Implementing evidence based cost effectiveness in health: targeting utilisation and limiting use

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Running Title: *Targeting utilisation and restricting use*

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Abstract

Background: The use of a cost effectiveness criterion in funding decisions for drugs and medical services has the potential to increase value for money in health care service provision. The use of cost effectiveness analysis has become more popular in the decision to fund medical services, but less attention has been paid to the cost effectiveness of actual practice in subsequent treatment provision. Open ended 'fee for service' systems such as Australia's Medical Benefits Scheme and Pharmaceutical Benefits Scheme incorporate few obvious incentives to use services in a fashion that is consistent with the evidence on cost effectiveness.
Aim: To assess the current tools used by Australian funding and regulatory authorities to target utilisation of health services to those indications and populations where they have been demonstrated to be effective and cost effective. The paper evaluates the strengths and weaknesses (including regulatory burden) of a range of mechanisms to improve on the cost effective provision of fee for service health care.
Method: A literature review and a series of semi-structured interviews with policy makers who have been responsible for design and implementation of the current mechanisms used in Australia to manage the introduction and funding of new drugs and health services. The policy tools identified include: item descriptors and clinical guidelines, audit and feedback, authorisation, fixed period interim funding, and contracts.
Results: In the absence of effective controls on inappropriate use of pharmaceuticals and medical services, decisions for subsidy may be unnecessarily conservative. When the effectiveness or cost-effectiveness of an intervention cannot be demonstrated for the general patient population, policy makers may be reluctant to risk funding approval. Regulatory strategies such as prior approval appear to have low unit costs but the success of any restriction depends on the degree and cost of monitoring and enforcement of breaches of the regulation especially where there is not clinician acceptance of the appropriateness of targeting utilisation. Other financial strategies such as contracts with providers may have been successful in limiting expenditure but their impact on efficiency is not clear.

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BACKGROUND:

The use of economic evidence in decisions over medical technologies has become more widespread internationally in the past decade. Those who pay for health care have recognised the need to identify the technologies that offer value for money. They recognise that if the health care system is to maximise health outcomes with a limited budget then the cost of new interventions needs to be explicitly compared to the social willingness to pay for demonstrated health outcomes. The role of economic evaluation in the decision process varies from country to country. In countries such as Australia, the UK, Denmark, Finland, Norway, Portugal, Belgium, the Netherlands and some Canadian Provinces value for money is a consideration in purchasing and pricing decisions. Of these countries Australia, Finland and Portugal have a national requirement for evidence on cost effectiveness before reimbursement of prescription drugs and other health technologies[1].

Australia for example has had formal cost-effectiveness assessment as a prerequisite to subsidy of new pharmaceuticals under Australia's national health insurance system since 1993[2]. The Pharmaceutical Benefits Advisory Committee (PBAC) was the first national funding body to require formal evidence of cost-effectiveness.[3] A parallel system for the approval of medical services was established in 1998[4]. The Medical Services Advisory Committee (MSAC) advises the Australian Minister for Health and Ageing on evidence of the safety, effectiveness and cost-effectiveness of new and existing medical services: consultations, surgical procedures, diagnostic imaging and pathology services. It makes a recommendation to the Minister as to whether a public subsidy for the service should be provided for patients treated privately under Australia's publicly-subsidised health insurance system. MSAC bases its recommendations for funding on a systematic review of the clinical evidence on clinical need, safety, effectiveness and cost-effectiveness.

Both the clinical effectiveness and the cost effectiveness of a service are directly related to the population on which evidence has been gathered. It is rare that a procedure can be shown to be effective and cost-effective for an entire population of patients. A service will be more likely to be cost effective when it is provided to those who will benefit most, at a point in the disease pathway when it is most effective, and by providers who are most skilled in its delivery.

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[1] **Harris AH**, Buxton M, O'Brien B, Rutten F and Drummond M. Using economic evidence in reimbursement decisions for health technologies: experience of 4 countries *Rev. Pharmacoeconomics Outcomes Res*. 2001;1(1):7-12

[2.] Birkett DJ, Mitchell AS, McManus P. A cost effectiveness approach to drug subsidy and pricing in Australia. *Health Affairs* 2001;20:104-114.

[3] Salkeld, G., A. Mitchell, et al. Pharmaceuticals. In G. Mooney. and. R.B. Scotton, Economics and Australian Health Policy Allen & Unwin, 1998: 115-136.

[4] http://www.health.gov.au/msac/bckgrd.htm (accessed 26 August 2004)

In the extreme, providing a service to a sub-group of the population where the service has been demonstrated to be ineffective in improving health cannot be a cost effective policy. Where there is evidence of some differential effect in a sub-group of the population, and they could be included or excluded from public funding then the decision should be made using standard decision rules. If the incremental cost effectiveness ratio is below the acceptable threshold or equivalently the net benefit of their inclusion is not positive then they should be excluded. As Coyle et al[5] discuss we can define and quantify the efficiency gains from stratification based upon heterogeneity between patients in terms of costs, outcomes or both. Subgroups may be defined by their differential responses to the service (disease risk, detection from screening by age or risk category, response rates by stage of disease, or prior history of therapy from drugs). There may exist any number of strata defined by treatment modifying factors for which an incremental cost effectiveness ratio or net benefit can be calculated. The optimal level of stratification in an analytic sense could be defined on statistical or clinical grounds. Where there is no statistically significant or clinically significant difference in costs or outcomes across those who might benefit there is no value in stratification. In addition if the cost of identifying and limiting use to the sub-groups exceeds the value of the net benefits from stratification, then stratification is sub-optimal. In that case the average cost and effectiveness across the combined population are the relevant decision parameters. A key issue for policy in this area, that has not been part of routine analyses, is therefore the cost of implementation of a funding mechanism that targets use in sub-groups of the population.

In situations where there is evidence of benefit only for particular indications, or for particular subgroups of the population, decision-makers may be reluctant to authorise unrestricted funding, denying access even to patients who would benefit. Policy makers want to ensure that so called leakage of service use into patient groups or indications where usage may be ineffective and/or not cost-effective is limited. The conventional response has been to attempt to limit usage to sub-groups of patients where the ratio of costs to benefits is acceptable (net benefits are positive). This is the most common approach in systems where regulation takes some account of cost effectiveness. In Ontario for example a *Section 8*" reimbursement means that the physician must make written application to the Ministry to justify the prescription of a particular pharmaceutical usually in the "limited use" category where reimbursement is restricted to patients who meet certain clinical criteria. An example would be the recent approval of Cox-2 inhibitors that are intended to be used selectively on patients who have failed simple NSAID therapy or who are otherwise at high risk of gastric events. In Australia some Cox-2 inhibitors are restricted on the Pharmaceutical Benefits Scheme to the symptomatic treatment of osteo-arthritis (but not rheumatoid arthritis). In other cases the extent of restrictions on use, and the methods to achieve those limits have gone further than a stated intention to offer conditional reimbursement to sub-groups in the population. They have involved more sophisticated mechanisms of subsidy and regulation such as monitoring and enforcement of restrictions and introducing provider incentives.

