Manual of resource items and their associated costs

for use in major submissions to the Pharmaceutical Benefits Advisory Committee involving economic analyses
(Version 4.0)

December 2009

Pharmaceutical Benefits Advisory Committee
Preface to Version 4.0

As with the previous versions of the *Manual of Resource Items and their Associated Costs*, 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 Australian Government Department of Health and Ageing (DoHA):


http://www.pbs.gov.au/html/pdf/industry/Useful_resources/Manual  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 Pharmaceutical Benefits Advisory Committee (PBAC).

Version 4.0 of the *Manual* includes several changes and updates to the previous version. The first change is that in Subsection 4.1 Proposed drug, the *Manual* now recommends, for simplicity and to be consistent with current practice, that only the Dispensed Price for Maximum Quantity (DPMQ) be used to calculate a weighted average for the proposed drug under evaluation. Previously, there were accepted add-ons for this calculation, including premiums and below general co-payment add-ons. Information is also added to this Subsection and Subsection 4.2.1 PBS Drugs on the Chemotherapy Pharmaceutical Access Program (CPAP) and other section 100 programs.

Another change is the addition of Subsection 4.5 Drug administration costs. This is a new section that focuses on the variation in administration costs according to the treatment setting. In particular, this section focuses on administration costs for infusions.

Subsection 6.2 Non-admitted patient services is updated to reflect that the Australian Ambulatory Classes (AAC) are no longer the correct source for unit costs for non-admitted patient services. In line with the *PBAC Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3)*, sponsors are now directed to use the National Hospital Cost Data Collection (NHCDC) to find the correct unit costs for non-admitted patients – specifically outpatient clinic and emergency department unit costs.
Subsection 8.1 Residential care now captures the move away from using the Resident Classification Scale (RCS) to the Aged Care Funding Instrument (ACFI) in calculating residential care subsidy rates.
Record of updates

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<th>Date</th>
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<tr>
<td>August 1992</td>
<td>Version 1.0</td>
<td>Manual released drawing on advice from consultant.</td>
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<tr>
<td>November 1993</td>
<td>Version 2.0</td>
<td>Update to unit costs for ‘Hospital services’ and ‘Community-based services’ Sections.</td>
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<td>November 2002</td>
<td>Version 3.0</td>
<td>Update to unit costs for ‘Hospital services,’ amalgamation of ‘Nursing home’ and ‘Hostel accommodation’ Sections into a ‘Residential care and accommodation’ Section. Addition of a new Section on ‘Variation to unit costs for PBS budget analysis.’</td>
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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 Pharmaceutical Benefits Scheme (PBS) to incorporate an economic as well as a clinical evaluation. PBAC has also endorsed Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3) for the conduct of economic evaluations and financial analyses. These are also available from the Pharmaceutical Evaluation Section (PES) of the Australian Government Department of Health and Ageing (DoHA) and on the DoHA website at: http://www.health.gov.au/internet/main/publishing.nsf/Content/pbacguidelines-index

In order to ensure consistency and comparability, both within and between major submissions to PBAC and over time, it is essential that major submissions to 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 sponsors 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 sponsors 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 inquiries about any aspects of its contents or use should be forwarded to:

The Pharmaceutical Evaluation Section
MDP 952
Department of Health and Ageing
GPO Box 9848
Canberra ACT 2601
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 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 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 sponsors preparing submissions to 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; and
- from sources which are regularly maintained where possible to ensure that the vast majority are kept up-to-date.

This fourth version 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 (for example, allied health services and over-the-counter drugs) have rarely, if ever, had a pivotal impact on these conclusions. For other types of resources (for example, 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 (for example, 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 (for example, 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 PBAC.
The preferred approach for either circumstance is to prepare two base case presentations of the affected economic evaluation and to ensure that the base case can be fully respecified. 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 PBAC assess the importance of the unit cost to its decision as to whether to recommend listing. The justification in a submission 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. 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. As necessary, the advice of the PES of DoHA 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 PBAC Guidelines, and is available from DoHA. 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, hospital services, diagnostic and investigational 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. Sponsors 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 main 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. Sponsors 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 Section 9, the Manual specifies the preferred method for determining variations to unit prices of PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS) drugs when conducting financial analyses from the PBS/RPBS perspective rather than the societal perspective.

