

Commonwealth Department of Health and Ageing

**MANUAL OF RESOURCE ITEMS
AND THEIR ASSOCIATED COSTS**

for use in major submissions to the
Pharmaceutical Benefits Advisory Committee
involving economic analyses

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PREFACE TO SECOND REVISION

Several changes have been made to ensure that the *Manual* is up to date. The sources for most of the unit costs are provided so that frequent revisions to the *Manual* will not be necessary. Where available, an Internet site that contains the sources of costs is provided, to allow the reader to ensure that the unit costs they are using are the most up-to-date available. These sites are hyperlinked in the electronic version of the *Manual* on the Internet, and the addresses of the sites are found in Appendix 1. The expected frequency of updates for these source documents (where available) is at Appendix 2.

The latest version of the *Manual* can be found on the website of the Department of Health and Ageing: <http://www.health.gov.au/pbs/pubs/manual/index.htm>. It is advisable that the latest electronic version of the *Manual* and the source documents are consulted prior to finalising a major submission to the PBAC.

The *Manual* updates the costs for acute diagnosis related groups (DRGs), and provides information regarding breaking DRGs into patient-relevant data.

The Department of Health and Ageing is currently working with stakeholders to improve the scope and quality of nationally consistent data regarding non-admitted patients. In recent months considerable progress has been made on the development of a national minimum data set for Emergency Department care. Work to improve the availability of nationally consistent data about activity in outpatients department is also a high priority.

Nursing Home and Hostel Accommodation services have been amalgamated into Residential Care and Accommodation. The Resident Classification Scale (RCS) is used to cost the daily care requirements of Australians in Residential Care and Accommodation.

A new section, Section 9, has been introduced in this revision of the *Manual* that covers the variations to unit costs (by excluding the patient co-payment) for financial analysis prepared according to Section 4.3 of the *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee*.

1. INTRODUCTION

From the beginning of 1993, the Pharmaceutical Benefits Advisory Committee (PBAC) has required submissions for the listing of a new drug on the PBS to incorporate an economic as well as a clinical evaluation. The PBAC has also endorsed *Guidelines* for the conduct of economic evaluations and financial analyses. These are also available from the Pharmaceutical Evaluation Section (PES) of the Department of Health and Ageing.

In order to ensure consistency and comparability, both within and between major submissions to the PBAC and over time, it is essential that major submissions to the PBAC use consistent measures of medical and other health-related services relevant to drug therapies, and cost (or price) them in a consistent manner. This *Manual of Resource Items and their Associated Costs* has been developed to ensure such consistency and is to be used by pharmaceutical companies in preparing economic evaluations.

This *Manual* has been designed as a result of a study of the range of medical and other health-related services which may be affected by the introduction of new drugs to the PBS. The services included in the *Manual* are based upon economic evaluations and financial analyses conducted in Australia and overseas, and refined during discussions with pharmaceutical companies and medical professionals involved in clinical trials of drugs. The principles adopted in determining the prices of services are similarly based on economic protocols established overseas in economic evaluations, within the context of readily available and suitable data in Australia.

This *Manual* is a dynamic document. That is, it is subject to ongoing review and periodic updating. As prices change and new data sources become available, the *Manual* will change. Users of the *Manual* and other interested parties are encouraged to contribute to, and participate in, this process of change and improvement. Any suggestions on ways in which the *Manual* may be improved are welcome, and inquires about any aspects of its contents or use should be forwarded to:

The Pharmaceutical Evaluation Section
MDP 83
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GPO Box 9848
Canberra ACT 2601
pbs@health.gov.au: attention PES

2. GENERAL PRINCIPLES AND RECOMMENDATIONS

This *Manual* identifies the types of resources that are commonly or occasionally relevant to economic evaluations included in major submissions to the PBAC, together with the natural unit of measurement and the unit cost for each resource type. The list of resource types is not exhaustive, and if other resource charges are considered relevant, a case can be made in a submission for their inclusion.

As stated in the introduction, the original objective of the *Manual* was to strike a balance between comparability and accuracy in the determination of unit costs. To some extent, this reduces the accuracy of these unit costs, for example by adopting average rather than true marginal costs for hospital episode and residential care costs.

Achieving greater comparability of unit costs provides for a “reference case” across economic evaluations considered by the PBAC. This also means that decisions as to whether to list a drug on the PBS are influenced by the drug itself, rather than the selection of unit costs. Furthermore, all those preparing submissions to the PBAC can be confident that all other submissions are referring to the same set of costs, thus improving transparency. There are other advantages to this approach. The unit costs are:

- independently verifiable;
- made as accessible as possible (a feature of this revision is the inclusion of extensive referencing to relevant Internet sites); and
- from sources which are regularly maintained where possible to ensure that the vast majority are kept up-to-date.

This second revision maintains the objective of balancing comparability and accuracy, but is now also based on the experience of applying the *Manual* for more than a decade. History indicates that resources and their unit costs have had a varying impact on the conclusions of economic evaluations. Some types of resources (eg allied health services and over-the-counter drugs) have rarely, if ever, had a pivotal impact on these conclusions. For other types of resources (eg medical services and other PBS drugs), any costing issues usually arise from the number of resources changed, rather than the unit cost of each resource. Occasionally, the unit cost does become important (eg hospital costs to deliver cancer chemotherapy or claims of heterogeneity across hospital services within an AR-DRG). In addition, occasionally resource types that are not identified in this *Manual* (eg variations in hospital duration or hospital component costs) have been included in submissions and these are considered on a case-by-case basis.

