7 Estimating Costs

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To every extent possible, the costing methods recommended here should be used to enable comparisons across analyses. However, alternative cost values should be used in sensitivity analyses.

7.1 Costs Included in PHARMAC Analyses

Key Recommendation: The range of costs included in analyses depends on the level of analysis undertaken. All costs that significantly influence the results should be included. A wider range of costs should be included in more detailed analyses.

Costs included in PHARMAC analyses are outlined in Table 9.

Table 9: Costs Included in PHARMAC Analyses

Cost	Details
Pharmaceutical	Community and hospital pharmaceuticals.
Hospital inpatient	Diagnostic Related Group (DRG) prices for inpatient diagnosis, treatment and/or procedures.
Hospital outpatient	Health care professional costs. DRG prices. Laboratory and diagnostics.
Direct patient health care	General practitioner visits. Pharmaceutical co-payments. Home or continuing care.

The reporting of costs should state how units were measured, how resources were valued and how final cost figures were derived. Further guidance on the presentation of cost data is included in Chapter 11.

With more rapid analyses, costs that do not materially influence the results may be excluded. In such cases, calculation of additional costs may require considerable time and may complicate the analysis unnecessarily without making any material difference to the result. Justification should be given for the exclusion of costs.

Costs that are the same in both treatment arms can be validly excluded if there is no significant difference in mortality rates or time periods between treatments.

Cost data should be obtained from New Zealand. International prices and costs should not be used in analyses due to differences in resource use in New Zealand, even after exchange rate adjustments.

7.2 Pharmaceutical Costs

Key Recommendations: Pharmaceutical costs should use net pricing from the pharmaceutical supplier, be based on the dose used in the key clinical trials (unless there is evidence of efficacy for different doses in clinical practice) and take into account the lower price of a future generic pharmaceutical. Dispensing fees and pharmacy mark-up should be included. The cost of co-administered pharmaceuticals and any significant costs with administering the pharmaceutical should also be taken into account.

7.2.1 Price of Pharmaceutical(s)

Pharmaceutical costs should be restricted to pharmaceuticals listed or considered for listing on the Pharmaceutical Schedule (53 (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/references/#ref53)). For cost-utility analyses, the goal is to assess the value of the proposed pharmaceutical as a possible use of health system funds. Therefore in cost-utility analyses, the total pharmaceutical cost should be included regardless of whether it is paid partly by the patient or entirely by the government.

For pharmaceuticals listed on the Pharmaceutical Schedule (53 (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/references/#ref53)), the net price of the pharmaceutical should be used, as negotiated with the supplier. The analysis should state whether the price is confidential. If the net price of the proposed intervention or the comparator is unknown at the time of analysis, include a wide range of prices in the sensitivity analysis.

When calculating the cost of a pharmaceutical intervention and comparator pharmaceutical(s), consideration should also be given to the length of the pharmaceutical patent and the time until a generic pharmaceutical is likely to become available. It is recommended that in cases where the patent expiry is within 10 years from expected date of pharmaceutical funding, the expected time and price reduction from a likely generic pharmaceutical should be included in the analysis. If the patent expiry is after 10 years from expected date of funding, a conservative proxy should be used for the estimated time until the introduction of a generic pharmaceutical and subsequent price reduction (eg 25 years until expiry and 70% price reduction with introduction of generic). This should be varied in the sensitivity analysis.

Pharmaceutical costs included in the analysis should include not only the cost of pharmaceuticals used to treat the disease or condition, but also the cost of pharmaceuticals used to treat any significant side-effects of treatment.

It is recommended that pharmaceutical prices be deflated by 2% per year in the sensitivity analysis (not the base-case analysis) as a proxy for inflation in other prices. The impact of this amendment should be discussed in the report.

7.2.2 Medical Devices

Medical devices have costs that may differ to those for medicines and which need to be taken into account.