The aim of this paper is to describe the policy instruments available for funding health services where there are differences in net benefits within the population who might benefit from those services. The paper also considers when it might be optimal to use these

[5] Coyle, D., M. Buxton, et al. (2003). "Stratified cost-effectiveness analysis: a framework forestablishing efficient limited use criteria." Health Economics **12**: 421–427.

instruments taking account of the evidence on their effectiveness and the cost of implementation in different health care systems. The focus is on the Australian health system where evidence on cost effectiveness has been used systematically for reimbursement decisions for the longer than anywhere else and where there has been some experience of the use of some of the available instruments to limit use to sub-groups where there is evidence of acceptable cost effectiveness. A limited amount of international evidence is considered, but the discussion is generalisable, not just to jurisdictions where cost effectiveness evidence is part of the decision process, but wherever coverage choices need to be made.

STUDY METHODS

A semi-structured questionnaire was devised by the authors to elicit information on the range of approaches currently or previously used in the Australian health care system, their strengths and limitations (including costs), and the preconditions for successful application. Interviews were conducted with 23 experienced officers from the Medicare Benefits Branch and Pharmaceutical Benefits Branch of the Department of Health and Ageing , from the Department of Veterans Affairs and from the Health Insurance Commission . In addition a search of the international literature on the evaluation of mechanisms that target the use of health services was conducted. This was not a comprehensive systematic review but relied on an electronic search of the key approaches identified in interviews, approaches discussed in key health economics texts, literature suggested by informants, and the bibliographies of these papers.

MECHANISMS FOR TARGETING USE OF TECHNOLOGIES

Regulation and subsidy

There are two key mechanisms for influencing what services are publicly subsidised and for whom. In a reimbursement system, regulation provides a simple mechanism for limiting subsidy to those who are targeted (including for cost effectiveness reasons). Regulation often takes a light form in the self regulation of providers. Guidelines from professional bodies or a national advisory group provide advice to providers on what service to offer when how and to whom. In a similar fashion a schedule of subsidies or patient benefits can be published that limit use to particular groups or clinical conditions. In the latter case some legal sanctions for a breach of those limits can be imposed. The success of this approach will depend largely on the acceptance by the profession of the guidelines and in the case of sanctions how energetically the authorities monitor and enforce the limitation. One approach is to require prior approval before a subsidised service can be provided. This can be written, telephone or electronic approval. Again the success of this approach will depend on the acceptability of the limits on the discretion of providers and the willingness to monitor and enforce any sanctions associated with a breach of those limits.

Figure 1 illustrates an approach to health services coverage determination that includes economic evaluation.

Figure 1: An approach to health service coverage decisions

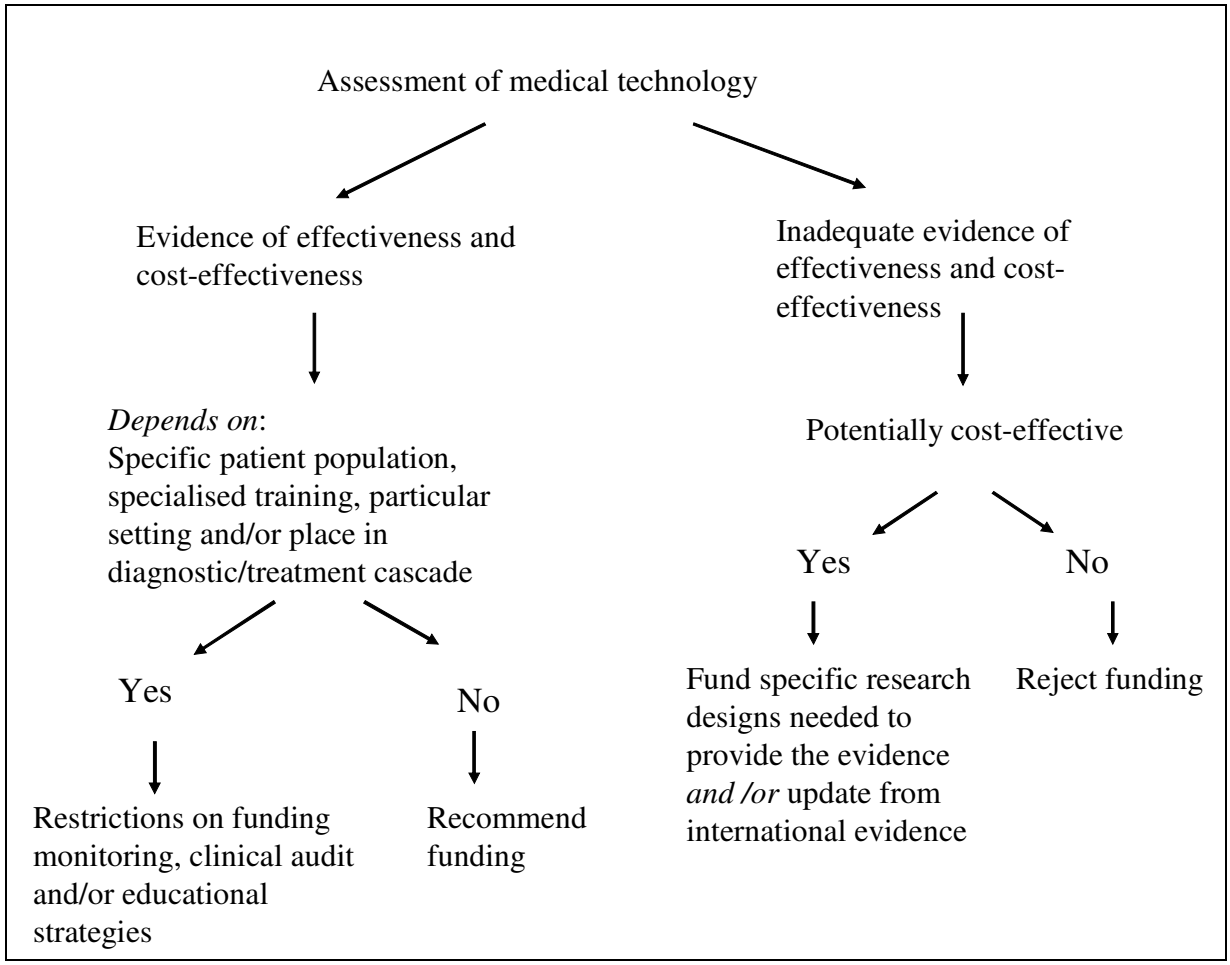


Table 1 summarises the approaches used in Australia identified as a result of interviews with officers from areas of national health policy and when they are likely to be effective. Each of the approaches is then considered in more detail.

Table 1: Mechanisms available for encouraging targeted use of technologies

Mechanism	Description	Usefulness
Behavioural change mechanisms		
Guidelines production and dissemination	Printed or electronic educational material on appropriate use disseminated in various forms, CME points, opinion leaders, educational outreach visits	Can be complementary to any other strategy
Training strategy	Strategies to achieve a minimum standard of competence in the use of a technology	Relevant where effectiveness is operator dependent. May be achievable by self regulation in some circumstances
Utilisation review	Statistical review of broad trends in use and substitution patterns	If done systematically could highlight where a technology is outside of cost effective use
Individual audit and feedback	Audit of individual practice measured against benchmark with individual feedback	Has intuitive appeal as effective and some evidence in the medicines area but may be expensive for low use products
Funding mechanisms		
Health program grant	Grant to a restricted set of providers to provide service under prescribed conditions in a particular location	Could be used to limit providers to those most effective; the need for renewal of program may provide some mechanism for re-assessment of evidence; historically these have been costly to administer and limited to services requiring large capital investments
General fee for service reimbursement	Open listing for reimbursement on the benefits schedules of Medicare	Where the service or technology has been found to be effective and cost effective in an unrestricted population or practice setting.

