
Utilisation and Cost Model Workbook for PBAC Submissions User Manual

Version 1.4

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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), you must ensure that data flow logically throughout the worksheets and that any methods and assumptions used are clearly explained and consistent, where applicable, with the economic model(s) used in your 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 you have the option of completing your 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 your submission to the PBAC, you are 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 version 10.8 of the Workbook that is available from the [PBAC website](#)

The Workbook consists of the following worksheets:

- 0. Title
- 1. Overview
- 2a. Patients – incident
- 2b. Patients – prevalent
- 2c. Patients – GF
- 2d. Patients – DTG
- 2e. Scripts – market
- 3a. Scripts – proposed
- 3b. Impact – proposed (pub)
- 3c. Impact – proposed (eff)
- 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. Persistent population
- 12. Copies of data
- Template

The worksheet names provided above 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.

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 five 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:



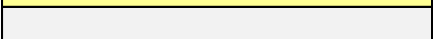

	Data inputs - DoH
	Data inputs - applicant
	Output cells
	Optional cells not used

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:



Impact: affected medicines (effective price) ** 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 PBAC 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*. DoH updates the Schedule monthly and it is available from [PBS Publications](#).
- PBS Items – a PBS Item code in the Schedule of Pharmaceutical Benefits identifies a combination of form and strength of a particular medicine.

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 educational purposes within this User Manual.

4.7.1 User Manual Notes

The following icons appear in the text of the manual to draw your attention to items of particular importance.



New – this section of the manual describes a new feature or changed operation of the Workbook since the last release.



Information – explains how a section of the model works in detail where a more detailed explanation is required or refers you to another section of the user manual.



Warning – explains a section of the model that if used incorrectly, could produce unexpected or undesirable results.



Error – explains a section of the model that if used incorrectly, will produce errors in other section of the Workbook.

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

The worksheet provides general information about the submission as background to the financial model.

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	✓	✗
2a. Patients - incident	✗	✗
2b. Patients - prevalent	✗	✗
2c. Patients - grandfathered	✗	✗
2d. Patients - duration of treatment groups	✗	✓
2e. 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. Persistent 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 determines which areas of the Workbook are available for data entry.



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 persistent population
 - 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



- Identify the script split source – select from¹:
 - Current market
 - Proposed market
- 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). This information provided in the Administrative Notes section at the top of the relevant listing on the PBS Schedule.

Source [Chemotherapy Items for Public Hospital use - Explanatory Notes](#)
 Body System [ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS > ANTINEOPLASTIC AGENTS > OTHER ANTINEOPLASTIC AGENTS](#)
 ▸ [Note](#)
 Special Pricing Arrangements apply.

Figure 8 SPA note in PBS Schedule

Structure of the model		
Identify the script source	Epidemiology	
Incident patients	Yes	Note: both incident and prevalent patients identified, check for double counting
Prevalent patients	Yes	
Grandfathered patients	Yes	Note: both prevalent and grandfathered patients identified, check for double counting
Market-share impact	Copayment only	
Script split source	Current market	
Proposed listing results in	Substitution	Note: new medicine will affect a PBS listed medicine - net impact shows interaction of proposed and existing medicines
Affected medicine has SPA	Yes	

Figure 9 Structure of the model selections

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

¹ This option supports situations where the current market does not distinguish between initial and continuing treatment, but your proposed listing is required to distinguish between the two phases of treatment. If both the current and proposed market have the same structure, please select *Current market*.

5.2 Worksheet 1. Overview

This worksheet provides a high-level overview of the submission. You are to complete all the cells in this worksheet with a yellow background. The following information is required:

- General information
 - Medicine / molecule name
 - Brand name
 - Applicant company
 - PBAC meeting
 - Agenda Item (completed by DoH)²
 - Submission type – select from:
 - Submission
 - Resubmission
 - Other
 - Codependent – if your medicine is linked to a submission to MSAC³, then this field should be set to *Yes*
 - First year of listing
 - Submission category⁴ – select from:
 - Category 1
 - Category 2
 - Category 3
 - Category 4
 - Resubmission pathway⁵ – select from:
 - Early resolution
 - Facilitated resolution
 - Early re-entry
 - Standard re-entry
- Financial impact
 - PBS impact (auto populated by the Workbook)
 - RPBS impact (auto populated by the Workbook)
 - Declining population (completed by DoH)
 - MBS impact (auto populated by the Workbook)
 - SA impact (auto populated by the Workbook)
 - Complex authority (auto populated by the Workbook)
 - Reporting required (completed by DoH)
 - Flow-ons (auto populated by the Workbook)

² If you are updating the model post PBAC, please complete this field.

³ The Medical Services Advisory Committee (MSAC) is an independent non-statutory committee that appraises new medical services proposed for public funding.

⁴ The worksheet will only display *Submission category* depending on your response to *Submission type*.

⁵ The worksheet will only display *Resubmission pathway* depending on your response to *Submission type*.

- Evaluation
 - Clinical advisory board – were the estimates based on advice from an advisory board
 - Evaluator review – was the model evaluated (completed by DoH)
 - DUSC review – was the model reviewed by DUSC (completed by DoH)
 - ESC review – was the model reviewed by ESC (completed by DoH)
 - PBAC review – was the model reviewed by PBAC (completed by DoH)
- Cost drivers (completed by DoH)
- PBAC / MSAC outcomes (completed by DoH)
- Regulatory information
 - ATC code – Level 1⁶
 - 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 indication⁷ – 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 restriction, then you should show this as **three** restrictions. If you have both Section 100 public hospital and Section 100 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.
 - To open each restriction, click on the plus sign in the worksheet margin. You can close each section by clicking on the minus sign in the worksheet margin.

Schedule of Pharmaceutical Benefits information	
60	
61	
62	
63	
64	
65	Restriction 1 of 4
80	Restriction 2 of 4
95	Restriction 3 of 4
110	Restriction 4 of 4
125	** NOT USED **
140	** NOT USED **
155	** NOT USED **
170	** NOT USED **
185	** NOT USED **
200	** NOT USED **
215	** NOT USED **
230	** NOT USED **
245	** NOT USED **

Figure 10 Closed section

⁶ This information is available from [WHO Collaborating Centre for Drug Statistics Methodology](#)

⁷ This information is available from [Australian Register of Therapeutic Goods](#)

Schedule of Pharmaceutical Benefits information		
Restriction 1 of 4		
Category / Program	GE	General
Treatment phase		
Episodicity		
Severity		
Condition		
PBS indication		
Treatment criteria		
Clinical criteria		
Population criteria		
Manner of administration and form		
Restriction 2 of 4		

Figure 11 Open section

- 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 required⁸:
 - 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
 - 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



⁸ If you are updating the template post-PBAC, please check the Outcome section of your Minutes for the Restriction details, if they have been finalised.