Prices contained in this Manual were those current at the time of its revision (2009). 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. Sponsors should check with the PES of DoHA to ensure that they have the latest copy of the Manual.
4 Drugs

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 the dispensed maximum quantity for each PBS item 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

4.1.1 Proposed drug for general PBS

This refers to the drug which is the subject of the application for listing on the Schedule of Pharmaceutical Benefits, as identified on the DoHA form PB11, ‘Application to list a Drug or Medicinal Preparation as a Pharmaceutical Benefit.’ The current PB11 form is available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-pb11.htm

Except where identified otherwise below, 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 current Schedule is available at: www.pbs.gov.au/html/healthpro/publication/list

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 Pharmaceutical Benefits Remuneration Tribunal (PBRT), and are periodically varied (see Appendix 2). At the time of publication, the approved mark-up was as follows:

- List price ≤ $30, approved mark-up 15%;
- List price ≥ $30.01, but ≤ $45, approved mark-up $4.50;
- List price ≥ $45.01, but ≤ $180, approved mark-up =10%;
- List price ≥ $180.01, but ≤ $450, approved mark-up = $18;
- List price ≥ $450.01, but ≤ $1750, approved mark-up = 4%;
- List price ≥ $1750.01, approved mark-up $70.

Sponsors should therefore ascertain the current dispensing fee and use the most up to date approved mark-up and apply them to the List Price to derive the equivalent of
the DPMQ for the proposed drug. Current dispensing fees are available from the
PBS website under the ‘Health Professionals’ section in ‘Explanatory Notes:
Community Pharmacy Agreement, and current pricing is available from the latest
Agreement. At the time of publication, these details were found under paragraph
14.4, page 9, of the *Fourth Community Pharmacy Agreement*. This document is
available on the DoHA website at:
4CA2570D000803429/$File/4CPA%20October%2007.pdf

When the price for the proposed drug is determined on the basis of cost-
minimisation, and the main comparator for a proposed drug is a PBS-listed drug to
which special pricing arrangements apply – and so the effective price is not known,
then the DPMQ in the current *Schedule of Pharmaceutical Benefits* should be used
in establishing the price until such time as the effective price can be revealed to the
sponsor. To determine whether a product has special pricing arrangements, consult
the relevant PBS Therapeutic Relativity Sheet. These are available at:
pricing-therelev.htm

### 4.1.2 Proposed Highly Specialised Drug

In all cases, except private hospital patients, the price to be applied to a proposed
Highly Specialised Drug dispensed under section 100 of the *National Health Act
1953* is the ex-manufacturer’s price, as found in the Highly Specialised Drug section
of the *Schedule of Pharmaceutical Benefits*. The current Schedule is available at:

For the proportion of a proposed Highly Specialised Drug dispensed through private
hospitals, the price to be applied is the ex-manufacturer’s price plus the normal PBS
ready-prepared dispensing fee plus a mark-up ascertained as follows:
- 10% for drugs with a price ex-manufacturer of less than $40;
- $4 for drugs with a price ex-manufacturer of between $40 and $100;
- 4% for drugs with a price ex-manufacturer of between $100.01 and $1000;
- $40 for drugs with a price ex-manufacturer of greater than $1000.

The basis for remunerating dispensing fees and mark-ups for Highly Specialised
Drugs dispensed through private hospitals is updated with each Community
Pharmacy Agreement, and the current basis is available from the latest Agreement.
At the time of publication, details of fees and mark-ups were found under paragraph
22, page 15, of the *Fourth Community Pharmacy Agreement*.

The calculation of the weighted average price for a proposed Highly Specialised
Drug should be based on the proportions dispensed across other patients and private
hospital patients for the closest therapy that is currently listed (and specifically the
main comparator drug if that is PBS-listed) and the relevant price for each setting.
See Subsection 4.2.2 for further details on this calculation.
4.1.3 Proposed drug for other section 100 programs

The price to be applied to drugs proposed for section 100 listing under the Botulinum Toxin Program, the Human Growth Hormone Program, the IVF/GIFT Program, the Opiate Dependence Program, or the Special Authority Program is the ex-manufacturer’s price, as found in the relevant section of the Schedule of Pharmaceutical Benefits.