Mechanism	Description	Usefulness
Restricted reimbursement	Listing for reimbursement on the benefits schedules of Medicare with conditions specifying in whom and/or how the technology is to be used	Encourage its provision in the way that offers value for money by supply of information
Reimbursement with prior approval	Telephone or written approval (based on receipt by the government of an assurance from the requesting practitioner that the technology is being used in a manner that is consistent with a set of specified conditions) before practitioner is able to provide the subsidised service	Encourage its provision in the way that offers value for money by introduction of transaction and time costs and threat of audit into the decision to provide a service.
Interim funding	Funding for a fixed period	Allows for time to collect new evidence where the expected value of that information is high (good chance of decisive information for a service that could offer value for money)
Contract or agreements with providers	Agreement with provider or requesting practitioner to achieve target (volume, cost, indication)	Most useful where provider can influence volume directly; success may depend on the incentive provided by the financial and professional implications of a breach of contract
Incentive payments	Bonus paid if target achieved	Could be used within a contract or extra to reimbursement to provide incentive to target a sub-group, restrict volume or cost. Has been used for GP immunisation in Australia

Behavioural Change Strategies

There is a range of initiatives from government and professional bodies that seek to improve the quality of service delivery, diagnostic test ordering, and prescribing of medicines. These have included setting standards, giving guidance, and clinical governance initiatives (eg academic detailing, auditing and feedback on comparative performance), and latterly educating patients on the use of medicines.

We have not done a systematic review of strategies of behavioural change in clinical practice. A review is about to be published by Eccles, Grimshaw et al as a NHS HTA monograph (reported on NICS | Conference presentation http://www.nicsl.com.au/new/video.aspx). One conclusion from this review is that there is a lack of generalisability in the literature in part because interventions are typically not well described and most interventions have a number of components making it difficult to assess the effectiveness of individual interventions. Educational materials sent to doctors, audit and feedback review may be more effective than has previously been reported in for example Grimshaw et al (2001)[6]. The general view has been that multifaceted interventions have a greater effect although this may depend on how synergistic the different interventions are. There is a lack of evidence on the impact of individual interventions. The one which is most often assumed to have the greatest impact - educational outreach or academic detailing – seems to have only a relatively modest impact. Where it appears to show more promise is where it is an active review providing feedback on the performance of the clinician or group of clinicians in comparison with a standard or peer group.

Inadequate education of clinicians was considered by many interviewees to be a cause of use of technologies outside the restrictions stipulated for an item in the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS). For example, it was considered that there is some use of item 66551 (quantitation of glycosylated haemoglobin) for screening despite the restriction on this item (see examples above) because of misguided perceptions that this is the best way of diagnosing diabetes.

The PBS has attempted to address this issue by using the National Prescribing Service (NPS) infrastructure to educate requesting practitioners and consumers about the PBS listing of new drugs or changes to PBS listing of existing drug. RADAR, an online service from NPS, is published near the time of each 'yellow book' - the Schedule of Pharmaceutical Benefits. The service is used to provide information about new medicines and changes to PBS listings that are important to GPs, pharmacists and other health professionals involved in primary care management of patients. For example, moxifloxacin (Avelox®) was recently listed on the PBS. RADAR provided discussion of: reasons for PBS listing of moxifloxacin; the appropriate therapeutic positioning of moxifloxacin; dosing and safety issues associated with moxifloxacin[7]. Other organisations such as the National Institute of Clinical Studies (NICS) have a role in the implementation

[6] Grimshaw J.M. et al. Changing provider behaviour: an overview of systematic reviews of interventions. *Medical Care*. 2001; 39:II-2 II-45

[7] http://www.npsradar.org.au/moxifloxacin.php (Accessed: November 2003)

of evidence into clinical practice and MSAC may wish to consider a closer relationship with such organisations or another means to educate providers on the rationale for targeting the use of health technologies.

At this stage the literature does not give a clear guide to what works and what does not in the area of clinician behavioural change. There is even less on the cost of these strategies. They may work better if part of a multifaceted approach in a setting that includes for example funding restrictions. However there are undoubtedly areas where it may be difficult to implement funding restrictions and recommendations for information dissemination strategies, auditing and performance feedback to the professional groups or individual clinicians is one approach. However decision makers would need to consider the evidence on particular strategies as well as their cost in the context of that particular treatment or test before making any recommendation.

Restrictions on funding

The primary mechanism used in Australia to limit use of a technology to circumstances where it has been determined to be of acceptable cost effectiveness is the specification of a restriction (or use of a descriptor) that details the conditions under which the technology can be used. The construction of a descriptor is fundamentally a funding based approach to utilisation but it can be part of a multifaceted approach that includes behavioural change strategies. Parameters that may be incorporated in a descriptor include patient eligibility criteria, directions for use such as frequency or duration, and the characteristics of requesting practitioner or provider. Some detailed examples in the Australian context are provided in Appendix 1.

Implementing restrictions

The method of implementing limits on use can affect the degree of compliance with the restriction. Pharmaceutical benefits under the PBS can be classified into three broad categories:

- unrestricted benefits – which have no restrictions on their therapeutic uses;
- restricted benefits – which can only be prescribed for specific therapeutic uses; and
- authority required benefits – which are restricted and require prior approval (by telephone or in writing) from the HIC or the DVA before an approved pharmacist can make a supply.

As at 30 June 2003, of the 1,451 PBS items listed, 778 are restricted to use for a particular condition or purpose. Of these 778 items, 288 are subject to criteria set by the Pharmaceutical Benefits Advisory Committee that limits supply to a PBS authority prescription[8]. The HIC is currently developing an electronic authority system that will provide prescribers with an alternative to the existing manual authority approval process. Currently, practitioners requesting or delivering Medicare services are not required to

[8] HIC Annual Report 2002-2003: http://www.hic.gov.au/abouthic/resources/our_organisation/annual_report/02_03/HIC_AR03_ch5.pdf (Accessed November, 2003)

obtain prior approval before ordering a Medicare benefit. However, some exceptions exist - a panel of specialist advisers (MCRAP) determine a patient's eligibility for certain services eg, cosmetic surgery, and access to thyrogen is provided through a program grant and ordered through the HIC with prior authorisation for registered patients. Thus, in general, Medicare items are similar to restricted benefit items on the PBS.

While the pharmacist takes responsibility for dispensing the prescription the responsibility for compliance with any restriction on the PBS remains with the prescriber. Any audit, feedback or incentive mechanisms have been focussed on the prescriber with only a limited role for the pharmacist in ensuring that any restrictions are met. Where a prior authorisation is required for a benefit, the pharmacist can only provide a pharmaceutical benefit if they have received an approved authority prescription. If a pharmacist is presented with an authority prescription and is not sure if it has been approved, he or she is required to contact the HIC. Similarly where there are restrictions on the provision of diagnostic services the provider will determine whether he or she has received a legitimate documented order for a medical benefit. While there are some key differences, in both cases the ultimate auditor of services is the HIC, but the two step process of ordering and delivery of the service offers an additional opportunity to ensure that the service does not breach the requirements of the schedule.