It is expected that there will continue to be circumstances where either the *Manual* does not identify a particular resource, or an alternative to the recommended unit cost for an identified resource may be more accurate and that substituting a different, but justifiable unit cost could influence the conclusions of the PBAC.

The preferred approach for either circumstance is to prepare two base case presentations of the affected economic evaluation. The first would be presented according to the unit costs recommended in the *Manual*, in order to promote the comparability of PBAC decisions. The second would adopt the alternate costs. This would assist the PBAC assess the importance of the unit cost to its decision as to whether to recommend listing. The submission’s justification for the alternative unit costs should be made as part of this second presentation. Two sets of sensitivity analyses should be presented, one for each base case.

It is conceivable that there might be a resource which is to be included in an economic evaluation, but is not included in this *Manual*, and for which the only unit cost available has not been recently updated. In addition, the unit costs recommended in Section 7.2 pertaining to the Australian Ambulatory Classification (AAC) were generated in 1992 and have not been updated. In both circumstances, the unit costs should be adjusted for inflation. The appropriate deflator to be used is the one that most specifically relates to the health care sector. The Australian Bureau of Statistics has recommended that the most appropriate deflator is the Implicit Price Deflator (IPD) for government final consumption expenditure on hospital and clinical services. For the period 30 June 1992 to 30 June 2001, the impact of this IPD is to increase the unit cost by 1.189. For other periods, the advice of the PES of the Department of Health and Ageing should be sought (refer to the address on page 1).

3. HOW TO USE THIS MANUAL

This *Manual* is to be used in conjunction with the *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee: including major submissions involving economic analyses*, available from the Commonwealth Department of Health and Ageing. It lists medical and other health-related services that may be affected by drug therapies. It also provides prices to be used when costing those services relevant to drug therapies in the economic evaluation of drugs in the context of the PBS.

The *Manual* comprises separate sections relating to different categories of health care: drugs, medical services, diagnostic and investigational services, hospital services and community-based services. Within each of these categories individual resource items are identified, classified, and the units of measurement defined. In addition, their associated price is presented in order to determine their value in an economic evaluation. Preparers of major submissions to the PBAC should ensure that the data collected during the conduct of clinical trials include those resource items relevant to the economic evaluation for both the new drug therapy and its comparator, using (or at least compatible with) the classifications and units of measurement contained in this *Manual*.

A description of each service category is contained at the beginning of each section, together with explanatory notes on their units of measurement. Preparers of major submissions to the PBAC are advised to familiarise themselves with each section to ensure that the data gathered during clinical trials are compatible with these requirements.

Whilst every effort has been made to provide a comprehensive list of resource items relevant to drug therapies and their economic evaluation, occasions may arise in an economic evaluation of a drug where an item is identified which is not included in this *Manual*. In such cases the general principles associated with the pricing of the resource category relevant to that item should be applied. A full explanation should be provided in the economic evaluation of the nature of the resource item and the data sources used to determine its price.

In a new Section 9, the *Manual* now specifies the preferred method for determining variations to unit prices of PBS drugs when conducting financial analyses from the PBS perspective rather than the societal perspective.

Prices contained in this *Manual* were those current at the time of its revision (August 2002). These prices will periodically be updated and the *Manual* revised as necessary. The vast majority of prices that are likely to be used in submissions are not contained in this *Manual*. Instead, cross-references including all the most frequently used prices are made to other sources (see Appendix 1), which are themselves frequently updated (see Appendix 2). As the *Manual* is now also available on the Internet, hyperlinks to relevant data sources have been included. Preparers of major submissions to the PBAC should check the Health Access and Financing Divisions publications website or liaise with the PES of the Department of Health and Ageing to ensure that they have the latest copy of the *Manual*.

4. DRUGS UNDER EVALUATION

This category of resource item refers to all drugs used as part, or as a by-product of, the non-hospital treatment therapy in which the proposed drug or its main comparator applies. Drugs prescribed or used in a hospital setting are excluded from this category and are included in the category 'Hospital Services'.

The unit of measurement to be applied to all categories of drugs is mg per day together with the prescribed period of treatment. In some instances, such as drugs administered by aerosol spray, alternative units of measurement may be more appropriate. In such instances details of the unit of measurement used should be specified and based on the normal recommended dosage.

There are three main categories of drugs used in economic evaluations.

4.1 Proposed drug

This refers to the drug which is the subject of the application for listing on the Schedule of Pharmaceutical Benefits, as identified on the Department of Health and Ageing form PB11, 'Application to list a Drug or Medicinal Preparation as a Pharmaceutical Benefit'. The price applied to this drug for the purpose of its economic evaluation is the equivalent of the 'Dispensed Price for Maximum Quantity' as defined in the Schedule of Pharmaceutical Benefits.

