
Utilisation and Cost Model Workbook for PBAC Submissions User Manual

Version 1.0

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3 Abbreviations and acronyms

Term	Definition
ABS	Australian Bureau of Statistics
AEMP	agreed ex-manufacturer price
AIHW	Australian Institute of Health and Welfare
AR	Authority Required
ARTG	Australian Register of Therapeutic Goods
ATC	Anatomical Therapeutic Chemical
CEA	cost-effectiveness analysis
CUA	cost-utility analysis
DoH	Department of Health
DPMA	dispensed price for maximum amount
DPMQ	dispensed price for maximum quantity
EFC	efficient funding of chemotherapy
ICER	incremental cost-effectiveness ratio
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NIP	National Immunisation Program
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PI	Product Information
QALY	quality-adjusted life year
RPBS	Repatriation Pharmaceutical Benefits Scheme
RSA	Risk Sharing Arrangement
SA	Services Australia (formerly Department of Human Services)
SPA	Special Pricing Arrangement
TGA	Therapeutic Goods Administration

4 Background

4.1 Introduction

The User Manual has been designed to assist applicants to complete the *Utilisation and Cost Model Workbook* (Workbook) required as part of submissions to the Pharmaceutical Benefits Advisory Committee (PBAC). The Department of Health (DoH) developed the Workbook to streamline the validation of an applicant's utilisation and financial estimates by the PBAC, followed by review and agreement by the DoH, other relevant portfolio agencies including the Department of Finance as part of the Pharmaceutical Benefits Scheme (PBS) listing process. The Workbook and hence this User Manual are not designed to support applications to the PBAC regarding vaccines proposed for the National Immunisation program (NIP).

The primary audience for the completed Workbook is the PBAC and, as such, it is important to ensure that applicants complete the Workbook comprehensively and accurately. As outlined in the *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee Version 5.0* (Guidelines), applicants must ensure that data flow logically throughout the worksheets and that any methods used are clearly explained and consistent, where applicable, with the economic model(s) used in the submission.

Hence, this User Manual provides practical, systematic guidance in the style of a reference manual to explain the functionality provided in the Workbook. As each applicant has the option of completing its submission using an epidemiological approach, a market-share approach, or a mixed approach, the Workbook supports each of these three scenarios. Specific guidance on how to complete the Workbook for each scenario is included in Section 4 of the Guidelines and in this User Manual. In case of inconsistencies between the Guidelines and this User Manual, the User Manual will take precedence.

The Guidelines are available on the [Pharmaceutical Benefits Advisory Committee \(PBAC\) website](#).

4.2 Utilisation and Cost Model Workbook

As part of its submission to the PBAC, each applicant is required to estimate the likely use of the proposed medicine in clinical practice and the resulting financial impacts on the Australian Government health-related budgets. These estimates are to be fully presented by completing the Workbook, including all data, calculations, and methods used in their generation.

This manual relates to Release 3 of the Workbook that is available from the [PBAC website](#)

The Workbook consists of the following worksheets¹:

- 0. Title
- 1. Overview
- 2. Patients – summary
 - 2a. Patients – incident
 - 2b. Patients – prevalent
 - 2c. Patients – GF
 - 2d. Scripts – market
- 3a. Scripts – proposed
- 3b. Impact – proposed (pub)
- 3c. Impact – proposed (eff)

¹ The worksheet names provided below are the tab names rather than the descriptive names that appear in the header of each worksheet. Section 4.6.8 describes the worksheet naming convention used in the Manual.

- 4a. Scripts – affected
- 4b. Impact – affected (pub)
- 4c. Impact – affected (eff)
- 5. Impact – net
- 6. Net changes – SA
- 7. Net changes – MBS
- 8. ABS population
- 9. AIHW population
- 10. Registry population
- 11. Prevalent population
- 12. Copies of data
- Template

4.3 Hidden worksheets

There are two hidden worksheets in the Workbook:

- References
- ChangeLog

The *Reference* worksheet contains all the data used to drive drop-down lists and calculations across the Workbook. **DO NOT** edit or delete any elements in this worksheet, as it will stop the Workbook from functioning correctly.

The *ChangeLog* worksheet provides details of the changes made in each version of the Workbook since v77. There have been three public Releases of the Workbook, but behind the scenes, there have been versions that DoH has not publicly released. The limited numbers of Releases was to ensure stability to the work that applicants were required to do as part of the submission. These intermediate versions resolved errors that applicants identified between Releases and provided enhancements based on industry feedback.

4.4 Hidden rows and columns

There are many hidden rows and columns in the Workbook. They are generally to the right of the area where you interact with the Workbook. These elements are formatted like the rest of the Workbook, except that the text is red. **DO NOT** edit or delete any of these elements in the Workbook, as it will stop the Workbook from functioning correctly. If you choose to unhide these elements while you are working on the Workbook, please hide them before submitting the Workbook.

Total initial patients					
2020	2021	2022	2023	2024	2025
0	0	0	0	0	0
0	0	0	0	0	0
0	0	0	0	0	0

Figure 1 Hidden text in the Workbook

4.5 Macros

There are no macros provided with the Workbook.

4.6 Conventions used in the Workbook

The Workbook follows a numbers of conventions to facilitate ease of use. The sections below briefly describe each convention.

4.6.1 Worksheet colour coding

Each worksheet in the Workbook is colour coded to denote its function. The banner at the top of the worksheet and the worksheet’s tab use these colours. The following colours are used:

	Background
	Population (epidemiology)
	Scripts
	Costs
	Data
	Extra sheets added

Figure 2 Worksheet colour coding

4.6.2 Cell colour coding

Each cell in the Workbook is colour coded to explain its function. The following colours are used:

	Data inputs - DoH
	Data inputs - applicant
	Output cells
	Optional cells not used

Figure 3 Cell colour coding

4.6.3 Information messages

The Workbook contains validation code and provides informational messages to highlight how the Workbook is behaving. An example of the message is below:

Note: no flow-ons to other medicines

Figure 4 Example information message

4.6.4 Error messages

The Workbook contains validation code and provides error messages when it appears that the model contains errors. An example of the message is below:

Error: missing PBAC recommendation

Figure 5 Example error message

4.6.5 Information banners

In the banner of each worksheet, there are information messages that show if a worksheet is not required. *Worksheet 0. Title* drives this functionality for mandatory worksheets. If a worksheet is optional or you have not completed it, then it will also show a message indicating that. An example of the message is below:

Patients: summary **** NOT REQUIRED ****

Figure 6 Example worksheet banner

4.6.6 Cross-references

The Manual uses the following labels for cross-referencing purposes:

- Section – other parts of the manual
- Part – elements of a worksheet in the Workbook
- Worksheet – worksheets in the Workbook
- Guideline Section – sections in the Guidelines

4.6.7 Terminology

The Manual uses the following terms:

- Schedule of Pharmaceutical Benefits – the Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the *National Health Act 1953*. The Schedule is update monthly and is available from [PBS Publications](#).
- PBS Items – a combination of form and strength of a particular medicine is identified by a PBS Item code in the Schedule of Pharmaceutical Benefits.

4.6.8 Worksheet naming

The Manual will refer to a worksheet in the following manner:

- In the body of the text, *Worksheet 2. Patients* (worksheet tab name)
- In the Overview boxes and titles, *Worksheet 2. Patients: summary* (worksheet banner title)

4.7 Structure of the User Manual

The User Manual follows the structure of the guidance in Section 4 of the Guidelines. The User Manual consists of the following sections:

- Background
- Mandatory worksheets
- Epidemiological approach
- Market-share approach
- Estimation of scripts for the proposed medicine
- Estimation of changes in use and cost of affected medicines
- Net changes – PBS / RPBS (Published / Effective Price)
- Net changes – SA
- Net changes – MBS
- Data sources

In each section, the User Manual will provide instructions on how to fulfil the information requests outlined in Section 4 of the Guidelines by completing the relevant worksheets in the Workbook. Each section on data entry has a screen shot of a worked example of a fictional submission and includes cross-references to the relevant subsection in the Guidelines.

Please note that the inputs used as part of the worked example do not represent any actual listing and DoH created them solely for the purpose of this User Manual.

5 Mandatory worksheets

Overview

❑ Worksheet 0. Title

The worksheet provides a table of contents of the required and completed worksheets, a description of the worksheet and cell colour coding and selections to determine how the rest of the Workbook functions.

❑ Worksheet 1. Overview

Provides information about the submission including general information about the medicine, regulatory information, Schedule of Pharmaceutical Benefits information, existing listings, flow-ons to affected medicines, comparator / clinical trials, economics / SPA / RSA and patient count / costs.

5.1 Worksheet 0. Title

This worksheet provides a general guide to the Workbook, including the following parts:

- Introduction – includes a brief introduction to the Workbook, which includes the version number and release date of the Workbook.
- Table of contents – includes hyperlinks to all worksheets in the Workbook and a checklist that highlights which worksheets you should complete based on your selections and which worksheets you have completed. There is also a comments section for you to explain the use of a particular worksheet.

