
Manual of resource items and their associated unit costs

**For use in submissions to the
Pharmaceutical Benefits Advisory Committee
involving economic analyses**

Version 5.0

December 2016



Australian Government

Department of Health

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Record of updates

Date	Version	Summary of changes
August 1992	Version 1.0	Manual released drawing on advice from consultant.
November 1993	Version 2.0	Update to unit costs for 'Hospital services' and 'Community-based services' sections.
November 2002	Version 3.0	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'.
December 2009	Version 4.0	Update to 'Drugs', 'Hospital services' and 'Residential care' sections.
December 2016	Version 5.0	Update to all sections.

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Abbreviations and acronyms

Term	Definition
ACFI	Aged Care Funding Instrument
AEMP	approved ex-manufacturer price
AHI	Administration, Handling and Infrastructure
AR-DRG	Australian Refined Diagnosis Related Group
DPMA	dispensed price for maximum amount
DPMQ	dispensed price for maximum quantity
EFC	Efficient Funding of Chemotherapy
MBS	Medicare Benefits Schedule
NHCDC	National Hospital Cost Data Collection
PBAC	Pharmaceutical Benefits Advisory Committee
PBAC Guidelines	<i>Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee</i>
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme

Preface

As with previous versions of the *Manual of resource items and their associated costs* (the manual), 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 ensure that readers use the most up-to-date unit costs. These sites are hyperlinked in the [electronic version of the manual](#) on the [Pharmaceutical Benefits Scheme website](#), and the URLs of the sites are listed in Appendix 1.

Sponsors are advised to consult the latest version of the manual and the source documents before finalising a submission to the Pharmaceutical Benefits Advisory Committee.

Version 5.0 of the manual includes several changes and updates to the previous version.

Section 4 'Medicines, medicinal preparations or vaccines' has been updated to give advice on calculating prices for various settings, including public and private hospitals, various s100 programs, and the National Immunisation Program. Subsection 4.5 'Medicine administration costs' has been simplified to a preference for using only the relevant Medicare Benefits Schedule (MBS) fee if the medicine or medicinal preparation is administered by infusion.

Section 5 'Medical services, including investigative, diagnostic and allied health services' has been updated to include professional services provided by a qualified medical practitioner, as well as other health care practitioners. This change follows the availability of MBS data for selected nonmedical health professionals. Section 5 also includes the information on diagnostic and investigational services that was previously found in Section 7.

Section 6 'Hospital services' now separates nonadmitted hospital care from emergency department services, because they are different concepts and each has a different classification.

Section 7 is now titled 'Community-based services', following the relocation of information on diagnostic and investigational unit costs to Section 5. Subsection 7.2 'Home care' has been added in Version 5.0 to include the current cost of providing complex care to older people living in their own homes.

Subsection 8.2 'Calculating the financial unit cost of medical services from the perspective of the MBS' is new to Version 5.0 and clarifies the Medicare rebate amount to be used as the unit cost.

1 Introduction

Since 1993, the Pharmaceutical Benefits Advisory Committee (PBAC) has required that submissions to list a proposed medicine on the Pharmaceutical Benefits Scheme (PBS) incorporate an economic evaluation, as well as a clinical evaluation. The PBAC has also endorsed *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee* (Version 5.0) (the PBAC Guidelines) for conducting economic evaluations and financial analyses. The [PBAC Guidelines](#) are available from the PBS website.

To ensure consistency and comparability within and between submissions to the PBAC and over time, it is essential that submissions use consistent measures of medical and other health-related services relevant to therapy involving a medicine, and cost them in a consistent manner. This manual has been developed to help sponsors to ensure consistency when preparing economic evaluations.

This manual has been designed to reflect the range of medical and other health-related services that may be affected by the introduction of new medicines to the PBS. The services included in the manual are based on economic evaluations and financial analyses conducted in Australia and overseas, particularly in submissions to the PBAC. The principles adopted to determine the unit costs of services are based on widely accepted methods and analyses.

This manual is a dynamic document that is subject to ongoing review and periodic updating. As unit costs change and new data sources become available, the manual will also change. Users of the manual and other interested parties are encouraged to contribute to, and participate in, this process of change and improvement. Suggestions to improve the manual are welcome, and inquiries about any aspects of its contents or use should be directed to:

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2 General principles and recommendations

This manual identifies the types of resources that are relevant to economic evaluations in 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; if other resource types are considered relevant, a case can be made in a submission to include these.

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 episodes and residential care.

Comparability of unit costs provides for a ‘reference case’ across economic evaluations considered by the PBAC. This means that decisions to list a medicine on the PBS are influenced by the medicine itself, rather than the selection of unit costs. It also improves transparency, because all sponsors preparing submissions to the PBAC can be confident that all other submissions are referring to the same set of costs.

Other advantages to this approach are that the unit costs are independently verifiable, accessible, and from sources that are regularly maintained (where possible) to ensure that the vast majority of unit costs are up to date.

Version 5.0 of the manual maintains the objective of balancing comparability and accuracy, but is now also based on the experience of applying the manual for more than two decades. History indicates that resources and their unit costs have had a varying impact on the conclusions of economic evaluations. Some types of resources (eg over-the-counter medicines) have rarely, if ever, had a pivotal impact on these conclusions. For other types of resources (eg medical services and other PBS medicines), costing issues usually arise from the number of resources changed, rather than the unit cost of each resource. Occasionally, the unit cost becomes important (eg claims of heterogeneity across hospital services within an Australian Refined Diagnosis Related Group [AR-DRG]), and variations have been included in submissions. These are considered on a case-by-case basis.