The PB11 form requires the applicant seeking listing to propose a List Price (i.e. a maximum price to the pharmacist) for the proposed drug and thus constitutes the formal application for PBS listing. The List Price is then further adjusted for the currently approved level of mark-up and the currently approved fixed composite dispensing fee to derive the Dispensed Price for Maximum Quantity (DPMQ). The dispensing fee and approved mark up are fixed by the Pharmacy Remuneration Tribunal (PRT), and are periodically varied (see Appendix 2). At the time of publication, the approved mark-up was as follows:

- List price < \$180, approved mark-up = 10%
- List price > \$180 but ≤ \$450, approved mark-up = \$18
- List price > \$450, approved mark-up = 4%

Preparers of major submissions to the PBAC should therefore ascertain the current dispensing fee and use the most up to date approved mark-up (available from the *Manual* on the Internet) and apply them to the List Price to derive the equivalent of the DPMQ for the proposed drug.

If the DPMQ of a drug is less than the statutory general patient contribution rate arrangements between the Government and the Pharmacy Guild of Australia allow for an extra charge to be added to the price up to a maximum of the general patient contribution rate. The method for calculating this extra charge is given in Section 4.2.1. In most instances where the DPMQ for the proposed drug is less than the statutory general patient contribution, so will be the comparator drug. In these cases, having determined the appropriate extra charged for the comparator drug (as per the method in Section 4.2.1), preparers of major submissions to the PBAC should apply the same extra charge to the price of the proposed drug.

In all cases, except private hospital patients, the price to be applied to a Highly Specialised Drug proposed for Section 100 listing is the Price to Commonwealth (which is the ex-manufacturer's price without any mark-ups or dispensing fees) as found in the relevant section of the *Schedule of Pharmaceutical Benefits*.

For the proportion of Highly Specialised Drugs dispensed through private hospitals, current remuneration rates comprise the normal PBS ready-prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer not more than \$40; or
- \$4 for drugs with a price ex-manufacturer more than \$40 but not more than \$100; or
- 4% for drugs with a price ex-manufacturer more than \$100.

Details of the price components used in the economic evaluation should be specified in the submission. For further information, refer to Sections 2.8 and Section 3.5 and Appendices F and I of the *PBAC Guidelines*.

4.2 Main comparator drug and co-prescribed drugs

Co-prescribed drugs are those prescribed in conjunction with, or affected by, the proposed drug or its comparator therapy. Two types of drugs are included in this category.

4.2.1 PBS drugs

These include co-prescribed drugs already included in the *Schedule of Pharmaceutical Benefits*. The price to be applied to a pack of each drug for the purpose of an economic evaluation is the DPMQ as defined in the *Schedule of Pharmaceutical Benefits*, plus any applicable premiums or charges. The submission should specify the effective date of the Schedule of Pharmaceutical Benefits that was used to derive the price of a drug when finalising the economic evaluation.

If the DPMQ of the drug is less than the general patient contribution, then an extra charge may be added to the price, provided that the total does not exceed the general patient contribution rate. The extra charge comprises a fee for the pharmacist to record the prescription on the patient's Prescription Record Form and an additional charge agreed between the Government and the Pharmacy Guild of Australia. The extra charge is applied only in a proportion of these cases. In order to determine the weighted average of this additional charge, the following procedure should be followed.

Preparers of major submissions to the PBAC should refer to "Table 2" in the most recent version of *Australian Statistics on Medicines*. For any particular drug, the final number in the row marked 'Survey' may be referred to as 'a'. Similarly, the final number in the row marked 'PBS/RPBS' may be referred to as 'b'. The ratio $a / (a + b)$ should then be multiplied by the extra charge to derive the weighted average extra charge. This figure should then be added to the DPMQ and any applicable premiums, with the resulting price used for the purpose of economic evaluations.

The general patient contribution is specified in the Schedule of Pharmaceutical Benefits, along with any additional fees for safety net prices, such as the charge to record the prescription on the patient's Prescription Record Form. The additional charge is agreed between the Government and the Pharmacy Guild of Australia, and is currently set at 10% of General Patient Contribution + \$0.50, with a maximum

amount payable set at the general patient contribution. The basis for these charges is available in the ‘Third Community Pharmacy Agreement’ between The Commonwealth of Australia and The Pharmacy Guild of Australia and successor agreements. Details of the price components and calculations should be provided in the submission.

Costs should be adjusted if there are several generic alternatives on the PBS where a brand premium applies. In such cases the price should be further adjusted according to the volume of prescriptions for each brand processed by the PBS over the most recent 12 months.

4.2.2 Non-PBS drugs

Non-PBS drugs are those co-prescribed drugs that are not listed on the PBS. The price to be applied to these drugs for the purpose of economic evaluation should be gained through the Arrow Private Prescription Program.

Arrow Pharmaceutical Products supplies the majority of Australian pharmacies through the Arrow Private Prescription Program. The maximum price to a patient at an Arrow-participating pharmacy for non-PBS drugs is listed on the Arrow Pharmaceutical Products website. Where possible, these prices should be used. For drugs that are not available through the Arrow Private Prescription Program, prices should be sourced from a direct-order company such as Pharmacy Direct, which is in competition with Arrow Pharmaceutical Products. The details of where the prices used in the economic evaluation originated should be included and justified in the submission.