- 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
- Episodicity⁹
- 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 use 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. These are the **only** restriction levels where AR – Electronic are valid.

⁹ Episodicity refers to the condition and appears infrequently in the Schedule. This is not referring to the frequency of dosing with the medicine.

Listing type	New	Restrictions
Max quantity (packs)	4	AR - Telephone
Max quantity (units)	8	AR - Electronic
Repeats	5	

Figure 12 Telephone + electronic restrictions

Listing type	New	Restrictions
Max quantity (packs)	4	AR - Streamlined
Max quantity (units)	4	
Repeats	5	

Figure 13 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 (completed by DoH)
 - Avg annual patients – (auto populated by Workbook for the epidemiological approach)
 - Treatment period – select from:
 - Chronic (continuous duration of treatment – greater than 12 months)
 - Extended (finite duration of treatment – greater than 12 months)
 - Episodic (finite duration of treatment – less than 12 months)
 - Method of calculation (completed by DoH)
 - Scripts / year or scripts / course – the numbers of scripts a patient is expected to receive during a year or a complete course of treatment



○ Complex treatment costs – select from:

- Yes
- No

Treatment period	Episodic	Published DPMQ	\$6,065.00
Scripts / treatment course		Effective DPMQ	\$5,775.00
Complex treatment costs		Yes	

Medicine	Scripts / treatment course	Published DPMQ	Effective DPMQ
Allegorimab	5	\$1,175.00	\$1,125.00
Allaccept	2	\$95.00	\$75.00
Total		\$6,065.00	\$5,775.00

Figure 14 Complex treatment costs

If you select *Yes* for Complex treatment costs, you can add up to five elements into the overall cost to a patient. If the propose medicine has an SPA, the Effective DPMQ column will also be available for entry.

Treatment period	Episodic	Published DPMQ	\$1,175.00
Scripts / treatment course	3.00	Effective DPMQ	\$1,125.00
Complex treatment costs		No	

Medicine	Scripts / treatment course	Published DPMQ	Effective DPMQ
Total		\$0.00	\$0.00

Figure 15 Simple treatment costs

If you select *No* for Complex treatment costs, the Workbook will use the DPMQ from the first row of Section 3 of *Worksheet 3b. Impact – proposed (pub)* multiplied by the number of scripts / year or course of treatment that you indicated. If the propose medicine has an SPA, the Workbook will use the DPMQ from the first row of Section 3 of *Worksheet 3c. Impact – proposed (eff)* multiplied by the number of scripts / year or course of treatment that you indicated

DoH provides the information collected in the *Worksheet 1. Overview* to portfolio agencies¹⁰ and the Department of Finance as background to the submission as these agencies do not receive the full text of the submission.

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

¹⁰ Portfolio agencies include the Department of Veterans' Affairs and Services Australia.

6 Epidemiological vs market-share

The diagram below shows the different components that will be required to provide the foundation for the scripts numbers for your proposed medicine.

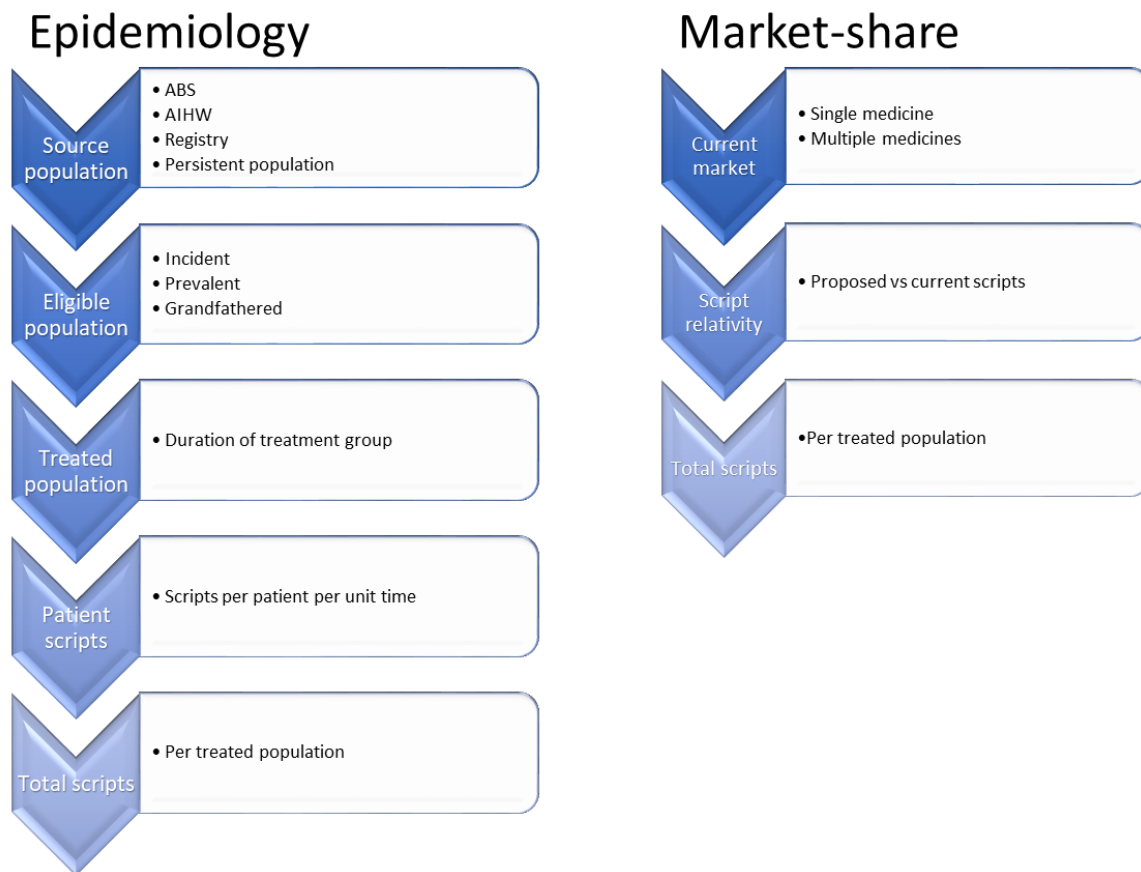


Figure 16 Deriving proposed scripts

Section 7 shows the steps required to derive a script volume from one or more epidemiological sources. Section 8 shows the steps required to derive a script volume from one or more market-share sources.

i If you are defining a mixed model, you will need to build elements of both these approaches. DoH recommends that you start with the branch that produces the majority of your scripts. For example, if you are modelling a market-share approach that will also include some patients currently enrolled in a patient familiarisation program, you should start with the market-share elements described in Section 8. Once you have completed this work, return to Section 7 and complete the definition of your grandfathered population.