Table of contents	Required	Completed
1. Overview	✔	✘
2. Patients	✘	✘
2a. Patients - incident	✘	✘
2b. Patients - prevalent	✘	✘
2c. Patients - grandfathered	✘	✘
2d. Scripts - market	⚠	✘
3a. Scripts - proposed	✔	✘
3b. Impact - proposed (Published price)	✔	✘
3c. Impact - proposed (Effective price)	✘	✘
4a. Scripts - affected	✘	✘
4b. Impact - affected (Published price)	✘	✘
4c. Impact - affected (Effective price)	✘	✘
5. Impact - net	✔	✔
6. Net changes - SA	⚠	✘
7. Net changes - MBS	⚠	✘
8. ABS population	⚠	✘
9. AIHW population	⚠	✘
10. Registry population	⚠	✘
11. Prevalent population	⚠	✔
12. Copies of data	⚠	✘

Figure 7 Workbook table of content

- Worksheet and cell legend – clarifies the function of the coloured worksheets and cells in the Workbook.
- Structure of the model – your responses to these questions determine which areas of the Workbook are available for data entry and you **MUST** complete them prior to working on the rest of the model.

The following information is required:

- Identification of script source – select from:
 - epidemiology – based on a population from Australian Bureau of Statistics (ABS), Australian Institute of Health and Welfare (AIHW), registry data or prevalent pool
 - market-share – based on script volumes of an existing PBS listed medicine
 - mixed model – contains elements of both epidemiology and market-share
 - DoH forecast – for use by DoH only
- If you select an epidemiology or mixed model, identify which of the following patient sources relate to your proposed medicine.
 - incident
 - prevalent
 - grandfathered
- If you select a market-share or mixed model, then identify whether the proposed medicine will substitute for existing medicines or be adjunctive. If you select *Substitution*, then *Worksheet 5. Impact – net* will show the combined impact of listing the proposed and any consequential changes to existing listing. If you select *Adjunctive*, then the Workbook assumes that you are adding the proposed medicine to an existing medicine to produce a new therapy, **without** affecting any existing listing.
- Select whether any of the affected medicine(s) have a Special Pricing Arrangement (SPA).

Structure of the model	
Identify the script source	Epidemiology
Incident patients	Yes
Prevalent patients	Yes
Grandfathered patients	Yes
Market-share impact	Copayment only
Proposed listing results in	Substitution
Affected medicine has SPA	

Note: both incident and prevalent patients identified, check for double counting

Note: both prevalent and grandfathered patients identified, check for double counting

Note: new medicine will affect a PBS listed medicine - net impact shows interaction of proposed and existing medicines

Figure 8 Structure of the model selections

- Guidance – offers key points of general guidance to consider during completion of the Workbook.

5.2 Worksheet 1. Overview

This worksheet provides a high-level overview of the submission. The following information is required:

- General information
 - Medicine / molecule name
 - Brand name
 - Applicant company
 - PBAC meeting
 - Agenda Item (completed by DoH)
 - Submission type
 - Codependent
 - First year of listing
- Financial impact (auto populated by the Workbook and DoH)
- Cost drivers (completed by DoH)
- PBAC / MSAC outcomes (completed by DoH)
- Regulatory information
 - ATC code – Level 1²
 - ATC code – Level 2
 - ATC code – Level 3
 - ATC code – Level 4
 - ATC code – Level 5
 - Dosing and administration – from the Product Information (PI) for this indication **only**
 - TGA indication³ – for the proposed indication **only**
- Schedule of Pharmaceutical Benefits information
 - Restriction count – you can create up to 20 restrictions for a proposed medicine. If you are seeking a grandfathered, initial and continuing restrictions, then this should be shown as three restrictions. If you have both Section 100 public hospital and private hospital, then this should be two restrictions. The value you select for this field will open the corresponding number of restrictions in the following Part of the worksheet.
 - Flow-ons – if your proposed medicine is expected to change the restrictions of other, currently listed PBS medicines, then this field should be set to *Yes*
 - For each restriction the following information is required:
 - Category / Program – select from:
 - CA – Section 100 Community Access
 - CT – Section 100 EFC related
 - DB – Prescriber's Bag
 - GE – Section 85 General
 - GH – Section 100 Human Growth Hormone
 - HB – Section 100 Highly Specialised Drugs – Public hospital
 - HS – Section 100 Highly Specialised Drugs – Private hospital
 - IF – Section 100 IVF/GIFT
 - IN – Section 100 Efficient Funding of Chemotherapy – Private hospital
 - IP – Section 100 Efficient Funding of Chemotherapy – Public hospital
 - MD – Section 100 Opiate Dependence
 - MF – Section 100 Botox
 - PL – Palliative Care

² This information is available from [WHO Collaborating Centre for Drug Statistics Methodology](#)

³ This information is available from [Australian Register of Therapeutic Goods](#)

- PQ – Section 100 Para/Quad
 - R1 – RPBS
- If your proposed medicine will list on the Section 100 Public hospital and Section 100 Private hospital programs, then you will need to show **both** restrictions
 - Treatment phase – select from:
 - Grandfathered
 - Initiating
 - Continuing
 - All – this option is used if there is no distinction between initiating and continuing supply
 - Balance of supply
 - Episodicity
 - Severity
 - Condition
 - PBS indication – (auto populated by the Workbook)
 - Treatment criteria
 - Clinical criteria
 - Population criteria
 - Manner of administration and form – taken from the PI for a proposed medicine or the information on the Schedule of Pharmaceutical Benefits for an existing medicine
 - Listing type – select from:
 - New – this listing adds a previously unlisted medicine to the PBS
 - Amended – this listing adds a new form / strength of a PBS listed medicine
 - Extended – this listing adds a new indication / population to a PBS listed medicine
 - Price change – (DoH only)
 - Max quantity (packs)
 - Max amount (mg) – for Efficient Funding of Chemotherapy (EFC) listings, Max quantity (units) – for all other listings
 - Repeats
 - Restrictions – select from:
 - unrestricted
 - restricted
 - AR – streamlined
 - AR – telephone
 - AR – written
 - If you have selected AR – telephone or AR – written in the restriction field, you can select AR – electronic as the second restriction type.

Listing type	New
Max quantity (packs)	4
Max quantity (units)	8
Repeats	5

Restrictions
AR - Telephone
AR - Electronic

Figure 9 Telephone + electronic restrictions

Listing type	New
Max quantity (packs)	4
Max quantity (units)	4
Repeats	5

Restrictions
AR - Streamlined

Figure 10 Streamlined restriction

- Existing listings of the proposed medicine
 - PBS Item code(s) of the existing listings of the medicine – for the proposed indication **only**
- Flow-ons to other currently listed medicines
 - PBS Item code(s) of the existing listings of the medicine(s)
 - Current restriction wording as it appears on the Schedule of Pharmaceutical Benefits
 - Expected restriction wording after this listing
- Comparator / clinical trials
 - Details of the comparator medicine(s)
 - Details of clinical trials presented in the submission, if appropriate. This detail is optional for minor submissions.
- Economics / SPA / RSA
 - Economic analysis – select from:
 - Cost-effectiveness
 - Cost-minimisation
 - Price change
 - Cost comparator – for a cost-minimised listing, which medicine was used as the comparator
 - SPA requested – are you seeking a Special Pricing Arrangement (SPA) for this listing
 - RSA requested – are you seeking a Risk Sharing Arrangement (RSA) for this listing
 - Join existing RSA – are you seeking to join an existing RSA
- Patient count / costs
 - Avg annual patients & source – DoH to complete
 - Avg annual patients – (auto populated by Workbook for the epidemiological approach)
 - Source of cost to patient – DoH to complete
 - Treatment period – select from:
 - Annual
 - Course of treatment
 - Method of calculation – DoH to complete
 - Scripts / year or scripts / treatment – the numbers of scripts a patient is expected to receive during a year or a complete course of treatment
 - Model review
 - Clinical advisory board – were the estimates based on advice from an advisory board
 - Evaluator review – was the model evaluated (DoH to complete)
 - DUSC review – was the model reviewed by DUSC (DoH to complete)
 - ESC review – was the model reviewed by ESC (DoH to complete)
 - PBAC review – was the model reviewed by PBAC (DoH to complete)

DoH provides the information collected in the *Worksheet 1. Overview* to portfolio agencies⁴ and the Department of Finance as background to the submission as these agencies do not receive the full text of the submission.

⁴ Portfolio agencies include the Department of Veterans' Affairs and Services Australia (formerly Department of Human Services).

Certain information that you entered in this worksheet populates the rest of the worksheets in the Workbook. These include:

- Medicine / molecule name
- Brand name
- TGA indication
- First year of listing

6 Epidemiological approach

Overview

For an epidemiological approach, you define the population by completing some or all of the following worksheets, as required.

If your model takes a market-share approach, this section is not required unless you wish to include grandfathered patients. Please turn to Section 7 to continue with defining a market-share model.

Worksheet 8. ABS population - 3222.0 Series B

Derive the eligible population of patients who would utilise the proposed medicine based on the ABS population.

Worksheet 9. AIHW population

Derive the eligible population of patients who would utilise the proposed medicine based on a data series from the AIHW.

Worksheet 10. Registry or other

Derive the eligible population of patients who would utilise the proposed medicine based on registry data or another population source other than ABS or AIHW.

Worksheet 11. Prevalent population

Derive the eligible population of patients who would utilise the proposed medicine based on a historical prevalent population. For example if this listing treats patients who were diagnosed in the six years prior to the listing.

Worksheet 2. Patients: summary (auto populated)

Summarises data taken from the incident, prevalent and grandfathered patients worksheets to total the population and show a split between initiating and continuing patients, if applicable, and PBS and RPBS. No input is required from the applicant on this worksheet.

Worksheet 2a. Patients: incident

The numbers of incident patients with the medical condition targeted by the proposed medicine.

Worksheet 2b. Patients: prevalent

The numbers of prevalent patients with the medical condition targeted by the proposed medicine.

