - Approval Process of Medicines and Their Use and via the relevant Clinical Streams and SESLHD DTC.
- Report all incidents and adverse reactions associated with medicines via the IMS+ incident management system. These will be reviewed by the local site Medication Safety Committee and escalated to the SESLHD DTC as appropriate.

SESLHD Directors of Pharmacy or Delegates

- Ensure all SESLHD Pharmacy staff adhere to the SESLHD MF when reviewing or supplying medicines for SESLHD inpatients or outpatients.
- Report all incidents and adverse reactions associated with medicines via the IMS+ incident management system.

NSW Medicines Formulary Committee

- Oversee the maintenance of the NSW MF and review ‘in scope’ formulary applications.
- Facilitate communication (via NSW MFC secretariat) of NSW MF decisions to the DTCs of NSW hospitals, local health districts, District Directors of Pharmacy and/or Directors of Pharmacy.

5. DEFINITIONS

SESLHD Medicines Formulary (MF): a comprehensive list of medicines authorised for use within SESLHD which may include restrictions or guidelines for the use of the medicine listed. The SESLHD MF includes a list of medicines approved for use in inpatient and outpatient settings.
The Medicines Formulary excludes medicines used as part of research or clinical trials and approved for use within SESLHD by the relevant Human Research Ethics Committee. The SESLHD DTC must be notified of any clinical trials involving medicines occurring in SESLHD and has oversight of clinical trials that involve medicines in the organisation.

Medicines: includes medicines registered or listed on the Australian Register of Therapeutic Goods (ARTG), unregistered medicines and medicines made available under access programs. Therapeutic Goods of Australia (TGA) - registered blood products provided under the National Blood Authority are excluded from this definition.

Unrestricted medicine: can be used in accordance with:
A. Therapeutics Goods Administration (TGA) Product Information.
B. NSW endorsed reference texts e.g., Australian Medicines Handbook (AMH), Therapeutic Guidelines (eTG) and State and National Guidelines.

Off-Label use: The use of a registered medicine other than that specified in the TGA-approved product information including when the medicine is prescribed or administered:

- For another indication
- At a different dose
- Via an alternate route of administration
- For a patient of an age or gender outside the registered use

Unregistered medicine: A medicine or dosage form that is not currently approved for use in Australia and hence is not entered on the Australian Register of Therapeutic Goods.
Formulary applications for Special Access Scheme (SAS) medicines will be considered by the SESLHD DTC as outlined in Appendix D. SAS medications will be considered by the NSW MFC on a case-by-case basis.

Medicines Access Programs: offered by Pharmaceutical Companies (sponsors) to facilitate deferred cost, cost-free or subsidised access to medicines for specific patients or patient groups.

Medicines Access Programs include: -

- Compassionate Use Programs
- Expanded Access Programs
- Product (or Patient) Familiarisation programs
- Cost-Share programs.

SESLHD DTC approval is required when prescribing medicines funded through a Medicines Access Program (MAP).

Where multiple patients are treated under the same MAP, an application should be made to have the MAP added to the SESLHD MF.

For individual patients, an application should be submitted via the Comprehensive IPU process. Documentation outlining the condition of the MAP must also be included.

All MAPs must comply with Council of Australian Therapeutic Advisory Group (CATAG) Managing Medicines Access Programs: Guiding principles for the governance of Medicines Access Programs in Australian hospitals

Medicines under Clause 37 and Part 8 of the Poisons and Therapeutic Goods Regulation:

- Acitretin, clomiphene, cyclofenil, dinoprost, dinoprostone, etretinate, follitropin beta, hydroxychloroquine, isotretinoin for oral use, luteinising hormone, ivermectin, tretinoin for oral use, urofollitrophin (human follicle stimulating hormone). Clinicians must have Authority to prescribe these medicines under Clause 37 of the Poisons Regulation prior to prescribing.

SESLHD Formulary Categories Reference Guide: assists SESLHD clinicians in how to manage medicines based on their specific SESLHD Formulary Category (Appendix B).

IPU: Individual Patient Use applications are a request for approval to use a medication for an individual patient, either where the requested medication is not listed on the SESLHD MF or where the formulary restrictions are not met. There are 2 SESLHD IPU approval pathways: Comprehensive or Streamline.