7 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 8 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. Persistent 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 2a. Patients: incident**

The incident patient population with a medical condition targeted by a medicine.

☐ **Worksheet 2b. Patients: prevalent**

The prevalent patient population with a medical condition targeted by a medicine.

☐ **Worksheet 2c. Patients: grandfathered**

The grandfathered patient population with a medical condition targeted a medicine.

☐ **Worksheet 2d. Patients: duration of treatment groups**

The patient days, weeks or months of treatment that a patient population will receive.

7.1 Worksheet selection – populations

There are three steps required to develop a treated patient population:

- Identify the source population
- Identify the sub-set of patients in the overall population who will receive treatment
- Identify the duration of treatment for a treated patient.

The rest of this section will guide you through the steps necessary to complete each of these steps.

You can develop an overall population based on one of four population types in the Workbook:

- ABS
- AIHW
- Registry
- Persistent population

7.1.1 Linking patient populations



Once you name a population in any of the four population worksheets, the Workbook will use this name to link the population to the patient worksheets. If you subsequently decide to change this name, you will see the following error message on the patient worksheet. The error can be resolved by reselecting the population from the drop-down list.

GF 1: Other 1: Applicant CAPS: People (2021-2026)	
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
Other 1: Applicant CAPS: People (2021-2026)	
Description	
Error: invalid population selected, reselect	

Figure 17 Broken population link

7.1.2 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 (leave blank to include all people)
- maximum age – select 0 to 100 (leave blank to include 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 listing¹¹

¹¹ 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 historically diagnosed patient population as the basis for a persistent population.



- population type – select from:
 - incidence
 - prevalence
- rate – shown as a rate per population, the example below shows 1:100,000 (leave blank to include all people)
- source – indicate where the rate was drawn from

ABS 1: People 18 - 100 yrs inclusive (2021-2026) - (Incidence)

	Minimum	Maximum	Population	Start year
Included ages	18	100	People	

	Rate	per		Source
Incidence	1.0	100,000	0.000010	AIHW data table

Population used

2021	2022	2023	2024	2025	2026
204	208	211	214	217	221

Populations	2021	2022	2023	2024	2025	2026
Persons	20,429,953	20,757,917	21,082,471	21,411,852	21,744,502	22,073,220
Male	10,025,775	10,185,789	10,343,847	10,504,073	10,666,179	10,825,956
Female	10,404,178	10,572,128	10,738,624	10,907,779	11,078,323	11,247,264

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

7.1.3 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 using the *Template* worksheet provided and link it back to this worksheet. Once you make the necessary selections, the data will become visible. For each population, the following information is required:

- name – a unique name of the population
- data series – the AIHW Data series the data was drawn from
- 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 1: Diabetic patients: People (2020-2025)

Name	Diabetic patients	Data series	AIHW - incidence of insulin treated disease 2017
------	-------------------	-------------	--

Population	People	Start year	
------------	--------	------------	--

Population used

2020	2021	2022	2023	2024	2025
2,496	2,519	2,595	2,709	2,654	2,742

Populations	2020	2021	2022	2023	2024	2025
Persons	2,496	2,519	2,595	2,709	2,654	2,742
People	2,496	2,519	2,595	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 19 AIHW population: people with insulin-treated diabetes

7.1.4 Worksheet 10. Registry or other population

This worksheet allows the definition of up to 10 different populations based on Registry or another defined population¹². If you require more complex data manipulation, you should add the source as an additional worksheet at the end of the Workbook using the *Template* worksheet provided and link it back to this worksheet. Once you make the necessary selections, the data will become visible. For each population, 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

Other 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 20 Registry population: NSW Cancer Registry

7.1.5 Worksheet 11. Persistent population



This worksheet allows the definition of up to 10 different populations based on previously diagnosed patients. The worksheet starts up to six years before the first year of listing to derive the total population eligible for treatment. However, your population does not have to use all the prior years. You could confine your population to just the six listing years. If you require more complex data manipulation, you should add the source as an additional worksheet at the end of the Workbook using the *Template* worksheet provided and link it back to this worksheet. Once you make the necessary selections, the data will become visible.

You can create these populations with any combination of the following:

- Constant rate of persistence
- Variable rate of persistence
- Constant rate of eligibility
- Variable rate of eligibility

¹² This can include Compassionate Access Programs or Patient Familiarisation Programs.

If you enter a rate into the persistence field and leave the individual year rates blank, then the Workbook applies the same rate across all year. The same applies to the eligibility rate.

For each population, the following information is required:

- Indication – used as the name of the population
- the source of the data
- starting patient cohorts
- constant persistence rate – the persistence rate that will be applied to **all** years of each patient cohort
- variable persistence rate – the persistence rate that will be applied to **each** year for each patient cohort
- persistence rate source – where you obtained the persistence rates
- constant eligibility rate – the eligibility rate that will be applied to **all** years of each patient cohort
- variable eligibility rate – the eligibility rate that will be applied to **each** year for each of patient cohort
- eligibility rate source – where you obtained the eligibility rates
- include starting population in total – do you want the initial population included in the totals for each year

In the examples below, you can see the impact of including the starting cohort in the totals. There may be situations where you want to use a persistent population to show treatment in a second and subsequent year, but using a different dosing regimen. In this situation, you would use the initiating patients as your cohort for the persistent population. Once you had included the persistence and eligibility rates, you would exclude the starting population from the totals that would leave you with the patients in the second and subsequent years.



If you select both the constant and variable persistence rates, the worksheet will apply the **constant** rate.



If you select both the constant and variable eligibility rates, the worksheet will apply the **constant** rate.



The years referred to in the variable persistence rates are years from the first year of **each** cohort, not from the first year in the table, in the examples below 2016.

