Queensland Health

Guideline

Management and Governance of Individual Patient Approvals for Medicines and other Therapeutic Goods

1. Purpose

This document has been developed to guide hospitals and Health Service Districts to manage, in a consistent way, individual patient approvals for access to medicines for indications which are not included on the Queensland Health List of Approved Medicines (LAM). A robust process, managed by hospital/District medicines committees, must be in place to ensure that access to medicines is equitable across the State, medication usage is evidence based, patient safety is assured and financial sustainability is maintained.

2. Scope

This guideline shall apply to the processes undertaken when Queensland Health (QH) clinicians wish to prescribe, for QH public patients, medicines which are not included on the LAM. This includes prescribing items that are not listed on the LAM, despite being included on the Pharmaceutical Benefits Scheme (PBS), and prescribing LAM medicines for other than the LAM indications.

It does not include all considerations associated with off-label use, and does not include items that are LAM listed as Medical Superintendent signed Authority Protocols (MSAP[1]) .

3. Background

Queensland Health's limited formulary reduces unnecessary duplication of medicines. Refer to *Appendix D* for details on how it applies to enteral nutrition products, PBS medicines and all inpatient and outpatient prescribing.

4. Principles

4.1 Governance and management of all applications for IPA is the responsibility of hospital/District medicines committees. The Queensland Health Medicines Collaborative (QHMC) will support communication between these committees and QHMAC, to promote consistent state wide processes. Refer Flowchart *Appendix A.*

4.2 Initiation and continuation of therapy: All QH clinicians must comply with the LAM when prescribing for patients of Queensland public hospitals and institutions.

4.2.1 When a clinical need to initiate a non-LAM medicine/indication is identified, IPA must be sought from the hospital/District medicines committee.

[1] LAM appendix 8: www.health.qld.gov.au/qhcss/mapsu/documents/lam/lam.pdf

4.2.2 When a requirement is identified to continue an inpatient on a non-LAM therapy, and when their own medicine[2] cannot be used, approval must also be obtained through a robust mechanism, with oversight by the hospital/District medicines committee as decided locally.

4.3 Approval periods and extension of approvals:
4.3.1 IPAs must be granted for a defined and limited period of time. Ongoing approval must only be considered after the prescriber has provided a report on the response to treatment using objective outcome measures.

4.3.2 Emphasis is on the prescriber taking responsibility for the ongoing monitoring of the patient's response, with appropriate cessation of treatment in the event of side-effects or lack of efficacy.

4.3.3 If new information emerges relating to the efficacy, cost (including PBS subsidy status) or LAM listing of a medicine, the hospital/District medicines committee can reserve the right to review relevant IPAs.

4.4 Outpatient approvals:
4.4.1 The Queensland public hospital system is not an alternate funding mechanism for community patients. Private community patients are not to be referred to QH facilities solely with the intent to gain access to non PBS subsidised medicines.

4.4.2 An IPA for use by an outpatient must take into account the total cost impact on QH, including all associated costs such as the load on outpatient clinics and resources required to dispense the medication, and ensure that processes are in place at the patient's local hospital to ensure continuity of supply and regular review of the on-going need for the medicine.

4.4.3 Follow up must occur in a QH facility and include documentation of response to therapy and side effects recorded in the patient's QH medical file.

4.5 External advice: The committee may identify circumstances where external consultation could be sought.
4.5.1 Expert Support: A range of expert advisers are to be identified to provide support to sites without expert or fully resourced medicines committees and for the occasions where a District committee does not have expertise in a specific area of practice. External expert advice (such as an on-call clinical pharmacologist, nominated senior specialist or another medicines committee) should be sought as required.

4.5.2 High cost medicines which are not listed on the LAM: High cost medicines are those with either a high unit cost or with a high volume of use resulting in an overall high cost. Advice from another hospital or District high cost medicines committee could be sought when the anticipated cost of treatment is, for example, >$10,000 per patient per year/course, or $100,000 per hospital per year.

[2] QH Guideline. Use of Patient's Own Medicines.

Processes are also to be identified to review and share information on medicine committee approvals of high cost non-LAM items.

