SESLHD POLICY COVER SHEET

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KEY TERMS	Drug, medicine, formulary, individual patient use (IPU), special access scheme (SAS), access program, prescriber, pharmacy, medicines use evaluation (MUE), evaluation of medicine
SUMMARY	This document describes the ongoing management of Drug Formulary in SESLHD, processes for addition and amendment, and definition of eligibility to access medicines via SESLHD facility pharmacies. It also describes the processes for access to non-formulary medicines

1. POLICY STATEMENT

This document describes the ongoing management of the Drug Formulary in SESLHD, the processes for addition and amendment to the formulary and the processes for access to non-formulary medicines. The policy also defines the eligibility for access to medicines via SESLHD Pharmacy Services.

2. AIMS

- To maintain a drug formulary system to regulate the medicines available for initiating patient treatment in facilities within South Eastern Sydney Local Health District (SESLHD).
- To detail a standard framework of processes for evaluation of medicines for inclusion in the Drug Formulary.
- 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 medicines via SESLHD pharmacy services.

3. TARGET AUDIENCE

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

4. RESPONSIBILITIES

Quality Use of Medicines Committee (QUMC)

- Review and revise Drug Formulary policy and associated procedures as necessary.
- Timely review and assessment of formulary applications according to adopted procedures.
- Clear and effective communication of formulary decisions.
- Monitor implementation of, and compliance with the formulary.
- Review usage of formulary items where required and any associated incidents or adverse events.
- Undertake Individual Patient Use (IPU) evaluations for high-cost medicines, where there are complex considerations and/or at the request of the facility DTC/SUMC using standardised decision-making framework.
- Monitor IPU decisions reported by facilities.

SESLHD Clinical Stream/Services

- Coordinate and ensure relevant clinical consultation and review of formulary applications.
- Provide recommendations to QUMC regarding formulary applications via the Service Director/Manager.

Local Drug and Therapeutics or Safe Use of Medicines Committees (DTC/SUMC)

- Monitor local implementation and compliance with the Drug Formulary policy.
- Recommend changes to formulary.

- Review formulary usage locally and report to QUMC.
- Undertake Individual Patient Use (IPU) evaluations (where QUMC review is not required) using the decision framework of this policy and report IPU approvals and outcomes to QUMC.
- Maintain a register of IPU decisions and report to QUMC as required.

Clinical Staff

- Ensure medication use is consistent with formulary and associated guidelines.
- Request review and or additions to formulary within policy framework and via relevant Clinical Service/Stream.
- Report all incidents and adverse reactions associated with the use of formulary items or IPU items to QUMC or local DTC/SUMC.

Pharmacy Departments

- Maintain formulary status in iPharmacy system.
- Ensure adherence to the Drug Formulary policy when supplying medicines.

5. DEFINITIONS

Drug Formulary: a list of medicines authorised for use within SESLHD which may include restrictions or guidelines for the use of the medicine listed, but excludes medicines used as part of research or clinical trials and approved for use within SESLHD by the relevant Human Research Ethics Committee. The current Drug Formulary is accessible to all SESLHD staff via the intranet at http://seslhnweb.lan.sesahs.nsw.gov.au/Drug_Committee/Formulary.asp

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

Off-Label use: The use of a 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.

Medicines Access Programs: include expanded or early access, compassionate use or product familiarisation programs where a medicine is provided free of charge, at a reduced price or via a cost-share arrangement for specific patients or patient groups.

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 formulary or where the formulary restrictions are not met.

Eligible Patients:

- Hospital inpatients
- All patients on discharge from the hospital, in accordance with facility business rules
- Medicare eligible persons attending an approved outpatients clinic requiring medicines that are only available through a public hospital, or that would otherwise be inaccessible to the patient in the community (e.g. due to cost), at the discretion of the facility.
- Medicare eligible persons with a valid prescription for an S100 subsidised medicine, written by an eligible prescriber (see below).
- Non-Medicare eligible persons, under circumstances approved by the hospital's General Manager or being treated under a refugee program, medicines access program, or other externally funded program.
- 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)
- Any person specifically approved by the hospital's General Manager or delegate.