These costs include, but are not limited to:

- one-off costs:
    - capital
    - disposal of current device(s)
    - costs of switching out devices already in use
    - implementation
- fixed costs**:**
    - hiring additional staff
    - overheads
    - training
- costs associated with use**:**
    - operating costs
    - maintenance and repair
    - consumables.

Further information on measuring medical device costs in New Zealand is included in the *Cost Resource Manual*, available on the PHARMAC website.

7.2.3 Dose of Pharmaceutical(s)

The dose of the pharmaceutical should be the dose used in the key clinical trials, providing this reflects clinical practice in New Zealand. In cases where the dose in the clinical trials does not reflect current clinical practice or expected clinical practice upon introduction, the dose should be based on that used in clinical practice, providing there is some evidence of efficacy at the proposed dose. In cases where there is no evidence available, analyses should consider different scenarios where the dose (but not the effectiveness) is varied.

Any dose adjustments over time should also be taken into account.

The dose of the pharmaceutical may depend on the weight or surface area of the patient. The average weight of adults in New Zealand is currently approximately 79.6 kg(54 (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/references/#ref54)); however, it may be necessary to adjust this according to the age and/or gender of the population treated.

In some cases, it is necessary to take into account any drug wastage that may occur due to inappropriate vial size; non-compliance; or if infusions cannot be stored once prepared.

7.2.4 Dispensing Fees and Pharmacy Mark-Up

The cost of dispensing community pharmaceuticals (the 'dispensing fee') and the pharmacy mark-up should be included in analyses. Note that for pharmaceuticals dispensed from hospital pharmacies, a dispensing fee should only be included if the pharmaceuticals are dispensed for outpatient use.

Details on the current dispensing fee and pharmacy mark-up are provided in the *Cost Resource Manual*, available on the PHARMAC website.

7.2.5 Administration of Pharmaceutical(s)

The cost of administering a pharmaceutical should be included in the analysis.

Pharmaceutical administration costs may include:

- laboratory/diagnostic tests or procedures required prior to the initial administration or each administration
- pre-medication to prevent any potential side-effects
- pharmacist time to prepare infusion (this cost only needs to be included in cases where the preparation of the infusion has a relatively significant impact on pharmacist time)
- material costs required to deliver infusion (eg infusion line, saline, filter, alcohol swabs, etc)
- nurse and/or specialist time required to administer treatment
- 'bed cost' associated use of outpatient facilities
- post-administration monitoring by nurse
- probability of attending appointment to have pharmaceutical administered (this may be necessary in cases where compliance is low, such as with intravenous typical antipsychotics)
- cost of home visits for administration.

Further information on pharmaceutical administration costs in New Zealand is included in the *Cost Resource Manual*, available on the PHARMAC website.

7.2.6 Co-administered Pharmaceutical(s)

The cost of any pharmaceuticals that need to be co-administered with the treatment should be included in the analysis.

7.3 Hospital Inpatient Costs

Key Recommendation: Hospital inpatient costs can be calculated using DRG codes and should be included in the CUA.

It could be argued that cost offsets do not need to be taken into account in the CUA, as often these are not realised. For example, a new treatment may prevent or shorten hospital stays but the beds freed up will be occupied by another patient.

Thus, DHBs may not gain direct financial savings, but rather more people with other conditions will receive treatment.

However, hospital cost offsets are part of the net resource use of a drug intervention, and measuring long-term net resource use is the goal of CUA. Hence, any savings to DHBs will manifest either as discrete savings through services no longer being used, or through those resources being deployed elsewhere. For this reason, hospital inpatient costs should be included in the CUA.

7.3.1 Calculation of Hospital Costs

Hospital costs can be calculated using Diagnostic Related Group (DRG) prices. DRGs are a hospital patient classification system that provides data relating the number and types of patients treated in a hospital to the resources required by the hospital(55 (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/references/#ref55)). To a certain extent, DRG prices are able to capture the resources used by a particular group of patients and severity of conditions, and so are useful when estimating hospitalisation costs.

