Purpose

To outline the Drug and Therapeutics Committee's approval processes for drug use within Barwon Health. These processes cover the introduction of new drugs, high cost or off label drugs for individual patients, urgent requests, restricted formulary drugs, familiarisation programs, special access scheme drugs and policies on drug use.

Target Audience

Registered Nurses (RN)
Enrolled nurses (EN) (unless notation prevents medication administration)
Prescribing practitioners
Pharmacists, Pre-registrant pharmacists and pharmacy technicians

Definition

N/A

Procedure

Application for New Drugs to be used within Barwon Health

New drugs listed on the Pharmaceutical Benefits Scheme Drugs (PBS) including Section 100 (S100) Highly Specialised Drugs.

The therapeutic and economic evaluation undertaken by the Pharmaceutical Benefits Advisory Committee (PBAC) to list pharmaceuticals on the PBS is accepted by the Drug and Therapeutics Committee as sufficient justification for listing a drug on the Barwon Health formulary for use in accordance with PBS criteria. However to formally list the drug a medical practitioner is required to e-mail or write to the Secretary of the Drug and Therapeutics Committee requesting the listing which will then be reviewed at the next meeting of the Committee.

New Drugs, Non-PBS/non S100

Application for listing is made on the Drug Formulary Proforma for New Drug Submission available on Prompt. Consideration is given to the rationale for the request, current drugs available for the indication, efficacy and level of evidence, prescribing restrictions and cost.

Special Access Scheme (SAS)

The SAS (2011, para. 5) refers to arrangements which provide for the import and/or supply into Australia of an unapproved therapeutic good for a single patient, on a case by case basis. Patients are grouped into two categories under the scheme:

- Category A patients are defined as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.
- Category B patients are all other patients that do not fit the Category A definition.

With the exception of drugs of abuse where the manufacture, possession, sale or use is prohibited by State or Territory law; any unapproved therapeutic good can potentially be supplied via the SAS.

Applications under the Special Access Scheme are made to the Therapeutic Goods Administration (TGA) by registered medical practitioners, preferably the treating doctor. Forms are available through Pharmacy or the TGA website (http://www.tga.gov.au/hp/access-sas.htm).

Applications are forwarded to the Pharmacy Department for processing. SAS drugs which incur a significant cost to the organisation are referred to the Drug and Therapeutics Committee for approval at the discretion of the Director of Pharmacy. The medical practitioner is responsible for obtaining patient consent prior to use of a SAS drug.

Restricted Formulary Drugs

Drugs approved by the Committee with restrictions on authorised prescribers or indications are listed on Prompt. See Restricted Drugs List
Use of any of the listed medications for indications other than those listed requires an Individual Patient Usage (IPU) Application Form to be submitted to Drug & Therapeutics Committee for approval.

For Antibiotic prescribing restrictions, refer to the Restricted Antimicrobial Prescribing and Guidance DS Policy.

Product Familiarisation Programs (PFP)

These programs are offered by the pharmaceutical industry to provide public hospital patients with the opportunity to access newly registered medicines, during the early prescriber familiarisation phase of the product and prior to possible inclusion on the Pharmaceutical Benefits Scheme (PBS). A PFP must be approved by the Committee before commencement to ensure the risks of inappropriate discontinuation of therapy for patients or unanticipated costs to Barwon Health are averted.

Individual Patient Use (IPU) drugs

Requests for high cost, non-PBS or off label drug indications for individual patients are to be made on the Individual Patient Usage (IPU) Application Form available on Prompt. In evaluating the application the Committee considers rationale for the request, previous therapy and outcomes, alternative therapies, measures of success and cost. The signatures of the authorising consultant and head of unit are required. Expertise external to the Committee members can be sought in evaluating the proposal.

It is recognised that that timely decisions are required for urgent IPU requests. The process for approval involves email agreement between at least two consultant medical staff members of the Committee and the Director or Deputy Director of Pharmacy. Expertise external to the Committee members can be sought in evaluating the proposal.

Further advice on these processes is available from the Director of Pharmacy and Secretary Drug and Therapeutics Committee, Greg Weeks on (03) 4215 1591.

Clinical Documents with Drugs

Clinical Guidelines/procedures/protocols relating to drug therapeutics, prescribing, dispensing and administration require the approval of the Drug and Therapeutics Committee prior to uploading onto PROMPT.

Evaluation

Regular document revision and review of relevant ‘RiskMan’ Reports

Key Aligned Documents

Drug and Therapeutics Committee TOR, PROMPT: Barwon Health \ Terms of Reference \ Committees & Working Groups

Drug Formulary Proforma for New Drug Submission, PROMPT: Barwon Health \ Pharmacy \ Pharmacy \Forms Template Worksheet Checklist

Individual Patient Usage (IPU) Application Form, PROMPT: Barwon Health \ Pharmacy \ Pharmacy \Forms Template Worksheet Checklist

Restricted Antimicrobial Prescribing and Guidance DS Policy, PROMPT: Barwon Health \ Pharmacy \ Pharmacy

Restricted Antimicrobial Prescribing Protocol, PROMPT: Barwon Health \ Pharmacy \ Pharmacy

Restricted Drugs List, PROMPT: Barwon Health \ Pharmacy \ Pharmacy \ Clinical Guidelines & Procedures

Key Legislation, Acts & Standards

National safety and quality health service standards (2011, June). Retrieved June 22, 2012 from http://www.safetyandquality.gov.au/wp-content/uploads/2011/01/NSQHS-Standards-Sept2011.pdf

NSQHS standards: **4.1.2**

References

Australian Government, Department of Health & Ageing, (n.d).Therapeutic Goods Administration, *Category A form special access scheme* [Reference 2949 (1008)]. Retrieved June 28, 2012 from http://www.tga.gov.au/pdf/forms/access-forms-sas-categorya.pdf (SAS Category A form).

Australian Government, Department of Health & Ageing, Therapeutic Goods Administration, (n.d). *Category B form special access scheme* [Reference 2950 (1008)]. Retrieved June 28, 2012 from http://www.tga.gov.au/pdf/forms/access-forms-sas-categoryb.pdf (SAS Category B form).

Australian Government, Department of Health & Ageing, Therapeutic Goods Administration (TGA), (2011, June 9). *Special access scheme*. Retrieved June 28, 2012 from http://www.tga.gov.au/hp/access-sas.htm

Victorian Therapeutics Advisory Group (VicTAG). (2005). Guidelines for product familiarisation programs in public hospitals. Retrieved August 26, 2013 from http://www.victag.org.au

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