A number of other factors were considered important in the implementation of descriptors that had implications for the degree to which the requesting practitioner complied with the restrictions.

1. Restrictions that do not have a clinical foundation or are designed simply to limit expenditure will not be readily accepted by practitioners even if they have the force of legislation.. A clear, well-understood clinical basis for a restriction (eg, greater efficacy in a particular patient group) will mean that practitioners are more likely to comply with the restriction.
2. The prospect of audit improves compliance with restrictions. Descriptors work best when they are independently and objectively confirmable so that effective audits can be performed by the HIC to check that requesting practitioners/providers are prescribing/providing a service in accordance with the descriptor (eg, requiring specific results from a laboratory test). Opportunities for subjective interpretation of terms should be avoided where possible. The PBS restriction on imatinib[9] is an example of a restriction that does not require interpretation by the prescriber. The definition of the accelerated phase of chronic myeloid leukaemia is unambiguous as specific quantitative criteria are specified to define the condition. Details that are not auditable may be included in the MBS as part of rules of interpretation or as part of explanatory notes accompanying the schedule (eg, in regard to tests for Fragile X (Items 73300 and 73305), it was considered necessary that appropriate genetic counselling be provided to the patient. However, the delivery of such counselling cannot be easily independently and objectively confirmed as it may be provided by a variety of providers (eg, the treating practitioner, a genetic counselling service, a clinical geneticist) on referral.
3. The ability of the HIC to cross-refer to other records can sometimes be used to assist in verification of a patient's eligibility for a benefit (eg, example given above where

[9] http://www1.health.gov.au/pbs/scripts/disps100.cfm?genname=IMATINIB%20MESYLATE (accessed 14 September 2004)

abnormal TSH required before patient is eligible for full suite of thyroid function tests, the HIC pays for item 66719 only if patient has previously received item 66716).

4. The involvement of requesting practitioners in the crafting of a restriction may result in greater compliance with a restriction. The PBS eligibility criteria for etanercept were drafted in consultation with the peak body representing rheumatologists. This resulted in a joint statement from the peak body and PBAC being released explaining the availability of etanercept. It was hoped that this would result in greater compliance with the criteria specified in the restriction.
5. It may be that a degree of self regulation is possible or that professional bodies can be used as part of an authority or monitoring system. Such claims would need to be critically assessed before this approach could be more widely adopted.
6. Technologies that have a barrier to use (eg, an adverse safety profile) are less likely to be used in wider populations. These technologies are often reserved for conditions that cannot be treated adequately otherwise. A restriction for these technologies may be redundant, although wide dissemination of information about safety concerns might be necessary.
7. There is a perceived need for greater education of requesting practitioners in the rationale behind restrictions applying to particular health services both within Medicare and the PBS. Compliance with any written restrictions on Medicare items would be considerably improved if those restrictions were perceived as appropriate and not arbitrary. However, it has been said that direct attempts to use the Medicare Benefits Schedule as an educational tool have not been successful. For example, at one stage, the descriptors for microbiological tests for hepatitis were changed so that 17 specific clinical scenarios were outlined. These scenarios were linked to a set of appropriate tests. However, this exercise failed and demonstrated that clinicians do not read the schedule in sufficient detail for it to be a guide to treatment. In this case it seems that the pathology services table is largely read by pathologists but not clinicians.
8. Informed patients could also assist in ensuring technologies and services are used appropriately. The education of patients in the details of appropriate service use may be difficult to achieve. Attempts at involving patients have been largely unsuccessful.
9. One problem identified with descriptors and rules is that changing them can be a slow process (because a change in legislation is required). This can result in descriptors and rules that restrict medical practice inappropriately and may disadvantage patients eg, for some time item 66536 (quantitation of HDL cholesterol) was only available for patients who had a total cholesterol level above a certain threshold when best medical practice called for patient assessment of both LDL and HDL.
10. Political sensitivities can frustrate attempts to restrict items to particular specialists. To overcome such sensitivities it has been necessary to use a form of words indicating that the request for the technology was made "by, or on the advice of, the specialist or consultant physician". However, use of this term introduces difficulties for auditing, as no documentation of this advice is necessary. Another problem is that patients may be treated by practitioners who are not formally recognised as specialists in a particular field eg, hepatologists would generally be recognised as appropriate specialists in the treatment of patients with hepatitis C however some venereologists working in sexual health clinics have also specialised in the treatment of hepatitis C and are responsible for the management of patients with hepatitis C. It would therefore be inappropriate to restrict ordering of services such as quantitation of HCV RNA load in plasma or serum in the evaluation for antiviral therapy of a patient with chronic HCV hepatitis (item

69442) or nucleic acid amplification and determination of Hepatitis C virus (HCV) genotype (item: 69443) to hepatologists.

Published evidence on the effectiveness of restrictions on the reimbursement of medical services

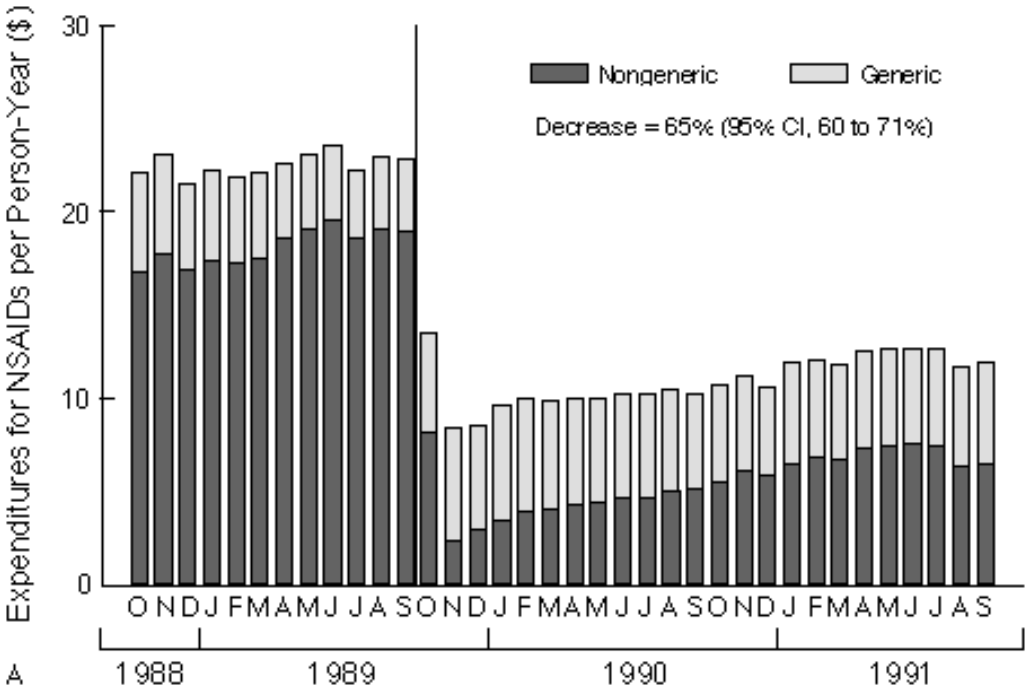
There is little published evidence on the effectiveness of restrictions on service use. One study Smalley et al (1995), assessed annualised rates of expenditure on NSAIDs among all enrolees in Tennessee Medicaid before and after the introduction of a prior authorisation (by telephone, fax or in writing) program for non generic NSAIDS, found:

- a reduction of 53% in mean annual expenditure on NSAIDS at two years (see Figure 1);
- days of NSAID use decreased by 19%;
- no evidence that the use of other drugs or medical services increased;
- in those who were regular NSAID users the decrease was even more marked with similarly no evidence of increase use of other drugs or services.

