Behind the system

Ins and outs of the Pharmaceutical Benefits Scheme

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The Pharmaceutical Benefits Scheme (PBS) is, despite some anomalies and restrictions, making medications affordable for all Australians. Here is an overview of the scheme, including an insight into the listing process.

Australians enjoy access to a wide choice of subsidised medications, particularly compared with other countries. For example, annual costs for elderly Americans on prescription medications were estimated to be about US$1200 (A$2000) in 2000, with an average prescription costing about US$40 (A$70)[1], whereas Australians generally have to pay a maximum of about $23 for a prescription for a medication that is listed on the PBS.

The Pharmaceutical Benefits Scheme (PBS) was set up in 1948 as an 'essential drugs' list. It has grown considerably since then: in the financial year 2000 to 2001 it spent over $4 billion on subsidising medications for all Australians (Figure).[2] However, the subsidy process is selective and requires demonstration of comparative effectiveness and cost-effectiveness – a process that sometimes seems at odds with doctors' wishes in the community. The Repatriation Pharmaceutical Benefits Scheme (RPBS) is available to veterans and eligible dependents, and includes certain medications and dressings not available on the PBS.

Many GPs are surprised by the amounts of money that they generate in prescription costs. For example, according to a recent National Prescribing Service audit, an average GP each year generates $50,000 worth of prescriptions for statins alone.[2] The total cost of prescriptions generated by most GPs exceeds their billings under Medicare.

In this article we provide an overview of the regulatory systems for medications in Australia, some tips and tactics for navigating the PBS, and some insight into why some pharmaceuticals are subsidised by the PBS and some are not.

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Australian regulatory systems for medications

Knowing which medication to prescribe is difficult enough. Sometimes knowing how to prescribe and what it might cost the patient can be equally daunting, particularly to those starting out in general practice. The profusion of regulatory systems, brands of drugs, rules and regulations, which can all change every few months, may leave prescribers confused. To understand the rules, we need some understanding of the structure of the systems.

The two barriers to accessing to any pharmaceutical are regulations and cost.

For regulation, we can classify medications as:

- over the counter (OTC) medications – as approved by the Therapeutic Goods Administration (TGA), which regulates whether pharmaceuticals are prescription or nonprescription
- complementary (alternative) medicines – which now have loose regulation through the TGA
- TGA-approved prescription medications.

A prescription pharmaceutical must be approved by the TGA, from the advice of the Australian Drug Evaluation Committee (ADEC), based on adequate information about safety and efficacy. When the pharmaceutical and its product information are approved, the product information will appear in compendia such as MIMS.

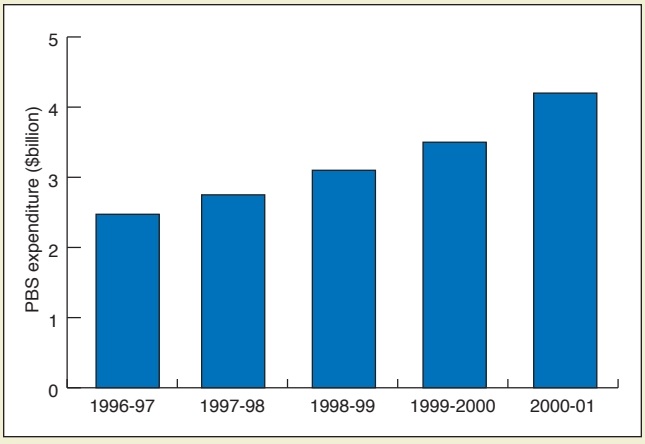

Figure. Annual PBS expenditure over the five years 1996 to 2001.

Once a pharmaceutical has approval, the PBS, RPBS and/or State formularies may decide to subsidise its cost. A subsidised medication may fall into one of three categories:

- PBS/RPBS listed – which may have an unrestricted, restricted, authority or section 100 listing (see the box on PBS listings on this page)
- State hospital formulary listed – with formularies varying between States and even hospitals within States
- private prescription – most commonly, patients with private insurance covering prescriptions receive a two-thirds refund on items up to $70.00; the rebate offered is only for non-PBS prescribed medications for recognised medical conditions or ailments.