4.1.4 Proposed chemotherapy drug dispensed through CPAP

Under the Chemotherapy Pharmaceuticals Access Program (CPAP), the Australian Government funds eligible drugs for dispensing by day and non-admitted public hospital patients in participating hospitals. These chemotherapy drugs are also dispensed through the normal arrangements. Chemotherapy drugs available under this program are listed in the Chemotherapy Pharmaceuticals Access Program Supplement (CPAP Supplement) to the Schedule of Pharmaceutical Benefits. The CPAP Supplement is available at: www.pbs.gov.au

For the proportion of a proposed chemotherapy drug dispensed under the CPAP arrangements, the price to be applied is the ex-manufacturer’s price. For the remaining proportion of a proposed chemotherapy drug dispensed under the normal arrangements, the price to be applied is the DPMQ.

The calculation of the weighted average price for a proposed chemotherapy drug which is eligible under the CPAP arrangements should be based on the proportions dispensed across the CPAP arrangements and the normal arrangements for the closest therapy that is currently listed (and specifically the main comparator drug if that is PBS-listed) and the relevant price for each setting. See Subsection 4.2.4 for further details of this calculation.

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 main comparator therapy. Two types of drugs are included in this category.

4.2.1 General PBS drugs

These include co-prescribed drugs already included in the Schedule of Pharmaceutical Benefits. Except where identified otherwise below, 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.
4.2.2 Highly Specialised Drugs

In all cases, except private hospital patients, the price to be applied to a Highly Specialised Drug dispensed under section 100 of the National Health Act 1953 is the ex-manufacturer’s price, as found in the relevant section of the Schedule of Pharmaceutical Benefits. The current Schedule is available at: http://www.pbs.gov.au/html/healthpro/publication/list

For the proportion of a Highly Specialised Drug dispensed through private hospitals, the price to be applied is the ex-manufacturer’s price plus the normal PBS ready-prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than $40;
- $4 for drugs with a price ex-manufacturer of between $40 and $100;
- 4% for drugs with a price ex-manufacturer of between $100.01 and $1000;
- $40 for drugs with a price ex-manufacturer of greater than $1000.

The basis for remunerating dispensing fees and mark-ups for Highly Specialised Drugs dispensed through private hospitals is updated with each Community Pharmacy Agreement, and the current basis is available from the latest Agreement. At the time of publication, details of fees and mark-ups were found under paragraph 22, page 15, of the Fourth Community Pharmacy Agreement.

The calculation of the weighted average price for a Highly Specialised Drug should be based on the proportions of the drug dispensed across other patients and private hospital patients and the relevant price for each setting.

Before calculating the weighted average price of a Highly Specialised Drug, sponsors will need to determine the most recent annual volumes of the drug dispensed across other patients and private hospital patients.

The most recent annual volume dispensed for other patients, which is updated on a quarterly basis, can be determined by requesting this information from the Hospital Pharmaceuticals Section of DoHA through: pbs@health.gov.au

In order to determine the most recent annual volume dispensed for private hospital patients, the relevant PBS item numbers and dates corresponding to other patients can be put into a calculator on the Pharmaceutical Benefits Schedule Item Reports page of the Medicare Australia site. The calculator is located at: https://www.medicareaustralia.gov.au/statistics/pbs_item.shtml

To calculate the weighted average price for a Highly Specialised Drug, first calculate \( a = \text{the volume dispensed for other patients multiplied by the ex-manufacturer's price} \). Then calculate \( b = \text{the volume dispensed for private hospital patients multiplied by the relevant price determined above} \). The weighted average price is then calculated as \( (a+b) \) divided by the total volume dispensed.
4.2.3 PBS drugs dispensed through other section 100 programs

The price to be applied to drugs with section 100 listing under the Botulinum Toxin Program, the Human Growth Hormone Program, the IVF/GIFT Program, the Opiate Dependence Program, or the Special Authority Program is the ex-manufacturer’s price, as found in the relevant section of the Schedule of Pharmaceutical Benefits.