Worksheet 2c. Patients: grandfathered

The numbers of grandfathered patients with the medical condition targeted by the proposed medicine.

6.1 Worksheet selection – populations

You can use four population types in the Workbook:

- ABS
- AIHW
- Registry
- Prevalent pool

6.1.1 Worksheet 8. ABS population - 3222.0 Series B

This worksheet allows the definition of up to 10 different populations based on the ABS 3222.0 Series B data. Once you make the necessary selections, the data will become visible. The worksheet contains the data for males, females and people. For each population, the following information is required:

- minimum age – select 0 to 100 (select 0 for all people)
- maximum age – select 0 to 100 (select 100 for all people)
- population – select from:
 - people (includes both male and female)
 - male
 - female
- start year – only required if it is not the first year of listing⁵
- incidence – shown as a rate per population, the example below shows 1:100,000

Australian population 1: People 18 - 100 yrs inclusive (2020-2025)

	Minimum	Maximum		Population	Start year
Included ages	18	100		People	

	Rate	per	
Incidence	1	100,000	0.000010

Population used

	2020	2021	2022	2023	2024	2025
	201	204	208	211	214	217

Populations	2020	2021	2022	2023	2024	2025
Persons	20,100,838	20,429,953	20,757,917	21,082,471	21,411,852	21,744,502
Male	9,865,989	10,025,775	10,185,789	10,343,847	10,504,073	10,666,179
Female	10,234,849	10,404,178	10,572,128	10,738,624	10,907,779	11,078,323

Figure 11 ABS population: people aged 18 – 100 and incidence of 1:100,000

⁵ This can occur when you have a population that starts before the treatment period covered by the estimates. This is the case when developing a diagnosed patient population as the basis for a historical prevalent pool.

6.1.2 Worksheet 9. AIHW population

This worksheet allows the definition of up to 10 different populations based on AIHW data. You can obtain AIHW population data from the [AIHW website](#). If you require more complex data manipulation, you should add the source as an additional worksheet at the end of the Workbook and linked back to this worksheet. Once you make the necessary selections, the data will become visible. For each population required, the following information is required:

- the name of the population
- the AIHW Data series used as the source
- population – select from:
 - people (includes both male and female)
 - male
 - female
- start year – only required if it is not the first year of listing
- the numbers of people for each year in the appropriate row

AIHW population 1: Diabetes patients: People (2020-2025)							
Name	Diabetes patients					Data series	AIHW Incidence of insulin-treated diabetes 2017
Population	People					Start year	
Population used							
	2020	2021	2022	2023	2024	2025	
	2,496	2,519	2,559	2,709	2,654	2,742	
Populations	2020	2021	2022	2023	2024	2025	
Persons	2,496	2,519	2,559	2,709	2,654	2,742	
People	2,496	2,519	2,559	2,709	2,654	2,742	
Male	1,471	1,463	1,491	1,541	1,539	1,618	
Female	1,025	1,056	1,104	1,168	1,115	1,124	

Figure 12 AIHW population: people with insulin-treated diabetes

6.1.3 Worksheet 10. Registry or other population

This worksheet allows the definition of up to 10 different populations based on Registry or another defined population⁶. If you require more complex data manipulation, you should add the source as an additional worksheet at the end of the Workbook and linked back to this worksheet. Once you make the necessary selections, the data will become visible. For each population required, the following information is required:

- the name of the population
- the source of the data
- population – select from:
 - people (includes both male and female)
 - male
 - female
- start year – only required if it is not the first year of listing
- the numbers of people for each year in the appropriate row

⁶ This can include Compassionate Access Programs.

Other population 1: Bone cancer patients: People (2010-2015)							
Name	Bone cancer patients					Source	NSW Cancer Registry
Population	People	Start year			2010		
Population used							
	2010	2011	2012	2013	2014	2015	
	39,629	40,925	42,068	42,509	42,764	43,378	
Populations	2010	2011	2012	2013	2014	2015	
Persons	39,629	40,925	42,068	42,509	42,764	43,378	
People	39,629	40,925	42,068	42,509	42,764	43,378	
Male	22,455	23,207	23,828	23,372	23,272	23,926	
Female	17,174	17,718	18,240	19,137	19,492	19,452	

Figure 13 Registry population: NSW Cancer Registry

6.1.4 Worksheet 11. Prevalent population

This worksheet allows the definition of up to six different populations based on previously diagnosed patients. The worksheet starts five years before the first year of listing to derive the total population eligible for treatment. If you require more complex data manipulation, you should add the source as an additional worksheet at the end of the Workbook and linked back to this worksheet. Once you make the necessary selections, the data will become visible. For each population required, the following information is required:

- the indication
- the name of the population
- the source of the data
- persistence rate – the percentage of patient who will continue treatment in a subsequent year

Prevalent pool 1: Traumatic Brain Injury (2014-2025)												
Indication	Traumatic Brain Injury											
Source	ABS Epidemiology											
Persistence	80%											
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Cohort 1	716	573	458	367	293	235	188	150	120	96	77	62
Cohort 2		729	583	467	373	299	239	191	153	122	98	78
Cohort 3			742	594	475	380	304	243	195	156	124	100
Cohort 4				751	601	481	385	308	246	197	157	126
Cohort 5					764	611	489	391	313	250	200	160
Cohort 6						771	617	493	395	316	253	202
Cohort 7							784	627	502	401	321	257
Cohort 8								797	638	510	408	326
Cohort 9									809	647	518	414
Cohort 10										822	658	526
Cohort 11											835	668
Cohort 12												848
						Total	2,221	2,404	2,561	2,696	2,814	2,919

Figure 14 Prevalent population: Traumatic brain injury

6.2 Worksheet selection – patient types

In *Worksheet 0. Title*, you identified that the model you are building is an epidemiological approach. This marks *Worksheet 2d. Scripts – market* as ****Co-payment only**** and unlocks the epidemiological worksheets. You are then able to identify which of the following type of patients you are including in the model.

Structure of the model	
Identify the script source	Epidemiology
Incident patients	Yes
Prevalent patients	Yes
Grandfather patients	Yes

Note: both incident and prevalent patients identified, check for double counting

Note: both prevalent and grandfathered patients identified, check for double counting

Figure 15 Patient population selection

The Workbook will highlight if you have selected both incident and prevalent patients to remind you to check for double counting. The same check happens when you select both prevalent and grandfathered patients as the grandfathered patients would normally be a subset of the total prevalent pool of patients.

6.2.1 Defining the co-payment groups

Before linking your populations to the individual patient groups, you will need to define co-payment groups. The Workbook uses these groups to calculate PBS / RPBS splits and co-payments and the public / private hospital splits required for MBS Items. Details on how to set up these groups is contained in Section 7.1.1.

6.2.2 Worksheet 2. Patients: summary

Worksheet 2. Patients summarises data taken from the incident, prevalent and grandfathered patients worksheets to total the population and show the split between initiating and continuing patients, if applicable, and the split between PBS and RPBS. No input is required from you on this worksheet. There are four parts to the worksheet:

- Summary of patients
- Incident patients
- Prevalent patients
- Grandfathered patients

6.2.2.1 Summary of patients

Estimated results from the following sections will flow through to this summary worksheet. This indicates the total numbers of initiating patients and total numbers of continuing patients, if applicable, split by PBS and RPBS.

6.2.2.2 Incident patients

This indicates the total numbers of incident patients, if applicable, split by initiating and continuing patients.

6.2.2.3 Prevalent patients

This indicates the total numbers of prevalent patients, if applicable, split by initiating and continuing patients.

6.2.2.4 Grandfathered patients

This indicates the total numbers of grandfathered patients, if applicable, split by initiating and continuing patients.

6.2.3 Worksheet 2a. Patients: incident

This worksheet is for estimating the numbers of incident patients using an epidemiological approach. Relevant guidance for this worksheet is included in Section 4.2.1 of the Guidelines. There are three parts to the worksheet:

- Summary of patients
- Detail of incident patients
- Methods and assumptions

6.2.3.1 Summary of patients

Estimated results from the following sections will flow through to the summary table. This shows the total numbers of initiating patients and total numbers of continuing patients, if applicable.

Where the numbers of patients in a cohort (patients starting treatment in a particular year) is dependent on the prior year, rows 17 to 26 and rows 28 to 37 allows you to indicate the annual persistence rate for patients in each cohort. If the treatment duration for your proposed medicine is less than 12 months, then you can ignore this section and collapse this part of the worksheet. The results of these two tables are available through the *Total treated incident patients* option when selecting populations in *Worksheet 3a. Scripts – proposed*.

6.2.3.2 Detail of incident patients

The worksheet allows you to define up to 10 incident patient populations. You can develop multiple populations to support either different uptake rates or other factors that affect the use of your proposed medicine.

For each population, the following information is required:

- Patient source – select from:
 - ABS
 - AIHW
 - Other
 - Prevalent pool
- Population name – select from the populations defined in Section 6.1.
- Description – if there are multiple incident populations, add a description so you can differentiate between them.
- Once you make these selections, the Workbook automatically populates the row titled *Incident population*.
- Eligibility – identify up to 10 factors that will affect patient eligibility for the proposed medicine. For each criterion the following information is required:
 - Description – a description of the criterion
 - Eligibility rate – the percentage of patients you expect to meet this criterion each year
 - Source – the source of this criterion
- Patients electing treatment – the percentage of patients who you expect to elect treatment each year
- Co-payment group – select the *Co-payment group* you want to assign to this patient group. You defined these groups in *Worksheet 2d. Scripts – market* (Section 7.1.1).

