<table>
<thead>
<tr>
<th>NAME OF DOCUMENT</th>
<th>Medicine: Drug Formulary Policy</th>
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<tbody>
<tr>
<td>TYPE OF DOCUMENT</td>
<td>Policy</td>
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<tr>
<td>DOCUMENT NUMBER</td>
<td>SESLHD/183</td>
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</tbody>
</table>
| DATE OF PUBLICATION | September 2008  
Revised: September 2010  
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| RISK RATING      | Medium                         |
| LEVEL OF EVIDENCE| Best practice                  |
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| FORMER REFERENCE(S) | SESIAHS PD 178                 |
| EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR | Executive Medical Director |
| AUTHOR           | Julie Thompson, D&QUMC Pharmacist Co-ordinator on behalf of D&QUMC  
AreaDrugcommittee@sesiahs.health.nsw.gov.au |
| KEY TERMS        | Drug, formulary, individual patient use (IPU), special access scheme (SAS), access program, prescriber, pharmacy, drug use evaluation (DUE), 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. |
1. POLICY STATEMENT
   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.

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 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
   **Drug and Quality Use of Medicines Committee (D&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 and any associated incidents or adverse events

   **Local Drug and Therapeutics Committees (DTC)**
   - Monitor local implementation and compliance with District policy
   - Recommend changes to formulary
   - Review formulary usage locally and report to D&QUMC
   - Undertake Individual Patient Use (IPU) evaluations using the decision framework of this policy and report IPU approvals and outcomes to D&QUMC

   **Clinical Staff**
   - Ensure therapy selection is consistent with formulary and usage consistent with associated guidelines
   - Request review and or additions to formulary within policy framework
   - Report all incidents and adverse reactions associated with the use of formulary items or IPU items to D&QUMC or local DTC

   **Pharmacy Departments**
   - Maintain formulary status in iPharmacy system
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.

Medicines: include registered or listed medicines, off-label use of medicines, unlicensed use of medicines and medicines made available under access programs. Registered or listed medicines have been evaluated and/or approved by the Therapeutic Goods Administration (TGA) and entered into the Australian Register of Therapeutic Goods.

Off-Label medicine use: the use of a registered medication that is not included in the TGA approved product information or which is disclaimed in the product information.

Unlicensed use: the use of a medicine or a dosage form which has not been evaluated or approved for use in Australia by the TGA.

Access programs: include expanded or early access, compassionate use or product familiarisation programs.

IPU: Individual Patient Use of a medicine rather than formulary listing of the medicine.

Eligible Patients:
- Hospital inpatients
- All Patients on discharge from the hospital
- Medicare eligible persons attending an approved outpatients clinic requiring items available only through a public hospital Medicare eligible persons with valid prescriptions for S100 subsidised HIV medications seen by accredited General Practitioners
- Non-Medicare eligible persons, under circumstances approved by the hospital’s General Manager or being under a refugee 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 (e.g. Director of Clinical Services)

Ineligible Patients:
- As per current Ministry of Health policy

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 (plus accredited S100 anti HIV medication prescribers).
- Any Registrar or Resident Medical Officer assisting in a clinic established by the hospital.
6. POLICY

The D&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 site/network Drug and Therapeutics Committees (DTC) will review all IPU applications using the processes of this policy. Such applications may be referred to D&QUMC where there are significant cost or practice implications. Local DTC will report IPU applications and outcomes to D&QUMC for review and monitoring.

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

Access programs must comply with Guiding Principles for Medicines Access Programs in Australian Public 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 applications will be published by the D&QUMC (see Appendix A for formulary applications and Appendix C for IPU applications).
- Senior clinicians, clinical units or clinical streams wishing to use the medicine 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).

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 unlicensed medicine use will also be reviewed in accordance with SESLHDPD/182.
- Any relevant clinical protocols which will be simultaneously reviewed for approval.

6.3 Approval Process

- Consideration and review of applications will occur at the next relevant 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, local DTC, relevant clinical streams, 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 staff education / training or specific patient education requirements with the approval.

- Applicants will be informed of the outcome of IPU applications, together with details and or restrictions of the approval, monitoring and reporting requirements. The applicant will also be notified of any staff education / training or specific patient education requirements with the approval. IPU decisions will be communicated to D&QUMC by local DTC.
- 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 D&QUMC.