4.2.4 PBS drugs dispensed through CPAP

For the proportion of a chemotherapy drug dispensed under the Chemotherapy Pharmaceuticals Access Program (CPAP), the price to be applied is the ex-manufacturer’s price, as found in the CPAP Supplement to the Schedule of Pharmaceutical Benefits.

For the remaining proportion of a chemotherapy drug dispensed under the normal arrangements, the price to be applied is the DPMQ, as found in the Schedule of Pharmaceutical Benefits.

The calculation of the weighted average price for a chemotherapy drug which is eligible under the CPAP arrangements should be based on the proportions of the drug dispensed across the CPAP arrangements and the normal arrangements and the relevant price for each setting.

Before calculating the weighted average price of a chemotherapy drug, including its use under CPAP, sponsors will first need to ensure that the chemotherapy drug is eligible for listing under CPAP, and if so, locate the PBS item number(s) under both the normal dispensing arrangements and CPAP. The different PBS item numbers are necessary to determine the proportions dispensed under the normal arrangements and under the CPAP arrangements. In order to determine the most recent annual volume dispensed under each arrangement, the relevant PBS item numbers and dates can be put into a calculator on the Pharmaceutical Benefits Schedule Item Reports page of the Medicare Australia site. The calculator is located at: https://www.medicareaustralia.gov.au/statistics/pbs_item.shtml

To calculate the weighted average price for a chemotherapy drug eligible under CPAP, first calculate \( a = \) the volume dispensed under CPAP multiplied by the ex-manufacturer’s price. Then calculate \( b = \) the volume dispensed under the normal arrangements multiplied by the DPMQ. The weighted average price is then calculated as \( \frac{a+b}{\text{total volume dispensed}} \).

4.2.5 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 at:
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. Current Pharmacy Direct prices are available at: http://www.pharmacydirect.com.au

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 main 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, nebuliser 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.

4.5 Drug administration costs

Where there are additional medical service costs of administering the drug, these costs should be included. The most common circumstance where these arise is if a drug is administered by infusion. They extend beyond the costs of the drug delivery system (see Subsection 4.4 above).

The cost of administering a drug varies by treatment setting. Different unit costs will need to be derived for each relevant setting. Taking chemotherapy infusion as the most frequently encountered example, a different unit cost will be relevant if chemotherapy is administered as an inpatient or an outpatient, or in a public or private hospital (see figure below). Note that the cost of administering a drug to an inpatient in a public hospital is only relevant to a submission which can show a reduction in use of a drug in this setting as a result of the requested PBS listing.
In order to calculate the chemotherapy administration cost alone for each relevant setting, sponsors should subtract the Average Direct Component Cost for Pharmacy from the Average Total Cost of the applicable Australian Refined Diagnosis Related Group (AR-DRG). The Average Direct Component Cost for Pharmacy is found in the National Hospital Cost Data Collection (NHCDC) under the column ‘Pharmacy’. The NHCDC provides national cost weights for AR-DRGs and other statistics relevant to health service costing and planning. The ‘Overhead’ costs under ‘Pharmacy’ should not be subtracted from the Average Total Cost of the relevant AR-DRG.


Since the AR-DRGs and NHCDC are subject to review, the submission should specify the effective date of the AR-DRG Classification and NHCDC round used when finalising the economic evaluation (ie AR-DRG v5.1, Round 12 (2007-8)).

In a limited number of circumstances, unit costs from the Medical Benefits Schedule (MBS) for administering a drug are available under particular MBS items, for example chemotherapy, sympatholytic agents, chronic intractable pain,
immunomodulating agents, botulinum toxin, amnioinfusion for therapeutic purposes, epidural or intrathecal infusion, baclofen and verteporfin.

If no MBS item is available for the administration of a proposed new drug, a standard MBS consultation item should be used. Sponsors should use their clinical judgement in the selection of the MBS item relevant to the economic evaluation, and should provide justification for the items selected, including with respect to the duration of administration (specifically the time in which the prescriber is taking an active role to administer the drug), the type of prescriber involved (eg general practitioner, specialist, consultant physician), and whether the type of consultation is an initial or subsequent consultation.