Incident 1: Australian population 1: People 0 - 100 yrs inclusive (2020-2025)

Identify the numbers of incident patients who would be eligible for the proposed medicine.

Patient source	ABS		Australian population 1: People 0 - 100 yrs inclusive (2020-2025)				Description
	Number of patients						
	2020	2021	2022	2023	2024	2025	
Incident population	259	263	267	271	276	280	
Eligibility							Source
EOOC Status > 2	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	SMART clinical trial
Overall eligibility (%)	75.000%	75.000%	75.000%	75.000%	75.000%	75.000%	
Eligible patients (#)	194	197	200	204	207	210	
Initiating treatment							Source
Patients electing treatment (%)	85.00%	85.00%	85.00%	85.00%	85.00%	85.00%	Clinician survey
Continuing treatment							Source
Patients electing treatment (%)	75.00%	75.00%	75.00%	75.00%	75.00%	75.00%	Clinician survey
Initiating patients (#)	165	168	170	173	176	178	
Continuing patients (#)	146	148	150	153	155	157	
Co-payment group	1						

Figure 16 Incident patient population

6.2.3.3 Methods and assumptions

Ensure that you outline all your methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

For additional guidance, refer to incidence data in Section 4.2.1 of the Guidelines.

6.2.4 Worksheet 2b. Patients: prevalent

This worksheet is for estimating the numbers of prevalent patients using an epidemiology-based approach. Relevant guidance for this worksheet is included in Section 4.2.1 of the Guidelines. There are three parts to the worksheet:

- Summary of patients
- Detail of prevalent patients
- Methods and assumptions

6.2.4.1 Summary of patients

Estimated results from the following sections will flow through to the summary table. This shows the total numbers of initiating patients and total numbers of continuing patients, if applicable.

Where the numbers of patients in a cohort (patients starting treatment in a particular year) is dependent on the prior year, rows 17 to 26 and rows 28 to 37 allows you to indicate the annual persistence rate for patients in each cohort. If the treatment duration for your proposed medicine is less than 12 months, then you can ignore this section and collapse this part of the worksheet. The results of these two tables are available through the *Total treated prevalent patients* option when selecting populations in *Worksheet 3a. Scripts – proposed*.

6.2.4.2 Detail of prevalent patients

The worksheet allows you to define up to 10 prevalent patient populations. You can develop multiple populations to support either different uptake rates or other factors that affect the use of your proposed medicine.

For each population, the following information is required:

- Patient source – select from:
 - ABS
 - AIHW
 - Other
 - Prevalent pool
- Population name – select from the populations defined in Section 6.1.
- Description – if there are multiple prevalent populations, add a description so you can differentiate between them.
- Once you make these selections, the Workbook automatically populates the row titled *Prevalent population*.
- Eligibility – identify up to 10 factors that will affect patient eligibility for the proposed medicine. For each criterion the following information is required:
 - Description – a description of the criterion
 - Eligibility rate – the percentage of patients you expect to meet this criterion each year
 - Source – the source of this criterion
- Patients electing treatment – the percentage of patients who you expect to elect treatment each year
- Co-payment group – select the *Co-payment group* you want to assign to this patient group. You defined these groups in *Worksheet 2d. Scripts – market* (Section 7.1.1).

Prevalent 1: Other population 1: Bone cancer patients: People (2020-2025)						
Identify the numbers of prevalent patients who would be eligible for the proposed medicine.						
Patient source	Other		Other population 1: Bone cancer patients: People (2020-2025)			
	Number of patients					
	2020	2021	2022	2023	2024	2025
Prevalent population	39,629	40,925	42,068	42,509	42,764	43,378
Eligibility						
ECOG status > 1	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%
Overall eligibility (%)	25.00%	25.00%	25.00%	25.00%	25.00%	25.00%
Eligible patients (#)	9,907	10,231	10,517	10,627	10,691	10,845
Initiating treatment						
Patients electing treatment (%)	65.00%	70.00%	70.00%	75.00%	75.00%	80.00%
Continuing treatment						
Patients electing treatment (%)	60.00%	65.00%	65.00%	70.00%	70.00%	75.00%
Initiating patients (#)	6,440	7,162	7,362	7,970	8,018	8,676
Continuing patients (#)	5,944	6,650	6,836	7,439	7,484	8,133
Co-payment group	1					

Figure 17 Prevalent patient population

6.2.4.3 Methods and assumptions

Ensure that you outline all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

For additional guidance, refer to prevalence data in Section 4.2.1 of the Guidelines.

6.2.5 Worksheet 2c. Patients: grandfathered

This worksheet is for estimating the numbers of grandfathered patients using an epidemiology-based or market-share approach. Relevant guidance for this worksheet is included in Section 4.2.1 of the Guidelines. There are three parts to the worksheet:

- Summary of patients
- Detail of grandfathered patients
- Methods and assumptions

6.2.5.1 Summary of patients

Estimated results from the following sections will flow through to the summary table. This shows the total numbers of initiating patients and total numbers of continuing patients, if applicable.

Where the numbers of patients in a cohort (patients starting treatment in a particular year) is dependent on the prior year, rows 17 to 26 and rows 28 to 37 allows you to indicate the annual persistence rate for patients in each cohort. If the treatment duration for your proposed medicine is less than 12 months, then you can ignore this section and collapse this part of the worksheet. The results of these two tables are available through the *Total treated prevalent patients* option when selecting populations in *Worksheet 3a. Scripts – proposed*.

6.2.5.2 Detail of grandfathered patients

The worksheet allows you to define up to five (5) grandfathered patient populations. You can develop multiple populations to support either different uptake rates or other factors that affect the use of your proposed medicine.

If you draw a population from a compassionate access program, only a proportion may meet the PBS restriction. You must account for in the eligibility proportion calculation and explain the basis of the proportion used.

If you have used a prevalent patient population, ensure that you have not double counted patients by also including them in the Grandfathered population.

For each population, the following information is required:

- Patient source – select from:
 - ABS
 - AIHW
 - Other
 - Prevalent pool
- Population name – select from the populations defined in Section 6.1.
- Description – if there are multiple prevalent populations, add a description so you can differentiate between them.
- Once you make these selections, the Workbook automatically populates the row titled *Grandfathered population*.
- Eligibility rate – the percentage of patients eligible for the proposed medicine each year.
- Patients electing treatment – the percentage of patients who you expect to elect treatment each year.
- Co-payment group – select the *Co-payment group* you want to assign to this patient group. You defined these groups in *Worksheet 2d. Scripts – market* (Section 7.1.1).

GF 1: Other population 2: Acme CAPS: People (2020-2025)

Identify the numbers of grandfathered patients who would be eligible for the proposed medicine.
 If some of the current grandfathered patients will NOT meet the proposed PBS restriction, please explain why.

Patient source	Other population 2: Acme CAPS: People (2020-2025)						Description
	Number of patients						
	2020	2021	2022	2023	2024	2025	
Grandfathered population	50	55	55	60	60	65	
Eligibility							
Patients meeting proposed restriction %	65.00%	65.00%	65.00%	65.00%	65.00%	65.00%	Source Sponsor assumption
Patients meeting proposed restriction (#)	33	36	36	39	39	42	
Initiating treatment							
Patients electing treatment (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	Source Sponsor assumption
Continuing treatment							
Patients electing treatment (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	Source Sponsor assumption
Initiating patients (#)	33	36	36	39	39	42	
Continuing patients (#)	33	36	36	39	39	42	
Co-payment group	1						

Figure 18 Grandfathered patient population

6.2.5.3 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

For additional guidance, refer to grandfathered data in Section 4.2.1 of the Guidelines.

7 Market-share approach

Overview

For a market-share approach, you define the script volumes by completing the following worksheet.

If your model takes an epidemiological approach, this section is only required to derive the patient co-payments. Once you have completed the co-payment calculation, please turn to Section 6 to continue defining an epidemiology model.

Worksheet 2d. Scripts: market-share

Provide information on the script volumes of current medicines that will be affected by the proposed medicine or adjunctive to the proposed medicine. In addition, this worksheet provides the weighted average co-payments, PBS / RPBS split and public / private hospital split.

7.1 Worksheet selection

In *Worksheet 0. Title*, you identified that the model you are building is a market-share approach. This marks all the epidemiology related worksheets as ****NOT USED**** and unlocks *Worksheet 2d. Scripts – market*.

Structure of the model	
Identify the script source	Market share
Patient populations included	** NOT USED **
Incident patients	
Prevalent patients	
Grandfather patients	

Figure 19 Market-share selection

7.1.1 Worksheet 2d. Scripts: market-share

The market-share approach uses this worksheet to estimate the dispensed volume of the proposed medicine with reference to the extent of its substitution of currently listed medicines. It also determines the average split between PBS and RPBS volumes, average split between public hospital and private hospital setting volumes, and the weighted co-payments for the PBS and RPBS.

For estimates based on an epidemiological approach, you are only required to complete Part 2 of the worksheet.

One of the key functions of this worksheet is to allow you to define co-payment groups. A co-payment group is a combination of PBS Items that you wish to consider as a single item for the purposes of defining the PBS / RPBS split or weighted co-payments. In addition, if the medicines are listed in Section 100, a co-payment group can be used to determine the public / private hospital split. In the following example, the initiating and continuing PBS Items for abatacept are included in the same co-payment group. The Workbook uses the script volumes to derive the PBS / RPBS split, 98.79% and 1.21% respectively. The Workbook further uses the script volumes to produce a weighted co-payment for the PBS / RPBS, \$18.58 and \$4.27 respectively.