However, a disadvantage of DRG prices is that they do not distinguish between the 'fixed' costs necessary to run a service regardless of patient numbers (overheads, minimum staffing levels, etc) and the marginal costs (the extra costs incurred in treating each new patient). They are, therefore, average prices, and do not provide an accurate estimate of the opportunity cost of resources.

Even though it is preferable to use marginal costs to estimate the cost of hospitalisation, data on average costs are more readily available and in most cases are sufficient. Average costs are, however, likely to overestimate the opportunity cost of hospitalisation.

In cases where the cost of hospitalisation is the main driver of the results of the analysis, further work should be undertaken to determine the marginal cost. Any adjustments to DRG prices should be justified in the report.

Adjustments that may need to be made to DRG prices are outlined in Table10.

Table 10: DRG Adjustments

DRG Adjustment	Details
Complexity	DRG prices should be adjusted for more severe conditions.
Volume of patients	In cases where more than one DRG code needs to be used, the cost per admission should be weighted by the number of discharges under each DRG code.
Mechanical ventilation	DRG prices should be adjusted for mechanical ventilation co-payments when relevant.

7.3.2 Capital Costs, Depreciation, and Hospital Overhead Costs

Capital and overhead costs are generally included in DRG prices, and do not need to be estimated separately in the majority of CUAs. However, these costs should be included if significant.

7.4 Other Health System Costs

Key Recommendation: CUAs should include hospital outpatient costs. Terminal costs associated with the primary condition being treated should be included in CUAs if these costs are likely to be significantly different between treatment arms or if they occur at significantly different times.

7.4.1 Hospital Outpatient Costs

Hospital outpatient costs may include:

- hospital outpatient or community-based services required for administration of the pharmaceutical (eg nurse and specialist time required for infusions)
- laboratory and diagnostic tests
- emergency department visits
- specialist visits and primary care services
- community based services (eg nurse home visits, residential care, home help, hospice care).

The cost of outpatient hospital visits should be estimated using the specialist consultation cost or same-day DRG costs. This cost is particularly relevant when subsidies for pharmaceuticals are only available when prescribed by specialists.

Laboratory and diagnostic tests can be costed as per test/procedure. Care should be taken to ensure that these costs are not included in the DRG costs, to avoid double-counting.

7.4.2 Terminal Care Costs

A large proportion of costs are incurred in the last few months of a person's life, which can affect the cost-effectiveness of a treatment. These costs should be included in CUAs if they are likely to significantly impact the results. This is most likely to occur in cases where patients are receiving palliative care in their final few months of life and a new treatment improves survival, or if the costs occur at significantly different times.

In cases where patients die in hospital, terminal care costs can be calculated from DRG prices. In cases where patients receive palliative care in the community (eg terminal cancer patients), terminal care costs can be calculated as the cost of home visits (nurse and specialist), hospice care, and/or hospital care. Due to uncertainty, a range of costs should be included.

The cost of terminal care should, however, be restricted to the terminal costs associated with the primary condition being treated.

7.5 Direct Patient Health Care Costs

Key Recommendations: Include direct patient health care costs in CUAs. These should be restricted to health care costs that government partially subsidises, and should be based on the cost to government plus the additional cost to the patient. These costs include general practitioner visits, pharmaceutical co-payments, and home or continuing care.

Direct patient health care costs included in CUAs should be restricted to health care costs that the government partially subsidises through Vote:Health. The cost included in the CUA should be the cost to government plus any additional cost to the patient.

Direct patient health care costs include:

- general practitioner visits
- pharmaceutical co-payments
- home or continuing care.

Direct patient health care costs do not include:

- lost wages as a result of sickness
- cost of premature mortality
- non-government-subsidised costs such as private hospital, physiotherapy, or unsubsidised pharmaceuticals.