If a sponsor considers that the circumstances of administering a proposed new drug warrant that a new MBS item should be established, then the advice of the PES of DoHA should be sought (refer to the address on page 1) and this fact included in the submission to PBAC with a justified indicative unit cost.

Where it is known or expected that the drug is being, or will be administered, in more than one relevant setting, sponsors will need to estimate the proportion of administrations in each setting. A weighted average unit cost should then be calculated using the proportion of all administrations in each relevant setting as the basis for the weighting.
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 Medicare Benefits Schedule (MBS), as presented in the most recent version of the Medicare Benefits Schedule book issued by DoHA. The current MBS is available at: http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Medicare-Benefits-Schedule-MBS-1. Sponsors should use their clinical judgement in the selection of the MBS 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 MBS.

Since both the structures of the MBS and its associated Schedule Fees are subject to periodic review and amendment, sponsors should ensure that they use the most recent available version. The submission should specify the effective date of the MBS used when finalising the economic evaluation.
6 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, v14 2008* (available from the Australian Institute of Health and Welfare website: [http://www.aihw.gov.au/publications/index.cfm/title/10326](http://www.aihw.gov.au/publications/index.cfm/title/10326)) non-admitted care includes care provided to a patient who receives care or services in an emergency or outpatients department, but ‘who is not formally admitted at the time when the care is provided.’

Sponsors 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 DoHA should be sought (refer to the address on page 1).

6.1 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 main 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 AR-DRG Classification are available on the DoHA website at: [http://www.aihw.gov.au/publications/index.cfm/title/10326](http://www.aihw.gov.au/publications/index.cfm/title/10326)

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. Additional information about AR-DRGs can be requested from the Casemix Section directly via e-mail: casemix-hfs@health.gov.au

The submission should specify the effective date of the AR-DRG Classification and cost weights used when finalising the economic evaluation (ie AR-DRG v5.1, Round 12 (2007-8)). If a sponsor wishes to justify the application of costs obtained from the National Private Sector Cost Weights for a particular AR-DRG, the submission should provide evidence to show that the particular hospital service is more widely provided in the private hospital setting than in the public hospital setting. These costs should be presented in a sensitivity analysis in place of using costs from the National Public Sector. Sponsors should also justify the addition of any particular medical and diagnostic investigational costs borne by the MBS incurred during an admission to a private hospital.

Due to persistent concerns about whether the cost estimates are verifiable when disaggregated beyond an episode of hospitalisation, it cannot 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 DoHA 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/archive/costweights01/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.

6.2 Non-admitted patient services

Non-admitted patient services include all hospital services provided to a patient who receives care or services in an emergency or outpatients department, but ‘who is not formally admitted at the time when the care is provided.’ Non-admitted services from acute care hospitals have been classified according to the NHCDC.

Where the introduction of drug therapy is expected to result in a variation in the number of presentations to emergency departments, the units of measurement should be by triage category according to the NHCDC as average cost per presentation. There are five triage categories that are determined according to the Australian Triage Scale (ATS):
1. Immediately life-threatening.
2. Imminently life-threatening.
3. Potentially life-threatening or important time-critical treatment or severe pain.
4. Potentially life-serious or situational urgency or significant complexity.
5. Less urgent.

Information on how to assess a patient for allocation to a triage category is found on pages 5-7 of the Guidelines for the Implementation of the Australasian Triage Scale in Emergency Departments. This document is available on the Australian College of Emergency Medicine (ACEM) website at: http://www.acem.org.au/media/policies_and_guidelines/G24_Implementation__ATS.pdf

Where the introduction of drug therapy is expected to result in a variation in the number of presentations to outpatient visits, the units of measurement should be by service type according to NHCDC as average cost per occasion of service. In the current Round 12 report, these are listed on pages 145-149. For example, Outpatient Allied Health services costs are found in Table 120 under ‘Average Cost per Occasion of Service’ ‘Round 12’ in the current Round. Sponsors should use their clinical judgement in the selection of the NHCDC cost relevant to the economic evaluation, and should provide justification for their selection.