Where the manual does not identify a particular resource, or where an alternative to the recommended unit cost may be more accurate and relevant for the PBAC’s decisions, the preferred approach is to prepare two base-case presentations of the economic evaluation and to ensure that the base case can be fully respecified. Present one base case according to the unit costs recommended in the manual (to promote comparability of PBAC decisions) and one base case that uses the alternative costs. Justify the use of alternative unit costs, and present two sets of sensitivity analyses, one for each base case. This helps the PBAC to assess the importance of the unit cost to its decision.

Resources could be included in an economic evaluation that are not included in this manual, and for which the only unit cost available has not been recently updated. The Australian Bureau of Statistics has recommended that the most appropriate deflator in these circumstances is the [Implicit Price Deflator](#) for government final consumption expenditure on hospital and clinical services.

3 How to use this manual

This manual is to be used in conjunction with the PBAC Guidelines. It lists medical and other health-related services that may be affected by therapy involving a medicine, and provides unit costs for services that are relevant to the economic evaluation of these therapies in the context of the PBS.

The manual comprises separate sections that relate to different categories of health care: medicines, medical services, hospital services and community-based services. Within each of these categories, individual resource items are identified and classified, and the units of measurement are defined. The associated unit costs are also presented to determine their value in an economic evaluation. Section 8 specifies the preferred method for determining variations to unit costs of PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS) medicines when conducting financial analyses from the PBS/RPBS perspective rather than the societal perspective.

Sponsors are advised to familiarise themselves with each section of the manual to ensure that the data gathered during clinical trials for both the proposed medicine and its main comparator are compatible with these requirements.

Some economic evaluations may identify an item that is not included in this manual. In these cases, apply the general principles associated with establishing the unit cost in the resource category relevant to that item. Explain the nature of the resource item and the data sources used to determine its unit cost.

Unit costs in this manual were current at the time of its revision (2016). These unit costs will periodically be updated, and the manual will be revised as necessary. The vast majority of unit costs that are likely to be used in submissions are not contained in this manual – instead, cross-references are made to other sources that include all the most frequently used unit costs (see hyperlinks throughout the manual, and Appendix 1).

The phrase ‘medicine or medicinal preparation’ within the manual should be interpreted as being the same as the phrase ‘drug or medicinal preparation’ under the *National Health Act 1953*.

As necessary, seek advice from the Pharmaceutical Evaluation Branch of the Australian Government Department of Health about how to determine a suitable unit cost (see contact details on page 1).

4 Medicines, medicinal preparations or vaccines

This category of resource item refers to all medicines, medicinal preparations or vaccines used as part of, or as a by-product of, nonhospital treatment with the proposed product or its main comparator. The category covers medicines and medicinal preparations to be considered for listing on the PBS, and vaccines to be considered for listing on the National Immunisation Program.

This category does not include medicines or medicinal preparations that are prescribed or used in an inpatient public hospital setting that are not subsidised through the PBS – these are referred to in Section 6 ‘Hospital services’.

4.1 Proposed medicine, medicinal preparation or vaccine

Except for Subsection 4.1.3, the ‘proposed medicine, medicinal preparation or vaccine’ refers to the medicine, medicinal preparation or vaccine that is the subject of the application for listing on the Schedule of Pharmaceutical Benefits, as identified on the Department of Health form PB11, ‘Application to list a drug or medicinal preparation as a pharmaceutical benefit’. The [current PB11 form](#) is available from the department’s website.

The PB11 form requires the applicant to propose an approved wholesaler price (ex-manufacturer price), which constitutes the formal application for PBS listing.

Depending on the dispensed settings described in Subsections 4.1.1–4.1.2, the dispensed price for maximum quantity (DPMQ) or the dispensed price for maximum amount (DPMA) may constitute any number of the following:

- the approved ex-manufacturer price (AEMP)
- a wholesale mark-up
- a pharmacy mark-up
- the relevant fixed dispensing fee
- any other fees associated with dispensing.

For more information, refer to the [explanatory notes](#) on the department’s website.

Following PBAC recommendation of a medicine, medicinal preparation or vaccine for listing, the sponsor and the department may negotiate a price other than the dispensed price. Such negotiations may lead to agreed prices based on average or weighted pricing techniques.

It is possible to have only a single price for a medicine or medicinal preparation on the PBS. If different prices are determined for different PBS restrictions, the final PBS price will be weighted between the various prices based on estimates of use across the various restrictions.

In some cases, the price for the proposed medicine or medicinal preparation is determined on the basis of cost minimisation, and the main comparator is a PBS-listed medicine that has a special pricing arrangement with a confidential effective price. In these situations, use the DPMQ or DPMA in the current Schedule of Pharmaceutical Benefits to establish the price until the department can reveal the effective price.

To determine whether a PBS-listed product has a special pricing arrangement, consult the notes for that product in the current Schedule of Pharmaceutical Benefits or the relevant [PBS Therapeutic Relativity Sheet](#), available on the department's website.