Urgent IPU Requests: where the patient is deemed in a life-threatening situation and a decision regarding non-formulary medicine use is required immediately via a verbal approval from the local site DCS (or site equivalent) or approved delegate. Retrospective applications must be submitted in accordance with SESLHD IPU approval pathways: Comprehensive or Streamlined.

Eligible Patients:

- Hospital inpatients
- All patients on discharge from the hospital
- Medicare eligible persons attending a SESLHD outpatient clinic
- Medicare eligible persons with a valid prescription for an S100 subsidised medicine, written by an Authorised Prescriber.
- Medicare ineligible persons (PD2021_021), under circumstances approved by the hospital's General Manager or being treated under a refugee program, medicines access program, or other externally funded program. For example, NSW GL2023_015: HIV treatment for people in NSW who are not eligible for Medicare.

- Any person attending a public health clinic (i.e., sexual health, sexual assault or being treated for a disease subject to any arrangements made during a declared health emergency).

Note: the patient must have a Medical Record Number (MRN) at the SESLHD hospital where the prescription is presented, for the local site pharmacy to dispense it.

Authorised Prescribers (for outpatients):

- Any Registered Medical Practitioner accredited to or employed by the hospital to provide services to outpatients, in a clinic or after an admission.
- Accredited S100 HIV or Hepatitis B prescribers as per Prescriber Maps - ASHM

6. SESLHD MEDICINES FORMULARY POLICY

The SESLHD MF digital publishing platform and other relevant information are accessible to all SESLHD staff and can be found on the SESLHD Quality Use of Medicines Intranet page.

6.1 Formulary Application Process

- SESLHD formulary applications are submitted under Formulary Submissions via the NSW Medicines Portal. The formulary submission will be reviewed initially by a SESLHD DTC secretariat to determine whether the submission will be progressed to the NSW MFC. Medicines that are considered 'out of scope' for the NSW MF will be finalised by the SESLHD DTC.
- The SESLHD DTC uses a standard decision algorithm to guide its decision process, which is based on an algorithm from the NSW Therapeutic Advisory Group (NSW TAG). This algorithm is recommended for use in all NSW hospitals to encourage consistency in approach and equity of access to pharmaceuticals for hospital patients in NSW. The SESLHD DTC will consider not only clinical issues, but also economic issues in the decision process. Economic analysis may be undertaken on either a cost- effectiveness or cost minimisation basis, depending on the circumstances.
- The SESLHD DTC may request a proposed SESLHD prescribing protocol or medicine guideline to be submitted in conjunction with the application.

6.2 Formulary Review Process

- Review of SESLHD formulary applications will follow the Decision Algorithm outlined above for Evaluation of Medicines considering clinical evidence (efficacy and safety) and economic issues.
- Applications for off-label or unregistered medicine use will also be reviewed in accordance with SESLHDPD/182: Off-label use of registered medicines and use of unlicensed medicines.

6.3 Formulary Approval Process

- Consideration and review of complete SESLHD formulary applications will occur at the next relevant SESLHD DTC meeting for all applications received up to 2 weeks prior

to the scheduled DTC meetings.

- All applications and outcomes will be recorded by the SESLHD DTC secretariat.
- Applicants, relevant Clinical Streams/services, and pharmacy departments will be informed of the outcome of formulary applications, together with details of approved indications, prescribing restrictions and monitoring and reporting requirements following the SESLHD DTC meeting. The applicant will also be notified of any required protocol finalisation, staff education or specific patient education requirements.
- Site/service Medication Safety Committees, Directors of Pharmacy and relevant clinicians will receive a list of MF updates, including NSW MF decisions from the SESLHD DTC secretariat, following the SESLHD DTC meeting.
- Clinicians may appeal formulary decisions when they feel the approval process has not been documented or when circumstances or level of evidence for the use of the medicines has changed since the submission.

6.4 Formulary Monitoring Process

- Formulary approvals may have a review date set at the time of approval.
- Clinicians will be responsible for reporting to the SESLHD DTC any adverse events associated with the use of the medicine, in addition to other reporting requirements as set out in the conditions of the approval.
- Compliance with formulary approval, resource utilisation and outcomes of treatment may be subject to a Medicines Use Evaluation (MUE) process.
- Medicines will be considered for deletion from the formulary when evidence or information emerges that the medicine is no longer efficacious, unsafe or inferior to alternatives, or is to be discontinued from the Australian market.