If a patient presenting for a non-admitted service is admitted to hospital for care, it is essential that there is no ‘double counting’ of costs and that only the appropriate AR-DRG cost for an ‘admitted patient’ is used. In other words, a patient’s initial ‘non-admitted’ cost should not be counted in addition to the ‘admitted’ cost.
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 Medicare Benefits Schedule (MBS), as presented in the most recent version of the Medicare Benefits Schedule issued by DoHA. The current MBS is available at: http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Medicare-Benefits-Schedule-MBS-1 Sponsors should use their clinical judgement in the selection of the MBS 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 MBS.

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

If no MBS item is available for a particular diagnostic and investigational service, the advice of the PES of DoHA should be sought (refer to the address on page 1) and this fact included in the submission.
8 Community-based services

8.1 Residential care

Residential care refers to care 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 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 provision of residential care is categorised according to the Aged Care Funding Instrument (ACFI), which replaced the Resident Classification Scale (RCS) from 20 March 2008. The ACFI is based primarily on the resident’s dependency (need for care) rather than on care planning or care provided by an aged care home.

The ACFI consists of twelve care need questions. Diagnostic information about mental and behavioural disorders and other medical conditions is also collected. Information from the ACFI is used to categorise residents as having low, medium or high care needs in each of the following three care domains:

- Activities of daily living (ADL)
- Behaviour (BEH)
- Complex Health Care (CHC)


Sponsors should assess which resident categories would follow therapy using the proposed drug or its main comparator therapy, and the extent of any variation expected on the resident’s level of dependency. Sponsors will need to calculate the number of days affected by the therapies. The unit of measurement for economic evaluations is the sum of the appropriate Daily ACFI Subsidy Rate and the basic daily care fee.

The subsidy paid for a resident will be the lesser of the sum of the amounts payable for the three care domains (ADL + BEH + CHC) and the maximum Daily ACFI Subsidy Rate. The maximum Daily ACFI Subsidy Rate as at 1 July 2009 is $150.54, and is set to increase on a yearly basis. Where the ACFI category is unknown, or the effects are spread uniformly across all categories, the average across all categories should be used. Sponsors should use their clinical judgement in their selection of the appropriate ACFI category. The submission should justify the ACFI category selected. Daily ACFI Subsidy Rates are available at:
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 DoHA website at: http://www.health.gov.au/internet/main/publishing.nsf/Content/ageing-finance-resfees.htm

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 to admitted or non-admitted patients. 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.

Table 1: Cost per consultation for Allied Health Professionals

<table>
<thead>
<tr>
<th>Allied Health Professional</th>
<th>Cost per Consultation ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial</td>
</tr>
<tr>
<td>Clinical psychologists/Clinical counsellors</td>
<td>119.75</td>
</tr>
<tr>
<td>Diabetes educators</td>
<td>78.40</td>
</tr>
<tr>
<td>Dietitians</td>
<td>80.30</td>
</tr>
<tr>
<td>Occupational therapists</td>
<td>79.05</td>
</tr>
<tr>
<td>Osteopaths</td>
<td>57.55</td>
</tr>
<tr>
<td>Physiotherapists</td>
<td>57.55</td>
</tr>
<tr>
<td>Podiatrists</td>
<td>57.55</td>
</tr>
<tr>
<td>Social workers</td>
<td>57.55</td>
</tr>
<tr>
<td>Speech pathologists</td>
<td>96.00</td>
</tr>
</tbody>
</table>

These costs are from fee schedules for allied health practitioners, provided by the Australian Government Department of Veteran Affairs (DVA). They were taken as fees listed under ‘Rooms’ in the schedule of fees. ‘Rooms’ indicates the fees for attending an allied health professional in their clinic or practice, as opposed to fees indicated for visits in the home, hospital or other care facilities. Updated costs are available from the DVA website: http://www.dva.gov.au/service_providers/Fee_schedules/Pages/index.aspx

Sponsors 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 10 of the PHIAC ‘A Reports’ and can be accessed online at: http://www.phiac.gov.au/for-industry/industry-statistics/datatablesphiaca/ 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 the ‘All States Combined’ report 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,’ 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 national cost of a HACC home nursing service in 2009 is $76 per hour.