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

Ineligible Patients:

- As per Ministry of Health policy PD2012_068

Eligible 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 medication prescribers.
- Any Registrar or Resident Medical Officer assisting in a clinic established by the hospital.

6. POLICY

The QUMC will review all new medicines, and new uses for existing medicines, prior to addition to the Drug Formulary or amendment to the Drug Formulary.

Where medicine use is not expected to be routine and formulary listing not required, local facility Drug and Therapeutics or Safe Use of Medicine Committees (DTC/SUMC) will review IPU applications using the processes of this policy. IPU applications for high cost medicines (exceeding $10,000 per course or per twelve month period) must be referred to QUMC. QUMC will also review IPU applications where there are complex considerations and/or on the request of facilities. Local DTC/SUMC will regularly report IPU applications to QUMC for review and monitoring.

Both formulary and IPU applications will be considered using processes adapted from NSW Therapeutic Advisory Group (TAG).

All Medicines Access Programs 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

SAS medications will be considered as listed in Appendix F.

The approved medicines will only be available to eligible patients and prescribers.

6.1 Application Process

- Information packages to assist applicants will be published by the QUMC (see Appendix A for formulary applications and Appendix C for IPU applications).
- Senior clinicians, clinical units or Clinical Streams/services may apply. Applications will not be accepted from external sources or for ineligible patients.
- All applications should include appropriate objective evidence to support the application (see Appendix E).
- All applications must be fully completed and typed. Handwritten applications will not be accepted.
- For all formulary applications, consultation with relevant clinicians throughout SESLHD and endorsement of the relevant SESLHD Clinical Stream(s) or service(s) is required. Where there is no relevant district Clinical Stream or service, evidence of peer review and agreement must be provided.

6.2 Review Process

- Review of applications will follow the relevant Decision Algorithm 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.
- Any relevant clinical protocols will be simultaneously reviewed for approval.

6.3 Approval Process

- Consideration and review of applications will occur at the next relevant QUMC meeting for all applications received up to 2 weeks prior to the scheduled meetings.
- Urgent review mechanisms must be available to applicants based on clinical need when requested.
- All applications will be recorded and the outcome documented.
- 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 within 2 weeks of review. The applicant will also be notified of any protocol finalisation, staff education / training or specific patient education requirements with the approval.
- Local DTCs/SUMs will receive a list of formulary updates each month

- Applicants will be informed of the outcome of IPU applications, together with details and or restrictions of the approval, monitoring and reporting requirements within two weeks of review. The applicant will also be notified of any staff education / training or specific patient education requirements with the approval.
- A report of IPU decisions will be provided to QUMC by local DTC/SUMC annually.
- Clinicians may appeal decisions in writing when they feel the approval process has not been as documented or when circumstances or levels of evidence for the use of the medicine have changed since submission. Appeals against IPU decisions must be referred to QUMC.

6.4 Monitoring Process

- Formulary approvals may have a review date set at the time of approval.
- Clinicians will be responsible for reporting to the QUMC 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.
- 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 to the relevant committee.
- Reporting of patient outcomes may be requested for IPUs for treatment courses with a pre-defined end date.

7. DOCUMENTATION

Information for Formulary Applications – Appendix A
Decision Algorithm for Evaluation of Medicines for Formulary Listing – Appendix B
Information for IPU Applications – Appendix C
Decision Algorithm for Evaluation of Medicines for IPU Approval – Appendix D
Decision Algorithm for Evaluation of High Cost IPU applications – Appendix E
Supporting Evidence Information – Appendix F
Formulary Processes for Special Access Scheme (SAS) Medicines – Appendix G
Formulary Submission Form - District Form F021
IPU Application Form - District Form F020
Patient Consent for Exceptional Use of Medicine – MRN form S0199
IPU Report Form - District Form F019

8. REFERENCES

External References

NSW Health PD2013_043 - Medication Handling in NSW Public Health Facilities

NSW Health PD2016_033 Approval Process of Medicines for Use in NSW Public Hospitals

Managing Medicines Access Programs, CATAG. May 2015

PD2012_068 Outpatient Pharmaceutical Arrangements and Safety Net Arrangements

Internal References

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

9. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
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	Minor review - 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 Approved by Executive Sponsor
November 2020	6	Approved by Quality Use of Medicines Committee Published by Executive Services.