6.4 Monitoring Process

- All approvals will have a review date set at the time of approval.
- During this period of time, clinicians will be responsible for reporting to the D&QUMC any adverse events associated with the use of the formulary item or guideline in addition to other relevant reporting requirements.
- Compliance with formulary approval, resource utilisation and outcomes of treatment may be subject to a Drug Use Evaluation (DUE) process. Continued or further IPU approvals are conditional upon completion and submission to local DTC of the SESILHD IPU Report Form

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
- Supporting Evidence Information – Appendix E
- SAS – Appendix F
- 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 Therapeutic Advisory Group (2003) Off-label use of registered medicines and use of medicines under the personal importation scheme in NSW public hospitals
  - NSW Health PD2008_037 Medicines – Evaluation of Medicines for Use in Public Hospitals
Guiding Principles for Medicines Access Programs in Australian Public Hospitals

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

9. REVISION & APPROVAL HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision No.</th>
<th>Author and Approval</th>
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<tr>
<td>Sept 2008</td>
<td>0</td>
<td>Julie Thompson, Area Drug Committee Pharmacist Co-ordinator on behalf of the Area Drug Committee. Approved by Area Drug Committee 10 July 2008. Approved by Executive Sponsor Elizabeth Koff, Director Clinical Operations and Clinical Council Committee 24 September 2008.</td>
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<td>Sept 2009</td>
<td>1</td>
<td>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.</td>
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<tr>
<td>April 2012</td>
<td>2</td>
<td>Updated links and rebadged for LHD, patient eligibility revised - Julie Thompson, D&amp;QUMC Pharmacist Co-Ordinator on behalf of SESLHD D&amp;QUMC. Approved by SESLHD D&amp;QUMC 12 April 2012</td>
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<td>June 2012</td>
<td>2</td>
<td>Changes and review approved by Executive Medical Director</td>
</tr>
<tr>
<td>October 2012</td>
<td>2</td>
<td>Updated link to Guiding Principles for Medicines Access Programs in Australian Public Hospitals</td>
</tr>
<tr>
<td>September 2014</td>
<td>3</td>
<td>Maintenance of formulary and iPharmacy updated, links and external references updated. Julie Thompson, D&amp;QUMC Pharmacist Co-Ordinator on behalf of SESLHD D&amp;QUMC. Approved by SESLHD D&amp;QUMC 9 October 2014</td>
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<tr>
<td>December 2014</td>
<td>3</td>
<td>Changes and review endorsed by Director Clinical Governance</td>
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Appendix A: Information for Formulary Applications

The D&QUMC considers all submissions for additions and amendments to the Drug Formulary on area district wide basis.

The relevant application form (SESLHD Formulary Submission Form - F021) should be completed and supplementary evidence provided by the clinician requesting approval (the applicant). In most cases it will be appropriate for prescribing guidelines to be proposed as part of the submission. (For details regarding evidence see appendix E).

Once completed, these forms and requested supplementary evidence should be forwarded to the secretariat of the D&QUMC as below.

The completed submission and evidence will be considered by the D&QUMC. Supplementary information may be prepared or requested by the co-ordinator of the D&QUMC in consultation with the applicant and/or site pharmacy departments.

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

The D&QUMC will use a standard decision algorithm to guide its decision process. This decision algorithm is based on a NSW TAG algorithm 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 D&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. familiarisation program)

use the SESLHD Formulary Submission Form - F021 and submit to the D&QUMC at AreaDrugCommittee@sesiahs.health.nsw.gov.au

Complete applications lodged by the last Thursday of each month will be considered by the D&QUMC at its meeting the following month (except January when the committee is not scheduled to meet).
Appendix B: Decision Algorithm for Evaluation of Medicines for Formulary Listing (Adapted from NSW TAG March 2008)

Is this drug approved by TGA for the requested indication?
- YES
  - Is it PBS funded?
    - NO
      - SEE Note 1
    - YES
      - Has it been rejected by the PBAC?
        - YES
          - REJECT
        - NO
          - Define population
  - NO
    - Is it approved by TGA for another indication?
      - NO (Or label)
      - Are there advantages over current therapy?
        - Safety: Yes: Minor / Significant No (Equivalent)
        - Efficacy: Yes: Minor / Significant No (Equivalent)
        - Evidence:# Yes I II III IV
        - Is there a clear clinician-led guideline/protocol for drug use? Yes No
    - Is the request for the same population or setting?
      - YES
        - REJECT
      - NO
        - Consider pharmacoeconomic evaluation
          - 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 pre-test or post-test/pre-test outcomes
              (From NHMRC interim levels of evidence 2005; www.nhmrc.gov.au/publications/_files/levels_grades05.pdf)
        - Evidence of cost-effectiveness?
          - YES
            - APPROVE
          - NO
            - REJECT
      - NO
        - Net cost per annum:
          - > $10,000/ patient / treatment course: Yes No
          - > $50,000/ year total expenditure: Yes No
          - (Level of confidence in cost estimate: High Low)
  - NO
    - SEE Note 2
    - Is exceptional use justified in an individual patient? *
      - NO
        - APPROVE
      - YES
        - REJECT

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

Adapted from NSW TAG
March 2008
Appendix C: Information for IPU Applications

Individual Patient Usage (IPU) applications should be submitted to the local site Drug and Therapeutics Committee using the area approved forms (SESLHD IPU Application Form - F020). IPU applications are assessed using a standard decision algorithm. Continued IPU approval is dependent upon completion and submission of the SESLHD IPU Report Form - F019 to the local committee.