4.6 "Urgent" and "out-of-session" approvals:

4.6.1 Circumstances where "urgent" approvals (ie after hours) are requested so that medicines can be commenced immediately will be uncommon and must not include occasions where prescribers have not planned ahead. Urgent approvals will only be given in life threatening circumstances where delaying treatment would lead to significant patient mortality/morbidity.

4.6.2 The District committee may establish a mechanism for approvals to be granted "out-of-session", where it is agreed that a decision cannot wait until the next meeting of the medicine committee (eg delegation of this role to the Medical Superintendent or another medicines committee delegate). However, for high cost medicines, decisions must be delayed (unless urgent) until the next meeting of the appropriate committee.

4.6.3 Details of these "urgent" and "out of session" applications and approvals must be forwarded immediately to the hospital/District medicines committee to be recorded and tracked to inform future decisions and approvals.

4.7 Delegation to approve out of session requests:

4.7.1 Delegations should be minimised to allow the resources of hospital/District medicines committees to be targeted at assessing applications that are considered to be high risk or high cost. Where delegations are used, they must be approved by the medicines committee for a discrete period of time and be minuted accordingly.

4.7.2 All delegations must be made in writing and outline the scope, and identify suitable thresholds to initiate progressing to the full medicines committee, or to QHMAC. The committee should produce consensus guidelines for the delegate to follow in the future for that particular medicine for the particular indication.

4.7.3 Delegated approvals must always be recorded and reported to the medicines committee and are generally not the mechanism to put in place local "blanket approvals"(see 4.8). Where guidelines have not yet been put in place by the committee, delegates must justify their decision making to the medicines committee next time the committee meets.

4.7.4 Committees may choose to have mechanisms in place to streamline "minor" approvals. They may decide that some approvals are suitably delegated to the local Medical Superintendent, a head of department (including Director of Pharmacy) or local hospital specialist. For instance, the District committee might agree that the local Medical Superintendent (or another delegate) give individual patient approval where clinical justification exists for items under a certain value $1000 per patient or $10,000 per annum – refer *Appendix B.*

4.8 Patient group ("blanket") approvals:

4.8.1 Patient group approvals are strongly discouraged. They can cause disruption to the management of patients when they are transferred between health care facilities, leading to financial, clinical and administrative issues at the receiving hospital, and they do not reflect the Queensland Health intent of equity of access. For these reasons, Districts are encouraged to forward submissions for patient group approvals to QHMAC for consideration.

4.8.2 If QHMAC does not endorse the addition of an item to the LAM or does not endorse its use in the proposed patient group, hospital/District medicines committees must review the evidence to support a need for current patients to continue on the medication, and carefully consider the initiation of any new patients on the item.

4.8.3 Decisions should be made locally, and statewide, to identify trigger levels where IPA applications should no longer be managed locally. At the stage where their large volume or broad impact is significant, these should be forwarded to QHMAC. IPA trigger levels at a single site may be a proportion of drug budget and are likely to vary between facility. (Refer Flowchart Appendix A.) If QHMAC does not subsequently endorse this use, District committees should review and reconsider these local IPAs.

5. Processes:

5.1 Applications for Individual Patient Approval:

All applications to hospital/District medicines committees for initiation of non-LAM therapy for individual patients must present evidence of efficacy, safety and cost compared to alternate therapies on the LAM. Applications are to be made on the state wide request form (*separate document)*.

5.2 When Individual Patient Approval has been granted:

5.2.1 Record keeping and review: Suitable records of approvals must be kept. Review of clinical progress and reporting of outcomes is essential to ensure learnings are shared and processes are rigorous. In addition, this reporting provides a mechanism for ceasing the provision of funded drug if there is a lack of benefit or if detriment is occurring. Some elements of these records may currently be maintained in systems such as iPharmacy. Refer *Appendix C*.

5.2.2 Funding: Where IPAs are granted, this model may result in the initiating hospital bearing the ongoing cost for that drug unless there is appropriate consultation[3]. The financial impact on small sites must be borne in mind when patients are transferred back to their local hospital and measures should be put in place to assist this transition in patient care.