4.1.1 Proposed medicine or medicinal preparation for supply as a pharmaceutical benefit under s85 of the *National Health Act 1953*

Where an s85 PBS listing is being sought, the price for the proposed medicine or medicinal preparation is the equivalent of the DPMQ as defined in the Schedule of Pharmaceutical Benefits.

Community pharmacy setting

Where a medicine or medicinal preparation is dispensed in the [community pharmacy setting](#), the DPMQ is determined by the following:

- the AEMP
- a two-tier wholesale mark-up
 - for an AEMP up to and including \$930.06, a mark-up of 7.52% applies on the AEMP
 - for an AEMP greater than \$930.06, a flat \$69.94 mark-up applies on the AEMP
- a three-tier pharmacy mark-up in the form of the Administration, Handling and Infrastructure (AHI) fee. Pharmacy mark-ups are updated with each Community Pharmacy Agreement and are subject to yearly indexation. Determine the current AHI fees and apply them to the List Price (AEMP inclusive of wholesale mark-up)
- the relevant fixed dispensing fee of either
 - a ready-prepared fee, for a medicine or medicinal preparation that does not require further preparation or compounding, or
 - an extemporaneously prepared fee (in extemporaneously prepared products, where reconstitution requires a solvent, an additional water fee is applied)
- any other relevant fees associated with dispensing, such as
 - dangerous medicine fee for the supply of a Schedule 8 medicine
 - wastage fee where broken packs are involved.

These fees are subject to indexation. [Current fixed dispensing fees](#) are available on the department's website.

Private hospital setting

Where a medicine or medicinal preparation is dispensed in the private hospital setting, the DPMQ is determined by the following:

- the AEMP
- a flat wholesale mark-up of 11.1% applied on the AEMP
- a flat pharmacy mark-up of 1.4% applied on the List Price (AEMP inclusive of wholesale mark-up)
- the relevant fixed dispensing fee of either
 - a ready-prepared fee, for a medicine or medicinal preparation that does not require further preparation or compounding, or
 - an extemporaneously prepared fee (in extemporaneously prepared products, where reconstitution requires a solvent, an additional water fee is applied)
- any other relevant fees associated with dispensing, such as

- dangerous drug fee for the supply of a Schedule 8 medicine
- wastage fee where broken packs are involved.

These fees are subject to indexation. [Current fixed dispensing fees](#) are available on the department's website.

Public hospital setting

Where a medicine or medicinal preparation is dispensed in the public hospital setting, the DPMQ is determined by the following:

- the AEMP
- a flat wholesale mark-up of 11.1% applied on the AEMP.

No other mark-ups or fees apply when a medicine or medicinal preparation is dispensed in the public hospital setting.

4.1.2 Proposed medicine or medicinal preparation for supply as a pharmaceutical benefit under various s100 special arrangements of the *National Health Act 1953*

Section 100 Highly Specialised Drugs Program (s100 HSD)

Where an s100 HSD listing is being sought, the price to be applied to the proposed medicine or medicinal preparation is the equivalent of the DPMQ as defined in the Schedule of Pharmaceutical Benefits.

Where a medicine or medicinal preparation is dispensed in the s100 HSD private hospital setting or the s100 HSD community access setting, the DPMQ is determined by the following:

- the AEMP
- a four-tier pharmacy mark-up
 - for an AEMP for the listed maximum quantity of up to and including \$40.00, a mark-up of 10% applies on the AEMP
 - for an AEMP for the listed maximum quantity from \$40.01 up to and including \$100.00, a flat mark-up of \$4.00 applies on the AEMP
 - for an AEMP for the listed maximum quantity from \$100.01 up to and including \$1000.00, a mark-up of 4% applies on the AEMP
 - for an AEMP for the listed maximum quantity of greater than \$1000.00, a flat mark-up of \$40 applies on the AEMP
- the ready-prepared fee.

There is no wholesale mark-up or other fees associated with these dispensed settings.

Where a medicine or medicinal preparation is dispensed in the s100 HSD public hospital setting, the DPMQ is determined by the AEMP. No other mark-ups or fees apply when a medicine or medicinal preparation is dispensed in the public hospital setting.

Section 100 Efficient Funding of Chemotherapy (s100 EFC)

Prescribing and dispensing arrangements for certain infused or injected chemotherapy medicines subsidised by the PBS came into effect on 1 December 2011 under the Revised Arrangements for the Efficient Funding of Chemotherapy Drugs initiative.

Reimbursement for supplying an infusion is based on the cheapest combination of vials. Calculate the price of each individual vial (base price and mark-up) to determine the cheapest combination for the quantity and dose prescribed, as outlined in the proposed settings. The per-vial mark-up is calculated as follows:

- Determine the base price for maximum amount by multiplying the AEMP of each vial strength by the number of vials required to reach the maximum amount.
- Using the base price for maximum amount, determine the total mark-up applicable for the relevant dispensed setting.
- Calculate the per-vial mark-up by apportioning the total mark-up to the individual vial. The cheapest combination of vials is determined based on the per-vial price, which is the AEMP plus the per-vial mark-up.

Where an s100 EFC listing is being sought, the price to be applied to the proposed medicine or medicinal preparation is the equivalent of the DPMA adjusted for the amount suitable for the average patient receiving the therapy. The amount for the average patient will generally be supported by data from clinical trials.