Appendix A: Information for Formulary Applications

The QUMC considers all submissions for additions and amendments to the Drug Formulary on a district-wide basis.

The formulary application form (Formulary Submission Form - District Form F021) should be fully completed and supporting evidence provided by the clinician requesting approval (the applicant). In most cases it will be appropriate for a prescribing protocol to be proposed as part of the submission. For details regarding supporting evidence see appendix F.

Once completed, the application form and supporting evidence should be forwarded to the secretariat of the QUMC as below. If SESLHD Clinical Stream/Service review and endorsement has not been completed, the QUMC secretariat may forward the application to the relevant Stream(s)/Service(s) for review and endorsement.

The completed and endorsed submission and evidence will be considered by the QUMC at the next scheduled meeting. Supplementary information may be prepared or requested by the QUMC secretariat in consultation with the applicant and/or Clinical Stream and/or facility Pharmacy Service.

All of this information is important for appropriate decision making. **Missing information may delay the review and decision process.**

The QUMC uses a standard decision algorithm to guide its decision process. This decision algorithm is based on an algorithm from the NSW Therapeutic Advisory Group (NSW TAG) which 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 QUMC will consider not only clinical issues, but also economic issues. Economic analysis may be undertaken on either a cost-effectiveness or cost minimisation basis, depending on the circumstances.

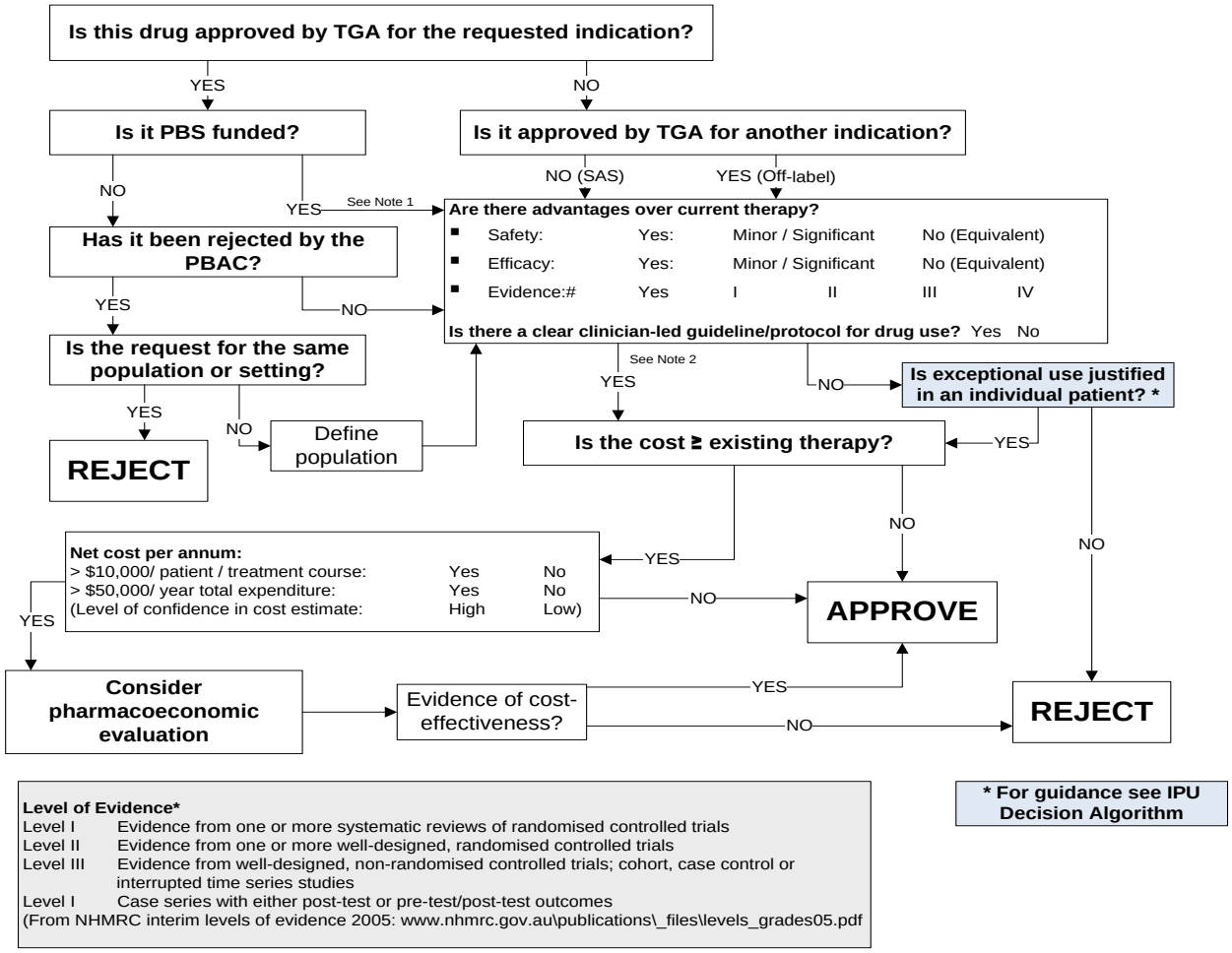
To seek approval for:

- **a new drug to be added to the formulary, or**
- **variation to an existing formulary listing, or**
- **use of a drug under other circumstances (e.g. medicines access program)**

use the Formulary Submission Form - District Form F021 and submit to the QUMC at SESLHD-DrugCommittee

Complete applications lodged by the 15th of each month will be considered by the QUMC at its meeting the following month (except January when the committee does not meet).

Appendix B: Decision Algorithm for Evaluation of Medicines for Formulary Listing (Adapted from NSW TAG March 2008)



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.

*** For guidance see IPU Decision Algorithm**

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 I	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

Adapted from NSW TAG
March 2008

Appendix C: Information for IPU Applications

To seek approval to use a drug on an individual patient basis

SESLHD IPU Application Form - District Form F020 should be fully completed and signed by the specialist requesting approval (or their delegate). The applicant should provide detailed responses to the application questions, not only providing information about the known safety and efficacy of the drug, but also the risks and benefits for the individual patient in the context of the patient's goals of treatment. All IPUs must be endorsed and signed by the Head of Department. Supporting evidence must be provided with the application (see Appendix F for guidelines)

Once completed and endorsed, the application form and supporting evidence should be forwarded to the facility Pharmacy Service via:

- **Prince of Wales Hospital**: Deputy Director of Pharmacy (or delegate)
  Ph 9382 2322
- **Sydney Hospital & Sydney Eye Hospital**: Chief Pharmacist
  Ph 9382 7380
- **The Sutherland Hospital**: Director of Pharmacy
  Ph 9549 7468
- **St. George Hospital**: Director of Pharmacy
  Ph 9113 3044
  SESLHD-STG-Pharmacy@health.nsw.gov.au
- **Royal Hospital for Women**: Senior Pharmacist
  Ph 9382 6716
- **War Memorial Hospital:** Senior Pharmacist
  Ph 9369 0214
- **Calvary Health Care Kogarah:** Pharmacist in charge
  Ph: 9553 3563

Evaluation

IPUs are reviewed by committee as follows:

- **IPUs with cost < $10,000 per course or per annum*:** Facility Drug and Therapeutics Committee / Safe Use of Medicines Committee (DTC/SUMC)
- **IPUs with cost >$10,000 per course or annum* and/or where there are complex considerations:** District Quality Use of Medicines Committee (QUMC)

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

In special circumstances, the facility DTC/SUMC may also request QUMC to review specific IPUs.