5.2.3 Advice of approval[4]: This must be circulated to the initiating hospital's pharmacy (or dietetics) department prior to presentation of the prescription. Where applicable, the patient's local hospital must also be contacted to ensure that there is a shared understanding of the need for therapy and an

[4] Refer to Guideline for achieving continuity of supply of nonLAM items (in draft at March 2010)

arrangement has been made to ensure patient therapy can be continued. Refer *Appendix C*.

5.3 Appeals:
There must be an avenue of appeal for unsuccessful applicants within each District, as decided locally.

5.4 IPAs are strongly discouraged when :
5.4.1 QHMAC has considered the medicine for the requested indication and rejected its addition to the LAM for the relevant patient group and where the applicant cannot identify strong grounds for a clinical need in a particular patient. (Access to all QHMAC recommendations are available on QHEPS at *QHMAC meeting outcomes*[5].)

5.4.2 The Pharmaceutical Benefits Advisory Committee has considered the medicine / indication / patient group and does not recommend Commonwealth funding.

5.4.3 A case does not meet the criteria of a Commonwealth funded access program for the proposed indication (eg Highly Specialised Drugs Program or the PBS).

5.4.4 When required for initiation of therapy, where a clinically similar item or one in the same therapeutic group is included on the LAM.

5.4.5 A clinical need is identified for a medicine with the potential for widespread use in Queensland public hospitals or a number of local individual approvals have already been given. In these cases, a submission should be made to QHMAC to request addition to the LAM.

6. Appendices

A. Flowchart – Governance of IPAs
B. Risk and Delegations
C. Records, Review and Advice
D. Background
E. Definitions

7. Associated documents

State wide Form: Individual Patient Request for Approval (included with Appendix 10 of the LAM) available at:
http://www.health.qld.gov.au/qhcss/mapsu/sdl.asp

8. Definitions

See *Appendix E*.

9. Stakeholders consulted

- Chairs, hospital/District medicines Committees (DTCs)
- Directors of Pharmacy
- Directors of Medical Services
- QHMAC and other members of the Queensland Health Medicines Collaborative
- Nutrition Subcommittee of QHMAC (NUSCO)