Smalley et al (1995)[10] concluded that prior authorisation was successful in reducing expenditure without undesirable changes in the use of other types of medical care. The generalisability of this study to the Australian context and to services where there is no clear equivalent alternative (generic vs. branded drug) is difficult to assess.

Figure 1: Annualised expenditure per person-year on NSAIDs over time

[10] Smalley WE, Griffin MR, Fought RI, Sullivan L, Ray WA. Effect of a prior authorizations requirement on the use of non-steroidal antinflammatory drugs by Medicaid patients. N Engl J Med 1995;332:1612-1617



Risk Sharing Agreements

Risk-sharing agreements (eg, price-volume agreements) have been introduced simultaneously with public funding of new medications in both Australia and the UK in recent years. The mechanism reduces total or marginal revenue to the provider as use increases beyond a target level. By themselves, they are crude as a mechanism to induce more cost-effective care as they do not provide a direct incentive to target those who would benefit most. However, these risk-sharing agreements are not introduced as stand-alone mechanisms. Rather, they are introduced as a means of "backing-up" restrictions and as such may be a powerful way of reinforcing incentives for technologies to be used in a way consistent with the evidence on cost effectiveness.

Various types of price-volume agreements, with varying degrees of sophistication, are possible. Examples of price-volume agreements that are possible include:

- an agreed discount schedule according to level of utilisation (eg, 5% general price reduction if the number of items processed exceeds 'N');
- agreed bonus deals (eg, cost listed is $X but the item is supplied on 2 for 1 deal so that, effectively, the price of the item is 50% of $X);
- different agreed prices for different populations (eg, a technology can be used to treat conditions A and B. A price of $X is acceptable when the technology is used to treat

condition A; a price of $Y is acceptable when the technology is used to treat condition B. The proportion of prescribing for conditions A and B is determined and this is used to determine an appropriate weighted average price;
- an outcomes guarantee where a discount schedule is established for varying levels of clinical improvement seen in the population (such an agreement would require development of a mechanism for capturing information about outcomes).

Different levels of transparency of price-volume arrangements are possible. Price-volume agreements may be made public if the sponsor of a technology does not object. However, there is currently no requirement in Australia for details of price-volume agreements to be publicly available. It is possible that making price-volume agreements public may improve compliance with these agreements.

In the UK, the NHS and five pharmaceutical manufacturers united for a "payment by results" scheme for disease-modifying drugs (such as interferon beta and glatiramer) used in the treatment of multiple sclerosis. Patients with relapsing and remitting multiple sclerosis or secondary progressive multiple sclerosis with prominent relapses who meet the Association of British Neurologists' guidelines will be eligible for subsidised treatment with these drugs. Eligible patients will undergo a lengthy assessment of their baseline level of disability, against which the disease progression and treatment effect will be compared each year for 10 years. Treatment will be funded by the NHS until it is deemed to be no longer effective. Groups of patients will be monitored over the lifetime of the scheme, and costs of the drugs to the NHS will be adjusted according to whether expected benefits to patients are realised. The price paid will drop if expected clinical improvement targets are not met.[11]

Similarly, details of an agreement between the Nottingham Health Authority in the UK and Parke-Davis/Pfizer of an outcome guarantee on statins have been published in the literature[12]. Under this agreement, repayments are indicated if target cholesterol concentration is not achieved by an agreed percentage of patients in four baseline groups. It can be envisaged that any attempts by the sponsors to dissociate themselves from these agreements are likely to be viewed negatively by the medical profession and the community. Although there are potential benefits associated with making details of price-volume agreements publicly available, there is a chance that fewer sponsors will be prepared to enter into any such agreement if this was a requirement.

Difficulties have arisen with price-volume agreements because:

- both government and sponsors may have difficulties in predicting use of technology in the future and where actual utilisation considerably exceeds forecast utilisation;
- it can be difficult and costly to legally enforce a price-volume agreement.

[11] Little, R. NHS to fund treatment for 10 000 patients with MS. *BMJ* 2002; 324: 316.
[12] Chapman, S., Reeve, E., Rajaratnam, G., Neary, R. Setting up an outcomes guarantee for pharmaceuticals: new approach to risk sharing in primary care. *BMJ* 2003; 326: 707-709.

It has been suggested that price-volume agreements may be more likely to succeed when:

- the establishment of the price-volume agreement is brought to the attention of the Cabinet at the time of establishment;
- reasonably accurate predictions of utilisation are made; such that the impact of a price-volume agreement is small (only small variations in price will be required).

Caps on expenditure

Expenditure caps on sets of substitutable services could be negotiated with providers. An example in Australia is the pathology agreement. In essence this is very similar to a risk sharing arrangement but if rigidly enforced, the burden of risk falls more heavily on the provider. In relation to the cost effectiveness of individual services, although caps on expenditure will reduce the risk of budget excesses, they do not explicitly assist in limiting use of technologies to circumstances where the technology has been found to be acceptably cost-effective. If a risk sharing arrangement or a budget cap were to focus the attention of providers more directly on the cost of care, it may lead them to ration care according to clinical need and in that sense assist in targeting patients in whom the service is likely to be of acceptable cost effectiveness. Physicians may feel ethically obligated to provide the service to those most likely to benefit, but there is no guarantee that this will be the outcome. The parallel evidence of budget holding discussed below is not encouraging.

Program Grants

A number of technologies have been funded under health program grants in Australia. Radiotherapy is a key example. They have often been used where the technology involves a large capital outlay on specialist equipment and the effectiveness of the technology is perceived to be operator dependent. A key feature of most program grants has been a two-part payment with capital funded separately from operating costs. For that reason they may offer different incentives to providers compared with a fee for a unit of service on the MBS. They may provide less incentive for intensive use of the technology (eg if capital is funded separately) and therefore for inappropriate use and they may also allow for more effective monitoring. However the issues of targeting are the same as with other contractual arrangements that leave the delivery of the service (to whom) in the hands of the requesting practitioner and provider. Without auditing on the basis of agreed performance measures there is no guarantee of adherence to the conditions of the program but there is the opportunity to include performance measures in the program grant.

A program grant could also be used as a means to fund a service for a specific period to allow the accumulation of evidence to support continued funding. In the past there have been cases where data collection was a condition of program funding (MRI is one example) but there was no clear research plan and the data collected proved not to be useful in making subsequent funding decisions. If this approach was to be used again then more careful consideration would need to be given to what evidence would need to be presented at the end of the proposed interim funding period, how it was to be collected and how it was to be analysed.