In most cases, you will only require a single co-payment group reflecting all the substituted PBS Items. If the treatment regimen you are proposing has multiple parts with significantly different patient category distributions, you should consider separating them into different co-payment groups. You can define a maximum of five co-payment groups across the 20 PBS Items.

Service volumes for calendar year 2019				PBS Services				RPBS Services		Co-payment group
Medicine / Molecule	Form / Strength	Item code	Treatment Phase	General - Ordinary Services	General - Safety Net Services	Concessional - Ordinary Services	Concessional - Free Services	RPBS - Ordinary Services	RPBS - Safety Net Services	
Atiscept	125 mg/mL Injection	9999F	Initiating	389	16	368	117	4	1	1
			Continuing	5,421	341	6,703	2,103	119	66	1
Atiscept	125 mg/mL Injection	9999G	Total	7,348	360	8,001	2,265	158	68	
			Co-payment	\$41.00	\$6.60	\$6.60	\$0.00	\$6.60	\$0.00	

Co-payments	PBS	RPBS	PBS	RPBS
Group 1	98.79%	1.21%	\$18.58	\$4.27

Figure 20 Defining a co-payment group

Relevant guidance for this worksheet is included in Section 4.2.2 of the Guidelines. There are four parts to the worksheet:

- Summary – aggregate scripts
- Identify the existing medicines that will form the basis for the proposed medicine
- Estimate the numbers of units affected
- Methods and assumptions

7.1.1.1 Summary – aggregate scripts

The summary table aggregates the estimated results from each of the detailed calculation sections. The summary table shows the total numbers of initiating scripts and total numbers of continuing scripts for the PBS and RPBS and an overall total.

7.1.1.2 Identify the existing medicine that will be the basis for the proposed medicine

This worksheet allows you to identify up to 20 currently listed PBS Items that you expect the proposed listing to substitute. For each PBS Item of a substituted medicine, the following information is required:

- Medicine / molecule name
- Form and strength
- PBS Item code
- Treatment phase – select from:
 - Initiating
 - Continuing
 - All (for a listing where there is no distinction between Initiating and Continuing)
- Script volumes by PBS / RPBS patient category for the most recent full calendar year of available data. This information is available for download from the [SA website](#).
- Co-payment group – select group 1 – 5
- If the currently listed medicine is available in Section 100 and has both a public and private hospital listing, then in the next two columns identify the prescribing environment to which it belongs. Otherwise, you can leave the next two columns blank.

Below the script volume table, the Worksheet provides two result tables. The first table shows the co-payment groups and their associated PBS / RPBS split and the resulting weighted co-payments.

The second table shows the co-payment groups and their associated public / private hospital split, if appropriate. If the derived public and private split is not appropriate, you can over-ride it below the table.

If you are developing an epidemiological approach, then no further data entry is required on this worksheet as the Workbook only uses it to determine the average patient co-payments. Please continue with Section 8.

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Service volumes for calendar year 2019

Medicine / Molecule	Form / Strength	Item code	Treatment Phase	PBS Services				RPBS Services		Co-payment group	Include in split		Total Services	PBS %	RPBS %
				General - Ordinary Services	General - Safety Net Services	Concessional - Ordinary Services	Concessional - Free Services	RPBS - Ordinary Services	RPBS - Safety Net Services		Public	Private			
Alaacept	125 mg/mL injection	9998F	Initiating	389	16	368	117	4	1	1		895	99.44%	0.56%	
Alaacept	125 mg/mL injection	9999G	Continuing	5,421	341	6,703	2,103	119	66	1		14,753	98.75%	1.25%	
Total				5,810	357	7,071	2,220	123	67						
Co-payment				\$41.00	\$6.60	\$6.60	\$0.00	\$6.60	\$0.00						

Co-payments	PBS	RPBS	PBS	RPBS
Group 1	98.79%	1.21%	\$18.58	\$4.27
Group 2	0.00%	0.00%	\$0.00	\$0.00
Group 3	0.00%	0.00%	\$0.00	\$0.00
Group 4	0.00%	0.00%	\$0.00	\$0.00
Group 5	0.00%	0.00%	\$0.00	\$0.00

Derived split	Public	Private	Over-ride split	Public	Private	Source
Group 1	0.00%	0.00%	Group 1			
Group 2	0.00%	0.00%	Group 2			
Group 3	0.00%	0.00%	Group 3			
Group 4	0.00%	0.00%	Group 4			
Group 5	0.00%	0.00%	Group 5			

Figure 21 Currently listed PBS medicine – Section 85

Service volumes for calendar year 2019

Medicine / Molecule	Form / Strength	Item code	Treatment Phase	PBS Services				RPBS Services		Co-payment group	Include in split		Total Services	PBS %	RPBS %
				General - Ordinary Services	General - Safety Net Services	Concessional - Ordinary Services	Concessional - Free Services	RPBS - Ordinary Services	RPBS - Safety Net Services		Public	Private			
Aligorimab	200 mg/40 mL injection, 40 mL vial	9999W	Initiating	1,026	3	605	36	31	1	1	No	Yes	1,702	98.12%	1.88%
Aligorimab	200 mg/40 mL injection, 40 mL vial	9999B	Initiating	512	0	325	9	4	0	1	Yes	No	850	99.53%	0.47%
Total				1,538	3	930	45	35	1						
Co-payment				\$41.00	\$6.60	\$6.60	\$0.00	\$6.60	\$0.00						

Co-payments	PBS	RPBS	PBS	RPBS
Group 1	98.59%	1.41%	\$27.51	\$6.42
Group 2	0.00%	0.00%	\$0.00	\$0.00
Group 3	0.00%	0.00%	\$0.00	\$0.00
Group 4	0.00%	0.00%	\$0.00	\$0.00
Group 5	0.00%	0.00%	\$0.00	\$0.00

Derived split	Public	Private	Over-ride split	Public	Private	Source
Group 1	33.31%	66.69%	Group 1			
Group 2	0.00%	0.00%	Group 2			
Group 3	0.00%	0.00%	Group 3			
Group 4	0.00%	0.00%	Group 4			
Group 5	0.00%	0.00%	Group 5			

Figure 22 Currently listed PBS medicine – Section 100 (public and private hospital listing)

7.1.1.3 Estimate the numbers of scripts

Based on the information you entered in Part 2, the Workbook will build a forecast of the existing medicine’s script volume over the six years from listing.

Each medicine you defined in Part 2 will have a table in this section. The following information is required:

- estimated annual rate of growth – currently average Australian population growth is 1.6%
- estimate the proportion applicable to the relevant indication
- estimate the proportion of the available medicine that your proposed medicine will affect (uptake rate for the proposed medicine)

Note that the script volumes will be negative, as your proposed listing will affect the existing scripts.

9998F - Allaccept 125 mg/mL injection - Initiating		Co-payment group 1						
	2019	2020	2021	2022	2023	2024	2025	
Estimated script volume	-895	-1,029	-1,132	-1,189	-1,248	-1,311	-1,376	
Estimated annual rate of growth	15.00%	10.00%	5.00%	5.00%	5.00%	5.00%		
Proportion applicable to indication	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%	
Proportion affected by the proposed medicine	0.00%	20.00%	30.00%	40.00%	50.00%	50.00%	50.00%	
Net effect - PBS	0	-41	-67	-94	-123	-129	-136	
Net effect - RPBS	0	0	-1	-1	-2	-2	-2	
Net effect - PBS / RPBS	0	-41	-68	-95	-125	-131	-138	

Figure 23 Estimate growth in existing medicine

7.1.1.4 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

8 Estimation of scripts of the proposed medicine

Overview

Once you have established the source for the scripts of the proposed medicine, an epidemiological or a market-share approach, this worksheet calculates the numbers of scripts expected from this listing.

Worksheet 3a. Scripts: proposed medicine

Provide information on the estimated script volumes of the proposed medicine and substitution rates to existing medicines.

Worksheet 3b. Impact: proposed medicine (published price)

Provide information on the estimated financial impact of the proposed medicine, using the published price.

Worksheet 3c. Impact: proposed medicine (effective price)

If you are requesting an SPA, provide information on the estimated financial impact of the proposed medicine, using the effective price.

8.1.1 Worksheet 3a. Scripts: proposed medicine

This worksheet estimates the volumes of the proposed medicine. Relevant guidance for this worksheet is included in Section 4.2.1 of the Guidelines. There are six parts to the worksheet:

- Summary – aggregate scripts
- Script volumes – epidemiological source
- Script volumes – market-share source
- Identify all forms and strengths of the proposed medicine
- Relate the proposed medicine to the existing market
- Methods and assumptions

8.1.1.1 *Summary – aggregate scripts*

The summary table provides the estimated results from each of the detailed calculation sections, the total numbers of scripts for the PBS and RPBS and an overall total.

8.1.1.2 *Script volumes – epidemiological source*

If you are using an epidemiological approach, this section shows the total script volumes expected for each medicine each year.

8.1.1.3 *Script volumes – market-share source*

If you are using a market-share approach, this section shows the total script volumes expected for each medicine each year.