[5] qheps.health.qld.gov.au/medicines/projects_initiatives/qhmac_outcomes.htm

10. Original version approved by: Consensus of the Queensland Health Medicines Collaborative, March 2010.

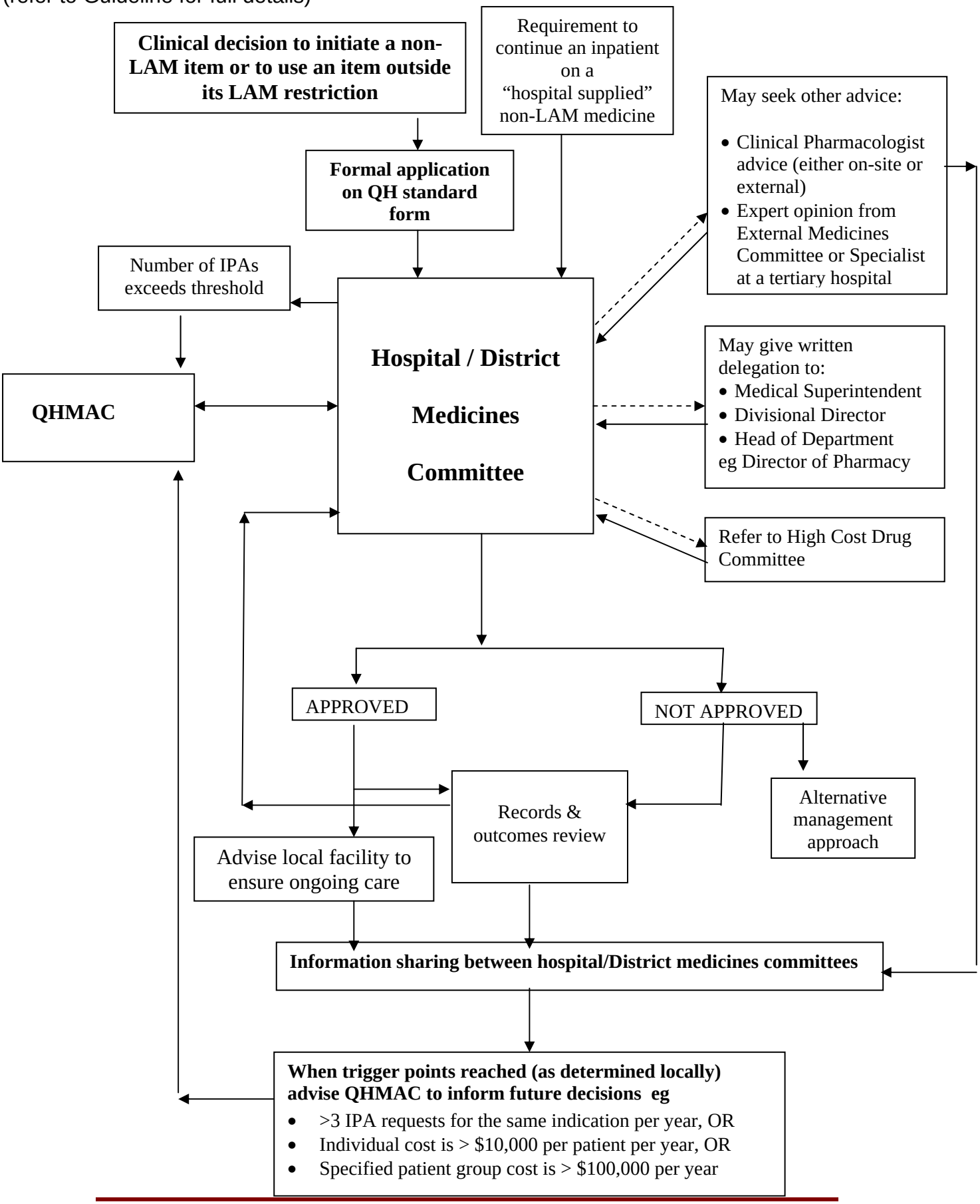
11. Further Information: For further general information please contact Medication Services Queensland: Telephone (07) 3131 6521

12. Amendment History

Revision	Date	Author/s	Amendments
	June 09 – June 10	S Christiansen	Draft in consultation
Version 1.3	May 2011	S Boydell	Updated on NUSCO advice with reference to nutritional items.
Version 1.4	May 2011	S Boydell	Included note at page 12 of 15 about revised version of state wide IPA request form (App 6)
Version 2.0	June 2011	S Boydell	Changed Appendices names from 1-5 to A-E and detached state wide IPA request form from guideline (so no longer Appendix 6) so now guideline is only 11 pages – made IPA request form a stand alone interactive document.

GOVERNANCE OF INDIVIDUAL PATIENT APPROVALS (IPAs) **APPENDIX A**

(refer to Guideline for full details)



RISK and DELEGATION: **APPENDIX B**

(a) **Risk**: Risk level relates to:

- risk to the patient of experiencing serious side effects;
- level of experience with use of a particular drug (ie length of time in market);
- the level of experience with the use of a drug to treat a particular indication or patient group (eg the elderly).

The level of risk diminishes as the level of familiarity and the volume of evidence grows for the use of a drug in a particular indication.

If IPAs for particular low risk and low cost agents become common, then the agents should be considered for either formulary listing or drafting of standardised reporting criteria and approval periods.

(b) **Delegation of approvals:** Delegations should take into account the relevant expertise and level of financial delegation of the delegate. However, it is generally preferable to nominate an individual member of the medicines committee who is independent of the particular area so that a balanced and objective decision can be made. External advice may need to be sought. Although the Director of Pharmacy may be delegated to approve non-LAM presentations of LAM PBS medicines for inpatient use, the Director of Cardiology would not always be delegated to consider approval requests for cardiovascular medicines, unless this was previously agreed for specific circumstances or medicines.