There are a number of reasons why a technology might be funded outside of the traditional fee for service schedule. These might include a desire to integrate treatment more fully with other aspects of a service eg drug addiction treatment. As noted, a second reason for funding outside the MBS schedule might be a concern to limit a treatment with a large capital outlay and a consequent strong incentive to sustain an adequate throughput, eg MRI. Clearly, political issues arise, as in the case of trastuzumab (Herceptin®), a drug used in the treatment of metastatic breast cancer. The drug was rejected by the PBAC for listing on the PBS[13]. However, the Australian Government established a program to finance the drug costs of trastuzumab for patients satisfying particular eligibility criteria. This program was implemented on 1 December 2001 by the HIC.

Contracts

The use of competitive contracting could result in lower prices but it is hard to see why it would target the use of services per se. This would depend on the conditions of the contract, and like program grants the quality of the service and its coverage would need as much monitoring as any other fee for service arrangement.

An example of the ability of preferred provider arrangements to change behaviour of providers was a trial in New Zealand by the Accident Compensation Commission of an endorsed provider network. Physiotherapists were paid a higher fee (with no co-payment for consumers) in return for participation in an accreditation program. The as yet unpublished results appear to suggest reduced claims and days lost from work from low back pain (see http://www.acc.org.nz/for-providers/resources/acc-news/acc-news-35---jun-2001.pdf). While providers were still paid on a fee for service basis, their participation in the accreditation program was a condition of enhanced funding. It may be that more broadly the opportunities for renegotiation of the conditions of a contract would provide an opportunity to change behaviour.

Budget Holding

It is possible for a funder of health care to devolve some of their budget to a provider who takes responsibility for providing a package of services. They may provide these services directly or purchase from others. Some respondents identified budget holding by doctors as a potential means of encouraging requesting practitioners and providers to consider more carefully both the costs and benefits of treatments and as a consequence target those patients in whom the treatment has been shown to be cost effective. In part this arises because the provider and the requesting practitioner become one income unit. There is some evidence from the UK of the impact of doctor budget holding for medical services on utilisation and costs. Much of this evidence is on drugs. Early studies suggested that GP fundholders were more successful in containing drug expenditure than non fundholders. Britain's Audit Commission found in 1994 that fundholding practices prescribed fewer drugs of limited clinical value and a higher ratio of corticosteroid to bronchodilator inhalers when compared with non-fundholding practices.[14] However such differences cannot

[13] Robotham, J. Funding Denied To Cancer Treatment. *Sydney Morning Herald.* September 15, 2001; p.27
[14] Audit Commission. *A prescription for improvement: towards more rational prescribing in general practice*. London: HMSO, 1994.

confidently be attributed to the influence of the scheme. Practices which entered fundholding were more likely to be larger, better organised, more highly computerised practices serving less deprived populations.[15] However in a study of 3 years of prescribing habits among a small group of practices, Surender et al (1995)[16] found that the increase in costs was highest among GP fundholders who did not dispense drugs themselves. In contrast, larger studies by Wilson et al (1995)[17] found the opposite result and a reduction in utilisation among patients of fundholders. The most comprehensive study, Harris and Scrivener (1996)[18], found a difference in cost escalation among fundholders of 6% less than non fundholding over 5 years, but even that comparatively small return was confounded by potential selection bias that limited the validity of any conclusion. The UK Audit Commission, in 1996, reported that until then fundholders had made relatively modest changes to patient benefits and management capacity, and they may not have provided sufficient improvements to justify their higher cost.

COST OF IMPLEMENTATION

The use of any mechanism to target utilisation has administrative costs. In principle, the gains from targeting would need to exceed the cost of administration for them to be worthwhile. If not then it may be better to fund use in sub-groups that show little benefit, as long as the average benefits across all groups exceed the average costs. Only if the cost of exclusion is lower than the net loss in the targeted sub-group is it worth considering investing extra resources to limit use.

Information provided by the Department of Health and Ageing suggests an administrative cost per prior approval claim of $1.10. No estimates are available on the marginal or average cost of an effective limit on the use of any type of service with any type of restriction. The HIC does monitor provider patterns of behaviour but the emphasis in more on individual aberrant provision of services criminal rather than population wide use of services beyond the point of effectiveness or cost effectiveness. The focus in monitoring is on identifying medical practitioners whose services appear abnormal when compared with their peers. A common prescribing "indicator" is the prescribing rate of a doctor (volume per patient or prescriptions per patient or per consulation). In most feedback programs (including that of the Australian Health Insurance Commission), the individual is compared with the average performance of her or his peers, which may not reflect best practice. It may be possible to develop more sophisticated and informative performance measures in relation to cost effective use such as ratio measures (ratio of prescriptions of new to old arthritic drugs for example by individual practitioner compared to a

[15] Audit Commission. *What the doctor ordered. A study of GP fundholders in England and Wales*. London: HMSO, 1996.

[16] Surender R, Bradlow J, Coulter A, Doll H, Stewart-Brown S. Prospective study of trends in referral patterns in fundholding and non-fundholding practices in the Oxford region, 1990-4. *BMJ* 1995;311:1205-8.

[17] Wilson RPH, Buchan I, Walley T. Alterations in prescribing by general practitioner fundholders: an observational study. BMJ 1995;311:1347-50

[18] Harris and Scrivener Harris CM. Scrivener G. Fundholders' prescribing costs: the first five years. BMJ. 1996 Dec 14;313(7071):1531-4,.

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benchmark)[19] By its very nature however a peer reference measure of inappropritate practice is not likely to be effective in monitoring use against a restriction that does not have general support within the medical profession.

The PBS uses restrictions widely and prior approval is common. Under the authority prescription approval arrangements, medical practitioners are required to obtain prior approval from HIC for all PBS authority prescriptions before an approved pharmacist can make a supply. As at 30 June 2003, of the 1,451 PBS items listed, 778 are restricted to use for a particular condition or purpose. Of these 778 items, 288 are subject to criteria set by the Pharmaceutical Benefits Advisory Committee that limits supply to a PBS authority prescription. During 2002–03, 4.76 million authority prescriptions were approved, with 4.49 million of these being handled by telephone.

Prior authorisation for drugs in Australia is focussed on the higher unit cost items. Of the 180 million PBS and Repatriation Pharmaceutical Benefits Scheme prescriptions processed by the HIC in 2003/4, only 6.5% required prior approval (Authority Required), but of $5.6 billion government expenditure on PBS & RPBS items, 25.7% was for Authority Required items. The average benefit paid for a prescription for an Authority Required item was $122.75 compared to $24.45 for non-Authority items.

Even in the case of prior approval it is unclear if use is within the intended limits of the authority restrictions. During 2002–03, the HIC source based audit program randomly reviewed 94,625 PBS-funded medicine supply events nationally. However random audits like this usually pick up only minor infringements of rules and are not designed to pick up systematic biases in prescribing for particular drugs outside of the approved use. The HIC also analyses aggregate prescribing data for drugs on the PBS that have been "identified as a high risk factor in relation to the program's sustainability"[20], but no details of the extent or effectiveness of this data analysis in changing behaviour has yet been published.

