GUIDELINES FOR THE FUNDING OF

EXCEPTIONAL DRUGS
IN
NSW & QUEENSLAND
PRIVATE HOSPITALS

Version 3 –December 2008

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&
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Approved by
NSW/QUEENSLAND EDL COMMITTEE

Operating under the auspices of the:
Australian Private Hospitals Association (APHA)
Australian Health Insurance Association (AHIA)

GUIDELINES FOR THE FUNDING OF EXCEPTIONAL DRUGS IN NSW & QLD

– CONTENTS –

1. INTRODUCTION

The Joint NSW Health Funds / Private Hospitals Pharmacy Working Party was initially formed in 1996 to consider issues relating to the provision of pharmaceutical services in private hospitals in NSW, particularly the issue of the Exceptional Drugs List (EDL). Following implementation in NSW the EDL was extended to Queensland

The purpose of the Working Party was to consider the issues of relevance and to prepare recommendations for consideration by the industry participants.

In preparing the findings and recommendations, participants acknowledged the requirements of the Trade Practices Act and the obligations of the parties to observe that Act at all times.

The participants involved in the Working Party also recognised the changing circumstances associated with the private health sector, including the development of Casemix and episodic payment models and the negotiating environment faced by both private health insurance funds and private hospitals.

Given the changing environment, The EDL Committee agreed in February 2004 that it was an appropriate time to undertake a review of the 1996 Guidelines. It was also agreed to amend the Guidelines to focus on the EDL rather than pharmacy items in general.

The EDL Committee agreed that irrespective of contractual arrangements between some funds and hospitals the EDL Committee continued to have relevance in the current environment. It was noted that the use of the EDL had changed over time and whilst mindful of current contractual arrangements, it was considered that the primary role of the EDL Committee in the future should be to maintain the list in line with PBS and contemporary practice changes rather than seek to expand it. In reviewing the Guidelines in December 2007, the EDL Committee reaffirmed this view.

2. EDL COMMITTEE COMPOSITION

Committee members agreed that it was important to ensure that the Committee remained a committee of experts rather than one based purely on organisational and sector representation and therefore should reflect a balance of members with private hospital, health fund, pharmaceutical and industry expertise.

Currently the Committee comprises:

- 3 Health Fund Representatives
- 3 Hospital Representatives
- 2 Industry Association Representatives.

Two of the current members are pharmacists and it was considered essential that the membership maintains a minimum of two pharmacists at any one time.

3. FREQUENCY OF MEETINGS

The EDL Committee will meet a minimum of three times per annum, following which, updates to the EDL will be issued to private hospitals and health funds dated January, May and September each year, together with an accompanying circular. Supplementary updates may be issued by the Committee in the event of any significant change to the PBS in a given month.

4. METHOD OF OPERATIONS

- The EDL Committee will meet regularly to review pharmaceuticals applicable to the private hospital sector in accordance with PBS amendments, with a view to issuing version controlled EDL updates as required. ,

- Secretariat services will be provided by the Private Hospitals Association of Queensland.

- The Chair will be elected annually by the members.

- A quorum will be four (4) members with at least two (2) representatives from both hospitals and health funds, one of whom must be a pharmacist.

- The Committee must work by member consensus and may not resolve issues by voting. In the event that consensus cannot be reached, the Committee may recommend resolution by individual negotiation

between a hospital and a health fund

- The Committee may co-opt any number of specialist advisors as observers.

- Members of the Committee may nominate an 'alternate' to attend meetings in the event of their unavailability.

5. KEY ACTIVITIES OF THE EDL COMMITTEE

The EDL Committee has determined that the key activities in the future will be to:

- Maintain the EDL as an industry resource document for the private health sector

- Review the EDL regularly and provide feedback to the industry on relevant PBS amendments affecting the list.

- Consider applications from hospitals and health funds in relation to Exceptional Drugs as defined in ***Appendix A.***

- Maintain a regime for Individual Patient Usage (IPU) assessment and review of usage

- Conduct relevant surveys to improve understanding regarding drugs in use within the private sector.

- Provide technical advice to Government and industry peak bodies and nominate appropriate personnel to relevant external committees (e.g. Highly Specialised Drugs Working Party – HSDWP).