Taking into account cost, anticipated benefit and whether an approval is for an inpatient, for extended use as an outpatient, or for a one-off supply, the hospital/District medicines committee might choose to delegate approvals to an individual in the following circumstances:

a) medicines for which QHMAC has provided guidance notes for IPA approval[6]
b) medicines for which cost effectiveness is likely and QHMAC has recommended that access to the medicine (for the requested indication or the specific patient group) is most suitably obtained through IPA[7]
c) to allow continuation of an inpatient's PBS medicine, when all other options to use the patient's own medicines[8] have been exhausted, and it is clinically imperative that therapy is not changed
d) use of a non-LAM form, strength or presentation of a LAM medicine, or a variant (eg flavour) of an enteral nutrition tender item, which is required for patient therapy
e) as a short term measure where no other option yet exists – refer 4.7.4

Such delegations should be intended to streamline patient care and should not constitute local "group" or "blanket" approvals for items QHMAC has not been asked to consider, or has rejected, for addition to the LAM. These delegations would not usually be suitable on initiation of therapy or when it is clinically appropriate to use a LAM item.

[6] LAM Appendix 9: www.health.qld.gov.au/qhcss/mapsu/documents/lam/lam.pdf
[7] qheps.health.qld.gov.au/medicines/projects_initiatives/qhmac_outcomes.htm
[8] QH Guideline: Use of Patient's Own Medicines

RECORDS, REVIEW and ADVICE: **APPENDIX C**

Record Keeping:

- All approvals, including verbal or telephone, require suitable record keeping which should include a tracking number or other identifier. In the case of urgent approvals, this may be done retrospectively.

- The record may be in electronic form (eg may be maintained in iPharmacy) and should include patient details (name, UR number, telephone, address) and details of treatment (including length of approval). It is preferable to include brief clinical details and rationale for approval.

Review and reporting:

Review and reporting is critical for clinical governance and audit – at the local and state levels.

All individual patient approvals should be tracked and measured locally. Patient outcomes and usage data should be reported to share learnings and inform future decisions.

- All approvals (including those made by the Committee or its delegate) should be recorded, collated and subject to peer review. Regular reports should be provided to the hospital/District medicines committee or hospital executive, as decided locally. QH Audit and Operational Review Unit will undertake regular audits of records of non-LAM use.

- Reports are essential to allow extension of approval past the end of the approval period.

- Specific recording and monitoring of prescribing against the agreed protocol may be undertaken and Drug Utilisation Evaluations should be conducted at regular intervals

- Approvals, non-approvals and treatment outcomes should be shared with other hospitals and Districts to allow collation of n=1 events to provide more meaningful and useful data state wide.

- Some IPA approvals may have the potential to be progressed to QHMAC for review and/or to the relevant pharmaceutical company for input or feedback.

Circulation of advice:

The specialist initiating therapy must:

a) arrange for the Pharmacy (or dietetics) department at the initiating hospital to be advised of the approval and relevant details. To allow timely supply and dispensing, this must be done prior to the patient presenting at pharmacy with the prescription.

b) take appropriate steps to ensure that the patient's local hospital has been contacted and that agreement has been reached to ensure safe and sustainable continuation of patient therapy, and that there is a process in place for regular review of the on-going need for therapy.

BACKGROUND: **APPENDIX D**

Unnecessary duplication of medicines:

Queensland Health believes that a state-wide approach to the availability of therapeutic substances in Queensland public hospitals limits duplication of effort and resources, and facilitates equity of access to medicines across the State. Queensland Health policy on unnecessary duplication of drugs states that "it is not accepted that making all marketed drugs available…would contribute to good medical practice or quality use of medicines, nor is it economically feasible" [9].

Hence only a limited selection of medicines, particularly when there is wide representation in a therapeutic group, are included on the LAM. (For example there is a limited number of LAM listed angiotensin converting enzyme inhibitors.) Decisions to limit the number of LAM items in a therapeutic group is based on clinical need and cost effectiveness. Items considered to have limited or insignificant clinical advantages over LAM therapies are often not listed on the LAM.

Generic prescribing and QH Standing Offer Arrangements (SOAs):

Medicines are generically listed on the LAM and generic prescribing is essential to ensure quality use of medicines[10,11]. QH enters into SOAs with pharmaceutical companies to obtain the most competitive prices for therapeutic goods. These arrangements, also referred to as "tenders", often result in only one brand of a particular generic medicine being available in QH hospitals. To maintain the integrity of the tender process, alternate brands of medicine must not be used without individual patient approval.