Persistent 1: Traumatic brain injury (2015-2026)												
Indication		Traumatic brain injury										
Source		ABS Data										
Cohort	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Cohort 1	716	716	573	458	367	293	235	188	150	120	96	77
Cohort 2	729		729	583	467	373	299	239	191	153	122	98
Cohort 3	742			742	594	475	380	304	243	195	156	124
Cohort 4	751				751	601	481	385	308	246	197	157
Cohort 5	764					764	611	489	391	313	250	200
Cohort 6	771						771	617	493	395	316	253
Cohort 7	784							784	627	502	401	321
Cohort 8	797								797	638	510	409
Cohort 9	809									809	647	519
Cohort 10	822										822	658
Cohort 11	835											835
Cohort 12	848											848

Variable persistence rate												
Year 1												
Year 2												
Year 3												
Year 4												
Year 5												
Year 6												
Year 7												
Year 8												
Year 9												
Year 10												
Year 11												

Constant persistence rate for all years 90.00%												
Source		Clinical advisory board										

Variable eligibility rate												
Year 1												
Year 2												
Year 3												
Year 4												
Year 5												
Year 6												
Year 7												
Year 8												
Year 9												
Year 10												
Year 11												
Year 12												

Constant eligibility rate for all years 90.00%												
Source		Clinical advisory board										

Include starting population in total No												
---	--	--	--	--	--	--	--	--	--	--	--	--

Total												
	1,999	2,163	2,305	2,426	2,533	2,627						

Figure 21 Persistent population: Traumatic brain injury – constant persistence

Persistent 1: Traumatic brain injury (2015-2026)																
Indication		Traumatic brain injury														
Source		ABS Data														
Cohort	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	Variable persistence rate			
Cohort 1	716	716	644	567	488	410	336	269	210	159	118	85	59	Year 1	80.00%	Constant persistence rate for all years
Cohort 2	728		728	659	577	492	417	342	274	213	162	120	88	Year 2	88.00%	Source Clinical advisory board
Cohort 3	742			742	668	588	505	425	348	278	217	165	122	Year 3	86.00%	
Cohort 4	751				751	676	595	512	430	352	282	220	167	Year 4	84.00%	
Cohort 5	764					764	688	605	520	437	358	287	224	Year 5	82.00%	
Cohort 6	771						771	694	611	525	441	362	289	Year 6	80.00%	
Cohort 7	784							784	706	621	534	449	369	Year 7	78.00%	
Cohort 8	797								797	717	631	543	459	Year 8	76.00%	
Cohort 9	809									809	728	641	551	Year 9	74.00%	
Cohort 10	822										822	740	651	Year 10	72.00%	
Cohort 11	835											835	752	Year 11	70.00%	
Cohort 12	848												848			
Note: overall not individual rates used																
Cohort	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	Variable eligibility rate			
Cohort 1		644	580	510	439	369	302	242	189	143	106	78	53	Year 1		Content eligibility rate for all years 90.00%
Cohort 2			659	585	520	447	375	308	246	192	146	108	78	Year 2		Source Clinical advisory board
Cohort 3				668	601	529	455	382	313	251	196	149	115	Year 3		
Cohort 4					676	608	535	460	387	317	254	198	150	Year 4		
Cohort 5						688	619	545	468	393	323	258	201	Year 5		
Cohort 6							694	625	550	473	397	326	260	Year 6		
Cohort 7								706	635	559	481	404	331	Year 7		
Cohort 8									717	646	569	489	410	Year 8		
Cohort 9										728	652	577	490	Year 9		
Cohort 10											740	666	586	Year 10		
Cohort 11												752	676	Year 11		
Cohort 12													763	Year 12		
Total							3,267	3,505	3,702	3,865	4,001	4,116				
															Include starting population in total	
															Yes	

Figure 22 Persistent population: Traumatic brain injury – variable persistence

7.2 Worksheet selection – patient types

In *Worksheet 0. Title*, you identified that the model you are building is an epidemiological approach. This marks *Worksheet 2e. 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 23 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 applies when you select both prevalent and grandfathered patients, as the prevalent patient pool would normally capture the grandfathered patients.

7.2.1 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 8.1.1.

7.2.2 Worksheet 2a. Patients: incident

This worksheet is for estimating the numbers of eligible incident patients from a previously defined overall population. 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

7.2.2.1 Summary of patients

The Summary of patients consolidates the results from the detailed sections of this worksheet. It shows the total numbers of initiating patients and total numbers of continuing patients, if applicable, that form the incident population.

1. Summary of patients						
The following table summarises the total patients per year.						
	2020	2021	2022	2023	2024	2025
Total initiating patients	323	329	334	339	345	350
Total continuing patients	275	279	284	288	293	297

Figure 24 Summary of incident patients



If you select an ABS population that you defined as a prevalent population, you will receive the following error message:

Incident 1: ABS 2: People 18 - 100 yrs inclusive (2021-2026) - (Prevalence)		
Identify the numbers of incident patients who would be eligible for the proposed medicine.		
Patient source	ABS	ABS 2: People 18 - 100 yrs inclusive (2021-2026) - (Prevalence)
		Error: prevalence source used for incident population
		Description

Figure 26 Prevalent population used to define incident patients

7.2.2.3 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.

7.2.3 Worksheet 2b. Patients: prevalent

This worksheet is for estimating the numbers of prevalent patients from a previously defined overall population. 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

7.2.3.1 Summary of patients

The Summary of patients consolidates the results from the detailed sections of this worksheet. It shows the total numbers of initiating patients and total numbers of continuing patients, if applicable, that form the incident population.

1. Summary of patients

The following table summarises the total patients per year.

	2020	2021	2022	2023	2024	2025
Total initiating patients	323	329	334	339	345	350
Total continuing patients	275	279	284	288	293	297

Figure 27 Summary of prevalent patients

7.2.3.2 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 a medicine.

For each population, the following information is required:

- Patient source – select from:
 - ABS
 - AIHW
 - Other
 - Persistent population
- Population name – select from the populations defined in Section 7.1.

- 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. Provide a source for this percentage.
- Continuing treatment source – identify the basis for calculating the continuing patient numbers, a proportion of the initiating patients or the overall eligible patients. Select from:
 - initiating patients
 - eligible patients
- Co-payment group – select the *Co-payment group* you want to assign to this patient group. You defined these groups in *Worksheet 2e. Scripts – market* (Section 8.1.1).



Prevalent 1: ABS 2: People 18 - 100 yrs inclusive (2021-2026) - (Prevalence)

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

Patient source	ABS 2: People 18 - 100 yrs inclusive (2021-2026) - (Prevalence)					
	2021	2022	2023	2024	2025	2026
Prevalent population	409	415	422	428	435	441

Eligibility	2021	2022	2023	2024	2025	2026
ECOG Status > 2	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 (#)	102	104	105	107	109	110

Initiating treatment	2021	2022	2023	2024	2025	2026
Patients electing treatment (%)	90.00%	90.00%	90.00%	90.00%	90.00%	90.00%

Continuing treatment	2021	2022	2023	2024	2025	2026
Patients electing treatment (%)	85.00%	85.00%	85.00%	85.00%	85.00%	85.00%

Continuing treatment source: **Initiating patients**

Initiating patients (#)	2021	2022	2023	2024	2025	2026
Continuing patients (#)	92	93	95	96	98	99
	78	79	81	82	83	84

Co-payment group: **2**

Description

Source

Source

Figure 28 Prevalent patient population



If you select an ABS population that you defined as a prevalent population, you will receive the following error message:

Prevalent 1: ABS 1: People 18 - 100 yrs inclusive (2021-2026) - (Incidence)

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

Patient source	ABS 1: People 18 - 100 yrs inclusive (2021-2026) - (Incidence)					
	2021	2022	2023	2024	2025	2026
Prevalent population						

Error: incidence source used for prevalent population

Description

Figure 29 Incident population used to define prevalent patients

7.2.3.3 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.