8.1.1.4 Identify all forms and strengths of the proposed medicine

This section allows you to define up to 20 proposed PBS Items (forms and strengths of your proposed medicine). For each proposed PBS Item, the following information is required:

- Medicine / molecule name
- Form and strength
- Treatment phase – select from:
 - Initiating
 - Continuing
 - All (for a listing where there is no distinction between Initiating and Continuing)
- Patient compliance rate
- Pack size
- Script calculation – the next three columns are used to calculate the numbers of scripts per patient in a year or treatment cycle. The elements that make up this calculation are:
 - Duration – duration of therapy, measure in the time units you select in the next column
 - Periods – this should align with the frequency of dosing, so if your proposed medicine is dosed every day, then select *Days* in the *Period* column. Select from:
 - Days
 - Weeks
 - Months
 - Scripts per period – the numbers of scripts a patient would require per time unit
- Scripts / year or scripts / course of treatment – (calculated by the worksheet)

Pack size	Duration (periods)	Period	Doses / period	Scripts / year
28	365.25	Days	1.00	13.04
10	52.00	Weeks	1.00	5.20
10	12.00	Months	1.00	1.20
56	365.25	Days	2.00	13.04

Figure 24 Example script calculations

The next three columns are only relevant if you are developing an epidemiological approach and you can ignore them if you are developing a market-share model.

- Population split – this allows you to split a single patient population across a numbers of different strengths of a medicine. The total for a patient population, split among the different strengths, must equal 100%.
- Population source – select from
 - Incident
 - Prevalent
 - Grandfathered
 - Totals⁷

⁷ The patient numbers provided through *Totals* should only be used when the persistence section of the patient population worksheet has been completed.

- Population name – select from the populations you defined in Section 7.

8.1.1.5 Relate the proposed medicine to the existing market (market-share only)

This section links the proposed medicine to existing medicines and captures the script equivalence to calculate volumes of the proposed medicine. The table presents the following columns:

- Medicine / Molecule – Existing – lists all the forms and strengths that you defined in Section 7
- Medicine / Molecule – Proposed – select from all the forms and strengths that you provided for your proposed medicine

Please relate the proposed medicine to the existing market.

Medicine / Molecule - Existing	Medicine / Molecule - Proposed
9998F - Allaccept 125 mg/mL injection - Initiating	Allaccept 100 mg/mL injection - Initiating

Figure 25 Relating proposed and existing medicines

The next table allows you to identify the script equivalence between your proposed medicine and the proposed medicine. This can be calculated either as a whole number or you can use a calculation. For example, if the existing medicine provides 30 days of treatment and the proposed medicine provides 28 days of treatment, then the entries would be as follows:

- Existing = 365.25 / 30
- Proposed = 365.25 / 28

This would produce the results shown below:

Script equivalence		Substitution rate
Existing	New	
12.2	13.0	1.07

Figure 26 Calculating script equivalence

- Patient compliance rate
- Current split – based on the split calculated in Part 2 of *Worksheet 2d. Scripts – market*
- If you require a different market split or you wish to vary it over time, then provide the split in the % of total columns. The percentage of total across all the proposed medicines must equal 100%.

8.1.1.6 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

8.2 Worksheet selection – Published and Effective prices

If you are requesting a Special Pricing Arrangement (SPA) for your proposed medicine and you select *Yes* to the SPA question on *Worksheet 1. Overview*, then complete:

- Worksheet 3b. Impact: proposed medicine (published price)
- Worksheet 3c. Impact: proposed medicine (effective price)

Otherwise, you only need to complete:

- Worksheet 3b. Impact proposed (pub)

8.2.1 Worksheet 3b. Impact: proposed medicine (published price)

This worksheet is for estimating the impact of the proposed medicine at the expected published price. There are four parts to the worksheet:

- Summary – aggregate financial impact
- Cost of individual forms / strengths
- Identify the cost for all forms / strengths of the proposed medicine
- Methods and assumptions

8.2.1.1 Summary – aggregate financial impact

The summary table provides the estimated results from each of the detailed calculation sections, the total numbers of scripts for the PBS and RPBS and an overall total.

8.2.1.2 Cost of individual forms / strengths

For each of the forms / strengths of your proposed medicine, a table shows the overall costs, less the co-payments and the resulting cost for the PBS and RPBS. The Workbook automatically calculates these costs and the co-payments, using the weighted co-payments calculated on *Worksheet 2d. Scripts – market*. The numbers of co-payments (one per script or one per original script [not on repeat scripts] for EFC medicines) is based on the details provided *Worksheet 6. Net changes – SA*.

8.2.1.3 Identify the cost for all forms / strengths of the proposed medicine

This section allows you to show the costs for each of the proposed PBS Items (forms / strengths) of your proposed medicine. For each PBS Item, the following information is required:

- Agreed Ex-Manufacturer Price (AEMP) – used for reference and not calculation
- Maximum quantity / maximum amount – used for reference and not calculation
- Dispensed Price for Maximum Quantity (DPMQ) / Dispensed Price for Maximum Amount (DPMA) – depending on the Section of the Schedule of Pharmaceutical Benefits you are requesting. If your proposed medicine will have a public and private hospital listing, you will need to enter **both** costs. The Workbook will then calculate a weighted price based on the public / private split calculated on *Worksheet 2d. Scripts – market*.
- Weighted average co-payment for PBS and RPBS – the Workbook uses the weighted co-payments calculated on *Worksheet 2d. Scripts – market*.

3. Identify the costs for all forms and strengths of the proposed medicine

For all forms and strengths of the proposed medicine, please provide the details as specified in the table.

Medicine / Molecule	AEMP	Max Qty Max amount	DPMA / DPMQ			Co-payment group	PBS co-payment	RPBS co-payment
Allacept 100 mg/mL Injection - Initiating	\$852.28	4	\$953.62			1	-\$18.58	-\$4.27
Allacept 100 mg/mL Injection - Continuing	\$852.28	4	\$953.62			1	-\$18.58	-\$4.27

Figure 27 Costs for a PBS medicine – Section 85
2. Identify the costs for all forms and strengths of the new medicine

For all forms and strengths of the new medicine, please provide the details as specified in the table.

Drug / Molecule	AEMP	Max Qty Max amount	DPMA / DPMQ			Co-payment group	PBS co-payment	RPBS co-payment
			Public	Private	Weighted			
Allogorimab 100mg - All	\$100.00	25mg	\$200.00	\$250.00	\$207.59	1	-\$22.66	\$0.00

Figure 28 Costs for a PBS medicine – Section 100 (public and private hospital listing)
8.2.1.4 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

8.2.2 Worksheet 3c. Impact: proposed medicine (effective price)

This worksheet is for estimating the impact of the proposed medicine at the expected effective price. The instructions for completing this worksheet are the same as for *Worksheet 3b. Impact – proposed (pub)*, except that the prices should show the effective price.

The Maximum quantity / Maximum amount column is automatically populated by the Workbook from *Worksheet 3b. Impact – proposed (pub)*.

9 Estimation of changes in use and financial impact of affected medicines

Overview

Based on the approach of the submission and whether a SPA is in place for the currently listed affected medicines, applicants are required to complete some or all of the following worksheets.

Worksheet 4a. Scripts: other medicines affected by this listing

Provide details of medicines that are likely to be affected by the listing of the proposed medicine

Worksheet 4b. Impact: affected medicines (published price)

Provide details of medicines that are likely to be affected by the listing of the proposed medicine and the estimated volume and costs of the affected medicines, using the published price.

Worksheet 4c. Impact: affected medicines (effective price)

If a SPA is in place for the currently listed affected medicines, provide information on medicines that are likely to be affected by the listing of the proposed medicine and the estimated volume and costs of the affected medicines, using the effective price.

9.1 Worksheet 4a. Scripts: other medicines affected by this listing

This worksheet estimates the volumes of medicines that your proposed medicine will affect. Affected medicines include those medicines which will decrease in use (including through substituted) because of the proposed medicine and those medicines which will increase in use because of the proposed medicine.

It should not include those medicines which will not have their utilisation volumes affected because of the proposed medicine (whether used concomitantly with the proposed medicine or not). Relevant guidance for this worksheet is included in Section 4.3.1 of the Guidelines. There are six parts to the worksheet:

- Summary – aggregate scripts
- Total script volumes – epidemiological
- Total script volumes – market-share
- Identify all forms / strengths – affected medicine – epidemiological
- Identify all forms / strengths – affected medicine – market-share
- Calculate PBS / RPBS split and public / private split
- Estimated numbers of affected units – market-share
- Methods and assumptions

9.1.1.1 Summary – aggregate scripts

The summary automatically contains the script volumes from either the epidemiological or the market-share models. The heading of this section will identify the source of the totals as either

Epidemiological or Market-share. If you do not make any changes on this worksheet then, this will be:

- epidemiology – *Worksheet 2. Patients*
- market-share – *Worksheet 2d. Scripts – market*

9.1.1.2 Total script volumes – epidemiological

If you are using an epidemiological approach, this section shows the total affected script volumes expected for each affected medicine each year.

9.1.1.3 Total script volumes – market-share

If you are using a market-share approach, this section shows the total affected script volumes expected for each affected medicine each year.

9.1.1.4 Identify all forms / strengths of affected medicines – epidemiological

If you have chosen an epidemiological approach for your model, this section will allow you to identify any other medicines that your proposed listing will affect.