All committees have out-of-session review processes in place for urgent IPU requests.

All IPU applications are assessed using a standard decision algorithm (appendix D). High cost or complex applications are further assessed by QUMC using a detailed decision-making framework developed by SESLHD Clinical Ethics Service (appendix E).

The following are considered as part of the decision-making process:

- Safety
- Efficacy
- Predicted individual patient benefit
- Patient goals of treatment
- Cost
- Value for money
- Fairness and equity

Communication of Outcomes of Evaluation

IPU decisions and reasons for decision are provided to the applicant in writing. Requests for review of a rejected IPU application must be made in writing to the Chair of the relevant review committee, stating clearly the reasons for the requested review.

Patient Consent

Where a medicine is requested for an off-label indication, or the medicine is unregistered, the applicant is required to pre-complete and submit with the application a Consent for Exceptional Use of Medicine Form (SEI020.025). If the IPU request is approved, the patient's consent to treatment should be obtained and documented. Consent forms are available to order from Salmat (code S0199).

Monitoring

Continued IPU approval is dependent upon completion and submission of the SESLHD IPU Report Form - F019 to the relevant committee at the requested time. Where the risks or costs associated with use of the medicine are not justified by the benefits, consideration must be given to whether it should be discontinued. This decision may require consultation between the patient, the applicant, the treatment team and the relevant committee.