Community pharmacy setting

Under the s100 EFC, where a medicine or medicinal preparation is dispensed in the [community pharmacy setting](#) (including by approved practitioners), the DPMA is determined by the following:

- the AEMP, derived for a single vial price
- a three-tier pharmacy mark-up in the form of the AHI fee. Pharmacy mark-ups are updated with each Community Pharmacy Agreement and are subject to yearly indexation. Determine the current AHI fees and apply them to the List Price (AEMP inclusive of wholesale mark-up)
- the per-vial medicine price
- the total maximum medicine price for the infusion or patient dose (calculated based on the cheapest combination of vials)
- the applicable dispensing fees, comprising
 - preparation fee
 - diluent fee
 - distribution/wholesale fee
 - ready-prepared/dispensing fee.

These fees are subject to indexation. [Current fixed dispensing fees](#) are available on the department's website.

Private hospital setting

Where a medicine or medicinal preparation is dispensed in the private hospital setting, the DPMA is determined by the following:

- the AEMP, derived for a single vial price
- a flat pharmacy mark-up of 1.4% applied on the AEMP
- the per-vial medicine price
- the total maximum medicine price for the infusion or patient dose, based on the cheapest combination of vials

- the applicable dispensing fees, comprising
 - preparation fee
 - diluent fee
 - distribution/wholesale fee
 - ready-prepared/dispensing fee.

These fees are subject to indexation. [Current fixed dispensing fees](#) are available on the department's website.

Public hospital setting

Where a medicine or medicinal preparation is dispensed in the public hospital setting, the DPMA is determined by the following:

- the AEMP
- the total maximum medicine price for the infusion or patient dose, based on the cheapest combination of vials
- the preparation fee.

No other mark-ups or fees apply when a medicine or medicinal preparation is dispensed in the public hospital setting.

More information on the [s100 EFC](#) can be found on the department's website.

Other s100 programs

Where an s100 listing is being sought under the following arrangements, the price to be applied to the proposed medicine or medicinal preparation is the equivalent of the DPMQ:

- In Vitro Fertilisation (IVF) Program
- Growth Hormone Program
- Botulinum Toxin Program
- Opiate Dependence Treatment Program.

Section 100 IVF Program and s100 Growth Hormone Program

Where a medicine or medicinal preparation is dispensed under the s100 IVF Program or the s100 Growth Hormone Program in the private hospital setting or the community pharmacy setting, the DPMQ is determined by the following:

- the AEMP
- a four-tier pharmacy mark-up
 - for an AEMP for the listed maximum quantity of up to and including \$40.00, a mark-up of 10% applies on the AEMP
 - for an AEMP for the listed maximum quantity from \$40.01 up to and including \$100.00, a flat mark-up of \$4.00 applies on the AEMP
 - for an AEMP for the listed maximum quantity from \$100.01 up to and including \$1000.00, a mark-up of 4% applies on the AEMP
 - for an AEMP for the listed maximum quantity of greater than \$1000.00, a flat mark-up of \$40 applies on the AEMP
- the ready-prepared fee.

No wholesale mark-up is associated with these programs.

Where a medicine or medicinal preparation is dispensed under these programs in the public hospital setting, the DPMQ is determined by the AEMP, and no other mark-ups or fees apply.

Section 100 Botulinum Toxin Program

Where a medicine or medicinal preparation is dispensed under the s100 Botulinum Toxin Program in the private hospital setting, the DPMQ is determined by the following:

- the AEMP
- a four-tier pharmacy mark-up
 - for an AEMP for the listed maximum quantity of up to and including \$40.00, a mark-up of 10% applies on the AEMP
 - for an AEMP for the listed maximum quantity from \$40.01 up to and including \$100.00, a flat mark-up of \$4.00 applies on the AEMP
 - for an AEMP for the listed maximum quantity from \$100.01 up to and including \$1000.00, a mark-up of 4% applies on the AEMP
 - for an AEMP for the listed maximum quantity of greater than \$1000.00, a flat mark-up of \$40 applies on the AEMP
- the ready-prepared fee.

No wholesale mark-up or other fees are associated with these dispensed settings.

Where a medicine or medicinal preparation is dispensed under this program in the public hospital setting, the DPMQ is determined by the AEMP, and no other mark-ups or fees apply.

Section 100 Opiate Dependence Treatment Program

Where a medicine or medicinal preparation is dispensed under the s100 Opiate Dependence Treatment Program, the DPMQ is determined by the AEMP, and no other mark-ups or fees apply.

4.1.3 Proposed vaccine for listing on the National Immunisation Program

Where a listing on the National Immunisation Program is being sought, the price to be applied to the proposed vaccine is the equivalent of the ex-manufacturer price, and no other mark-ups or fees apply.

4.2 Comparator and co-prescribed medicines or medicinal preparations

4.2.1 Comparisons of medicines or medicinal preparations prescribed under the PBS

Except where identified otherwise, the price to be applied to each PBS-listed medicine or medicinal preparation is the DPMQ as defined in the current Schedule of Pharmaceutical Benefits, plus any applicable premiums or charges. This applies to all non-s100 EFC settings.