There is no systematic evidence of a high marginal costs or a lack of effectiveness of current or potential prior approval system for drugs in Australia. However there are some clear cases where in spite of prior approval system leakage of use outside of the intended indication has been widespread and costly. An often quoted example is proton pump inhibitors. When proton pump inhibitors were first listed on the PBS for severe grades of ulcerative oesophagitis a large proportion of PBS prescriptions were written for other indications.[21] Conversely examples where utilisation of medical services has been demonstrated to go beyond the evidence of effectiveness or cost effectiveness are less obvious. This may be because MSAC has been reluctant to fund technologies because of a

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[19] Jane Robertson, Jayne L Fryer, Dianne L O'Connell, Anthony J Smith and David A Henry. Limitations of Health Insurance Commission (HIC) data for deriving prescribing indicators. The Medical Journal of Australia 6 May 2002 176 (9): 419-424

[20] HIC Annual Report 2002-03

[21] Pillans PI, Kubler PA, Radford JM, Overland V. Concordance between use of proton pump inhibitors and prescribing guidelines. Med J Aust 2000;172:16-8.

concern that they would be used in ways that are not cost effective. In so doing MSAC may have reluctantly accepted that some users in whom the technology is of acceptable cost effectiveness would be deprived of publicly funded treatment. If that is the case it strengthens the need to find ways of effectively targeting use.

Consideration also needs to be given to cost of compliance with restrictions for requesting practitioners and providers. For example, obtaining authorisation for a technology can be a burden on providers. A recent study by the Productivity Commission estimated that getting a PBS authority took the prescribing doctor 3.3 minutes for a telephone authority and 9.5 minutes for written authority. With average hourly earnings of $63.84 this implies a cost of $3.50 for a telephone authority and $10.11 for a written authority[22]
The cost of implementation does not include monitoring and auditing of claims but for many services a cost of $10-15 per claim for prior approval is a substantial percentage of the cost of treatment. For others however, if effective in targeting use, it might be cost effective. Take for example the PBS restriction of the subsidy for etanercept for patients with rheumatoid arthritis that limits continued PBS-subsidised treatment to patients who have demonstrated an adequate response to treatment. There were 2807 PBS scripts for etanercept dispensed in the first 6 months of 2004 with an expenditure by government of $5,288,495. If we take an estimate of the administrative cost of the restriction at around $15 per script the total cost was $42,105. At a cost per script of $ 1888.26 for adults if the restriction reduced the number of scripts, that would have been wholly ineffective, by only 23 (less than 1%) then the restriction had net benefits. A more sophisticated analysis of the impact of the cost of implementation on the optimality of a particular restriction would also need to consider the size of the loss of benefits in those deprived of treatment. In the case of etanercept for example even those who do not meet the current restrictions on subsidy may have some benefits from treatment. This suggests that for a treatment with high unit costs and a potential for use in populations where it is ineffective, prior authorisation processes with initiation and continuation rules would appear to be very attractive. Even where adherence to the regulations is not 100% there could be net benefits in targeting a subsidy.

Support for such rules will be stronger among practitioners where it is easy to identify patients who will clearly not benefit rather than a continuous gradient of effectiveness across a heterogeneous population. There will be occasions however when it might cost effective not to recommend funding even if this means that a subgroup in the population will have reduced access to an effective (and cost effective) treatment. A well documented example in the PBS system was the treatment of erectile dysfunction where both sildenafil (Viagra®) and alprostadil (Caverject®) were refused public funding in spite of the PBAC apparently accepting that the agents were effective and acceptably cost-effective for a number of defined indications. Although not explicitly stated, the issue may have been the difficulty of restricting use to those indications, and the potential for very large expenditure growth in patient groups for whom cost effectiveness was not acceptable. In a press release, the Minister explained that the Government had decided, given the increasing

[22] Productivity Commission Research Report: General Practice Administrative and Compliance Costs, 31 March 2003

demands on the PBS, that funding for erectile dysfunction should not be a priority (http://www.health.gov.au/mediarel/yr2002/kp/kp02005.htm).

CONCLUSIONS

Currently coverage under the national health insurance scheme in Australia is recommended if there is evidence that the service is safe, effective and cost effective compared to current standard care. The most common method of public funding of pharmaceutical and medical services is a listing on the relevant schedule.
The types of mechanisms for targeting the use of medical services include:

1. Unrestricted listing on the benefit schedule with information dissemination strategies, clinical auditing and feedback strategies, or positive or negative financial incentive payments for achieving target utilisation.
2. Restricted listing on the benefit schedule (restricted by: patient type, indication, prior services, provider, location, and duration of service);
3. Restricted listing on the benefits schedule with prior telephone or written authorisation (restricted by: patient type, indication, prior services, provider, location, and duration of service);
4. Program grant with conditions of service (these might include for example a contractual agreement with providers on total expenditure and quality of service).

Typically MSAC and PBAC recommend funding on the basis of the average benefit achieved by the average provider at the average cost across all patients in all settings. The decision to recommend funding is based, amongst other considerations, on the view of the average expected net benefit across all patients. It may be that there is evidence that the medical service is likely to be more effective (and cost effective) in a subgroup of patients that may be at higher risk or suffer from a more severe or refractory form of the condition or that can be treated more effectively by providers with particular qualifications. MSAC has made recommendations that a technology be used as second line therapy or be provided by a specialist, but it has not often set firm criteria for such recommendations. It has not recommended any particular strategies to ensure compliance with those criteria, nor apparently considered the likelihood of success of any of those potential strategies. PBAC on the other hand has set detailed criteria for coverage of benefits for particular drugs and there have been a number of agreements with companies on annual total utilisation targets.

The evidence on the comparative effectiveness of each of these strategies is weak but there is some (largely anecdotal) evidence that the financial strategies have had some success particularly where there is clinician acceptance of the appropriateness of targeting utilisation. This is consistent with some evidence that a multifaceted approach might have advantages, and that clinical audit and feedback could be used to complement any funding restrictions.

The cost effectiveness of any of these strategies is unclear. The cost per prior approval appears low but the success of any restriction depends on the degree of monitoring and enforcement of breaches of the regulation. The extent, cost or effectiveness of those aspects of regulation in Australia is unknown

Given the cost to requesting practitioners as well as the regulator, what seems to follow is that prior approval efforts and resources should not go into devising authorisation systems for low cost technologies that are likely to be used in low-volumes. A risk-assessment of the likelihood of large financial costs should be conducted before considering whether restrictions are necessary and, if so, what method should be used to implement the restriction. It would also seem logical for economic evaluation of health care technologies to include sub-group analyses where relevant, but in doing so to include the cost of policy implementation. To do that however would require more work on the costs and effectiveness of restricting use to situations where net benefits have been demonstrated.

APPENDIX 1

Restrictions on funding

The primary mechanism used in Australia to limit use of a technology to circumstances where it has been determined to be of acceptable cost effectiveness is the specification of a restriction (or use of a descriptor) that details the conditions under which the technology can be used. The construction of a descriptor is fundamentally a funding based approach to utilisation but it can be part of a multifaceted approach that includes behavioural change strategies. Parameters that may be incorporated in a descriptor include the following:

PATIENT ELIGIBILITY CRITERIA ie, patient characteristics. These criteria may be specified at baseline (before treatment commences) and/or after treatment (continuation criteria). Criteria may be specified for factors such as age, sex, clinical condition (eg, osteoporosis, diabetes, etc), severity of clinical condition (eg, a requirement of specific results to specific tests), previous therapies and length of previous therapy, demonstrated response to therapy (in order to receive continued treatment).