4.3 Over-the-counter drugs

Over-the-counter drugs are those drugs for which no prescription is required, but whose consumption may be affected by the proposed drug or its comparator therapy. The price to be applied to a pack of each over-the-counter drug in an economic evaluation is the recommended retail price suggested by the manufacturer. The details of where the prices used in the economic evaluation originated should be included and justified in the submission. Where drugs are available both on the PBS and over-the-counter, the PBS price should be used.

4.4 Drug delivery systems

Drug delivery systems relate to consumables and equipment required for the delivery of some drugs, eg. insulin pens, nebulisor units. It is not feasible to identify and cost all such items in this *Manual*, as they are context-specific. Where such items are applicable to an economic evaluation, a price equivalent to the average price charged to the consumer should be used in the economic evaluation, and details provided of the basis on which it has been determined.

5. MEDICAL SERVICES

Medical services relate to professional services provided by, or on the behalf of, a qualified medical practitioner other than those provided in a hospital setting. Hospital-based medical services are included in the category 'Hospital services'.

The units of measurement to be used for medical services are defined in the classification of items in the Commonwealth Medicare Benefits Schedule (CMBS), as presented in the most recent version of the *Medicare Benefits Schedule book* issued by the Commonwealth Department of Health and Ageing. Preparers of major submissions to the PBAC should use their clinical judgement in the selection of the CMBS item relevant to the economic evaluation, and should provide justification for the items selected.

The price to be used for medical services in an economic evaluation is the Schedule Fee as presented in the CMBS.

Since both the structures of the CMBS and its associated Schedule Fees are subject to periodic review and amendment, preparers of major submissions to the PBAC should ensure that they use the most recent available version. The submission should specify the effective date of the CMBS used when finalising the economic evaluation.

6. DIAGNOSTIC / INVESTIGATIONAL SERVICES

Diagnostic and investigational services relate to imaging procedures, pathology tests and other investigational procedures, other than those conducted in a hospital setting. Hospital-based diagnostic and investigational services are included in the category 'Hospital Services'.

The units of measurement to be used for these services are defined in the classification of items in the Commonwealth Medicare Benefits Schedule (CMBS), as presented in the most recent version of the *Medicare Benefits Schedule book* issued by the Commonwealth Department of Health and Ageing. Preparers of major submissions to the PBAC should use their clinical judgement in the selection of the CMBS item relevant to the economic evaluation, and should provide justification for the items selected.

The price to be used for diagnostic and investigational services in an economic evaluation is the Schedule Fee, as presented in the CMBS.

Since both the structures of the CMBS and its associated Schedule Fees are subject to periodic review and amendment, preparers of major submissions to the PBAC should ensure that they use the most recent available version. The submission should specify the effective date of the CMBS used when finalising the economic evaluation.

7. HOSPITAL SERVICES

Hospital services are all services provided to patients in a hospital setting, including “hospital in the home”, where patients retain admitted patient status. They include all drugs, medical services, diagnostic/investigational services and allied health services provided to admitted and non-admitted patients.

Hospital services are comprised of two components, admitted and non-admitted patient care. As defined in the National Health Data Dictionary, v10 2001 (available from the Australian Institute of Health and Welfare website:

<http://www.aihw.gov.au/publications/hwi/nhdd10/index.html>) non-admitted care includes care provided to patients who receive care or services in an emergency or outpatients department, but do “not undergo a hospital’s formal admission process”.

Preparers of major submissions to the PBAC should use their clinical judgement in the selection of the classification relevant to the economic evaluation, and should provide justification for their selection.

If the service in question is neither for non-admitted patients, nor for admitted patients under an AR-DRG as described in the NHCDC (eg for a sub- or non-acute service), then the advice of the PES of the Department of Health and Ageing should be sought (refer to the address on page 1).

7.1 Admitted patient services

Admitted patient services comprise all hospital services provided to patients that ‘undergo a hospital’s formal admission process’. The introduction of a new drug may result in a reduction in the incidence of whole episodes of hospitalisation for a given illness or range of illnesses. In some cases it may also be feasible for a drug to result in an increase in whole episodes.

Where a drug therapy is anticipated to result in avoidance of (or an increase in) whole episodes of inpatient care, or where its comparator therapy includes whole periods of stay in hospital, the unit of measurement to be used is the Hospital Episode.

The cost for each episode varies according to the classification known as Diagnosis Related Groups (DRGs), which represent acute classes of patients with clinically similar diagnoses, and whose costs of treatment are relatively homogeneous. References for a list of DRGs according to their current Australian Refined Diagnosis Related Groups (AR-DRG) Classification are available on the website of the Department of Health and Ageing along with their current associated average costs provided on a per episode basis. Additional information can be requested from the Casemix Section directly via e-mail: casemix-hfs@health.gov.au.

AR-DRG costs can be obtained from the National Public Sector Cost Weights, in National Hospital Cost Data Collection (NHCDC). The cost shown in the column “Total Cost” for the relevant DRG should be used as the basis for determining the price for the episode of hospitalisation.

The submission should specify the effective date of the AR-DRG Classification and

cost weights used when finalising the economic evaluation (ie version 4.1 AR-DRG, Round 5 (2000-2001)).