6.5 SESLHD Pharmacy Outpatient Charges

Arrangements for the subsidised charge for a prescription are outlined in NSW Ministry of Health Policy Directive PD2022_027 - Pharmaceutical and safety net arrangements for outpatients and patients on discharge. Co-payment can be waived in individual patient circumstances of financial hardship (as per Delegation Manual) or if noted on the SESLHD MF.

7. IPU POLICY

In SESLHD there are two IPU approval pathways: Comprehensive or Streamline.

Comprehensive IPU

When a SESLHD authorised prescriber is initiating a request for use of:

- A medicine or indication which is not listed on the SESLHD MF, **or**
- A medicine listed on the SESLHD MF, but use is for an off-label indication, **or**
- An unregistered medicine which is not listed on the SESLHD MF.

Streamline IPU

When a SESLHD authorised prescriber is initiating a request for use of:

- Inpatient use of PBS S100 or Efficient Funding of Chemotherapy, **or**
- PBS approved indications for either:
    - PBS ineligible outpatient (e.g., Justice Health) **or**
    - Outpatients requiring financial support.

High Cost IPU

All IPUs with a cost > $10,000 per course or annum* must be approved by the General Manager prior to submission to the SESLHD DTC.

** Determined by the actual cost of the medicine, regardless of funding source.*

7.1 IPU Application, Review and Approval Process

Comprehensive IPU

- Comprehensive IPU applications must be completed on SESLHD Individual Patient Use- Application Form (or similar).
- Application form must be submitted to the relevant local site Pharmacy Service for review and local approval.
- Each SESLHD local site will determine and document the local site approval chain. At a minimum it should include a senior medical officer e.g., Director of Clinical or Medical Services, Head of Department, Clinical Program Director and Senior Pharmacist e.g., Director or Deputy Director of Pharmacy.
- Local site Pharmacy delegate to submit Comprehensive IPU to SESLHD DTC via SESLHD DTC IPU Database PowerApp.
- Application will be reviewed by SESLHD DTC Secretariat and circulated to DTC Executive members for consideration.
- SESLHD DTC Secretariat will advise the applicant and the relevant Pharmacy Service of the outcome including any restrictions, monitoring, and reporting requirements.
- Comprehensive IPUs will be tabled quarterly at the SESLHD DTC meeting.
- IPU approvals for ongoing or long-term treatments will be reviewed at a minimum of 12-monthly intervals. A review date will be set at the time of approval and at each review. Continued or further IPU approvals are conditional upon completion and submission of the SESLHD IPU Report Form (or similar) to the SESLHD DTC.

Streamline IPU

- Streamline IPU applications must be completed on the SESLHD Application for Use of a Highly Specialised Drug for an inpatient (Form F418).
- All applications must be recorded by the local Pharmacy Service providing the medicines in the PBS non-formulary medicines- SESLHD funding PowerApp.

- A report of streamline IPUs will be tabled quarterly at SESLHD DTC meeting.
- All IPU applications are assessed using a standard decision algorithm (Appendix E).
- Relevant High cost or complex IPU applications are further assessed using a detailed

  decision-making framework developed by SESLHD Clinical Ethics Service (Appendix F).
- The SESHD DTC secretariat is responsible for maintaining access to the SESLHD

  DTC IPU Database and PBS non-formulary medicines – SESLHD funding PowerApp. Requests for access should be submitted via email to mailto:SESLHD-DrugCommittee@health.nsw.gov.au

7.2 IPU Monitoring Process

- SESLHD IPU decisions will be monitored by the SESLHD DTC.
- Relevant Clinicians and/ or Heads of Departments will be requested by the SESLHD DTC to submit a formulary application if 3 or more IPUs have been submitted for the same indication.

8. DOCUMENTATION

- SESLHD Individual Patient Use- Application Form .
- SESLHD IPU Report Form
- SESLHD Application for Use of a Highly Specialised Drug for an inpatient (Form F418)
- Patient Consent to Exceptional Use of a Medicine – Form SEI020.025 (ordered from Stream Solutions)

9. REFERENCES

External References

- NSW Health PD2022_032 - Medication Handling. 11 August 2022
- NSW Health PD2022_056 - Approval Process of Medicines and Their Use. 2 December 2022
- NSW Health PD2022_017- Pharmaceutical and Safety Net Arrangements for Outpatients and Patients on Discharge. 8 June 2022
- NSW Health PD2021_021 Medicare Ineligible and Reciprocal Health Care Agreement
- Guiding Principles for the Governance of Medicines Access Programs in Australian Hospitals. June 2018
- NSW Therapeutic Advisory Group. Decision Algorithm for evaluation of medicines for Formulary listing in public hospitals. November 2009.