7.2.4 Worksheet 2c. Patients: grandfathered

This worksheet is for estimating the numbers of grandfathered patients from a previously defined overall population. You can use this population in either an epidemiology-based or a market-share model. 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

7.2.4.1 Summary of patients

The Summary of patients consolidates the results from the detailed sections of this worksheet. It shows the total numbers of initiating patients and total numbers of continuing patients, if applicable, that form the grandfathered population.

1. Summary of patients

The following table summarises the total patients per year.

	2020	2021	2022	2023	2024	2025
Total initiating patients	323	329	334	339	345	350
Total continuing patients	275	279	284	288	293	297

Figure 30 Summary of grandfathered patients

7.2.4.2 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
 - Persistent population
- Population name – select from the populations defined in Section 7.1.
- 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. Provide a source for this percentage.
- Continuing treatment source – identify the basis for calculating the continuing patient numbers, a proportion of the initiating patients or the overall eligible patients. Select from:
 - initiating patients
 - eligible patients
- Co-payment group – select the *Co-payment group* you want to assign to this patient group. You defined these groups in *Worksheet 2e. Scripts – market* (Section 8.1.1).

GF 1: Other 1: Applicant CAPS: People (2021-2026)

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	Other 1: Applicant CAPS: People (2021-2026)					Description
		Number of patients					
		2021	2022	2023	2024	2025	2026
Grandfathered population		40	0	0	0	0	0
Eligibility							
Patients meeting proposed restriction %	85.00%						
Patients meeting proposed restriction (#)	34	0	0	0	0	0	0
Initiating treatment							
Patients electing treatment (%)	100.00%						
Continuing treatment							
Patients electing treatment (%)	100.00%						
Continuing treatment source	Initiating patients						
Initiating patients (#)	34	0	0	0	0	0	0
Continuing patients (#)	34	0	0	0	0	0	0
Co-payment group	1						

Figure 31 Grandfathered patient population

7.2.4.3 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.

7.2.5 Worksheet 2d. Patients: duration of treatment groups

This worksheet is to describe the length of treatment received by a previously defined population. The manual refers to each of these populations as Duration of Treatment Groups (DTG). You can use these populations in both *Worksheet 3a. Scripts – proposed* and *Worksheet 4a. Scripts – affected* as well as *Worksheet 7. Net changes – MBS*. There are two parts to the worksheet:

- Summary of patient years of treatment
- Detail of duration of treatment groups

7.2.5.1 Summary of patient years of treatment

The Summary of patient years of treatment consolidates the results from the detailed sections of this worksheet. It shows the total numbers of patient years of treatment for initiating patients and continuing patients, if applicable.

Even if you have defined the different DTGs using days, weeks or months of treatment the worksheet expresses these totals in patient years of treatment.

7.2.5.2 Details of duration of treatment groups

The worksheet allows you to define up to 25 DTGs. You can develop multiple DTGs to support different durations of therapy based on the same population or different durations of therapy for individual populations.

This is most useful when you have a population that will receive the proposed medicine for a different duration of therapy than they do with the currently listed medicine.

For each DTG, the following information is required:

- Patient source – select from:
 - Incident
 - Prevalent
 - Grandfathered
- Population name – select from the populations defined in Section 7.2.
- Once you make these selections, the Workbook automatically populates the row titled *DTG #: Population source: duration*.
- If your model has initial and continuing phases then you will need to enter:
 - Duration of treatment (initial) – enter the number of days, weeks or months of treatment a patient will receive.
 - Time units – select the appropriate time units. Select from:
 - Days
 - Weeks
 - Months
 - Duration of treatment (continuing) – enter the number of days, weeks or months of treatment a patient will receive.
 - The worksheet will automatically populate the time units for the continuing phase¹³.
- If your model has all treatment together then you will need to enter:
 - Duration of treatment (initial) – enter the number of days, weeks or months of treatment a patient will receive.
 - Time units – select the appropriate time units. Select from:
 - Days
 - Weeks
 - Months

¹³ The time units for the initial and continuing phase **MUST** be the same.



Below are examples of how this you can use this functionality to support more complex regimens.

- Example 1 – Overall treatment less than 12 months
 - 100 initiating patients
 - 50 continuing patients
 - Initiating treatment = 3 months
 - Continuing treatment = 9 months
 - Initiating patient months of treatment
 - 3 months / 12 months * 100 patients = 25 patient months of treatment¹⁴
 - Continuing patient months of treatment
 - 9 months / 12 months * 50 patients = 37.5 patient months of treatment

DTG 1: Incident 1: ABS 1: People 0 - 100 yrs inclusive (2021-2026) - (Incidence): 3 + 9 Months

Identify the eligible patients who make up this duration of therapy.

Patient source	Incident	Incident 1: ABS 1: People 0 - 100 yrs inclusive (2021-2026) - (Incidence)					
		2021	2022	2023	2024	2025	2026
Initiating patients (#)		263	267	271	276	280	284
Continuing patients (#)		237	241	244	248	252	255
Duration of treatment	3.00 Months						
Initiating patients (#)		66	67	68	69	70	71
Year 1 cohort		66	0	0	0	0	0
Year 2 cohort		0	67	0	0	0	0
Year 3 cohort		0	0	68	0	0	0
Year 4 cohort		0	0	0	69	0	0
Year 5 cohort		0	0	0	0	70	0
Year 6 cohort		0	0	0	0	0	71
Total initiating patient months of treatment		66	67	68	69	70	71

Duration of treatment	9.00 Months						
Continuing patients (#)		178	180	183	186	189	192
Year 1 cohort		178	0	0	0	0	0
Year 2 cohort		0	180	0	0	0	0
Year 3 cohort		0	0	183	0	0	0
Year 4 cohort		0	0	0	186	0	0
Year 5 cohort		0	0	0	0	189	0
Year 6 cohort		0	0	0	0	0	192
Total continuing patient months of treatment		178	180	183	186	189	192

Figure 32 Patient population - defined duration (less than 12 months)

- Example 2 – Overall treatment more than 12 months
 - 100 initiating patients
 - 40 continuing patients
 - Initiating treatment = 6 months
 - Continuing treatment = 8 months
 - Initiating patient months of treatment
 - 6 months / 12 months * 100 patients = 50 patient months of treatment
 - Continuing patient months of treatment
 - Year 1 – 6 months / 12 months * 40 patients = 20 patient months of treatment
 - Year 2 – 2 months / 12 months * 40 patients = 6.67 patient month of treatment

DTG 1: Incident 1: ABS 1: People 0 - 100 yrs inclusive (2021-2026) - (Incidence): 6 + 8 Months

Identify the eligible patients who make up this duration of therapy.