The following are examples from the MBS and PBS of restriction of items by patient characteristics.

- The quantitation of glycosylated haemoglobin (item: 66551) has been accepted as being a cost-effective means of monitoring diabetes but has not been demonstrated to be acceptably cost-effective as a means of screening for diabetes. Therefore, the descriptor for this item explicitly states that it should be used "in the management of established diabetes". Explanatory notes (PP.10) to the schedule specify how the term "established diabetes" should be interpreted – "The requirement of "established diabetes" in this item may be satisfied by:
  a) a statement of the diagnosis by the ordering practitioner on the current request form or on a previous request form held in the database of the Approved Pathology Authority; or
  b) two or more blood glucose levels that are in the diabetic range and is contained in the database of the Approved Pathology Authority; or
  c) an oral glucose tolerance test result that is in the diabetic range and is contained in the database of the Approved Pathology Authority."
- The descriptor for 66719 (a suite of thyroid function tests) states that thyroid function tests (comprising the service described in item 66716 and 1 or more of the following tests – estimation of free thyroxine index, free thyroxine, free T3, total T3, thyroxine binding globulin) for a patient, if at least 1 of the following conditions is satisfied:
  a) the patient has an abnormal level of TSH;
  b) the tests are performed:
     (i) for the purpose of monitoring thyroid disease in the patient; or
     (ii) to investigate the sick euthyroid syndrome if the patient is an admitted patient; or
     (iii) to investigate dementia or psychiatric illness of the patient; or
     (iv) to investigate amenorrhoea or infertility of the patient;

c) the medical practitioner who requested the tests suspects the patient has a pituitary dysfunction;
d) the patient is on drugs that interfere with thyroid hormone metabolism or function.

Thus, apart from some exceptions ((b) to (d) above), an abnormal Thyroid Stimulating Hormone level (detected using item 66716) is required before patient is eligible for the full suite of thyroid function tests. The HIC is able to test if the patient has had item 66716 performed in the past and may refuse payment if a claim for this item has not previously been made (and the other conditions are not satisfied).

- One of the Authority Required PBS listings for imatinib (Glivec®) is as follows: Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of one or more of the following:
  1) percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%;or
  2) percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or
  3) peripheral basophils greater than or equal to 20%; or
  4) progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
  5) karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

  Applications for authorisation must be in writing and must include:

  a) a completed authority prescription form; and
  b) a completed Imatinib Mesylate (Glivec) PBS Authority Application – Supporting Information form, stating which of the above criteria are satisfied by the patient; and
  c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly.
- A set of continuation criteria are specified in the etanercept restriction for patients with juvenile arthritis that limits continued PBS-subsidised treatment with etanercept only to patients who have demonstrated an adequate response to treatment as manifested by:
  a) an active joint count of fewer than 10 active (swollen and tender) joints; OR
  b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; OR
  c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and

limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of the joint assessment must be provided.

DIRECTIONS FOR USE OF A TECHNOLOGY (eg, specification of a dose schedule, specification of prohibited concomitant therapies). An example from the PBS of restriction of an item by specification of directions for use of a technology is that for interferon alfa when used in the treatment of hepatitis C, which limits the treatment course to 3 million units subcutaneously 3 times weekly for up to 52 weeks.

FREQUENCY OR DURATION OF USE eg, specification of the number of times an item can be provided in a specified time frame. Examples from the MBS and PBS of restriction of items by frequency or duration of use include:

- the quantitation of glycosylated haemoglobin (item: 66551), which is limited to 4 tests per 12 month period;
- the PBS restriction applying to interferon alfa when used in the treatment of hepatitis C, which requires that treatment cease after 12 weeks if plasma HCV RNA remains detectable by an HCV RNA qualitative assay at this time. If HCV RNA becomes undetectable, the treatment course is limited to 52 weeks.
- Some subgroups of MRI services are limited to one benefit per item in a 12 month period

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CHARACTERISTICS OF REQUESTING PRACTITIONER eg, limiting prescribing to specialists in a field. Examples from the MBS and PBS of restriction of items by requesting practitioner characteristics include:

- quantitation of HCV RNA load in plasma or serum in the pre-treatment evaluation for antiviral therapy of a patient with chronic HCV hepatitis (item 69442) and nucleic acid amplification and determination of Hepatitis C virus (HCV) genotype (item: 69443), which both require that the request for the test be made by, or on the advice of, the specialist or consultant physician managing the treatment of the patient;
- pathology services, where the treating practitioner requesting the service must be a registered treating medical or dental practitioner
- the PBS restriction for etanercept when used in the treatment of patients with juvenile arthritis requires that the patient be treated by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology centre.
- MRI services must be requested by a recognised specialist medical practitioner (with some limited exceptions)

PROVIDER CHARACTERISTICS eg, limiting supply to accredited providers, limiting supply to accredited facilities. Examples from the MBS and PBS of restriction of items by provider characteristics include:

- medical ultrasound examinations (either R or NR type items), which are required to be performed by sonographers who are suitably qualified, involved in a relevant and appropriate Continuing Professional Development program and are registered on the Register of Accredited Sonographers held by the Health Insurance Commission;
- certain tests of public health significance which do not qualify for payment of Medicare benefits. Examples of services in this category include: Guthrie test for phenylketonuria; neonatal screening for hypothyroidism (T4/TSH estimation); neonatal screening for cystic fibrosis; neonatal screening for galactosemia; the detection of the presence of human immunodeficiency virus (HIV) except quantitation as specified in specific Medicare items. Specialist laboratories (generally funded by a university or teaching hospital) are used to perform these tests. Limiting performance of rare, expensive tests to small numbers of laboratories will assist in ensuring that any possible economies of scale are captured. This has also contributed to very good notification of these conditions. However, private pathologists claim that equity of access may be compromised by this type of approach.
- the supply of methadone and buprenorphine (used in the treatment of opiate dependence), which is limited to pharmacies approved to supply these agents by State and Territory governments;
- hyperbaric oxygen therapy, which is limited to treatment performed in a comprehensive hyperbaric medicine facility, under the supervision of a medical practitioner qualified in hyperbaric medicine;
- pathology services, where:
  - . if the specimen is collected at a collection centre, then the centre must be an Approved Collection Centre (ACC);
  - proprietors of pathology laboratories must be an Approved Pathology Authority(APA);
  - pathologists performing tests must be an Approved Pathology Practitioner (APP);
  - tests must be performed in an Accredited Pathology Laboratory (APL);
  - .

GEOGRAPHICAL LOCATION eg, restriction of a service to patients in intensive care units. Examples from the MBS and PBS of restriction of items by geographical location are:

- patients being treated in a hospital may be exempted from certain rules in the MBS eg, Rule 3.(2) in the Pathology Services table of the MBS indicates that a service should only be ordered for a patient once in any one day but Rule 4.(1) exempts certain blood tests for patients in an ICU from this rule.
- one of the patient groups permitted supply of certain laxatives (eg, bisacodyl) as a pharmaceutical benefit is “patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities”.

- benefits for MRI services are generally restricted to eligible machines;
- with regard to pathology no benefit will be payable for services provided by an APP on behalf of an APA if they are not performed in the laboratories of that particular APA.