- Decision Algorithm for Evaluation of Medicines for Individual Patient Use (IPU) Approval in Public Hospitals (NSW TAG November 2009)
- Poisons and Therapeutic Goods Regulation 2008- Reg 37
- CATAG. Rethinking medicines decision-making in Australian Hospitals- Guiding Principles for the Quality Use of Medicines 2013

Internal References

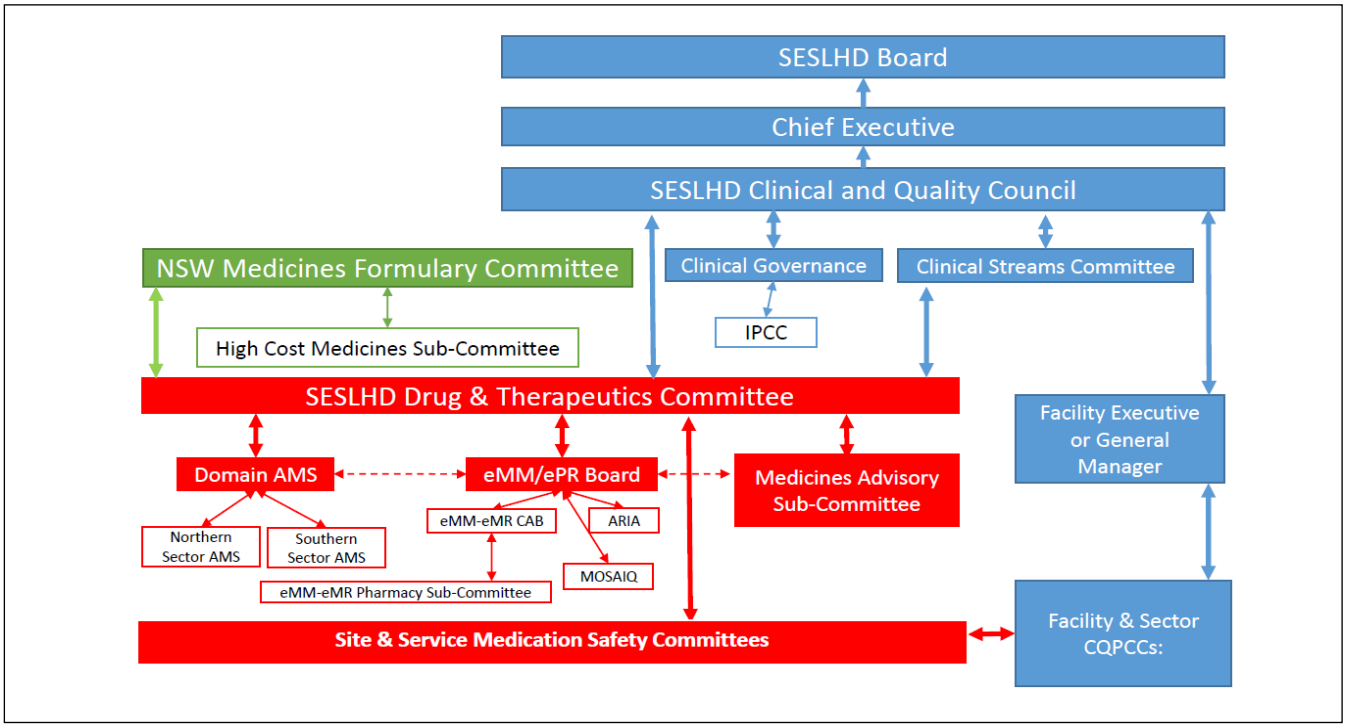
- SESLHDPD/182 Medicine: Off-label use of registered medicines and use of unlicensed medicines