For each PBS Item of an affected medicine, the following information is required:

- Medicine / molecule name
- Form and strength
- PBS Item code
- Treatment phase – select from:
 - Initiating
 - Continuing
 - All (for a listing where there is no distinction between Initiating and Continuing)
- Patient compliance rate
- Pack size
- Script calculation – the next three columns are used to calculate the numbers of scripts per patient in a year or treatment cycle. The elements that make up this calculation are:
 - Duration – duration of therapy, measure in the time units you select in the next column
 - Periods – this should align with the frequency of dosing, so if your proposed medicine is dosed every day, then select *Days* in the *Period* column. Select from:
 - Days
 - Weeks
 - Months
 - Scripts per period – the numbers of scripts a patient would require per time unit
- Scripts / year or scripts / course of treatment – (calculated by the worksheet)

Pack size	Duration (periods)	Period	Doses / period	Scripts / year
28	365.25	Days	1.00	13.04
10	52.00	Weeks	1.00	5.20
10	12.00	Months	1.00	1.20
56	365.25	Days	2.00	13.04

Figure 29 Example script calculations

- Co-payment group allows you to use one of the co-payment groups you defined in *Worksheet 2d. Scripts – market*.
- Expected change – this allows you to identify which affected medicines will have an increase or decrease in use because of your proposed listing. Select from:
 - Increase
 - Decrease
- Population split – this allows you to split a single patient population across a numbers of different strengths of a medicine. The total for a patient population, split among the different strengths, must equal 100%.
- Population source – select from
 - Incident
 - Prevalent
 - Grandfathered
 - Totals
- Population name – select from the populations you defined in Section 7.

9.1.1.5 Identify all forms / strengths of affected medicines – market-share

If you have chosen a market-share approach for your model, this section will allow you to identify any other medicines that your proposed listing will affect, noting that this will overlap with the substituted medicines identified for *Worksheet 2d. Scripts – Market*.

For each PBS Item of an affected medicine, the following information is required:

- Medicine / molecule name
- Form and strength
- PBS Item code
- Treatment phase – select from:
 - Initiating
 - Continuing
 - All (for a listing where there is no distinction between Initiating and Continuing)
- Script volumes by PBS / RPBS patient category for the most recent full calendar year of available data. This information is available for download from the [SA website](#).
- Co-payment group (this also allows you the option of using one of the co-payment groups you defined in *Worksheet 2d. Scripts – market*).
- If the medicine is available in Section 100 and has both a public and private hospital listing, then in the next two columns describe the prescribing environment to which it belongs. Otherwise, you can leave the next two columns blank.
- Expected change – this allows you to identify which other affected medicines will have an increase or decrease in use because of your proposed listing. Select from:

- Increase
- Decrease

9.1.1.6 Calculate PBS / RPBS co-payments and public / private splits

Based on the information from the co-payment groups you assigned to medicines in Section 2, the Workbook will apply the PBS / RPBS and the public / private splits you defined in *Worksheet 2d. Scripts- market*.

If the derived public / private split is not appropriate, you can over-ride it below the table.

9.1.1.7 Estimate the numbers of units affected

Each medicine you defined in Part 4 or Part 5 will have a table in this part. The following information is required:

- estimated annual rate of population growth – current Australian average is 1.6%
- estimated proportion applicable to the relevant indication
- estimated proportion of the medicine that your proposed medicine will affect (related to the uptake rate for the proposed medicine)

Note that the sign (+/-) of the script volumes will depend on what you selected in Section 2.

9998F - Allaccept 125 mg/mL injection - Initiating		Co-payment group 1					
	2019	2020	2021	2022	2023	2024	2025
Estimated script volume	-895	-1,029	-1,132	-1,189	-1,248	-1,311	-1,376
Estimated annual rate of growth	15.00%	10.00%	5.00%	5.00%	5.00%	5.00%	5.00%
Proportion applicable to indication	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%
Proportion affected by the proposed medicine	0.00%	20.00%	30.00%	40.00%	50.00%	50.00%	50.00%
Net effect - PBS	0	-41	-67	-94	-123	-129	-136
Net effect - RPBS	0	0	-1	-1	-2	-2	-2
Net effect - PBS / RPBS	0	-41	-68	-95	-125	-131	-138

Figure 30 Estimate change in medicine caused by the proposed listing

9.1.1.8 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

9.2 Worksheet selection – Published and Effective prices

If a medicine affected by your proposed medicine has an SPA that you are aware of, then complete:

- Worksheet 4b. Impact: affected medicines (published price)
- Worksheet 4c. Impact: affected medicines (effective price)

Otherwise, you only need to complete:

- Worksheet 4b. Impact affected (pub)

9.2.1 Worksheet 4b. Impact: affected medicines (published price)

This worksheet is for estimating the impact of the affected medicines at their published prices. Relevant guidance for this worksheet is included in Section 4.3.3 of the Guidelines. There are four parts to the worksheet:

- Summary – aggregate financial impact
- Cost of individual forms / strengths
- Identifying individual forms / strengths pricing
- Methods and assumptions

9.2.1.1 Summary – aggregate financial impact

The summary table provides the estimated results from each of the detailed calculation sections, the total numbers of scripts for the PBS and RPBS and an overall total.

9.2.1.2 Cost of individual forms / strengths

For each of the forms / strengths of the affected medicines, there is a table that shows the overall cost, the associated co-payments and the net cost for the PBS and RPBS. The Workbook automatically calculates these costs and the co-payments, using the weighted co-payments calculated on *Worksheet 4a. Scripts – affected*. The numbers of co-payments (one per script or one per original script [not on repeat scripts] for EFC medicines) is based on the details provided *Worksheet 6. Net changes – SA*.

9.2.1.3 Identify the costs for all forms / strengths of the affected medicines

This section allows you to show the prices for each of the PBS Items of the medicines affected by your proposed medicine. For each PBS Item, the following information is required:

- AEMP – used for reference and not calculation
- Maximum quantity / maximum amount – used for reference and not calculation
- DPMQ / DPMA – depending on the Section of the Schedule of Pharmaceutical Benefits you are requesting. If your proposed medicine will have a public and private hospital listing, you will need to enter **both** costs. The Workbook will then calculate a weighted price based on the public / private split calculated on *Worksheet 4a. Scripts – affected*.
- Weighted average co-payment for PBS and RPBS – the Workbook uses the weighted co-payments calculated on *Worksheet 4a. Scripts – affected*.

9.2.1.4 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

9.2.2 Worksheet 4c. Impact: affected medicines (effective price)

This worksheet is for estimating the impact of the medicines affected by your proposed medicine, with modifications for any known effective prices. The instructions for completing this worksheet are the same as for *Worksheet 4b. Impact – affected (pub)*, except that the prices should show the effective price where relevant.

The Maximum quantity / Maximum amount column is automatically populated by the Workbook from *Worksheet 4b. Impact – affected (pub)*.

10 Net financial implications for the PBS / RPBS (published & effective prices)

Overview

Worksheet 5. Impact: net PBS & RPBS (published & effective price)

This worksheet provides a summary of the net financial impact for PBS and RPBS based on published and effective prices. It shows the net impact of the proposed and affected listings on the PBS and RPBS.

10.1 Worksheet 5. Impact: net PBS / RPBS (published / effective price)

This worksheet provides a summary of the net financial impact for PBS and RPBS based on published and effective prices. It summarises the impact of the proposed medicine less affected medicine to show the cost of the proposed medicine to the PBS / RPBS.

There are two parts to the worksheet:

- Summary – published prices
- Summary – effective prices

10.1.1.1 Summary – published prices

The Workbook provides a summary of the net financial impact for PBS and RPBS for the proposed medicine net of the impact on any affected medicines, all at published prices. You do not need to enter anything in this section.

10.1.1.2 Summary – effective prices

If there are effective prices for the proposed or affected medicines, the Workbook provides a summary of the net financial impact for PBS and RPBS for the proposed medicine net of the impact on any affected medicines, using effective prices where known. You do not need to enter anything in this section.

11 Net changes – Services Australia

Overview

Worksheet 6. Net prescription and authority processing changes for Services Australia

Provide information about the numbers of scripts and authorisations required for the proposed medicine and affected medicines.

11.1 Worksheet 6. Net prescription and authority processing changes for Services Australia

This worksheet calculates the net changes for SA that result from your proposed listing. Relevant guidance for this worksheet is included in Section 4.5.1 of the Guidelines. There are five parts to the worksheet:

- Summary – aggregate scripts
- Summary – aggregate authorities
- Estimate of new volumes for SA as a result of the listing of the proposed medicine
- Estimate of affected volumes for SA as a result of the listing of the proposed medicine
- Methods and assumptions

11.1.1.1 Summary of scripts

Estimated results from the following sections will flow through to the summary table of scripts changes for the PBS and RPBS and an overall total. The aggregate results are in terms of transaction volumes only as Services Australia (formerly Department of Human Services) will undertake a detailed costing.

11.1.1.2 Summary of authorities

Estimated results from the following sections will flow through to the summary table of authority changes for the PBS and RPBS and an overall total. This table is summarised for each of the authority required (AR) levels:

- streamlined
- telephone
- written

11.1.1.3 Estimate of volumes for SA as a result of the listing of the proposed medicine

This section allows you to identify the relevant restriction information of each of your proposed forms / strengths of the proposed medicine.