In an s100 EFC setting, the price to be applied to a vial of each PBS-listed medicine or medicinal preparation is the DPMA adjusted for the amount suitable for the average patient receiving the therapy. The amount for the average patient will generally be supported by data from clinical trials.

Specify the effective date of the Schedule of Pharmaceutical Benefits used in the submission. The [current Schedule of Pharmaceutical Benefits](#) is available on the department's website.

When the price for the proposed medicine or medicinal preparation is determined on the basis of a comparison with a PBS-listed medicine that has a special pricing arrangement (ie the effective price is confidential), use the DPMQ or DPMA in the current Schedule of Pharmaceutical Benefits until the department can reveal the effective price. To determine whether a PBS-listed product has a special pricing arrangement, consult the notes for that medicine in the current Schedule of Pharmaceutical Benefits or the relevant [PBS Therapeutic Relativity Sheet](#), available on the department's website.

When the same PBS-listed medicine or medicinal preparation has different prices (eg a public hospital DPMQ and a private hospital DPMQ), calculate the weighted average price based on the proportions dispensed in each setting and the relevant price for each setting – that is:

$$[(\text{volume dispensed for public hospital patients} \times \text{relevant DPMQ}) + (\text{volume dispensed for private hospital patients} \times \text{relevant DPMQ})] \div \text{total volume dispensed}$$

4.2.2 Comparisons of medicines or medicinal preparations not prescribed under the PBS

For comparisons with vaccines listed on the [National Immunisation Program Schedule](#), refer to the department's website.

4.3 Over-the-counter medicines

Over-the-counter medicines are medicines for which no prescription is required, but whose consumption may be affected by the proposed medicine or main comparator. The unit cost for an over-the-counter medicine in an economic evaluation is the recommended retail price suggested by the manufacturer. Include and justify the origin of the details of the unit costs used in the submission. Where medicines are available both on the PBS and over the counter, use the PBS price.

4.4 Medicine delivery systems

Medicine delivery systems relate to the consumables and equipment required for the delivery of certain medicines or medicinal preparations (eg insulin pen or nebuliser unit). It is not feasible to identify and cost all such items in this manual because they are context specific. Where such items are applicable to an economic evaluation, use a price equivalent to the average price charged to the consumer, and provide details about how this price was determined.

4.5 Medicine administration costs

Additional medical service costs of administering a medicine or medicinal preparation may be included. This most commonly occurs when a medicine or medicinal preparation is administered by infusion. It does not occur with oral administration. The cost extends beyond the costs of the delivery system (Subsection 4.4).

Where an appropriate Medicare Benefits Schedule (MBS) item is available, the PBAC's preferred approach is to use the relevant MBS Schedule Fee for administering the medicine or preparation. For example, relevant MBS items exist for administering chemotherapy medicines, sympatholytic agents, therapeutic agents to manage chronic intractable pain, immune-modulating agents and botulinum toxin. Although claiming an MBS item in some settings would not be appropriate (eg for the administration of a medicine or medicinal preparation to a patient in a public hospital), the

relevant MBS Schedule Fee is the most suitable proxy for determining the economic cost across all administration settings.

If no MBS item is available for the administration of a proposed medicine or medicinal preparation, use the Schedule Fee of a standard MBS consultation item if the only purpose of the consultation is for the administration of the proposed medicine or medicinal preparation.

Use clinical judgment when selecting the MBS item relevant to the economic evaluation, and justify the item(s) selected, including with respect to:

- the duration of administration (specifically, the time during which the prescriber takes an active role in administering the medicine)
- the type of prescriber involved (eg general practitioner, specialist, consultant physician)
- whether the type of consultation is an initial or a subsequent consultation.

Justify any deviations from the MBS Schedule Fee.

If the circumstances of administering a proposed medicine or medicinal preparation suggest that a new MBS item should be established, seek the department's advice (see contact details on page 1), because this would require a codependent submission involving the Medical Services Advisory Committee.

5 Medical services, including investigative, diagnostic and allied health services

Medical services relate to professional services provided by a qualified medical practitioner or other health care practitioner, other than services provided in a hospital setting. Hospital-based medical services are included in Section 6 'Hospital services'.

The units of measurement to be used for medical services are defined in the classification of items in the most recent version of the [Medicare Benefits Schedule](#).

The MBS covers a wide range of medical services, including imaging procedures, pathology tests, other investigational procedures, and services rendered by (or on behalf of):

- a qualified medical practitioner
- a registered allied health professional
- a registered dentist or registered dental specialist
- an eligible nurse or eligible midwife.

Use clinical judgment when selecting the MBS item relevant to the economic evaluation, and justify the item selected.

The unit costs to be used for medical services in an economic evaluation are the Schedule Fees as presented in the MBS. Because the structure of the MBS and its associated Schedule Fees are subject to periodic review and amendment, ensure that the most recent version is used for the submission. Specify the effective date of the MBS used in the submission.

If no MBS item is available for a particular medical service, seek advice from the department (see contact details on page 1), and note this in the submission.

6 Hospital services

Hospital services are all services provided to patients in a hospital setting, including ‘hospital in the home’. They include all medicines, medical services, diagnostic and investigational services, and allied health services provided to patients.