Sponsors 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 10 of the PHIAC ‘A Reports’ and are available on line at: http://www.phiac.gov.au/for-industry/industry-statistics/datatablesphiaca/ 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 the ‘All States Combined’ report 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 a new drug may affect a wide range of community-based health services other than those listed previously. Examples of such services include Meals on Wheels and Community Health Services.

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 of a new drug on these services. Thus, these types of services have not usually been included in economic evaluations. However, a submission 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 on the provision of resources are recognised and considered.
9 Variation to unit costs of drugs for Section E of a submission to PBAC

9.1 Introduction

The financial analysis in a submission prepared according to Subsections E.2 - E.4 of PBAC Guidelines takes the perspective of the PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS). This means that cost components borne by payers other than the Australian Government are excluded from this financial analysis.

In practice, this means that non-PBS/RPBS 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/RPBS. This also means that the range of patient co-payments is subtracted from each PBS/RPBS drug’s unit cost.

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

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

There are currently six patient co-payment categories under the PBS, which are grouped into three co-payment amounts. Current information about the PBS/RPBS patient contribution rates are found at: http://www.pbs.gov.au/html/consumer/pbs/about. 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 disaggregation 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. The relevant co-payment should then be subtracted from the relevant DPMQ to calculate the unit cost to the PBS/RPBS in each category.

The disaggregation for the proposed drug should normally be assumed to be that of the closest therapy that is currently listed (and specifically the main comparator if it is PBS-listed).

For Highly Specialised Drugs, the ex-manufacturer’s price should be used for the proportion of product dispensed for other patients, without subtracting any patient contribution. For the proportion of product dispensed through private hospitals, the standard patient contribution should be subtracted based on the six patient co-payment categories above.

A proforma for estimating the extent of use and financial implications of the proposed drug is provided in an Excel format to aid sponsors in the preparation of submissions (this corresponds to Section E of the PBAC Guidelines). This proforma can be accessed on the DoHA website at:
**Appendix 1  Internet addresses mentioned in the Manual**

<table>
<thead>
<tr>
<th>Source</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemotherapy Pharmaceuticals Access Program (CPAP) Supplement</td>
<td><a href="http://www.pbs.gov.au">http://www.pbs.gov.au</a></td>
</tr>
<tr>
<td>Arrow Pharmaceutical Products</td>
<td><a href="http://www.arrowpharma.com/about.cfm#products">http://www.arrowpharma.com/about.cfm#products</a></td>
</tr>
<tr>
<td>Pharmacy Direct</td>
<td><a href="http://www.pharmacydirect.com.au">http://www.pharmacydirect.com.au</a></td>
</tr>
<tr>
<td>Resource</td>
<td>URL</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Casemix Section</td>
<td><a href="mailto:casemix-hfs@health.gov.au">casemix-hfs@health.gov.au</a></td>
</tr>
<tr>
<td>Department of Veteran Affairs for Allied Health Services fees</td>
<td><a href="http://www.dva.gov.au/service_providers/Fee_schedules/Pages/index.aspx">http://www.dva.gov.au/service_providers/Fee_schedules/Pages/index.aspx</a></td>
</tr>
</tbody>
</table>

If these links become broken, contact the PES of DoHA (refer to the address on page 1).
Appendix 2  Expected update frequency of sources


Pharmacy dispensing fees: updated yearly on 1 July.

Chemotherapy Pharmaceuticals Access Program (CPAP) Supplement: updated monthly.

Arrow Pharmaceutical Products prices: updated frequently.

AR-DRGs: new version released every two years.

NHCDC Rounds: updated annually.

The Medicare Benefits Schedule is updated regularly. A table with scheduled updates can be found at: http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/FAQ-Next_Update

Victorian Cost-Weights Study: updated annually.

Daily ACFI Subsidy Rates: updated yearly on 1 July.

Basic daily (residential) care fees: updated quarterly.

Allied Health Costs for Initial and Subsequent Consultations: updated annually.

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

PBS/RPBS patient contribution rate: updated 1 January each year.