There are overlaps and inconsistencies between these subsidy systems. For example, a patient in the community may be on one medication subsidised by the PBS, but when admitted to hospital may not have access to that medication because of the hospital formulary, and may be discharged on a different medication that is not available through the PBS system. Such anomalies often confuse patients, so clear explanations from general practitioners are important to help patients navigate the system.

PBS and RPBS listings

A medication subsidised by the PBS or RPBS will usually have one of the following listings:

- Unrestricted – it can be used for any of the indications given in the product information that is approved by the TGA
- Restricted – it can only be prescribed for a particular subset of indications in the product information (as listed in the Schedule of Pharmaceutical Benefits) but does not require special authority to do so
- Authority – the prescription is restricted to a particular subset of indications in the product information (as listed in the Schedule of Pharmaceutical Benefits) and requires prior approval by the Health Insurance Commission (HIC), in writing or by phone, before the medication is dispensed.

There are many reasons for the PBS requiring an authority listing, including safety requirements such as needing the medication to be commenced in hospital or under specialist care, or that the medication is only cost-effective for particular subgroups of patients or particular indications.

Section 100 Items

The largest group of Section 100 drugs are highly specialised drugs that may only be prescribed by GPs as maintenance therapy, and only under the guidance of the treating specialist. These medications include antiretroviral agents, post-transplant drugs and some anticancer drugs. Specialists prescribing for private hospital patients must gain an Authority prescription through the HIC. Public hospital patients access medications via arrangements made between the Commonwealth and State or Territory health departments.

Eligibility

Access to the PBS is restricted to Australian residents and visitors from those countries with which Australia has a reciprocal health care agreement – currently the United Kingdom, the Republic of Ireland (Southern Ireland), New Zealand, Malta, Italy, Sweden, the Netherlands and Finland. When patients visit the chemist, they must show appropriate identification, such as a Medicare card, a Department of Veterans' Affairs (DVA) card or a passport (see Case 1 on this page).

Non-routine prescribing

Increased maximum quantities

On the PBS, chronic medications are generally supplied for six months – one month's supply with five repeats. For patients on higher doses, who would have insufficient supply, a doctor can request an Authority for increased quantities. For example, if a standard prescription is 30 tablets with five repeats, a patient on a twice-daily dose may get an Authority for 60 tablets with five repeats. Similarly, patients with widespread eczema can obtain an Authority for increased quantities of topical corticosteroids.

Case 1. An overseas traveller in the outback

Case scenario

A 54-year-old Swedish woman has been travelling in Australia for several months. She is hypertensive with coronary heart disease and is currently on 100 mg of aspirin daily and two tablets of an ACE inhibitor daily. She is about to go travelling in the outback for two months and will not be able to get supplies while she is travelling. She asks for prescriptions to cover her for that period.

Commentary

Several questions need answering. Is the patient eligible for the PBS subsidy on her medications? What medication can be supplied? Can these be written on the same script?

Being a visitor from a country with which Australia has a reciprocal health care agreement, this patient is eligible for PBS subsidies. She will have to show her passport when she visits the pharmacy to claim the subsidy. If you endorse her prescription Regulation 24, the pharmacist will be able to supply the original and repeats of each prescription at the same time, which will give her an adequate supply for the time she is travelling in the outback. All this could be written on a single prescription form.

Regulation 24

When patients cannot readily access a pharmacy because they live or are travelling in a remote area, the prescribing doctor can endorse the prescription 'Regulation 24', which authorises the pharmacist to supply the original and repeats at the same time. The three qualifying conditions for Regulation 24 are that the patient needs the greater quantity of medication, he or she has a chronic illness and he or she would suffer great hardship trying to get supply on separate occasions.