Hospital services comprise care for admitted and nonadmitted patients. As defined in the Australian Institute of Health and Welfare’s Metadata Online Registry, [METeOR](#), an admitted patient is a patient who undergoes a hospital’s admission process to receive treatment and/or care. This treatment and/or care is provided over a period of time, and can occur in hospital and/or in the person’s home (for hospital-in-the-home patients). Nonadmitted care includes all hospital services and care provided to a patient who is not formally admitted at the time when the care is provided (eg in an outpatient clinic).

Use clinical judgment when selecting the patient classification relevant to the economic evaluation, and justify the selection.

Seek advice from the department (see contact details on page 1) if the service is for neither nonadmitted patients nor for admitted patients under an Australian Refined Diagnosis Related Group (AR-DRG) as described in the National Hospital Cost Data Collection (NHCDC) (eg for a subacute or nonacute service).

6.1 Admitted patient services

Admitted patient services comprise all hospital services provided to patients who undergo a hospital’s formal admission process. The introduction of the proposed medicine may reduce the incidence of whole episodes of hospitalisation for a given illness or range of illnesses, or, in some cases, it may increase whole episodes.

Where the introduction of the proposed medicine is anticipated to increase or decrease 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 AR-DRGs, which represent acute classes of patients with clinically similar diagnoses, and whose costs of treatment are relatively homogeneous. References for a list of AR-DRGs according to their [current AR-DRG classification](#) are available from the Australian Consortium for Classification Development.

Current AR-DRG costs can be obtained from an appendix to the [National Public Sector Cost Weights](#) (Round 18 at the time of publication), in the NHCDC. Use the cost shown in the ‘Total cost’ column for the relevant AR-DRG as the basis for determining the unit cost for the episode of hospitalisation. Use clinical judgment when selecting the NHCDC cost relevant to the economic evaluation, and justify the selection.

Specify the effective date of the AR-DRG classification and cost weights used in the submission (eg AR-DRG v7.0, Round 18 [2013–14]). Consider caveats identified in the NHCDC Cost Report and the NHCDC Independent Financial Review relating to each round of collection.

6.1.1 Use of alternative costs for admitted patients

Cost estimates may not be verifiable when disaggregated beyond an episode of hospitalisation. Therefore, 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 in particular components involved in an episode of hospitalisation, and/or important heterogeneity across a particular AR-DRG. The estimate of admitted patient hospital unit costs may be affected by more than one of these factors (eg both duration and heterogeneity).

If a variation to the admitted patient unit costs is considered to be relevant and important to a particular submission, seek advice from the department (see contact details on page 1). As generally recommended in this manual, present two analyses (each with complete sets of sensitivity analyses): one that is completely consistent with the manual (ie using either the cost weight for the full episode of hospitalisation from the NHCDC AR-DRG unit costs, or no unit cost at all), and one that uses the alternative approach. This follows the general principle of ensuring comparability across submissions, and allows the implications of using alternative costs to be assessed.

Clearly explain and justify the alternative unit costs. Demonstrate why breaking down the unit cost beyond a whole episode of hospitalisation is of particular importance to the economic evaluation. Present and explain full details of the approach used to generate the alternative unit costs, including how they are applied to the estimates of changes and the extent for each resource.

Duration of episode

Where the medicine reduces the duration of an episode of hospitalisation, it is usually assumed that the cheapest days of hospitalisation are avoided. Thus, the cost per day for each day of hospitalisation avoided should be less than the average cost per day (calculated as the cost per episode divided by the average length of stay). Unless an alternative approach can be justified in the submission, use the cheapest estimate of the cost per bed day from the current NHCDC cost weights. This is appropriately conservative where confidence in the data is not strong.

Component costs

Where the medicine changes the extent of resources provided during an episode of hospitalisation, the component costs reported in the NHCDC should not be used. Justify any alternative source of costs, and discuss the extent to which this affects the conclusions of the economic evaluation.

Heterogeneity

Only consider an alternative unit cost for a whole episode of hospitalisation if the submission can demonstrate that heterogeneity within a particular AR-DRG is sufficient to affect the conclusions of the economic evaluation. Explain why any cost per episode for the selected AR-DRGs from the recommended AR-DRG dataset varies from the cost per episode for the corresponding AR-DRG from the chosen alternative dataset.

6.2 Nonadmitted hospital care

Nonadmitted services from acute care hospitals are classified according to the [Tier 2 Non-Admitted Care Services Classification](#). Current Tier 2 class costs can be obtained from an appendix to the [National Public Sector Cost Weights](#) (Round 18 at the time of publication).

Where the introduction of the proposed medicine is expected to vary the number of nonadmitted patient service events, the units of measurement should be the average total cost per nonadmitted patient service event by Tier 2 class. Specify the effective date of the Tier 2 classification and cost weights used in the submission (eg Tier 2 v3.0, Round 18 [2013–14]). Use clinical judgment when selecting the NHCDC cost relevant to the economic evaluation, and justify the selection.

If a patient presenting for a nonadmitted 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. That is, a patient's initial nonadmitted cost should not be counted in addition to the admitted cost.

6.3 Emergency department services

Emergency department presentations have been classified by [Urgency Related Groups \(URGs\)](#). Current URG costs can be obtained from an appendix to the [National Public Sector Cost Weights](#) (Round 18 at the time of publication).