9. VERSION AND APPROVAL HISTORY

Date	Version No.	Version and approval notes
Sept 2008	0	Julie Thompson, Area Drug Committee Pharmacist Co-ordinator on behalf of the Area Drug Committee. Approved by Area Drug Committee10 July 2008. Approved by Executive Sponsor Elizabeth Koff, Director Clinical Operations and Clinical Council Committee 24 September 2008.
Sept 2009	1	Julie Thompson, Area Drug Committee Pharmacist Co-ordinator on behalf of the Area Drug Committee. Approved by Area Drug Committee 10 September 2009 and forms F188 and F189 revisions approved 10 December 2009.
April 2012	2	Updated links and rebadged for LHD, patient eligibility revised - Julie Thompson, D&QUMC Pharmacist Co-Ordinator on behalf of SESLHD D&QUMC. Approved by SESLHD D&QUMC 12 April 2012
June 2012	2	Changes and review approved by Executive Medical Director
October 2012	2	Updated link to Guiding Principles for Medicines Access Programs in Australian Public Hospitals
September 2014	3	Maintenance of formulary and iPharmacy updated, links and external references updated. Julie Thompson, D&QUMC Pharmacist Co-Ordinator on behalf of SESLHD D&QUMC. Approved by SESLHD D&QUMC 9 October 2014
December 2014	3	Changes and review endorsed by Director Clinical Governance
July 2015	3	References and links updated. Julie Thompson, D&QUMC Pharmacist Co-Ordinator on behalf of SESLHD D&QUMC. Approved by SESLHD D&QUMC 11May2015 (9.3)
February 2016	4	Minor changes and updates for consideration of QUM Approved by QUM 3 March 2016 (11.1)
April 2016	4	Updates endorsed by Executive Sponsor
April 2017	4	Minor updates made to forms references. Review dates to remain the same.
May 2018	5	Minor update to section 5 Definitions to include TGA-registered blood products provided under the National Blood Authority are excluded from this definition – endorsed by Executive Sponsor.
October 2020	6	Updates to IPU process in accordance with Clinical Ethics review. Updated definition of eligible patients to reflect current outpatient supply practices. Minor wording changes. References updated
November 2020	6	Approved by Quality Use of Medicines Committee Published by Executive Services.

29 August 2023	7.0	Major review. Updated in line with SESLHD Medication-related Committees and Associated Governance Restructure. Updated in line with NSW MFC and associated Governance. Updated in line with NSW Ministry of Health Policy Directive PD2022_056 - Approval Process for Medicine and their use. Approved at the July 2023 SESLHD Drug and Therapeutics Committee and August 2023 Clinical and Quality Council.

Appendix A: SESLHD Medication Related Committees



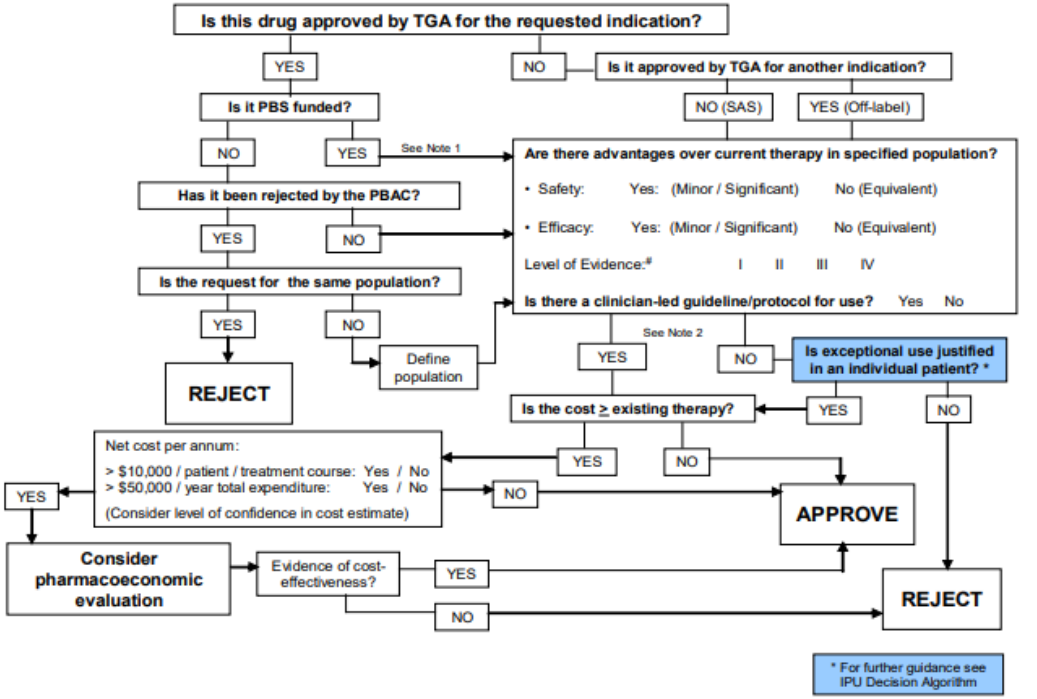
Appendix B: SESLHD Medicine Formulary Categories