- Provide an educational role for the sector and a forum to address private sector issues associated with Exceptional Drugs and the PBS including the Highly Specialised Drugs Program.

- To review and disseminate relevant information from the Australian Drug Evaluation Committee (ADEC), the Therapeutic Goods Administration (TGA) and any other relevant agencies.

- Engage with suppliers and providers where appropriate to review current practice.

- In considering items for inclusion on the EDL the Committee will consider the following criteria:

    - Cost
    - Frequency of Use
    - Other Funding Options
    - Intrinsic to the Episode of Care
    - Appropriateness of Use
    - New Technology
    - Coding System for Identification

6. EDL & CONTRACTING

Whilst it is acknowledged that the payment of benefits for pharmacy items is a matter for individual negotiation between a hospital and a health fund, the EDL Committee recommends that the principles defined below be recognised and accepted.

- The costs of a significant number of pharmacy items used routinely and intrinsic to the episode of care in the management of private hospital inpatients be included within the contracted rebates provided by health funds to private hospitals. *(Refer Section 6)*

- Subject to point 1 above, where appropriate, the Pharmaceutical Benefits Scheme (including Restricted, Authority and Section 100 arrangements) should be accessed for all pharmacy items other than those listed in this report as intrinsic to an episode of inpatient care (eg anaesthetic agents, analgesics).

- The "Exceptional Drugs List" (EDL) is an important reference tool and it is therefore recommended that the EDL be subject to negotiation with individual health funds and private hospitals as one element of the fund-hospital contract, irrespective of whether the EDL pharmacy items are bundled or not.

- Health fund-hospital contract negotiations should define the circumstances in which the patient may pay for those high cost items not covered in these proposed arrangements.

- The EDL is reviewed and updated regularly and therefore it is recommended that all users of this list ensure that the most recent version is referred to at all times.

- The EDL Committee will consider adding items to the schedule based on the merits of applications received. In circumstances where use of a particular high cost drug is very limited the EDL Committee may recommend that the item remain subject to an Individual Patient Usage (IPU) application being submitted to the fund. *(Refer Item 11 of this document for detailed criteria regarding addition to the EDL)*

7. ITEMS WHICH ARE NOT CONSIDERED ELIGIBLE FOR INCLUSION ON THE EXCEPTIONAL DRUG LIST (EDL)

- Drugs which are no longer available
- Drugs which do not have TGA Approval for the indication applied for, or which are not approved under the Special Access Scheme
- PBS, Authority and Restricted drugs which are only prescribed within the indications meeting PBS Authority or Restriction criteria
- Drugs which are deemed to be appropriately included in the accommodation, theatre or critical care costs because they are considered intrinsic to the episode of care
- Drugs for which there is a clinically appropriate alternative on PBS
- Drugs which the EDL Committee has determined would be addressed more appropriately via an Individual Patient Usage (IPU) process.

The Exceptional Drugs List Committee considers that the following types of drugs should be included in the normal accommodation charges of the hospital, and accordingly they are not generally included on the Exceptional Drugs List. A small number of exceptions to this may apply, and these are specified on the EDL.

- Analgesics (simple and narcotic)
- Antacids
- Antiemetics
- Antiseptic Solutions
- Diluents (water for injection, normal saline)
- Electrolytes
- Enemas, Laxatives and Suppositories
- Irrigation Fluids
- Intravenous Fluids
- Local Anaesthetics
- Mouth Washes
- Sedatives and Hypnotics
- Topical Agents
- Urinary Alkalinisers
- Urinalysis Agents
- Vitamins

The EDL Committee recommends that those types of drugs shown above should be included in the rebates for Accommodation, Theatre, ICU and CCU, unless specifically included on the Exceptional Drugs List.

8. EPISODE OF CARE

The EDL Committee has agreed that where reference is made to an "Episode of Care", this should relate to the current definition in the National Health Data Dictionary.

This definition relates to the "Episode of Care" for an admitted patient in hospital. In respect of drugs supplied, the EDL Committee considers that the "Episode of Care" pharmaceuticals would cover drugs that are used routinely pre-, during or post-procedure, as opposed to those drugs that are individually required due to the specific therapeutic needs of the individual patient; for example, drugs required to manage asthma for a surgical patient.