Local committees collate and report all IPU decisions to D&QUMC. More than three IPU applications for the same indication require a formulary application.

To seek approval to use a drug on an individual patient basis, use the SESIH IPU Application Form and submit to the applicable local site Drug and Therapeutics Committee.

- **Prince of Wales Hospital:** Associate Director of Pharmacy
  Ph 9382 2322   Fax 9382 2345

- **Sydney Hospital & Sydney Eye Hospital:** Chief Pharmacist
  Ph9382 7380   Fax 9382 7572

- **The Sutherland Hospital:** Director of Pharmacy
  Ph 9549 7468

- **St. George Hospital:** Deputy Director of Pharmacy
  Ph 9113 3079   Fax 9113 3996

- **Royal Hospital for Women:** Chief Pharmacist
  Ph 9382 6716   Fax 9382 6717

Contact local committee for relevant closing dates for applications.
IPU Decision Algorithm: *Is exceptional use justified in an individual patient?

1. Are there advantages over current therapy in this patient?
   - Safety: Yes: Minor / Significant  No (Equivalent)
   - Efficacy: Yes: Minor / Significant  No (Equivalent)
   - Level of Evidence: I  II  III  IV

2. Is there a clear clinician-led guideline/protocol for drug use?  Yes  No
   - If there is no high quality evidence supporting use of a particular medicine*, and it is not suitable for ‘exceptional indications’ or for the purpose of research, use of the medicine is generally not recommended

3. Is there Justification for exceptional use?
   - serious underlying disease or condition, and
   - some evidence to support beneficial support effect, and
   - potential benefits outweigh potential risks, and
   - standard therapy has been trialed or is inappropriate and
   - there is written informed consent (for off label or unlicensed use)

4. Is the cost ≥ existing therapy?  Yes  No
   - Net cost per annum: > $10,000 / patient / treatment course: Yes  No

5. Approval from Head of Division / Executive?  YES  NO
   - Consider Pharmacoeconomic evaluation

6. Have there been 3 or more IPU applications for this indication?  YES  NO
   - Complete Formulary Submission

7. 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

8. Approval from Head of Division / Executive?

9. Complete Formulary Submission

10. APPROVE

Adapted from NSW TAG March 2008

Appendix E: Supporting Evidence Information

Evidence supporting the 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 may be considered (reason for non-publication should be provided). For unpublished studies, sufficient detail must be provided to allow independent assessment of results.

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 local practice.

Indicate if study population(s) is (are) relevant to local 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*

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
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<tbody>
<tr>
<td>Level I</td>
<td>Evidence obtained from systematic review of relevant randomised controlled trials</td>
</tr>
<tr>
<td>Level II</td>
<td>Evidence obtained from one or more well-designed, randomised controlled trials</td>
</tr>
<tr>
<td>Level III</td>
<td>Evidence obtained from well-designed, non-randomised controlled trials or from well designed cohort, case control or interrupted time series studies</td>
</tr>
<tr>
<td>Level IV</td>
<td>Case series with either post-test or pre-test/post-test outcomes</td>
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Appendix F: Special Access Scheme (SAS) Medicines - Adapted from Prince of Wales document

All SAS medicines require TGA SAS paperwork and SESIH Consent for Exceptional Use of Medicine (Form S0199) to be completed. SAS medicines will be reviewed as follows:

<table>
<thead>
<tr>
<th>Reason for SAS status</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status changed due to economic reasons (i.e.: previously marketed in Australia but company has made an economic decision to no longer market).</td>
<td>Continue to be considered as formulary.</td>
</tr>
<tr>
<td>Status change due to safety concerns. Company in Australia no longer prepared to market.</td>
<td>Consider on case by case basis</td>
</tr>
<tr>
<td>Temporary Status change. Marketed stock unavailable and company imports overseas stock (which may not be registered in Australia) #</td>
<td>Continue to be considered as formulary.</td>
</tr>
<tr>
<td>Never marketed in Australia but marketed overseas with a large body of evidence supporting their therapeutic use</td>
<td>Assessed for formulary listing except in cases of emergency or for individual use when IPU is appropriate.</td>
</tr>
<tr>
<td>Never marketed in Australia or overseas but with a large body of evidence supporting their therapeutic use</td>
<td>Assessed for formulary listing except in cases of emergency or for individual use when IPU is appropriate.</td>
</tr>
<tr>
<td>Drugs never marketed in Australia or overseas with minimal evidence supporting their therapeutic use</td>
<td>IPU assessment</td>
</tr>
</tbody>
</table>

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

#: The D&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.