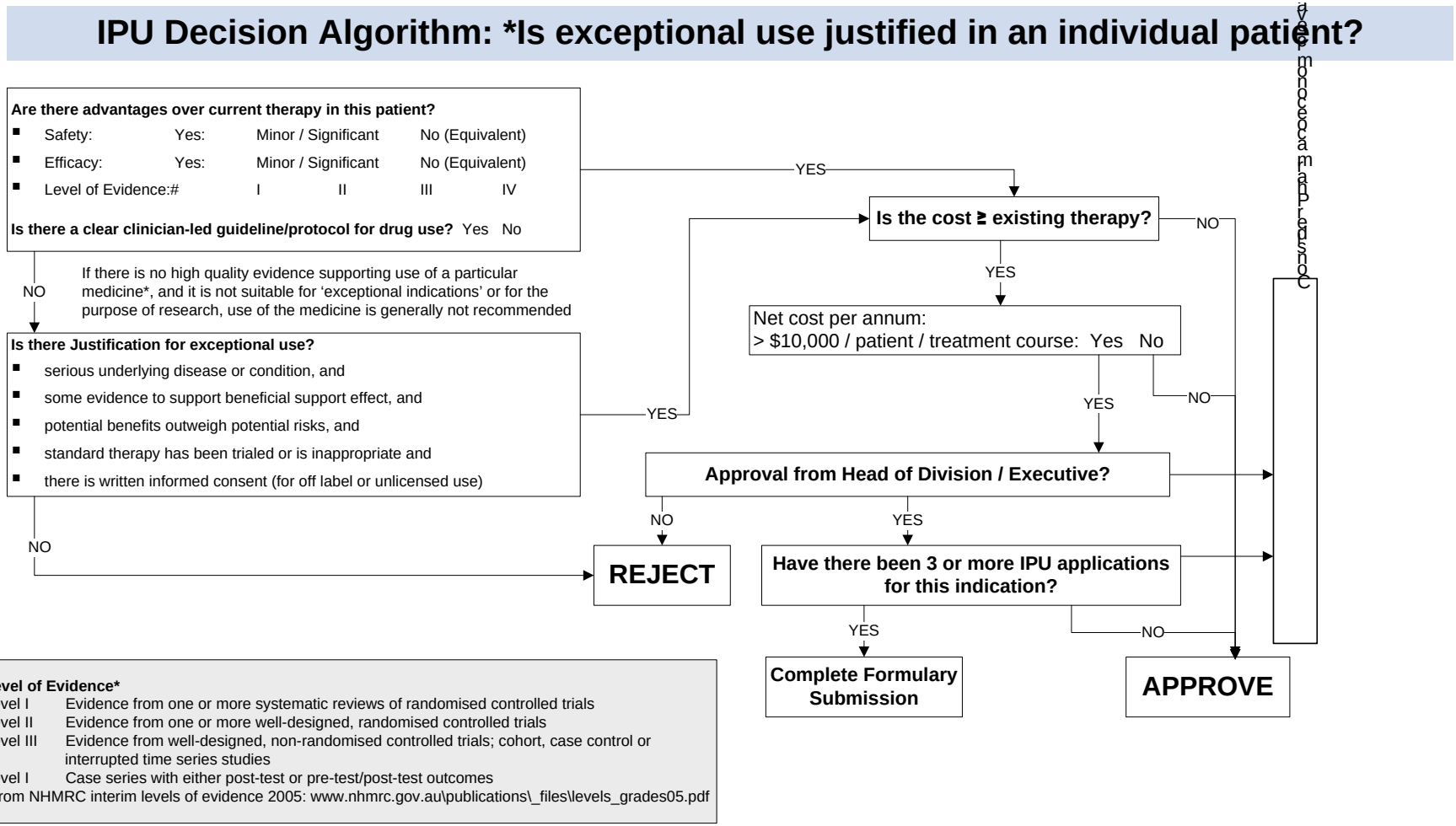
Questions

If you have any questions about the IPU application process or evaluation process please contact the Quality Use of Medicines Lead Pharmacist SESLHD-DrugCommittee@health.nsw.gov.au

Please note: Facility DTC/SUM Committees collate and report all IPU decisions to QUMC. Repeat IPU applications for the same drug and indication for different patients may require submission of a formulary application.

Appendix D: Decision Algorithm for Evaluation of Medicines for Individual Patient Use (IPU) Approval

(Adapted from NSW TAG March 2008)



Appendix E: 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 QUMC?		☐ 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 ☐	

Broader Justice/ Equity	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
	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 ☐

Appendix F: Supporting Evidence Information

Evidence supporting a formulary or IPU application should include all relevant randomised controlled trials and/or systematic reviews (meta-analyses). Copies of key papers should be included with the submission.

Unpublished studies and case reports may be considered, however sufficient detail must be provided to allow independent assessment of results. Reasons for not providing more robust sources of evidence should be stated in the application.

If no head-to-head studies are available for drug and comparator, other studies may be considered if they are likely to assist with decision-making, e.g. randomised, controlled studies with arms that include the various comparators.

Indicate if comparators, dosing regimens and duration of trial are relevant to proposed practice.

Indicate if study population(s) is (are) relevant to proposed practice.

Indicate if benefits are likely to extend beyond the period of the trial.

If post-hoc sub-group analysis is included, highlight the limitations of the analysis so that risks associated with decision-making can be assessed.

Grading for Level of Evidence*	
Level I	Evidence obtained from systematic review of all relevant randomised controlled trials.
Level II	Evidence obtained from one or more well-designed, randomised controlled trials.
Level III	Evidence obtained from well-designed, non-randomised controlled trials, or from well-designed cohort, case control or interrupted time series studies.
Level IV	Case series with either post-test or pre-test/post-test outcomes.

* From NHMRC additional levels of evidence and grades for recommendations for guideline developers (2009).

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

(Adapted from Prince of Wales document)

All SAS medicines require TGA SAS paperwork to be completed. SESIH Consent for Exceptional Use of Medicine (Form S0199) must be completed for each patient. SAS medicines will be reviewed 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 their 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

All SAS medicines added to formulary should be accessed via TGA Authorised Prescriber mechanisms when use is considered routine.

*# The QUMC is to be advised if previously marketed medicines are being imported from an overseas country where their manufacturing and regulatory standards are **not** in line with the recognised Australian/Europe/US standards.*