Costs of PBS medications

The three components of the total cost of a PBS medication are the PBS subsidy, the patient co-payment and other patient contributions. Patients, therefore, may have to pay two components:

- co-payment – for general patients, the maximum patient co-payment is currently $23.10, and for Concession Card holders is $3.70. Patients or families holding a Safety Net Entitlement Card receive free PBS medications for the rest of that calendar year.
- other payments – in addition to the co-payment, patients may have to pay a brand price premium (BPP) and/or a therapeutic group premium (TGP).

Brand price and therapeutic group premiums

Many medications listed on the PBS attract a brand price premium. The PBS has a baseline price for generic equivalents (the base price), and patients are required to pay any difference in price for brand medications (see Case 2 on this page). If there is no generic equivalent then the lowest priced brand is taken as the base price.

A therapeutic group premium can apply to drugs in the same class that are considered equivalent and one has a lower price (even if there is no generic equivalent). Therapeutic price premiums apply only to H_2-receptor antagonists, dihydropyridine-derivative calcium channel blockers and ACE inhibitors.

The PBS listing process

Comparative effectiveness and cost are key qualifying features for PBS subsidy. For listing on the PBS, a new pharmaceutical must show that it is either:

- equally effective to current PBS listed equivalent pharmaceuticals and has the same cost (or pays a brand price or therapeutic group premium), or
- more effective (or has less adverse effects) than current PBS listed pharmaceuticals and that this increment in effectiveness is acceptable value for money.

The PBS cannot afford to subsidise all medications. In recent years the growth has been over 15% per year (Figure).

Comparative effectiveness and cost-effectiveness

In making subsidy decisions, the main advisory committee, the Pharmaceutical Benefits Advisory Committee (PBAC), requires a submission that covers the following issues:

- the target group of the drug (requested indication)
- the comparator (the drug it is most likely to replace in practice)
- a summary of the effectiveness and comparative effectiveness, preferably based on randomised controlled trials
- an economics analysis of the incremental benefits and costs of the drug
- the financial implications for the PBS.

For a new pharmaceutical that is equally effective and the

Case 2. Cost issues

Case scenario

An 83-year-old widower with hypertension, congestive cardiac failure and asthma is taking the Tritace brand of ramipril 5 mg daily. A while ago he had been annoyed with a locum who had prescribed the Ramace brand and ticked the box preventing brand substitution, meaning he had to pay an extra $4.00 that time. More recently, the patient's blood pressure has been elevated, and from his son's report, you suspect suboptimal medication adherence may be a factor. You elect to increase his ramipril to 10 mg daily rather than swap him to another ACE inhibitor and risk complicating his medication regimen. What can be done to continue him on the same brand to assist compliance and at the same time save him any extra payment?

Commentary

There are two separate cost issues here: all the ACE inhibitors are base-priced drugs except ramipril 10 mg, which attracts a therapeutic group premium, and the brand Ramace has a brand price premium of $4.00 because the PBS only subsidises up to the lowest priced brand, i.e. Tritace 5 mg tablets.

To achieve our desire of continuing this patient on the same brand at an increased dose and also save him money, we will arrange for Tritace 10 mg capsules to be supplied on Authority prescription. This is done on the basis that transfer to a base price drug (such as quinapril 20 mg daily) would cause patient confusion and exacerbate existing compliance problems, which is one of the approved indications for an Authority script for Tritace 10 mg. This saves the patient from having to pay the therapeutic group premium.

The other options would be for the patient to pay the extra money or swap to another ACE inhibitor at maximal doses (such as quinapril 20 mg daily), but we have decided these are not suitable options in this case.

same cost as currently listed PBS pharmaceuticals, then the decision to list is quite straightforward. Whether to list becomes a more difficult decision when a pharmaceutical provides an important advance because this raises the difficult question of how much it is reasonable to pay for the additional benefit(s). The PBAC measures and compares the additional benefit and the additional cost in a process known as a cost-effectiveness analysis (CEA). This has been a routine requirement of the PBAC since 1993.

Example of cost-effectiveness analysis

Let us illustrate the process with the simple example of tissue plasminogen activator (tPA) compared with streptokinase for thrombolysis in acute myocardial infarction.