9. HOW TO USE THE EXCEPTIONAL DRUGS LIST

The Exceptional Drugs List can be used as a guide to those drugs, which have been assessed as not being suitable for inclusion in accommodation, theatre and critical care charges. However, in relation to Antibiotics, PBS Restricted and Authority drugs, and Section 100 drugs the specific recommendations detailed below should be adhered to.

The column on the List headed "Special Criteria" indicates where particular standards should be adopted and these are defined below:

9.1 Anti-Infective Agents **(including: Antibiotics; Antiviral Agents; Antifungal Agents)**

Anti-infective agents will be included on the Exceptional Drugs List if:

- the drug was required for other than the PBS indications and the "Victorian Drug Usage Advisory Committee - Antibiotic Guidelines" (which are recognised as national standards) are followed,

or in special circumstances:

- on the recommendation of a specialist microbiologist / pathologist.

It is proposed that the use of anti-infective agents as part of the Exceptional Drugs List be monitored by the hospital and be capable of being audited by the health funds.

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9.2 PBS Restricted / Authority Drugs

In isolated cases some PBS Restricted and Authority drugs may be included on the Exceptional Drugs List; however, there are a number of steps to be followed for these to be recognised:

- If the drug meets the PBS requirements it should always be prescribed via the PBS.

- The drug may be recommended by the EDL Committee for inclusion on the Exceptional Drugs List for special indications not covered under the PBS.

9.3 Section 100

Drugs listed on Section 100 of the Pharmaceutical Benefits Schedule will be included on the Exceptional Drugs List if:

- The prescription for the Section 100 item is a new order and not a continuation of drug therapy previously initiated and supplied under the S100 scheme, therefore patients should be encouraged to bring a supply of their S100 continuing medications on admission.

- Discharge S100 drugs will not be funded on the Exceptional Drugs List.

10. APPLICATION FOR NEW DRUGS TO BE REVIEWED FOR INCLUSION ON THE EXCEPTIONAL DRUGS LIST

Where a new drug is to be considered for inclusion on the Exceptional Drugs List, a written application should be submitted to the EDL Committee and forwarded to the Secretariat – PHAQ, PO Box 370, Kenmore, Qld 4069.

The application form is included as ***Appendix B.***

Relevant supporting documentation should accompany all applications and applicants should be aware that they may be required to provide additional information on request.

11. CRITERIA FOR ADDITION AND REMOVAL OF DRUGS FROM EXCEPTIONAL DRUGS LIST

11.1 Additions to List

Each Exceptional Drugs List item should meet criteria (i) to (v) inclusive

(i) New technology / New indications

These are new drugs which have either been recently approved by the Therapeutic Goods Administration (TGA) for marketing in Australia or existing drugs which have received TGA approval for a new indication.

(ii) Drugs not routinely part of the episode of care

These are drugs prescribed on an individual case basis, rather than routinely prescribed.

(iii) Appropriateness of use

Evidence of efficacy, safety and cost effectiveness of the drug for the particular indication.

(iv) Financial implications

Total cost of drug per episode of care or course of treatment will be considered for high acquisition cost items. Data to verify the cost effectiveness of the drug compared to alternative drug therapies and / or other treatment modalities will be considered.

(v) Special Circumstances

Any or all drugs that have been referred to the health funds under “Special Circumstances” in the preceding quarter.

11.2 Removal from List

Drugs may be removed where one or more of the following criteria apply.

(i) Old technology / Old indications

Drugs which no longer have marketing approval or are not recommended to be prescribed where previously they were indicated.

(ii) Ward stock in a specialist unit

Drugs which would generally be considered routinely prescribed or used in operating theatres, critical care units or labour wards.

(iii) Drugs routinely part of the episode of care

These are drugs which are considered a routine part of the episode of care.

(iv) PBS / RPBS listing

Drugs which gain approval for listing on the PBS or RPBS.

(v) Inappropriateness of use

Lack of evidence of efficacy, safety and cost effectiveness for the particular indication.

12. INDIVIDUAL PATIENT USAGE (IPU)

In some special circumstances an individual hospital may lodge a request to a health fund for funding of high-cost, non PBS/Non EDL drugs. These circumstances may also apply where a new drug is under review for inclusion on the Exceptional Drugs List.