Due to persistent concerns about whether the cost estimates are verifiable when disaggregated beyond an episode of hospitalisation, it can no longer be recommended that NHCDC cost weights be varied below the level of a whole episode. However, it could be argued that the cost of a whole episode from the NHCDC inadequately reflects different unit costs arising from changes in the duration of hospitalisation, changes to particular components involved in an episode of hospitalisation, and/or important heterogeneity across a particular AR-DRG. It might also become evident in the preparation of a particular submission that the estimate of admitted patient hospital unit costs is affected by more than one of the above, for example, both duration and heterogeneity.

If a variation to the admitted patient unit costs along these lines is considered to be relevant and important to a particular submission, the advice of the PES of the Department of Health and Ageing should be sought (refer to the address on page 1). As generally recommended in the *Manual*, two analyses should be presented (each with complete sets of sensitivity analyses). The first should be completely consistent with the *Manual* (ie either the cost weight for the full episode of hospitalisation from the NHCDC AR-DRG unit costs or no unit cost at all), and the second using the alternative approach. This follows the general principle of ensuring both comparability across submissions, and an assessment of the implications to the conclusions of the economic evaluation of using alternative costs.

In undertaking the second set of analyses, particular care should be taken in the submission in the explanation and justification of the alternative unit costs. The submission should demonstrate why breaking down the unit cost beyond a whole episode is of particular importance to the economic evaluation. Full details of the approach used to generate the alternative unit costs should be presented and explained, including how they are applied to the estimates of changes in extent of each resource.

Duration of episode: where the impact of the drug is to reduce the duration of an episode of hospitalisation, it should normally be assumed that the cheapest days of hospitalisation are avoided. Thus, the cost/day for each day of hospitalisation avoided should be less than the average cost/day calculated as the cost/episode divided by the average length of stay. Unless an alternative approach can be justified in the submission, the recommended approach is to use the cheapest estimate of the cost/bed day from the current NHCDC cost weights. This is appropriately conservative in the context of uncertainty.

Component costs: where the impact of the drug is to change the extent of resources provided within an episode of hospitalisation, the component costs reported in the NHCDC should not be used. Any alternative source should be justified, including a discussion on the extent to which the inclusion of this source of costs affects the conclusions of the economic evaluation.

Heterogeneity: an alternative unit cost for a whole episode of hospitalisation should only be considered if the submission can demonstrate that, within a particular AR-DRG, there is evidence of heterogeneity that is sufficient to affect the conclusions of

the economic evaluation. One option of an alternative data set component costs or heterogeneity could be to use the Victorian Cost-Weights Study, the latest version of which is available at: <http://www.dhs.vic.gov.au/ahs/weights0001.pdf>. An explanation should be provided as to why any cost/episode for the selected AR-DRGs from the recommended National AR-DRG data set varies from the cost/episode for the corresponding AR-DRG from the chosen alternative data set.

7.2 Non-admitted patient services

Non-admitted patient services include all hospital services provided to patients who do not undergo a hospital's formal admission process, and includes care or services provided to such patients in emergency and outpatients departments.

Non-admitted services from acute care hospitals have been classified according to the Australian Ambulatory Classification (AAC) as listed in Appendix 3. As these costs have not been updated since 1992, the costs in Appendix 3 have been increased from those provided in the previous edition of the *Manual* to reflect changes in the prices of hospital and clinical care. The IPD for government final consumption expenditure on hospital and clinical services was used to calculate the current cost (ie for 2001) as presented in Appendix 3.

Should further information be required about the nature and application of the AAC, refer to the following:

Lagaida, R and Hindle, D. *A Casemix Classification for Hospital Based Ambulatory Services. A report from the National Ambulatory Casemix Project.* State Health Publication Number: IC 92-89, Sydney, 1992.

Where the introduction of drug therapy is expected to result in a variation in the number of presentations to emergency departments or outpatient visits, the units of measurement should be the number of presentations or visits. The cost shown in the column headed 'Cost per visit', Appendix 3 should be used as the basis for determining the economic effects for the affected AACs. Preparers of major submissions to the PBAC should use their clinical judgement in the selection of the AACs relevant to the economic evaluation, and should provide justification for their selection.

8. COMMUNITY-BASED SERVICES

8.1 Residential care and accommodation

Residential care and accommodation refers to accommodation provided to residents of approved residential aged care facilities, formerly known as nursing homes and hostels.

The introduction of a new drug may result in the deferment (or acceleration) of an admission of a person to a residential care and accommodation facility, thereby affecting the weekly level of care required for the additional resident in residential care. The actual level of care affected will vary according to the level of dependency of the particular resident. Similarly, a new drug may result in a variation in the level of dependency for a person already in a residential facility, in which case the level of care required for their support will vary. In either case the effects should be included in the economic evaluation of the drug.

The unit cost measurements are categorised by eight different categories of residents. The categories are based on their relative care needs as assessed by the Resident Classification Scale (RCS) used by the Department of Health and Ageing. The RCS contains 20 questions about the residents' care needs. RCS categories 1-4 are considered high care – and these levels of care were previously provided by nursing homes. The subsidy amounts for permanent care recipients are provided as a rate per care recipient per day. Further details of the nature of this classification are contained in the Residential Care Manual and the Documentation and Accountability Manual Version 2.