For each of the forms / strengths of the proposed medicines, the following information is required:

- numbers of repeats
- authority type – select from:
 - unrestricted
 - restricted
 - AR – streamlined
 - AR – telephone
 - AR – written
- Electronic – is the proposed medicine going to be available through an electronic authority. This option is only available for medicines that are either AR – telephone or AR – written. Select from:
 - Yes
 - No
- EFC – is the proposed medicine going to list in Section 100 – EFC. The Workbook uses this to determine if an authority is required for each script or only for each original script (not repeat scripts). Select from:
 - Yes
 - No

3. Estimate of new volumes for Services Australia as a result of the listing of the proposed medicine

Please provide details of each of the forms and strengths of the proposed medicine

Medicine / molecule	Number of repeats	Total scripts	Authority type	Electronic	EFC
Allacept 100 mg/mL injection - Initiating	0	1	AR - Telephone	Yes	No
Allacept 100 mg/mL injection - Continuing	0	1	AR - Streamlined		No

Figure 31 Restriction information for proposed medicine

Below this table, the Workbook will display the expected change in script and authority volumes for each of the forms and strengths of the proposed medicine.

11.1.1.4 Estimate of changed volumes for SA as a result of the proposed medicine

This section allows you to identify the relevant restriction information of each of the existing forms / strengths of the affected medicines.

For each of the affected medicines, the following information is required:

- numbers of repeats
- authority type – select from:
 - unrestricted
 - restricted
 - AR – streamlined
 - AR – telephone
 - AR – written
- Electronic – is the affected medicine available through an electronic authority. This option is only available for medicines that are either AR – telephone or AR – written. Select from:
 - Yes
 - No
- EFC – is the affected medicine listed in Section 100 – EFC. The Workbook uses this to determine if an authority is required for each script or only for each original script (not repeat scripts). Select from:
 - Yes
 - No

4. Estimate of changed volumes for Services Australia as a result of the listing of the proposed medicine

Please provide details of each of the forms and strengths of the changed medicines

Form, strength and pack size	Number of repeats	Total scripts	Authority type	Electronic	EFC
9998F - Allacept 125 mg/mL injection - Initiating	5	6	AR - Telephone	Yes	No
9999G - Allacept 125 mg/mL injection - Continuing	4	5	AR - Streamlined		No
9999W - Allegorimab 200 mg/40 mL injection, 40 mL vial - Initiating	2	3	AR - Telephone	Yes	Yes
9999B - Allegorimab 200 mg/40 mL injection, 40 mL vial - Initiating	2	3	AR - Streamlined		Yes

Figure 32 Restriction information for affected medicine

Below this table, the Workbook will display the expected change in script and authority volumes for each of the forms and strengths of the affected medicines.

11.1.1.5 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

12 Net changes – Medicare Benefits Schedule

Overview

Worksheet 7. Net changes to the Medicare Benefits Schedule

Provide information about the numbers of MBS Items and indicative financial impact for the proposed and affected medicines.

12.1 Worksheet 7. Net changes to the Medicare Benefits Schedule

This worksheet calculates the net changes to MBS Items resulting from listing the proposed medicine. Relevant guidance for this worksheet is included in Section 4.5.2 of the Guidelines. There are six parts to the worksheet:

- Summary – aggregate financial impact
- Estimate volume increases to the MBS
- Relate the MBS Item to the proposed medicines
- Estimate volume decreases to the MBS
- Relate the MBS Item to the affected medicines
- Methods and assumptions

12.1.1.1 Summary – aggregate financial impact

Estimated results from the following sections will flow through to the summary table of aggregate results and the overall financial impact of the increased and decreased MBS Items, including a breakdown by PBS and RPBS. The Workbook calculates the financial impact at 80% of the Schedule fee⁸ and is indicative only. The Medical Benefits Division of DoH will undertake a detailed costing for the Department of Finance. When you complete the Workbook in the context of a codependent submission, for which MSAC also require an estimate of the financial implications, you should also estimate the net changes to the cost of the MBS according to the MSAC Guidelines.

12.1.1.2 Estimate volume increases to the MBS

For each MBS Item that you expect to **increase** in volume, the following information is required:

- MBS Item number
- MBS Item descriptor
- Proportion of public hospital use – automatically calculated by the Workbook
- Proportion of private hospital use – automatically calculated by the Workbook
- Proportion of in-patient services – the proportion of in-patient services in private hospital
- Proportion of out-patient services – automatically calculated by the Workbook
- Co-payment group – as defined in *Worksheet 2d. Scripts – market*

⁸ This figure is the average between the 75% and 85% rebate rate.

- The next three columns are related.
 - Basis of delivery – select from:
 - per patient – the MBS Item utilisation is related to patient numbers
 - per script of the proposed medicine – the MBS Item utilisation is related to script numbers
 - If *per patient* was selected, enter the numbers of services per patient per year
 - If *per script* was selected, enter the numbers of services per script of the proposed medicine
- Schedule fee – this is 100% of the Schedule Fee
- The next four columns are only available if you previously selected *per patient*
- Treatment phase – select from:
 - Initiating
 - Continuing
 - All (for a listing where there is no distinction between Initiating and Continuing)
- Population split – the proportion of the selected population who will receive this MBS Item
- Population source – select from:
 - Incident
 - Prevalent
 - Grandfathered
 - Totals
- Population name – select from the populations you defined in Section 7.

12.1.1.3 Relate the MBS Item to the proposed medicines

Part 3 allows you to relate all the MBS Items identified in Part 2 to the total script volume or a particular form and strength of a medicine. If you have set the basis of delivery for all the MBS Items in Part 2 to *per patient*, then this option will not be available. This information is used to determine the MBS Item volumes and hence the cost.

1.1 Estimate volume INCREASES to the MBS

List all the MBS items that will INCREASE as a result of the listing of the new medicine in the table below.
This may include services associated with: eligibility, monitoring, clinical management, AEs or administration of the medicine.

MBS Item Number	MBS Item Description	Proportion of public hospital use	Proportion of private hospital use	Proportion of in-patient services	Proportion of out-patient services	Co-payment group	Basis of delivery	Number of services per patient per year	Number of services per script	Scheduled fee (100%)	Treatment phase	Population split	Population source	Population name
23	Professional attendance by a general practitioner at consulting rooms	84.81%	15.19%	0.00%	100.00%	1	Per patient	1.00		\$38.20	All	100.00%	Incident	Incident 1: Australian population 1: People 0 - 100 yrs inclusive (2020-2025)

Figure 33 MBS calculation – per patient

1.2 Relate the MBS Item to the new patient/script source

MBS Item	Drug / Molecule - New	Calculation basis
23 - Professional attendance by a general practitioner at consulting rooms		All patients

Figure 34 Relating MBS Items to patients

1.1 Estimate volume INCREASES to the MBS

List all the MBS items that will INCREASE as a result of the listing of the new medicine in the table below.
This may include services associated with: eligibility, monitoring, clinical management, AEs or administration of the medicine.

MBS Item Number	MBS Item Description	Proportion of public hospital use	Proportion of private hospital use	Proportion of in-patient services	Proportion of out-patient services	Co-payment group	Basis of delivery	Number of services per patient per year	Number of services per script	Scheduled fee (100%)	Treatment phase	Population split	Population source	Population name
23	Professional attendance by a general practitioner at consulting rooms	84.81%	15.19%	0.00%	100.00%	1	Per script		1.00	\$38.20				

Figure 35 MBS calculation – per script

1.2 Relate the MBS Item to the new patient/script source

MBS Item	Drug / Molecule - New	Calculation basis
23 - Professional attendance by a general practitioner at consulting rooms		All scripts

Figure 36 Relating MBS Items to all scripts

1.2 Relate the MBS Item to the new patient/script source

MBS Item	Drug / Molecule - New	Calculation basis
23 - Professional attendance by a general practitioner at consulting rooms	Allegorimb 200mg tablet - Continuing	Specific medicine

Figure 37 Relating MBS Item to a specific script

12.1.1.4 Estimate volume decrease to the MBS

For each MBS Item that you expect to **decrease** in volume, complete this Part in the same manner as described in Section 12.1.1.2.

12.1.1.5 Relate the MBS Item to the affected medicines

Part 5 allows you to relate all the MBS Items identified in Part 4 to the total script volume or a particular form and strength of a medicine. If you have set the basis of delivery for all the MBS Items in Part 4 to *per patient*, then this option will not be available. This information is used to determine the MBS Item volumes and hence the cost.

12.1.1.6 Methods and assumptions

Ensure that you have outlined all methods and assumptions used in arriving at the estimates in this worksheet, including relevant steps and justifications for approaches and / or data used, in the space provided.

13 Justification of data sources

Overview

Worksheet 12. Copies of data

Provide information about all additional data sets used in the preparation of this submission.

13.1 Worksheet 12. Copies of data

The final worksheet in the Workbook allows you to provide details of any additional data or calculations that you have included in the preparation of your submission. Relevant guidance for this worksheet is included in Section 4.1 of the Guidelines. Include all additional data sets used in the preparation of this submission as new worksheets in this Workbook, after this *Worksheet 12. Copies of data*.

The only data that you need to include is data that has a direct impact on the calculations undertaken to derive the necessary estimates. Data that the Workbook already provides does not need to be included again, this includes:

- *Worksheet 8. ABS population*
- Data you provide in any of the population worksheets (*Worksheets 9-11*)
- PBS script data you provide in *Worksheet 2d. Scripts – market* or *Worksheet 4a. Scripts – affected*

For each additional data set you wish to include, input the following:

- description and purpose of the data – a concise explanation of the data and its purpose in the Workbook
- source – where is the data taken from
- category – select from:
 - disease epidemiological
 - pharmacoepidemiological
 - market data
 - commissioned
- relevance of the data to the Australian setting
- link to the relevant worksheet

13.2 Template worksheet

A blank worksheet with a title ribbon is included in the Workbook as the last tab, titled *Template*. If you wish to include additional worksheets in the Workbook, please make a copy this worksheet.