To enable a fund to consider such requests the following details may be sought:

- TGA Approval Number and Date of Effect
- Drug name (generic and trade), dosage and formulation, any special details eg the Special Access Scheme (SAS)
- Special requirements for SAS drugs (eg whether it is category A, B or C)
- Prescriber details, ie medical provider
- Reason why the drug has been prescribed, dosage, days per course, number of courses, anticipated duration of therapy (ie potential cost).
- Anticipated charge for the drug and what the charge includes (eg drug acquisition cost, dispensing fee, mixing fee, preparation fee, service fee, mark up)
- Price of the drug (eg Guild price, drug company list price, wholesaler's price)
- Likelihood of other charges associated with the drug therapy (eg monitoring, additional fluids)
- What is the standard treatment for the patient's condition? Reason for "standard drug therapy" not being prescribed? Are there less costly alternatives?
- Evidence that the drug will be successful
- Drug(s) which have been previously prescribed to meet the patient's condition
- Anticipated outcome of the drug therapy, how outcome will be evaluated, and what details can be provided (eg pain relief, maintenance)
- Has the drug therapy been discussed with the hospital Drug and Therapeutics Committee, the prescriber or senior hospital management?

- Alternatives for the patient if the request is refused (ie another drug, hospital transfer, patient to absorb cost)

- These principles have been encapsulated in a template attached as Appendix C which hospitals may wish to utilise when lodging IPU applications.

13. GENERAL INFORMATION

For explanations of the following, please refer to ***Appendix E:***

- Pharmaceutical Benefits Scheme (PBS)
- Section 100 Drugs
- Authority Drugs
- Special Access Scheme Drugs
- Clinical Trials
- Australian Drug Evaluation Committee (ADEC)
- Therapeutic Goods Administration (TGA)

APPENDIX A

EXCEPTIONAL DRUGS LIST – BACKGROUND
(Extract from 1996 Guidelines)

"An Exceptional Drugs List was first published by the Private Hospitals Association of NSW in 1987, following the introduction of the patient classification system of funding private hospital patients. This list was used for many years by private hospitals and health funds as a basis for the payment of pharmacy benefits.

Recently, however, there has been dissatisfaction with the Exceptional Drugs List within the industry as there is no accepted mechanism for adding, amending or deleting items from the List. This, together with substantial overlap with the PBS and, in the view of the health funds, substantial overlap with the benefits paid for accommodation, theatre fees and critical care, has resulted in many health funds and private hospitals developing their own lists of exceptional drugs, adding complexity to the system.

A Working Party with wide representation from the NSW health funds, private hospitals and pharmacies was convened in early 1996 to review the existing Exceptional Drugs List, make recommendations for a new list, and develop a process by which a new list could be maintained.

At all times the Working Party was conscious of the fact that any proposed list and review process may or may not be used by an individual health fund or private hospital during the negotiation of hospital and health funds contracts; ie the recommendations from the review are entirely optional.

In mid 1996 the Sub-Committee established by the Working Party produced a list of drugs which it recommended should form the basis of a new industry Exceptional Drugs List. Those situations in which drugs would normally be accessed through the PBS scheme, or via the private hospitals (through normal fees for accommodation, theatre or critical care), or by patients direct, were clearly identified.

As a guide, it was determined that the Exceptional Drugs List should only contain those "high cost, non PBS drugs which can neither reasonably nor appropriately be included in the accommodation, theatre or critical care fees". Items that are routinely used or are an intrinsic part of the episode of care are appropriately included in the accommodation, theatre and critical care fees and are not considered appropriate for inclusion on the Exceptional Drugs List. "

APPENDIX B

EXCEPTIONAL DRUGS LIST COMMITTEE

APPLICATION FOR REVIEW OF NEW DRUG FOR LISTING ON THE NSW/QLD EXCEPTIONAL DRUGS LIST

Information is needed to assist in evaluating new drugs and drug products that are currently:

- Not listed on the PBS
- TGA approved , including via Special Access Scheme
- A drug to replace a drug of similar classification already on the Exceptional Drugs List

Applications for review of new drugs must be made **by private hospitals or health insurance funds**. Applications received from drug companies or individual medical practitioners will not be considered.