Nutritional products:

All enteral, and many parenteral, nutrition products used in Queensland public hospitals and clinics are assessed by QHMAC, with advice from its Nutrition SubCommittee (NUSCO). Products deemed by the Committee to be efficacious and cost effective, and required by QH clients, are included in LAM (see state wide request form – separate document).[12] Not all variations of nutritional supplements are available and, as they are usually subject to tender arrangements, a selection of brands and flavours are available. Items which are not on the LAM or the current tender require a local approval.

The Pharmaceutical Benefits Scheme (PBS):

While QHMAC takes into account the PBS status of medicines when making a recommendation for inclusion on the LAM, the Committee does NOT include all PBS items on the LAM. Doctors prescribing in QH hospitals and institutions are required by the PBS Business Rules[13] to limit all prescribing to items on the LAM, and must request individual patient approval to prescribe non-LAM items, including those that are PBS listed. QH clinicians are not to prescribe non-LAM PBS medicines for public patients without appropriate approval being granted – despite the location at which the prescription is dispensed.

[9] LAM page vi: www.health.qld.gov.au/qhcss/mapsu/documents/lam/lam.pdf
[10] National Inpatient Medication Chart Guidelines: http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/com-pubs_NIMC-con/$File/24380-GuidelinesForNIMC2009.PDF
[11] NSWTAG Safer Medicines Group. Principles for consistent prescribing terminology 2006: http://www.ciap.health.nsw.gov.au/nswtag/publications/guidelines/TERMINOLOGY1206.pdf
[12] LAM Appendix 6: www.health.qld.gov.au/qhcss/mapsu/documents/lam/lam.pdf
[13] http://qheps.health.qld.gov.au/medicines/documents/general_policies/pbs_business_rules.pdf

DEFINITIONS: **APPENDIX E**

Individual Patient Approval (IPA) is the mechanism in Queensland Health public hospitals which allows a local approval to be given for patient access to medicines that are not included on the LAM for the required indication.

LAM – the Queensland Health List of Approved Medicines is the restricted list of medicines, and the indications for use, which have been approved by QHMAC for prescribing state wide in Queensland public hospitals and institutions. The LAM does not include all items which are listed on the PBS. See also "non-LAM" and "Pharmaceutical Benefits Scheme" below.

Medical Superintendent in this document refers to the Executive Director of Medical Services, Clinical Chief Executive Officer, Country Medical Superintendent or other medical officer who has the authority or been given the delegation to make clinical decisions to approve, or not approve, the use of non-LAM medicines.

Medical Superintendent signed Authority Protocols (MSAP) have been developed by QHMAC for a small number of medicines which QHMAC considers have very specific roles in therapy. MSAPs are detailed guidelines which have been developed to give Medical Superintendents assistance in identifying the most suitable patients for approval. It is envisaged that these forms may become available electronically to remove the administrative burden of medical Superintendents "signing off" these forms. These items are listed on the LAM and do not require "individual patient approval" as described in this policy.

Medicine: For the purpose of this document "medicine" refers to pharmaceuticals and other therapeutic substances including intravenous fluids and nutritional items.

Non-LAM medicine – medicines or indications not included on the LAM.
NB. Many items which are listed on the Pharmaceutical Benefits Scheme (PBS) are non-LAM medicines.

Pharmaceutical Benefits Scheme (PBS) operates within QH public hospitals and institutions through the PBS Access Program[14]. This Program allows Commonwealth subsidy for PBS medicines for QH outpatients, oncology day therapy patients and patients on discharge.

QHMAC – the Queensland Health Medicines Advisory Committee is the state-based advisory committee which makes recommendations on additions and changes to the LAM. Recommendations which are approved by the Committee Sponsor, acting on behalf of the Director-General of Queensland Health, are then included in the LAM and form Queensland Health policy.

SOA – Standing Offer Arrangements (SOAs) are in place for a number of therapeutic groups. Refer to Appendix D.

[14] http://qheps.health.qld.gov.au/medicines/documents/general_policies/pbs_business_rules.pdf