Patient source	Incident	Incident 1: ABS 1: People 0 - 100 yrs inclusive (2021-2026) - (Incidence)					
		2021	2022	2023	2024	2025	2026
Initiating patients (#)		263	267	271	276	280	284
Continuing patients (#)		237	241	244	248	252	255
Duration of treatment	6.00 Months						
Initiating patients (#)		132	134	136	138	140	142
Year 1 cohort		132	0	0	0	0	0
Year 2 cohort		0	134	0	0	0	0
Year 3 cohort		0	0	136	0	0	0
Year 4 cohort		0	0	0	138	0	0
Year 5 cohort		0	0	0	0	140	0
Year 6 cohort		0	0	0	0	0	142
Total initiating patient months of treatment		132	134	136	138	140	142

Duration of treatment	8.00 Months						
Continuing patients (#)		118	120	122	124	126	128
Year 1 cohort		118	39	0	0	0	0
Year 2 cohort		0	120	40	0	0	0
Year 3 cohort		0	0	122	41	0	0
Year 4 cohort		0	0	0	124	41	0
Year 5 cohort		0	0	0	0	126	42
Year 6 cohort		0	0	0	0	0	128
Total continuing patient months of treatment		118	160	162	165	167	170

Figure 33 Patient population - defined duration (more than 12 months)

¹⁴ A patient treated for 12 months would result in 12 patient months of treatment. Equally, two patients each treated for six months would also produce 12 patient months of treatment.

- Example 3 – Initial treatment 12 months or more
 - 100 initiating patients
 - 30 continuing patients
 - Initiating treatment = 12 months
 - Continuing treatment = 6 months
- Initiating patient months of treatment
 - 12 months / 12 months * 100 patients = 100 patient months of treatment
- Continuing patient months of treatment
 - Year 1 – 0 months * 100 patients = 0 patient months of treatment
 - Year 2 – 6 months / 12 months * 30 patients = 15 patient month of treatment

DTG 1: Incident 1: ABS 1: People 0 – 100 yrs inclusive (2021-2026) - (Incidence): 12 + 6 Months

Identify the eligible patients who make up this duration of therapy.

Incident 1: ABS 1: People 0 – 100 yrs inclusive (2021-2026) - (Incidence)							Incident 1: ABS 1: People 0 – 100 yrs inclusive (2021-2026) - (Incidence)						
Year	2021	2022	2023	2024	2025	2026	Year	2021	2022	2023	2024	2025	2026
Initiating patients (#)	263	267	271	276	280	284	Continuing patients (#)	237	241	244	248	252	255
Duration of treatment	12.00 Months						Duration of treatment	6.00 Months					
Initiating patients (#)	263	0	0	0	0	0	Continuing patients (#)	0	118	0	0	0	0
Year 1 cohort	263	0	0	0	0	0	Year 1 cohort	0	118	0	0	0	0
Year 2 cohort	0	267	0	0	0	0	Year 2 cohort	0	120	0	0	0	0
Year 3 cohort	0	0	271	0	0	0	Year 3 cohort	0	0	122	0	0	0
Year 4 cohort	0	0	0	276	0	0	Year 4 cohort	0	0	0	124	0	0
Year 5 cohort	0	0	0	0	280	0	Year 5 cohort	0	0	0	0	126	0
Year 6 cohort	0	0	0	0	0	284	Year 6 cohort	0	0	0	0	0	128
Total initiating patient months of treatment	263	267	271	276	280	284	Total continuing patient months of treatment	0	118	120	122	124	126

Figure 34 Patient population - defined duration (12 or more months of initial treatment)



The extended duration of treatment model interacts with *Worksheet 3a Scripts – Proposed* and it is important that you present the doses per period of treatment correctly. Section 9.1.1.4 explains this interaction in detail.

8 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 7 to continue defining an epidemiology model.

☐ Worksheet 2e. 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.

8.1 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 2e. Scripts – market*.

Structure of the model

Identify the script source	Market share
** NOT REQUIRED **	
Incident patients	
Prevalent patients	
Grandfathered patients	

Figure 35 Market-share selection

8.1.1 Worksheet 2e. Scripts: market-share

The market-share approach uses this worksheet to estimate the dispensed volume of the proposed medicine as a proportion 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 patient populations.

i 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, you can use a co-payment group to determine the public / private hospital split. In the following example, the initiating and continuing PBS Items for allaccept 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. *Worksheet 2a. Patients – Incident* (Section 7.2.2), *Worksheet 2b. Patients – Prevalent* (Section 7.2.3), *Worksheet 2c. Patients – GF* (Section 7.2.4) and *Worksheet 7. Net changes – MBS* (Section 13) use these co-payment groups to apply weighted co-payments and the public / private hospital splits.

Service volumes for calendar year 2020				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	
Ataccept	125mg/mL injection	9998F	Initiating	389	16	368	117	4	1	1
Ataccept	125mg/mL injection	9999G	Continuing	5,421	341	6,763	2,103	119	66	1
Total				7,348	360	8,001	2,265	158	68	
Co-payment				\$41.30	\$6.60	\$6.60	\$0.00	\$6.60	\$0.00	

Co-payments	PBS	RPBS	PBS	RPBS
Group 1	98.79%	1.21%	\$18.69	\$4.27

Figure 36 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

8.1.1.1 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.

8.1.1.2 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. The worksheet will identify the required year for you. 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 9.

Service volumes for calendar year 2020				PBS Services				RPBS Services		Include in split			Total Services	PBS %	RPBS %
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	Co-payment group	Public	Private			
Alisapt	125mg/mL injection	9998F	Initiating	389	16	368	117	4	1	1			895	99.44%	0.56%
Alisapt	125mg/mL injection	9999G	Continuing	5,421	341	6,703	2,103	119	68	1			14,753	98.75%	1.25%
Total				7,348	360	8,001	2,265	158	68						
Co-payment				\$41.30	\$6.60	\$6.60	\$0.00	\$6.60	\$0.00						

Co-payments	PBS	RPBS	PBS	RPBS
Group 1	98.79%	1.21%	\$18.69	\$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
Group 1	0.00%	0.00%
Group 2	0.00%	0.00%
Group 3	0.00%	0.00%
Group 4	0.00%	0.00%
Group 5	0.00%	0.00%