Completed applications should be submitted to:

The Secretary
NSW/QLD Exceptional Drugs List Committee
C/o Private Hospitals Association of Queensland
P.O. Box 370
Kenmore QLD 4069 ***Fax: 07 3279 7601***

PLEASE PRINT **ADD ADDITIONAL SHEET IF SPACE INSUFFICIENT**

REVIEW REQUESTED BY:

HOSPITAL ……

CONTACT PERSON .....……. **TEL .....…….....** **E-mail ……**

ADDRESS ……

1. DRUG REQUIRED	
1.1 Generic Name:……	Trade Name (s):……
1.2 Form(s):…….	Strength(s):……...
1.3 Manufacturer/Supplier:……...	
1.4 Cost per unit/pack:……...	
1.5 Cost per treatment:……... per ……... (per short course or per week at standard dosage)	
2. DRUGS OF SIMILAR THERAPEUTIC CLASSIFICATION CURRENTLY AVAILABLE	
2.1 Drug:……. Strength:……..…….Form:…..…….……Cost:……..	
2.2 Drug:……. Strength:……..…….Form:…..…….……Cost:……..	

3. REASON FOR REQUEST

Please state why the new drug is preferred to the alternative drug(s) currently available. We are interested in the clinical place for this agent, including efficacy, and safety details. Please enclose copies of key references ie. double blind randomised controlled trials

……
……
……
……
……
……
……
……

4. HAS THIS INDICATION FOR USE BEEN APPROVED BY THE AUSTRALIAN DRUG EVALUATION COMMITTEE?

Yes □ No □

Give details:……..
……
……

5. ESTIMATED NUMBER OF PATIENTS PER ANNUM

New patients (p.a.) ……..
Proportion of patients affected (p.a.) …….
Maintenance patients (p.a.):..……...
Estimated cost of drug (p.a): ……..

6 ECONOMIC ANALYSIS

Yes □ No □

Are you aware of any potential costs and cost savings implicit in the introduction of this drug (eg investigations, length of stay etc)?

Give details:……..
……
……

7. EVALUATION OF DRUG THERAPY

……
How will you evaluate the success of this therapy?
……
……

Has this request the support of the Drug and Therapeutics Committee at your hospital?

Yes □ No □
Give details:……..
……
……

Has this request the support of the Director of Medical Services or equivalent at your hospital?

Yes □ No □
Give details:……..
……
……

SUBMITTED BY: ..... **SIGNATURE: .....**
(NAME)

DATE: .....

Appendix C

IPU TEMPLATE

REQUEST FOR SPECIAL CONSIDERATION OF PAYMENT FOR EXTRAORDINARY DRUGS.

Guidelines

This form is to be used when requesting additional payment for high cost, non PBS exceptional drugs for individual patient use. These drugs will usually be high cost drugs that are not available to the patient via routine sources, such as drugs intrinsic to the episode of care, on the agreed exceptional drug list or on the PBS. For payment to be considered by the fund all areas of the form must be completed in legible writing. The fund will make every attempt to respond by the time indicated in section 1. We recognise that the decision to use a specific drug is one made between the prescribing clinician and the patient, however it is preferable to forward a submission to the health fund prior to the use of the drug as the health fund may not agree to contribute after the event.

Part 1 – to be completed by the hospital

Hospital Name and Contact Person _____

Hospital Fax and Phone Number _____

Date and Time request sent _____

Member Name _____ Membership Number _____

Health fund requested to respond by: *date and time* _____

Authorised Hospital Representative (Please print name) _____

(Signature) _____

Part 2 – to be completed by hospital or prescribing clinician

Patient name _____

Principal diagnosis _____

Surgical procedure performed _____

_____

_____ Date _____

Other diagnosis / Co morbidities _____

_____

Drug – Generic and Trade Name _____

Dosage and Formulation _____

Anticipated duration of Therapy _____ Number of courses_____

On which basis will the patient receive this therapy? outpatient □ day patient □ in patient □

What are the proposed number of visits if therapy is given on an outpatient / Day patient basis?_____

Proposed drug charge per dose $_____

Proposed drug charge for the entire course $_____

Proposed mark-up on cost of drug _____%

Part 3 – to be completed by the prescribing clinician

Is this drug TGA approved for this indication ? YES □ NO □

If YES – Date of Approval _____

Is this a SAS (IPU) drug ? YES □ NO □ If Yes, please list category and requirements, etc. _____

_____

Why is the drug therapy indicated ?_____

What is the standard treatment for this patient's condition ?_____

_____

Why hasn't standard drug therapy worked or been prescribed ? _____

_____

_____

Are there alternatives that are on the PBS or that are less costly ? No □ Yes □

If yes why are they not suitable in this instance ?_____

_____

Estimated success / outcome by using this drug ?_____

_____

If this request for additional benefits is unable to be met by the fund, what are the alternatives for this patient ?