7.5.1 GP Visits

The cost of a general practitioner (GP) visit should be based on the average cost to the patient plus any government subsidy (if applicable). Details are provided in the *Cost Resource Manual*, available on the PHARMAC website.

7.5.2 Pharmaceutical Co-payments

For CUAs, it is recommended that the total pharmaceutical cost be included, irrespective of whether it is paid partly by the patient or entirely by the government. As outlined above, pharmaceutical costs included in CUAs should be restricted to pharmaceuticals listed (or considered for listing) on the Pharmaceutical Schedule or funded by DHB hospitals.

7.5.3 Cost of Home or Continuing Care

The cost of home care or continuing care (rest home or private geriatric/ psychogeriatric care) should be included in CUAs, regardless of who is paying for these services (ie the family, DHB, Accident Compensation Corporation (ACC), or Ministry of Social Development). The inclusion of these costs also provides a proxy for the disutility associated with the requirement for additional care. Cost details are provided in the *Cost Resource Manual*, available on the PHARMAC website.

7.6 Direct Non-Health Care Costs

Key Recommendation: Costs to non-health care government sectors should not be included in CUAs.

7.6.1 Costs to Other Government Sectors

Costs to other non-healthcare government sectors that occur as a result of pharmaceutical funding decisions, but are not paid for out of the health budget (Vote: Health), should not be included in CUAs. These costs may, however, be considered in the report if they are significant.

7.6.2 Direct and Indirect Taxes and Transfer Payments

Direct and indirect taxes and transfer payments should not be included in CUAs, as these taxes and transfer payments merely represent the shifting of funds from one sector of the economy to another. They are also difficult to calculate correctly and may result in double counting.

7.7 Indirect Health Care Costs

Key Recommendation: Indirect future health care costs should not be included in CUAs.

7.7.1 Indirect Future Health Care Costs

Indirect future health care costs include those costs associated with patients living longer and hence consuming health care resources unrelated to their initial diagnosis or treatment. A key concern with including these costs in CUAs is that it would result in life-saving (or life-extending) treatments potentially being less cost-effective, hence biasing against those treatments that extend life. This is a particularly important issue when CUA results are used in the relative setting (ie where life-saving treatments need to be directly compared with treatments that improve quality of life). These costs are also very difficult to calculate and are associated with a significant amount of uncertainty. In most cases, limited data are available on these costs, and obtaining data may be time consuming. Further, future interventions may also be associated with health gains that would need to be taken into account in the analysis, significantly increasing the complexity of the analysis (and hence risk of error).

PHARMAC considers that interventions should be judged on their own merit in order to establish whether an intervention represents good value for money relative to other proposals. Therefore, it is recommended that indirect future health care costs are not included in CUAs. Note that all direct future health care costs should be included in the CUA (ie all costs directly related to the diagnosis and resulting treatment). It is recommended that CUAs include the costs associated with the entire episode of care, not just the initial treatment.

7.8 Indirect Patient Costs

Key Recommendations: Indirect patient costs should not be included in cost-utility analyses as costs. Reductions in such costs may be included as health benefits.

Indirect costs are those costs relating to lost productivity of a patient due to treatment, illness or death, or that of family members if they attend to patients. Many of these effects are counted as health benefits.

Examples of indirect patient costs that should be excluded from costs are:

- cost of patient or caregiver time off work (ie lost wages) and reduced productivity costs
- cost of premature mortality
- intangible costs (eg pain and suffering experienced as a result of a treatment)(56 (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/references/#ref56)).

Arguments and counter-arguments for including indirect costs which have been considered by PHARMAC when coming to the view that these effects should not be included in CUAs as costs are outlined in Table 11.