The GUSTO trial, with 40,000 patients randomised, clearly showed a small additional benefit of tPA over streptokinase (Table 1).[3] However, tPA is considerably more expensive, costing about $2200 per treatment compared with approximately $200 for streptokinase. Is the price difference worth the extra benefit? The PBAC requires details of the additional cost per unit of clinical benefit. We could, for example, calculate that the cost per life 'saved' was 2000/0.009 = $222,222 – i.e. the difference in cost divided by the difference in benefit. However, not all lives are 'equal', and we may prefer to look at life years gained. For example, if the further life expectancy of the additional survivors in GUSTO were 11 years then the cost per life year saved would be of the order of $20,000.

Cost-effectiveness = ($2200 – $200)/(0.078 – 0.069) x 11 years
= $2000/0.0009 x 11 years
= $20,000 (approximately) per extra life year gained.

Is this a reasonable amount to pay? There are no easy answers, but we have to recognise that the public purse is limited and so we would want the available funds spent as wisely as possible. The best method, therefore, is to rank possible interventions according to their cost-effectiveness. This provides a so-called Quality Adjusted Life Year (QALY) league table (Table 2).

There is no definite cut-off point above or below which something can be said to be 'cost-effective'. The best we can do within budget limits is to work down from the most to the least cost-effective. Whatever the cut-off, this process maximises the 'benefit' we can purchase from a limited budget.

Of course, there are many assumptions and problems in such analyses. However, decisions must be made about what can be subsidised and what cannot, and Australia's current PBS system leads the world in terms of its careful scrutiny and fairness in making subsidy decisions.[4]

Table 1. Tissue plasminogen activator versus streptokinase for thrombolysis[3]*

	Tissue plasminogen activator	Streptokinase
Percentage of patients dying or suffering disabling stroke	6.9	7.8 (p=0.006)
Approximate cost per treatment	$2200	$200

*Accelerated tissue plasminogen activator for myocardial infarction (GUSTO Trial); 40,000 patients randomised.

Table 2. Approximate cost per QALY* for selected interventions

Intervention	Group	Cost/year/person ($)	Cost/year of quality life gained ($)
Aspirin	Post AMI†	23	<0
Sabin vaccine	Children	3	<0
ACE inhibitor	Heart failure	260	<0 to 20,000
Statin	Post AMI	944	10,000
Mammography	50- to 65-year-old women	40	15,000
Misoprostol	Patients on NSAIDs	618	41,000
Mammography	40- to 49-year-old women	40	50,000
Flecainide‡	Post AMI	458	Infinite

* QALY = quality adjusted life year. † AMI = acute myocardial infarction. ‡ Treatments with no benefits have 'infinite' cost per life year gained.

Who can make a submission to the PBAC?

Requests for a PBS listing are generally made by pharmaceutical companies but can be made by anyone. All requests must conform to the submission requirements.

Some drugs are not on the PBS because they have not had a submission and some because they have been submitted but rejected. The 'commercial-in-confidence' nature of these submissions means that this is not currently public knowledge, but the Federal Government has indicated that from June 2003, the PBAC will make public its decisions not to recommend PBS listing, together with brief reasons for each decision. These rejections will accompany the current arrangements whereby the PBAC makes public its recommendations for PBAC listing.[5]

The future of the PBS

The PBS provides Australians with access to medications that improve or maintain both quality and length of life. This has proven expensive, with the PBS growing at around 14% per annum for the past 10 years.[6] The factors driving the growth include:

- more older people with chronic medical conditions needing medical treatment – leading to increasing numbers of prescriptions for, for example, statins, ACE inhibitors and proton pump inhibitors
- the increasing cost of research and development of new medications
- medications being prescribed for indications outside PBS restrictions ('leakage'), such as COX-2 inhibitors.

These (and other) pressures will force consumers, healthcare professionals, economists and politicians to reconsider how the PBS should meet the needs of Australians. It is important to realise that, despite some anomalies and restrictions, the PBS is working to retain affordable medications for all Australians. MT

Acknowledgements

The authors would like to thank Andrew Mitchell and the other anonymous reviewers for their constructive comments.

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