SESLHD Formulary Category	*Definition*	*iPharmacy identification*	*Explanation*
Formulary: inpatient initiation	Determined by NSW MF and the SESLHD DTC: evidence-based medicines for initiation	Formulary	Medicines that are approved for initiation in inpatients.
Formulary: continuity of medicine	Determined by SESLHD DTC: prescribing of pre-admission medicines as supported by evidence and high usage.	Formulary	Medicines that must not be initiated in inpatients as determined by the NSW MF Committee. Continue patient's pre-admission medicine if there is no clinical reason for change. Includes SESLHD high usage medicines (may include high usage fixed dosed combination medicines). Medicines may be included on imprest lists and general stock holdings in pharmacy.
Formulary: outpatient supply	Determined by SESLHD DTC.	Formulary	All medicines prescribed and administered in outpatient settings must conform with medicines and restrictions listed *as Formulary: inpatient initiation* and *Formulary: continuity of medicine.* Medicines that are approved for supply by SESLHD Pharmacy Services to SESLHD outpatients will have this additional annotation.
Formulary: conditional approval	Change request submitted to NSW MFC, awaiting outcome	Formulary	Medicines that are provisionally approved for initiation by SESLHD DTC, whilst awaiting review by NSW MFC.

SESLHD Formulary Category	*Definition*	*iPharmacy identification*	*Explanation*
Non-Formulary: use patient's own	Low usage, not stocked by SESLHD.		Continue patient's pre-admission medicine if there is no clinical reason for change. To facilitate immediate access, utilise patient's own medicine in line with SESLHD Policy Patient's Own Medicines. Medicine may be ordered if patient's own medicines is unavailable or deemed unsuitable.
Non-Formulary: for review	Lack of evidence to support medicine use or risk associated with use, not stocked by SESLHD.	Non-Formulary	Review and consider switching to a preferred alternative evidence-based medicine. Patient's own medicines can be used for continuation of therapy if appropriate. Consider including information in discharge summary for review post discharge. Any medicine decisions should be discussed with the patient and/or their carer and with the initiating prescriber if relevant.
Non-Formulary: restart on discharge	Maintenance therapy, low usage, not stocked by SESLHD	Non-Formulary	Medicines that will NOT have a clinical impact if withheld during the patient's inpatient admission, as determined by SESLHD DTC. If treating team determine ongoing treatment is necessary, use patient's own medicine in line with SESLHD Policy Patient's Own Medicines.
Non-Formulary: chart individual medicines	Combination products with high cost or low usage; not stocked by SESLHD.	Non-Formulary	Chart individual medicines stocked by SESLHD. Pharmacy will NOT procure or supply combination product.

Note*: iPharmacy identification is for procurement purposes only.*

Appendix C: Decision Algorithm for Evaluation of Medicines for Formulary Listing in Public Hospitals (NSW TAG November 2009)



Note 1:
Where a PBAC evaluation has been undertaken, the DTC may choose to accept the PBAC decision without further evaluation

Note 2:
Adequacy of evidence for comparative safety and efficacy should be assessed by the DTC in light of the clinical circumstances.* The need for a defined guideline/protocol for use should be determined on a case by case basis.