Table 11: Arguments (and Counter-Arguments) for the Inclusion of Indirect Costs

Arguments for Inclusion of Indirect Costs	Counter-Arguments
Sickness or treatment that results in inability for the patient or caregiver to work incurs a cost to individuals and employers in terms of replacement of sick workers, training the replacement, and lower levels of productivity.	The actual production loss for society from sickness is likely to be much smaller than the estimated value of potential production lost. For short-term absences, a person's work may be covered by others or made up by the sick person on their return to work. For long-term absences, an individual's work can be covered by someone drawn from the unemployed, albeit with friction costs (hiring, induction, upskilling costs, etc). Therefore, while absence from work may cost the individual or employer, it may not cost society very much. There are also ethical concerns with including lost productivity in analyses as costs rather than reductions in quality of life, as these costs tend to bias against those who are not in the paid labour force – particularly children, homemakers, retired people, the unemployed, and those unable to work because of disability, frailty or disease, including cognitive and psychological impairment. Incorporating differential earning levels will also result in valuing one group of individuals more than another, which is politically and ethically contrary to egalitarian values. It would also result in health care interventions being more likely to be directed towards well-paid working people.
There are costs associated with premature mortality in terms of loss of potential income; and savings in terms of future health care spending that would likely have occurred if the patient survived.	Similar ethical issues as with the inclusion of lost productivity costs (ie biases against those not working).
Intangible costs, such as pain and suffering experienced as a consequence of a treatment, may be significant.	Intangible costs are particularly difficult to measure and value. There are also ethical concerns with placing a monetary value on patient pain. The impact of treatment on pain and suffering can be taken into account when estimating quality of life. To also include a monetary cost would result in double-counting.

7.8.1 PHARMAC Perspective

PHARMAC recommends that indirect costs not be included in CUAs, for the following reasons:

- Including indirect costs would result in double-counting, as the impact of treatment on pain, suffering and inability to work is taken into account when estimating health-related quality of life.
- Indirect costs are often difficult to quantify accurately and require unrealistic assumptions, such as a zero rate of unemployment, which may invalidate CUA results.
- Incorporating differential earning levels will result in valuing one group of individuals more than another. For example, they tend to bias against those who are not in the paid labour force. This may result in treatments for women, child-carers, the elderly, and people living with cognitive or psychological impairment being found to be less cost-effective.
- The actual production loss for society from sickness is likely to be significantly lower than indicated by a priori estimates (eg work can be covered to an extent by the unemployed).
- PHARMAC's objective is to secure the best health outcomes from the funding provided. If societal costs were included in analyses, this could result in PHARMAC considering issues it has no control over. For example, an analysis including indirect costs could favour those with high incomes.

It is, however, recommended that indirect patient costs be incorporated in the quality-adjusted life year (QALY) estimates through the utility values.

7.9 Sourcing and Reporting of Cost Data

Key Recommendations: Only New Zealand costs should be used in CUAs. The use of cost data from overseas or clinical trials is not recommended. Expert clinical opinion should be sought regarding likely treatment patterns and applicability of resource use.

When reporting cost data, costs and savings should be categorised as either real cost savings, nominal cost savings, or additional costs.

7.9.1 Sourcing Cost Data

It is not recommended that cost data from overseas or clinical trials be used in CUAs because of potential differences in clinical practice, absolute and relative prices and the opportunities to redeploy resources. Obtaining New Zealand data may require approaching a variety of sources including PHARMAC, the Ministry of Health and DHBs.

Expert clinical opinion should be sought regarding likely treatment patterns and applicability of resource use.

7.9.2 Reporting Cost Data

When reporting cost data, it is recommended that costs and savings be separated into the following categories:

1. Real cost savings (ie cases where the funding of a new pharmaceutical will result in actual cost savings).
2. Nominal cost savings (ie cases where the funding of a new pharmaceutical is likely to result in reducing waiting lists and other non-monetary or non-tradable benefits).
3. Additional costs (ie where the funding of a new pharmaceutical results in additional tests, specialist consultations, hospitalisations, etc).

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Last updated: 10 August 2017