Over-ride split	Public	Private
Group 1		
Group 2		
Group 3		
Group 4		
Group 5		

Source
Group 1
Group 2
Group 3
Group 4
Group 5

Figure 37 Currently listed PBS medicine – Section 85

Service volumes for calendar year 2020				PBS Services				RPBS Services		Include in split			Total Services	PBS %	RPBS %
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	Co-payment group	Public	Private			
Allegorimab	200mg/ 40mL injection, 40 mL vial	9999W	Initiating	1,026	3	605	36	31	1	1	No	Yes	1,702	98.12%	1.88%
Allegorimab	200mg/ 40mL injection, 40 mL vial	9999B	Initiating	512	0	325	9	4	0	1	Yes	No	850	99.53%	0.47%
Total				7,348	360	8,001	2,265	158	68						
Co-payment				\$41.30	\$6.60	\$6.60	\$0.00	\$6.60	\$0.00						

Co-payments	PBS	RPBS	PBS	RPBS
Group 1	98.59%	1.41%	\$27.69	\$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
Group 1	33.31%	66.69%
Group 2	0.00%	0.00%
Group 3	0.00%	0.00%
Group 4	0.00%	0.00%
Group 5	0.00%	0.00%

Over-ride split	Public	Private
Group 1		
Group 2		
Group 3		
Group 4		
Group 5		

Source
Group 1
Group 2
Group 3
Group 4
Group 5

Figure 38 Currently listed PBS medicine – Section 100 (public and private hospital listing)

8.1.1.3 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 of scripts that are applicable to the 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 replace 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 39 Estimate growth in existing medicine

8.1.1.4 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.

9 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.

9.1.1 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

9.1.1.1 *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.

9.1.1.2 *Script volumes – epidemiological source*

If you are using an epidemiological approach, this section shows the total script volumes expected for each medicine each year. If you are using a market-share approach this section is not required.


9.1.1.3 *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. If you are using an epidemiological approach this section is not required.

9.1.1.4 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)

 The rest of the columns are only relevant if you are developing an epidemiological approach and you do not need to complete them if you are developing a market-share model.

- 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 in an epidemiological model. 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 40 Example script calculations

- 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%.

- Duration of Treatment Group – select from the populations you defined in Section 7.2.5.



As indicated in Section 7.2.5, it is important that you correctly identify the treatment rate for the duration you have identified. You should apply the following rules when defining the treatment:

- Chronic (continuous duration of treatment – greater than 12 months)
 - show the regimen required for 12 months of treatment
- Extended (finite duration of treatment – greater than 12 months)
 - show the regimen required for 12 months of treatment
- Episodic (finite duration of treatment – less than 12 months)
 - show the regimen required for **a course** of treatment

9.1.1.5 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 – select from the forms and strengths that you defined in Section 8
- 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 41 Relating proposed and existing medicines

The model will allow you to link the medicines the in the following ways:

- One existing medicine to one proposed medicine (1:1)
- One existing medicine to multiple proposed medicines (1:n)
- Multiple existing medicines to one proposed medicines (n:1)
- Multiple existing medicines to multiple proposed medicines (n:n)



If a medicine (existing or proposed) appears in the list more than once, the duplicated cells will be coloured red. This is a warning that the model presents to alert you to the possibility of double counting of scripts. It does not prevent you from having duplicates, as there are situations where you will need to model different relationships between proposed and existing medicines.

5. Relate the proposed medicine to the existing market

Please relate the proposed medicine to the existing market.

Medicine / Molecule - Existing	Medicine / Molecule - Proposed
9998F - Allaccept 125mg/mL injection - Initiating	Allegorimab 100mg/mL injection - Initiating
9998F - Allaccept 125mg/mL injection - Initiating	Allegorimab 200mg/mL injection - Continuing

Figure 42 Duplicate medicines warning

If you selected to base your script source split on the proposed market in *Worksheet 0. Title*, the next column allows you to allocate a proportion of the existing market that your proposed medicine will affect.

The next three columns of the table allows you to identify the script equivalence between your proposed medicine and the existing 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		
Existing	Proposed	Substitution rate
12.18	13.04	1.07

Figure 43 Calculating script equivalence

The final columns in the table are the annual substitution rates. If your model shows one to one relationships between the existing and proposed medicines then the substitution rate in each row would be 100%.

5. Relate the proposed medicine to the existing market											
Please relate the proposed medicine to the existing market.											
Medicine / Molecule - Existing	Medicine / Molecule - Proposed	Percentage of current scripts	Script equivalence			Substitution rate					
			Existing	Proposed	Substitution rate	2021	2022	2023	2024	2025	2026
9998F - Alaccept 125mg/mL injection - Initiating	Allegorimab 100mg/mL injection - Initiating	100.00%	12.18	13.04	1.07	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Figure 44 Market-share model with one existing medicine linked to one proposed medicine

However, if your model takes a single existing medicine and applies proportions of it to the multiple proposed medicines then the rates for that medicine will add to 100%, as shown below. This will most frequently occur when you are proposing multiple forms or strengths to replace an existing medicine.

5. Relate the proposed medicine to the existing market											
Please relate the proposed medicine to the existing market.											
Medicine / Molecule - Existing	Medicine / Molecule - Proposed	Percentage of current scripts	Script equivalence			Substitution rate					
			Existing	Proposed	Substitution rate	2021	2022	2023	2024	2025	2026
9998F - Allaccept 125mg/mL injection - Initiating	Allegorimab 100mg/mL injection - Initiating	100.00%	12.18	13.04	1.07	50.00%	55.00%	60.00%	65.00%	70.00%	75.00%
9998F - Allaccept 125mg/mL injection - Initiating	Allegorimab 200mg/mL injection - Continuing	100.00%	12.18	13.04	1.07	50.00%	45.00%	40.00%	35.00%	30.00%	25.00%

Figure 45 Market-share model with one existing medicine linked to multiple proposed medicines

If the substitution rates do not add to 100%, then the Worksheet will display an error message to the right of the row that contains the error.

Substitution rate					
2021	2022	2023	2024	2025	2026
100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
50.00%	45.00%	40.00%	35.00%	30.00%	25.00%

Error: substitution rates do not add to 100%

Figure 46 Substitution rate error

9.1.1.6 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.

9.2 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)

9.2.1 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

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 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 2e. 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*.

9.2.1.3 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 2e. Scripts – market*.
- If the default co-payment group is not appropriate for this proposed PBS Item, then an alternative can be selected from the drop-down list
- Weighted average co-payment for PBS and RPBS – the Workbook uses the weighted co-payments calculated on *Worksheet 2e. Scripts – market*.