Under the old funding arrangements nursing home (high care) rates for each resident classification were different in each State but hostel (low care) subsidies were set at uniform national levels. The introduction of the process of 'coalescence' and its successor the Funding Equalisation and Assistance Package will result in all States being paid at uniform national rates for RCS category 1-4 from 1 July 2006. Currently, funding for New South Wales for RCS category 1-4 is closest to the national average, and should be used in submissions. The Department of Health and Ageing website has the latest basic subsidy amounts for permanent care recipients.

RCS categories 5-8 are considered low care and these levels of care are equally funded for each State and Territory. The national cost for each category level should be used. As with RCS categories 1-4, the subsidy amounts are provided as a rate per care recipient per day, and the latest basic subsidy amounts for permanent care recipients are available on the Department of Health and Ageing website: www.health.gov.au/acc/finance/subsidies.htm. Justification should be provided for the selection of each RCS level used in the submission.

In addition to the government subsidy, all residents pay at least a basic daily care fee, indexed quarterly. For the latest value of the basic daily care fee contact the Aged Care Information Line on 1800 500 853 or visit the Department of Health and Ageing website: www.health.gov.au/acc/finance/resfess.htm.

Preparers of major submissions to the PBAC should assess which resident categories are affected by the proposed drug or its comparator therapy, and the extent of any variation expected on their level of dependency. The unit of measurement for

economic evaluations is the Number of Days of Stay affected by the therapy. Where the RCS category is unknown, or the effects are spread uniformly across all categories, the average across all categories should be used. Preparers of major submissions to the PBAC should use their clinical judgement in their selection of the appropriate RCS category. The submission should justify the RCS category selected.

8.2 Allied health services

Allied health services relate to those services provided by qualified allied health and paramedical professionals, other than those provided in a hospital setting. Hospital-based allied health services are included in the category ‘Hospital Services’.

The introduction of a new drug may result in a variation in the number of allied health services required. A range of such services has been identified, and a cost per consultation determined. These are shown in the following table.

Table1: Cost per consultation for Allied Health Professionals

Allied Health Professional	Cost per Consultation (\$)	
	Initial	Subsequent
Clinical psychologists/Clinical Counsellors	90.10	63.05
Dietitians	63.85	31.90
Occupational therapists	63.85	63.85
Physiotherapists	41.35	33.20
Podiatrists	38.20	32.85
Social Workers	41.60	20.40
Speech Pathologists	62.65	62.65

These costs are from fee schedules for allied health practitioners, provided by the Commonwealth Department of Veteran Affairs. Updated costs are available from the Department of Veteran Affairs website:
<http://www.dva.gov.au/health/provider/provider.htm>.

Preparers of major submissions to the PBAC should use their clinical judgement to determine which of these services are likely to be affected in the submission. The unit of measurement to be used is the number of consultations affected by the therapy. These should be valued for economic evaluations at the rates shown in the above table.

In the event of an allied health service being affected other than those listed above, the average cost of such service can be obtained from the Industry Statistics section of the Private Health Insurance Administration Council (PHIAC). These data are found on page 9 of the PHIAC ‘A Reports’. By dividing the total cost of services by the number of services, the mean cost per service can be obtained. The latest quarterly data from all states combined should be used. The date of the quarterly data used should be specified.

If an allied health service is not listed above or available from the PHIAC, such services should be identified and costed on the basis of the lowest fee charged for a standard consultation. Justification should be provided in the submission for the selection of allied health services, and where necessary, for the source and basis of the costs determined in the submission.

8.3 Home nursing

Home nursing services are provided by qualified nursing personnel at the patient's home or domicile. These exclude nursing services provided in residential care or in a hospital, details of which are included in 'Residential Care & Accommodation' and 'Hospital Services' categories respectively.

The introduction of a new drug may result in either an increase or a decrease in the number or duration of home nursing visits required. In such cases the effects should be recognised in the economic evaluation.

Unit costs for the Home and Community Care (HACC) program vary across the States and Territories. An estimated weighted average national cost of HACC services is \$56 per hour.

Preparers of major submissions to the PBAC should use their clinical judgement of measurement to determine the number and duration of such services likely to be affected in the economic evaluation, and provide justification for their assessment in the submission.

8.4 Ambulance services

The introduction of a new drug may result in either an increase or decrease in the use of ambulance services. If this is relevant to an economic evaluation, the unit of measure is each trip taken/avoided. The cost for an ambulance service should be obtained from the Industry Statistics section of the Private Health Insurance Administration Council (PHIAC). These data are found on page 9 of the PHIAC 'A Reports'. By dividing the total cost of services by the total number of services, the mean cost per service can be obtained. The latest quarterly data from all states combined should be used. The date of the quarterly data used should be specified in the submission.

8.5 Other community-based services

The introduction of new drugs often affect a wide range of community-based services other than those listed previously. It is recognised, however, that the identification of all such services is often a difficult and expensive exercise. Even more difficult is the quantification of the effects.