_____

_____

Additional information : _____

_____

Prescribing clinician: printed name and signature

Prescribing clinician: Phone and Fax Number

Part 4 – to be completed by the health fund

Fund contact name & telephone number

Fund Department / Title

Fund Approval / Denial

Fund contact signature & date

Appendix D

GENERAL INFORMATION

Pharmaceutical Benefits Scheme (PBS)

The Pharmaceutical Benefits Scheme (PBS) ensures that Australian residents have access to necessary and lifesaving medicines at an affordable price. Most medicines available on prescription are subsidised under the PBS.

PBS drugs provided to private patients in private hospitals are paid for by the Commonwealth. However, nearly all PBS drugs have a patient co-payment. Funds can insure the co-payment for PBS drugs for members on full hospital cover products provided through an Applicable Benefits Arrangement (ABA). Products with front-end deductibles (FEDs) and co-payments are considered full cover for this purpose.

Apart from the patient co-payment on PBS drugs there is no other patient gap payment on PBS drugs.

Funds can pay for non-PBS drugs in hospital through hospital products. The level of cover is at the discretion of the health fund.

The cost of pharmaceuticals in public hospitals is covered in the Australian Health Care Agreements. This means that public and private patients receive all pharmaceuticals at no charge in public hospitals.

Act References

Current provisions governing the operations of the PBS are embodied in ***Part VII*** of the ***National Health Act 1953*** (NHA).

Section 92 B of the NHA provides for funds being able to insure the co-payment for PBS drugs for members on full hospital cover products provided through an Applicable Benefits Arrangement.

Regulations:

National Health (Pharmaceutical Benefits) Regulations 1960.

Circulars

Circular HBF 591:

- Explanatory notes to amendments relating to the coverage of pharmaceutical benefits for health funds

Department of Health & Ageing

Contact the Department of Health & Ageing PBS Information Line if you require information on:

- The PBS, Co-payments and the PBS Safety Net
- Budget announcements and other recent PBS policy initiatives
- Listing and pricing processes of the PBS including Listing and Pricing Committees
- Alternative arrangements for medicines supplied under Section 100 of the National Health Act 1953 and other special supply programs
- Publications relevant to the Pharmaceutical Benefits Scheme

Telephone: 1800 020 613 Monday to Friday from 8.30 am – 5.00 pm (AEST)

This website (http://www.pbs.gov.au) contains details of the National Medicines Policy, listing and pricing of drugs on the PBS, pharmacy and government arrangements etc.

Section 100 Drugs

Under Section 100 of the PBS, the Commonwealth subsidises the cost of certain highly specialised, high cost medicines which are supplied only from hospitals to patients in the community.

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A General Practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person)

A patient will be required to pay a contribution for each supply of a Highly Specialised Drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement

Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Authority Drugs

Private Hospitals

In addition to the above requirements, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical Practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval or Authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia or by using Medicare Australia's Authority Freecall service (1800 888 333)

Prescribers must quote the provider number of the hospital when applying. Not more than two months supply (one month's supply in the case of Clozapine) with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital's dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready prepared dispensing fee plus a mark up. For information regarding current mark up rates please refer to http://www.pbs.gov.au

For further information regarding the Highly Specialised Drugs Program please contact either Medicare Australia (Tel: 132 290) or the Australian Government Adviser, the Highly Specialised Drugs Working Party Secretariat (Tel: 02 6289 7238)

Authority Prescription Applications

Prior approval is required for all "Authority required" items or requests for increased quantities and/or repeats. Authorisation is obtained by lodging an application using the REPLY PAID mail service or by using Medicare Australia's FREECALL telephone number:

Mail Applications:

Reply Paid No: 9857
PBS Authorities Section
Medicare Australia
GPO Box 9857
In your capital city

Telephone Applications:	Free Call 1800 888 333 Australia wide – 24 hour service

For telephone applications please have the following information available:

Patient	Medicare Number Surname First Name Full Residential Address (including postcode)
PBS Authority Prescription No:	Top right hand side of Authority Form
Your Prescriber Number:	Located below your address block on the personalised forms
Drug Information:	PBS Item Quantity Required Daily Dose Disease or Purpose Information

Special Access Scheme (SAS) Drugs

The Special Access Scheme (SAS) allows medical practitioners, under special circumstances, to prescribe drugs not yet approved for the Australian market for the treatment of patients with serious medical conditions. The treating practitioner deals directly with the Drug Safety Evaluation Branch of the Therapeutic Goods Administration on a case by case basis.

Requests by a doctor for individual patient approval to obtain drugs that are available only through the SAS must be directed to the Drug Safety & Evaluation Branch, Therapeutic Goods Administration:

Telephone: (02) 6232 8111 Fax: (02) 6232 8112
Or by mail to:
PO Box 100, Woden, ACT 2606

These contact details also apply for inquiries about access to unapproved therapeutic medicines.

Department of Veterans' Affairs

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Approvals Centre (VAPAC) using the free postal service:

REPLY PAID No 372
VAPAC (Veterans' Affairs Pharmaceutical Approvals Centre)
GPO Box 9998
BRISBANE QLD 4001

A 24 hour telephone service is available for RPBS enquiries and telephone approvals: Tel: 1800 552 580

Clinical Trials

Unapproved products may be supplied in clinical trials under special provisions which exempt these preparations from prior registration. Clinical trials should be approved by an institutional ethics committee prior to the drug(s) being prescribed. All costs associated with the clinical trial should be met by the sponsoring drug company, with the pharmacy costs associated with the trial negotiated prior to the clinical trial protocol submission to the ethics committee.

In some instances a marketed drug may form part of the trial protocol. In these cases the sponsor should meet these costs, but ultimately this will be negotiated with the sponsor and the local investigating doctor.

Further information on clinical trials may be obtained from:

http://www.tga.gov.au/ct/index.htm

Australian Drug Evaluation Committee (ADEC)

The Australian Drug Evaluation Committee (ADEC) was formed in 1963 and given the role of providing independent, scientific advice on new drugs within the policy framework of the time to the Federal Government. The Committee has continued to meet regularly since inception and when the *Therapeutic Goods Act 1989* (the Act) came into force; the Committee's establishment was carried forward under Regulation 36 (1) of regulations to the Act (the *Therapeutic Goods Regulations*). *The Therapeutic Goods Act* provides the legislative basis for the regulation of therapeutic goods and medical devices within Australia).

The ADEC is appointed by the Minister for Health & Ageing and provides advice to the Minister and the Secretary of the Commonwealth Department of Health and Ageing through the Therapeutic Goods Administration on:

- The quality, risk benefit, effectiveness and access within a reasonable time of any drug referred to it for evaluation
- Medical and scientific evaluations of applications for registration of prescription drugs (eg. New chemical entities, new forms of previously registered drugs and therapeutic variations to registered drugs).

The Committee also provides services to other Government departments, committees and community-based organisations on a wide variety of regulatory matters related to prescription medicines.

ADEC has two subcommittees as under:

The Adverse Drug Reactions Advisory Committee

Reports to ADEC on all matters relating to adverse drug reactions. The Committee publishes regular bulletins and contributes to the WHO Data Bank on adverse drug reaction reports.

Pharmaceutical Subcommittee

The Pharmaceutical Subcommittee makes recommendations to ADEC on the pharmaceutical chemistry, quality control, bioavailability and pharmacokinetics of prescription medicines proposed for registration in Australia. It may act as an arbitrator between the Therapeutic Goods Administration and the pharmaceutical industry.

Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health & Ageing. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

Further information may be obtained from the TGA website – http://www.tga.gov.au

EDL Secretariat

C/o Private Hospitals Association of Queensland
PO Box 370
Kenmore QLD 4069

Tel: (07) 3279 7600 Facsimile: (07) 3279 7601