Where the introduction of the proposed medicine is expected to vary the number of presentations to emergency departments, the units of measurement should be the average total cost per presentation by nonadmitted URG. Specify the effective date of the URG classification and cost weights used in the submission (eg URG v1.3, Round 18 [2013–14]). Use clinical judgment when selecting the NHCDC cost relevant to the economic evaluation, and justify the selection.

If a patient presenting to an emergency department 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. That is, a patient's initial nonadmitted emergency department cost should not be counted in addition to the admitted cost.

7 Community-based services

7.1 Residential care

Residential care refers to care provided to residents of approved residential aged-care facilities.

The introduction of the proposed medicine may defer or accelerate a person's admission to a residential care facility, thereby affecting the weekly level of care required for the new resident. The actual level of care affected will vary according to the level of dependency of the particular resident on admission to the residential care facility. Similarly, the proposed medicine may vary the level of dependency for a person already in a residential care facility, and, in turn, vary the level of care required for their support. In either case, the effects should be included in the economic evaluation of the medicine.

Residential care is categorised according to the Aged Care Funding Instrument (ACFI). 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 facility.

The ACFI consists of 12 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 care domains:

- activities of daily living
- behaviour
- complex health care.

Information and resources for conducting an [ACFI assessment](#) are available from the department's website. [Daily ACFI subsidy rates](#) are available from the department's website. 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's website.

Assess which resident categories would be affected by use of the proposed medicine or its main comparator, and the extent of any variation expected on the resident's level of dependency. Calculate the number of days affected by the therapies. The unit of measurement is the sum of the appropriate daily ACFI subsidy rate and the basic daily care fee.

If the ACFI category is unknown, the subsidy paid for a resident will be the sum of the amounts payable for the three care domains (activities of daily living + behaviour + complex health care). Where the effects are spread uniformly across all categories, use the average across all categories. Use clinical judgment when selecting the appropriate ACFI category relevant for the economic evaluation, and justify the selection.

7.2 Home care

A home care package is a coordinated package of care designed to help an older person with complex care needs to remain living in their own home. There are four levels of home care package – Level 1 receives the lowest subsidy, and Level 4 receives the highest subsidy. Care recipients may also be eligible for a number of supplements. The home care subsidy is paid as a daily rate,

depending on the level of package the care recipient receives. Home care funding is not determined by care type.

The introduction of the proposed medicine may defer or accelerate eligibility for a home care package, or affect the level at entry, depending on the assessed care needs of the individual. Similarly, the proposed medicine may vary the level of dependency for a person who already receives a home care package, which may vary the level of care required for their support. An individual's care plan may need to be renegotiated to direct more funds towards particular care types, such as medicines administration, resulting in a reduction of other care types. Alternatively, the individual may need to pay additional fees to access services beyond those available through package funds.

If the variation in dependency is significant, a reassessment may be required, which may result in eligibility for a different package level (either higher or lower) or referral to a different type of care, such as residential care.

An external assessment by an Aged Care Assessment Team determines the level of package at entry. A further assessment is required if the care recipient's care needs change to the extent that they need a different package level or enter residential care.

Assess the extent of any variation expected on the care recipient's level of dependency relating to the proposed medicine or its main comparator. The unit of measurement is the sum of the appropriate daily home care subsidy rate plus the basic daily care fee.

Information about current rates of [home care subsidy and supplements](#) is available from the department's website.

In addition to the subsidy, many care recipients pay a basic daily care fee. The basic daily care fee is separate from the income-tested care fee (which is used to substitute a portion of the daily government subsidy). Information about [current home care fees](#) is available from the department's website.

7.3 Home nursing

Home nursing services are those provided by qualified nursing personnel at the patient's home or residence. These do not include nursing services provided in residential care or in a hospital – these are included in 'Residential care' (Subsection 7.1) and 'Hospital services' (Section 6), respectively.

The introduction of the proposed medicine may increase or decrease the number or duration of home nursing visits required. Unit costs for nursing under the [Commonwealth Home Support Programme](#) (CHSP) may vary across the states and territories; the CHSP estimated the national cost in 2016 at \$91.83 per hour.

Use clinical judgment to determine the number and duration of services likely to be affected in this category, and justify their assessment in the submission.

7.4 Ambulance services

The introduction of the proposed medicine may increase or decrease the use of ambulance services. If this is relevant to an economic evaluation, the unit of measurement is each trip taken or avoided. Costs for ambulance services can be obtained from the quarterly statistics reports of the [Australian Prudential Regulation Authority](#). Use the latest quarterly data from the 'All states combined' report,

and divide the total cost of services by the total number of services, to obtain the mean cost per service. Specify the date of the quarterly data used in the submission.

7.5 Other community-based services

The introduction of the proposed medicine may affect a wide range of community-based health services other than those listed elsewhere in this manual. Examples of such services are Meals on Wheels and Community Health Services.

However, it is often difficult and expensive to identify all these services, and quantify the effects of a proposed medicine on them. Thus, these types of services have not usually been included in economic evaluations. However, these issues may be considered in the context of the social or community effects of the proposed medicine other than effects already recognised in the economic evaluation. This information is not necessarily expressed in monetary terms, but may supplement the economic evaluation by ensuring that all effects of the proposed medicine on the provision of resources are recognised and considered.