Examples of such services include Meals on Wheels and Community Health Services. As a general rule, these types of services are not usually included in economic evaluations. However, submissions may include consideration of these issues in the context of the social or community effects of a new drug therapy other than those already recognised in the economic evaluation. Such information, whilst not necessarily expressed in monetary terms, may supplement the economic evaluation by ensuring that all effects of the new drug are recognised and considered.

9. VARIATION TO UNIT COSTS FOR PBS BUDGET ANALYSIS

9.1 Introduction

The financial analysis of a submission prepared according to Section 4.3 of the PBAC *Guidelines* takes the perspective of the PBS. This means that cost components borne by payers other than the Commonwealth Government's PBS budget are excluded from this financial analysis.

In practice, this means that non-PBS drugs, over-the-counter drugs or drug delivery systems are excluded from this financial analysis because they incur no direct financial cost to the PBS. More importantly, this also means that the range of patient co-payments is excluded from each PBS drug's unit cost.

9.2 Calculating the unit cost of drugs from the perspective of the PBS

For nearly all drugs included in the financial analysis, from the perspective of the PBS, the unit cost to be used is the DPMQ minus the weighted average patient contribution.

There are currently seven patient co-payment categories under the PBS, which are grouped into three co-payment amounts. The highest co-payment is paid by General patients, a lower co-payment is paid by Concessional and Repatriation patients and under the General patient Safety Net provisions, and there is no co-payment under the Concessional patient and Repatriation patient Safety Net provisions. The proportion of usage across these patient co-payment categories should be reported for all currently listed drugs in the financial analysis for the most recent 12 months available. These proportions are then used to calculate the weighted average co-payment for each drug, which should be subtracted from the relevant DPMQ to calculate the unit cost to the PBS.

The weighted average co-payment for the proposed drug should normally be assumed to be that of the main comparator if it is PBS-listed. However, if the DPMQ of the proposed drug is expected to exceed the current General co-payment amount, but the DPMQ of the main comparator is below this co-payment, then particular care needs to be taken in calculating the net unit cost of the proposed drug to the PBS. This is because the volume of under co-payment use of the main comparator (for which there is no cost to the PBS) needs to be incorporated into the weighted average co-payment for the proposed drug. As necessary, the advice of the PES of the Department of Health and Ageing should be sought (refer to the address on page 1).

For Highly Specialised Drugs, the Commonwealth price should be used, without subtracting any patient contribution. This applies except for the actual or predicted proportion of prescriptions dispensed through private hospitals, for which patient contributions do apply.

APPENDIX 1: INTERNET ADDRESSES MENTIONED IN THE MANUAL

Department of Health and Ageing	http://www.health.gov.au/
Pharmaceutical Evaluation Section	pbs@health.gov.au
PBAC <i>Guidelines</i>	http://www.health.gov.au/haf/docs/pharmpac/gusubpac.htm
Schedule of Pharmaceutical Benefits	http://www1.health.gov.au/pbs/index.htm
Statutory general patient contribution rate.	http://www1.health.gov.au/pbs/contents/intro.htm
PB11 Form	http://www.health.gov.au/pbs/listing/pb11.htm
Australian Statistics on Medicines	http://www.health.gov.au/pbs/pubs/asm.htm
Medicare Benefits Schedule	http://www.health.gov.au/pubs/mbs/index.htm
Casemix Section	casemix-hfs@health.gov.au
National Hospital Cost Data: AR-DRG Cost Weights, Round 4	http://www.health.gov.au/casemix/costing/fc_r4.htm
Victorian Cost-Weights Study	http://www.dhs.vic.gov.au/ahs/weights0001.pdf
National Health Data Dictionary, v10	http://www.aihw.gov.au/publications/hwi/nhdd10/index.html
Aged Care Manuals	http://www.health.gov.au/acc/manuals/download.htm
Aged Care Fees	http://www.health.gov.au/acc/finance/resfees.htm
Aged Care Subsidies	http://www.health.gov.au/acc/finance/subsidies.htm
Home and Community Care	http://www.health.gov.au/acc/hacc/abouthacc.htm
Pharmacy Direct	http://www.pharmacydirect.com.au
Arrow Pharmaceutical Products	http://www.arrowpharma.com/about.cfm#products
Department of Veteran Affairs for Allied Health Services fees	http://www.dva.gov.au/health/provider/provider.htm
Health Insurance Commission	http://www.hic.gov.au/
Pharmacy Guild of Australia	http://www.guild.org.au/
PHIAC A Reports	http://www.phiac.gov.au/statistics/phiacareports/index.htm

If these links become broken, contact the PES of the Department of Health and Ageing (refer to the address on page 1).

APPENDIX 2: EXPECTED UPDATE FREQUENCY OF SOURCES

The Schedule of Pharmaceutical Benefits: updated four times a year (February, May, August and November).

Statutory general patient contribution: updated twice yearly (January and July).

Pharmacy dispensing fees: updated twice yearly.

The Medicare Benefits Schedule: distributed once a year (November) with a supplement produced in the following May.

Australian Statistics on Medicine: updated annually.

AR-DRGs: updated annually (August/September).

Victorian Cost-Weights Study: updated annually.

Arrow Pharmaceutical Products prices: updated frequently.

PHIAC for ambulance costs: updated on an ad-hoc basis.