*** Evaluation of evidence**
For more detailed guidance on evaluation of evidence, see Gazarian et al. MJA 2006;185: 544-548. In particular, refer page 545: Assessing appropriateness – evaluation of evidence

 # Level of Evidence

Level I	Evidence from one or more systematic reviews of randomised controlled trials
Level II	Evidence from one or more well-designed, randomised controlled trials
Level III	Evidence from well-designed, non-randomised controlled trials; cohort, case control or interrupted time series studies
Level IV	Case series with either post-test or pre-test/post-test outcomes

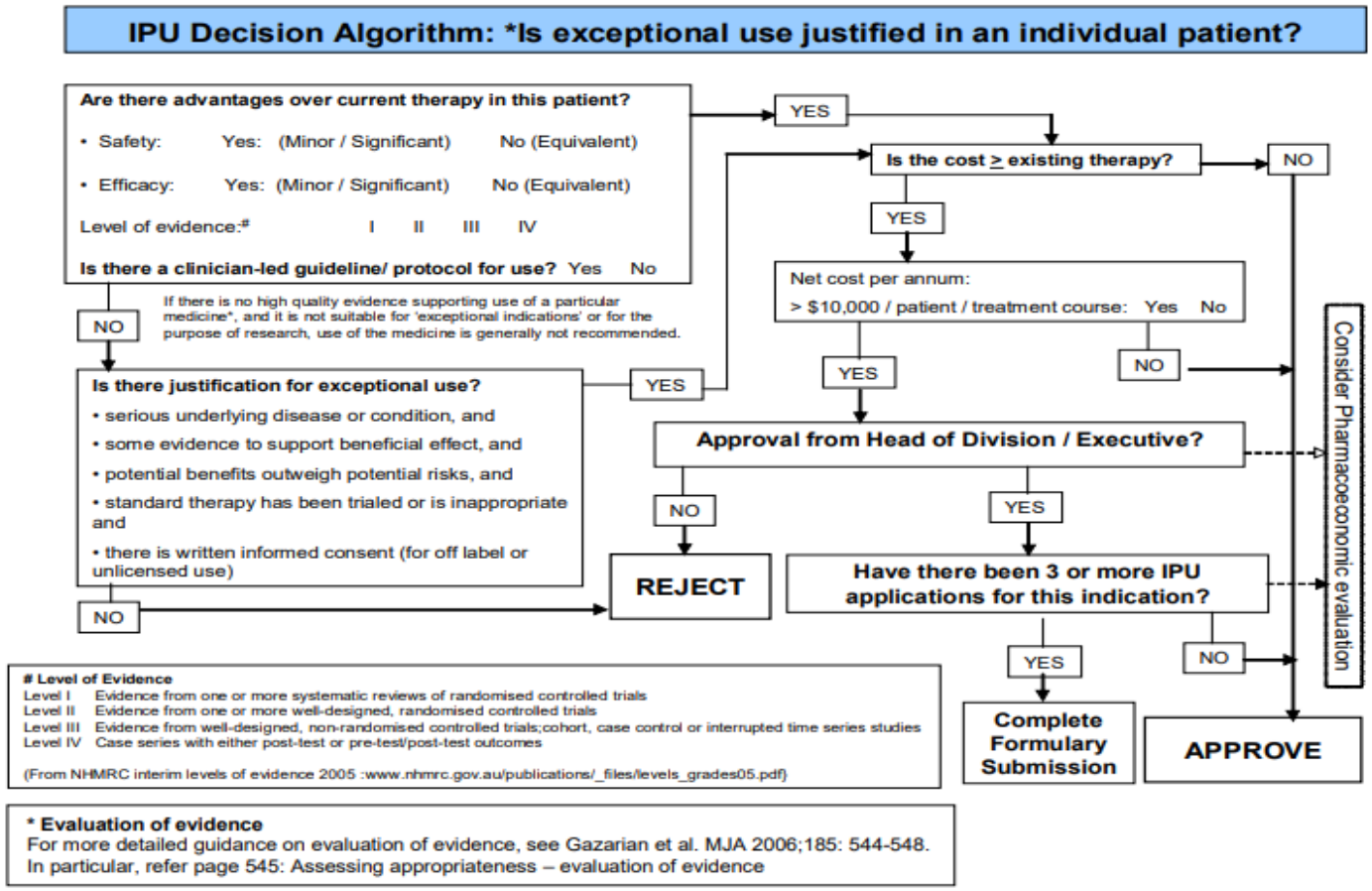
(From NHMRC interim levels of evidence 2005 :www.nhmrc.gov.au/publications/_files/levels_grades05.pdf)