8 Variation to unit costs of medicines for Section 4 of a submission to the PBAC

The financial analysis in a submission prepared according to Section 4 of the PBAC Guidelines takes the perspective of the Australian Government health budget. This means that cost components borne by payers other than the health budget of the Australian Government are excluded from this financial analysis.

In practice, this means that non-PBS/RPBS medicines, over-the-counter medicines and medicine delivery systems are excluded from this financial analysis because they incur no direct financial cost to the PBS/RPBS. It also means that the range of patient co-payments is subtracted from the unit cost of each PBS/RPBS medicine.

8.1 Calculating the unit cost of medicines or medicinal preparations from the perspective of the PBS/RPBS

For nearly all medicines or medicinal preparations included in the financial analyses, from the perspective of the PBS/RPBS, the unit cost to be used is the DPMQ (or DPMA, adjusted for the amount suitable for the average patient receiving the therapy, where relevant) minus the weighted average patient co-payment.

Current information about the PBS/RPBS [patient co-payment and safety net thresholds](#) is found on the department's website. 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.

Report the disaggregation of use across patient co-payment categories for all currently listed medicines in the financial analyses for the most recent 12 months available. Subtract the relevant co-payment from the relevant DPMQ to calculate the unit cost to the PBS/RPBS in each category.

The disaggregation for the proposed medicine or medicinal preparation is usually assumed to be that of the closest therapy that is currently listed (and specifically the main comparator, if it is PBS listed).

The [department's website](#) has a proforma in Excel format for estimating the extent of use and financial implications of the proposed medicine. Sponsors can use this to help prepare Section 4 of their submission.

8.2 Calculating the financial unit cost of medical services from the perspective of the MBS

For nearly all medical services included in the financial analysis, from the perspective of the MBS, the financial unit cost to be used is the rebate amount, which may be 75%, 85% or 100% of the Schedule Fee, or some other fixed amount, as defined for each item in the MBS. Although 85% of the Schedule Fee is the usual patient rebate for out-of-hospital services, and 75% is the usual patient rebate for in-hospital services, it is recognised that item-level data are not publicly available on

inpatient and outpatient ratios, bulk billing rates or patient contributions. On this basis, use the most likely applicable rebate, and justify the selection based on clinical opinion.

Use the most recent version of the MBS, and specify the effective date of the MBS used in the submission.

Appendix 1 Internet addresses

Table 1 lists the URLs of all hyperlinks included in this manual.

Table 1 Internet addresses used in this manual

Section of manual	Information source	URL
Preface	Manual of resource items and their associated unit costs	www.pbs.gov.au/info/industry/useful-resources/manual
	PBS	www.pbs.gov.au/pbs/home
Section 1	PBAC Guidelines	https://pbac.pbs.gov.au
Section 2	Implicit Price Deflator	www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/5206.0Mar 2016?OpenDocument
Section 4	PB11 form	www.pbs.gov.au/info/industry/useful-resources/pbs-forms
	PBS explanatory notes	www.pbs.gov.au/info/healthpro/explanatory-notes
	PBS Therapeutic Relativity Sheet	www.pbs.gov.au/info/industry/pricing/pbs-items/therapeutic-relativity-sheets
	Information on medicines or medicinal preparations dispensed in the community pharmacy setting	www.pbs.gov.au/info/general/sixth-community-pharmacy-agreement
	Fees, patient contributions and safety net thresholds	www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee
	Section 100 Efficient Funding of Chemotherapy	www.pbs.gov.au/info/browse/section-100/chemotherapy
	Schedule of Pharmaceutical Benefits	www.pbs.gov.au/browse/publications
Section 5	National Immunisation Program Schedule	www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/national-immunisation-program-schedule
	Medicare Benefits Schedule	www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home
Section 6	METeOR	http://meteor.aihw.gov.au/content/index.phtml/itemId/268957
	AR-DRG classification	https://www.accd.net.au/ArDrg.aspx?page=2
	National Public Sector Cost Weights	https://www.ihsa.gov.au/publications/australian-public-hospitals-cost-report-2013-2014-round-18
	Tier 2 Non-Admitted Care Services Classification	https://www.ihsa.gov.au/what-we-do/tier-2-non-admitted-care-services-classification
	Urgency Related Groups	https://www.ihsa.gov.au/what-we-do/urgency-related-groups-and-urgency-disposition-groups

Section of manual	Information source	URL
Section 7	Aged Care Funding Instrument (ACFI)	https://agedcare.health.gov.au/aged-care-funding/residential-care-subsidy/basic-subsidy-amount-aged-care-funding-instrument/aged-care-funding-instrument-acfi-assessment-pack
	Subsidy rates and care fees	https://agedcare.health.gov.au/aged-care-funding/aged-care-subsidies-and-supplements
	Basic daily care fee	https://agedcare.health.gov.au/aged-care-funding/aged-care-fees-and-charges
	Commonwealth Home Support Programme	https://agedcare.health.gov.au/programs/commonwealth-home-support-programme
	Australian Prudential Regulation Authority	www.apra.gov.au/PHI/Publications/Pages/Quarterly-Statistics.aspx
Section 8	Fees, patient contributions and safety net thresholds	www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee
	Proforma for estimating the extent of use and financial implications of the proposed medicine	https://pbac.pbs.gov.au

If these links are broken, contact the department (see contact details on page 1).