Allied Health Costs for Initial and Subsequent Consultations: updated annually

APPENDIX 3: HOSPITAL SERVICES OUTPATIENT SERVICE COSTS PER AAC

Using Australian Ambulatory Classes (AAC)

<i>AAC Group</i>	<i>Description</i>	<i>Cost per visit (\$)</i>
1	Psychotherapy doctor present	275
2	Psychotherapy no doctor present	64
3	Drug abuse	66
4	Other group service doctor present	199
5	Other group service no doctor present with <7 patients	63
6	Other group service no doctor present with >6 patients	75
Emergency department presentations		
7	Poisoning with procedure	59
8	Poisoning without procedure	36
9	Fractures, dislocations and sprains with procedure	84
10	Fractures, dislocations and sprains without procedure	38
11	Other trauma and musculoskeletal with procedure	49
12	Other trauma and musculoskeletal without procedure	29
13	Alcohol and drug abuse	76
14	Infectious diseases and immunologic	37
15	Headache	33
16	Other nervous	57
17	Ophthalmology with procedure	42
18	Ophthalmology without procedure	27
19	Ear, nose, throat and mouth with procedure	39
20	Ear, nose, throat and mouth without procedure	29
21	Emphysema, bronchitis and asthma	45
22	Other respiratory diseases with procedure	67
23	Other respiratory diseases without procedure	40
24	Cardiovascular with procedure	65
25	Cardiovascular without procedure	32
26	Digestive with procedure	49
27	Digestive without procedure	37
28	Skin with procedure	38
29	Skin without procedure	26
30	Endocrine and metabolic	43
31	Urinary tract infections	36
32	Other urinary and reproductive	52
33	Neonate	45
34	Antepartum care	67
35	Postpartum care	39
36	Malignancy	33
37	Mental diseases with procedure	50
38	Mental diseases without procedure	54

<i>AAC</i>	<i>Description</i>	<i>Cost per visit (\$)</i>
39	Well care and administrative doctor present with procedure	56
40	Well care and administrative doctor present without procedure	29
41	Well care and administrative no doctor present	14
42	Others including signs and symptoms	27

Outpatient visits

43	Cardiology doctor present	73
44	Cardiology no doctor present	25
45	Dermatology doctor present	40
46	Dermatology no doctor present	14
47	Endocrinology doctor present	81
48	Endocrinology no doctor present	38
49	Stoma therapy	42
50	Gastroenterology (other than stoma therapy)	120
51	Geriatrics doctor present	197
52	Geriatrics no doctor present	54
53	Haematology doctor present	55
54	Haematology no doctor present	11
55	Immunology doctor present	112
56	Immunology no doctor present	23
57	Neurology new patient	105
58	Neurology repeat patient	78
59	Oncology doctor present	90
60	Oncology no doctor present	40
61	Rehabilitation doctor present	107
62	Rehabilitation no doctor present	63
63	Renal	157
64	Thoracic doctor present	54
65	Thoracic no doctor present	24
66	Drug and alcohol doctor present	156
67	Drug and alcohol no doctor present	15
68	Psychiatry doctor present	45
69	Psychiatry no doctor present	23
70	Obstetric and gynaecology routine prenatal and postpartum care	38
71	Obstetric and gynaecology (other than routine prenatal and postpartum care)	49
72	Ear, nose and throat	39
73	Eye doctor present	40
74	Eye no doctor present	14
75	Pain new patient	144
76	Pain repeat patient	105
77	Orthopaedics	36
78	Dental	38
79	Anaesthetics	26
80	General medical doctor present	55
81	General medical no doctor present	13
82	General surgery doctor present	37
83	General surgery no doctor present	14
84	Radiation oncology - consultation	410

<i>AAC</i>	<i>Description</i>	<i>Cost per visit (\$)</i>
85	Radiation oncology - radiological supervision and interpretation	220
86	Radiation oncology - therapeutic radiology planning and device construction	266
87	Radiation oncology-radiation therapy	440
88	Urology	46
89	Clinical sciences	30
90	Orthotics	44
91	Hyperbaric medicine	219
92	Rheumatology	52
93	General paediatrics	44
94	Pharmacology	59
95	Occupational health and safety	17
96	Physiotherapy	33
97	Occupational therapy	43
98	Speech therapy	37
99	Dietetics new patient	30
100	Dietetics repeat patient	17
101	Social work	42
102	Podiatry	25
103	Psychology	68

Diagnostic services

104	Haematology	25
105	Chemical pathology	24
106	Microbiology	18
107	Immunology	17
108	Histopathology	21
109	Cytopathology	20
110	Infertility/ pregnancy	21
111	Basic pathology	7
112	Any combination of classes 104 to 111	59
113	Miscellaneous imaging	58
114	Computerized axial tomography scan	183
115	Radiographic examination of urinary tract and report, radiographic examination of alimentary tract and biliary system and report	130
116	Radiographic examination with opaque or contrast media and report	666
117	Preparation for radiological procedure: injection of opaque or contrast media or the removal of fluid	264
118	Other radiographic	52
119	Magnetic resonance imaging	183
120	Nuclear medicine	195
121	Any combination of classes 113 to 115,118 to 120	203

Notes on costs

(a) Group services have no drug and consumable costs.

(b) Emergency departments have no drug cost.