Appendix D: Formulary Processes for Special Access Scheme (SAS) Medicines

All SAS medicines require TGA SAS paperwork to be completed. SESLHD Consent to Exceptional Use of a Medicine Form must be completed for each patient. SAS medicines will be reviewed by the SESLHD DTC delegates as follows:

Reason for SAS status	Action
Status changed due to economic reasons i.e.: previously marketed in Australia but company has made an economic decision to no longer market	Formulary status to be reviewed with consideration for cost-benefit and ongoing access
Status change due to safety concerns	Consider on case-by-case basis
Temporary status change Marketed stock unavailable and company imports overseas stock (which may not be registered in Australia)	Continue to be considered as formulary
Never marketed in Australia but with a large body of evidence supporting its therapeutic use	Assessed for formulary listing or considered for individual patient use when case numbers are low
Never marketed in Australia with minimal evidence supporting therapeutic use	Via IPU approval only

Appendix E: Decision Algorithm for Evaluation of Medicines for Individual Patient Use (IPU) Approval in Public Hospitals (NSW TAG November 2009)



Appendix F: Ethical Decision Making Framework for Complex and High-Cost IPUs

Threshold Assessment	**Does the IPU application address threshold criteria?**	
	Have previous IPU applications for this medicine been accepted/ rejected?	☐ Yes ☐ No
	Should there be a formulary application associated with this IPU?	☐ Yes ☐ No
	Has the HOD endorsed the application? Including: in dept budget, clinically appropriate, not research	☐ Yes ☐ No
	Conflict of interest declarations provided?	☐ Yes ☐ No
	Justification for exceptional use provided?	☐ Yes ☐ No
	Standard treatment tried or not appropriate?	☐ Yes ☐ No
	Completed patient consent provided?	☐ Yes ☐ No
	Safety and efficacy approvals? For this indication or others?	☐ Yes ☐ No
	Details	
	Any alternative funding options?	☐ Yes ☐ No
	Details	
	Are there adequate plans to share outcome data?	☐ Yes ☐ No
	Details	
	Urgency? *Details*	
	Is this IPU ready for SESLHD DTC?	☐ Yes ☐ No
Individual Assessment	**What is the balance of risks, harms and benefits of the drug?**	
	Previous treatment outcomes?	*Details*
	Alternative treatment options?	*Details*
	Expected benefits from the medicine?	Cure? ☐ Prolonged survival? ☐ Improved quality of life? ☐ Alignment with patient specific goals? ☐
		Details
	Evidence for safety?	*Details*
	Evidence for efficacy?	*Details*
	Other harms or burdens of treatment?	*Details*
	Is the evaluation plan adequate?	☐ Yes ☐ No
	Clinical Benefit Rating:	High ☐ Medium ☐ Low ☐
	What is the cost?	
	Direct cost of the medicine?	*Details*
	Direct cost of alternative treatment?	*Details*
	Indirect cost of the medicine?	*Details*
	Indirect cost of the alternative treatment?	*Details*
	Ongoing commitment / obligation once started?	☐ Yes ☐ No
		Details

	Any anticipated savings or cost offsets?	*Details*
	Cost rating:	High ☐ Medium ☐ Low ☐
	What is the value of the potential health outcome? Is it proportional to the cost?	
	What outcome is the patient hoping for?	*Details*
	Is this realistic?	☐ Yes ☐ No
	Is the desired outcome likely?	☐ Yes ☐ No *Details*
	Does the proposed benefit align with the patient's specific goals?	Cure? ☐ Prolonged survival? ☐ How long? Improved quality of life? ☐ *Details*
	Any alternative approaches?	*Details*
	How acceptable are these?	*Details*
	What will be the relative quality of the patient experience: drug vs alternative treatment pathway?	*Details*
	On balance, does the likely outcome justify the cost?	☐ Yes ☐ No
Broader Justice/ Equity	Consistency? Sustainability? Vulnerable groups? Third party influence?	
	Does this application compare to previous similar applications within the district?	☐ Yes ☐ No *Details*
	In other LHDs?	☐ Yes ☐ No *Details*
	Will this application set a new precedent for standard of care?	☐ Yes ☐ No *Details*
	Are there other community interests that need to be taken into consideration such as protection of vulnerable groups?	☐ Yes ☐ No *Details*
	Are there pressures from third parties?	☐ Yes ☐ No
	Recommendation	Approve ☐ Do not approve ☐ Defer – further information required ☐