3. Identify the costs for all forms / 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 quantity Max amount	DPMA / DPMQ	DPMA / DPMQ	Co-payment group	Co-payment group	PBS co-payment	RPBS co-payment
Allegorimb 100mg/mL injection - Initiating	\$1,125.00	1	\$1,125.00	\$1,125.00		1	-\$18.69	-\$4.27
Allegorimb 100mg/mL injection - Continuing	\$1,125.00	1	\$1,125.00	\$1,125.00		1	-\$18.69	-\$4.27

Figure 47 Costs for a PBS medicine – Section 85

3. Identify the costs for all forms / 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 quantity Max amount	DPMA / DPMQ			Co-payment group	Co-payment group	PBS co-payment	RPBS co-payment
			Public	Private	Weighted				
Allegorimb 100mg/mL injection - Initiating	\$1,125.00	1	\$1,125.00	\$1,172.74	\$1,148.87		1	-\$18.69	-\$4.27
Allegorimb 100mg/mL injection - Continuing	\$1,125.00	1	\$1,125.00	\$1,172.74	\$1,148.87		1	-\$18.69	-\$4.27

Figure 48 Costs for a PBS medicine – Section 100 (public and private hospital listing)

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 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)*.

10 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 the listing of the proposed medicine are likely to affect.

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

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

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

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

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



This worksheet is only required in the following situations:

- a market-share approach where your proposed medicine is required to be given concomitantly with another medicine
- an epidemiological model where your proposed medicine will substitute for an existing medicine
- an epidemiological model where your proposed medicine is required to be given concomitantly with another medicine

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. 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

10.1.1.1 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 2e. Scripts – market*

10.1.1.2 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.

10.1.1.3 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.

10.1.1.4 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 49 Example script calculations

- Co-payment group allows you to use one of the co-payment groups you defined in *Worksheet 2e. 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%.
- Duration of Treatment Group – select from the populations you defined in Section 7.2.5.

10.1.1.5 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 2e. 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 2e. 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

10.1.1.6 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 of the worksheet, the Workbook will apply the PBS / RPBS and the public / private splits you defined in *Worksheet 2e. Scripts – market*.

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

10.1.1.7 Estimate the numbers of units affected

Each medicine you defined in Part 4 or Part 5 of the worksheet 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)

 The sign (+/-) of the script volumes will depend on what you selected in Section 2 of the worksheet (increase or decrease respectively).

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 50 Estimate change in medicine caused by the proposed listing

10.1.1.8 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.

10.2 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)

10.2.1 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

10.2.1.1 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.

10.2.1.2 Cost of individual forms / strengths

For each of the forms / strengths of the affected medicines, a table 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*.

10.2.1.3 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*.

10.2.1.4 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.

10.2.2 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)*.

11 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.

11.1 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

11.1.1.1 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.

11.1.1.2 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.

12 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.

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



12.1.1.1 Summary of scripts – aggregate scripts for all medicines

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 will undertake a detailed costing. This table is summarised for each of the authority required (AR) levels.

1.1 Summary - aggregate scripts for all medicines

The following table summarises the aggregate number of prescriptions of the proposed and affected medicines.

PBS scripts	2021	2022	2023	2024	2025	2026
Net change: No authority	0	0	0	0	0	0
Net change: AR - Streamlined	4,118	4,563	5,023	5,495	5,981	6,484
Net change: AR - Telephone	0	0	0	0	0	0
Net change: AR - Written	0	0	0	0	0	0
Net change in PBS	4,118	4,563	5,023	5,495	5,981	6,484
RPBS scripts						
Net change: No authority	0	0	0	0	0	0
Net change: AR - Streamlined	44	50	54	60	66	70
Net change: AR - Telephone	0	0	0	0	0	0
Net change: AR - Written	0	0	0	0	0	0
Net change in RPBS	44	50	54	60	66	70
Net change in scripts	4,162	4,613	5,077	5,555	6,047	6,554

Figure 51 Script summary



12.1.1.2 Summary of authorities – aggregate authorities for all medicines

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) levels¹⁵.

1.2 Summary - aggregate authorities for all medicines

The following table summarises the aggregate number of authorities of the proposed and affected medicines.

PBS authorities	2021	2022	2023	2024	2025	2026
Net change: AR - Streamlined	1,374	1,522	1,674	1,832	1,994	2,162
Net change: AR - Telephone	-1,357	-1,504	-1,656	-1,812	-1,972	-2,137
Net change: AR - Written	-124	-137	-151	-165	-179	-194
PBS authorities	-1,481	-1,641	-1,807	-1,977	-2,151	-2,331
Net change: AR - Electronic (T)	-1,357	-1,504	-1,656	-1,812	-1,972	-2,137
Net change: AR - Electronic (W)	-124	-137	-151	-165	-179	-194
RPBS authorities						
Net change: AR - Streamlined	14	18	18	20	22	24
Net change: AR - Telephone	-17	-19	-20	-22	-24	-26
Net change: AR - Written	-2	-2	-2	-2	-2	-3
RPBS authorities	-19	-21	-22	-24	-26	-29
Net change: AR - Electronic (T)	-17	-19	-20	-22	-24	-26
Net change: AR - Electronic (W)	-2	-2	-2	-2	-2	-3

Figure 52 Authority summary

12.1.1.3 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

¹⁵ The total number of authorities does not include the electronic authorities, as these are authorities that a prescriber obtain either telephone or written means. The table presents them discretely to allow SA to complete their costings.

- 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 53 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.

12.1.1.4 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 54 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.

12.1.1.5 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.

13 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.

13.1 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

13.1.1.1 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 fee¹⁶ 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.

13.1.1.2 Estimate volume increases to the MBS



This section allows you to include up to 20 MBS Items that you expect to **increase** in volume. For each item, the following information is required:

- MBS Item number
- MBS Item descriptor
- Proportion of public hospital use – automatically supplied based on the co-payment group
- Proportion of private hospital use – automatically supplied based on the co-payment group
- Proportion of in-patient services – the proportion of in-patient services in private hospital
- Proportion of out-patient services – automatically calculated by the Workbook

¹⁶ This figure is the average between the 75% and 85% rebate rate.

- Co-payment group – as defined in *Worksheet 2e. Scripts – market*
- 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
- Duration of Treatment Group – select from the populations you defined in Section 7.2.5.

13.1.1.3 Relate the MBS Item to the proposed medicines

Part 3 allows you to relate all the MBS Items identified in Part 2 of the worksheet 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 of the worksheet to *per patient*, then this option will not be available. This information is used to determine the MBS Item volumes and hence the cost.

2. Estimate volume INCREASES to the MBS

List all the MBS items that will INCREASE as a result of the listing of the proposed 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 Descriptor	Proportion of public hospital use	Proportion of private hospital use	Proportion of in-patient services	Proportion of out-patient services	Co-payment group	Delivery basis	Number of services / patient / year	Number of services / script	Scheduled fee (100%)	Treatment phase	Population split	Duration of treatment group
23	Professional attendance by a general practitioner at consulting rooms	45.79%	54.21%	0.00%	100.00%	1	Per patient	5.00		\$38.20	All	100.00%	DTG 1: Incident 1: ABS 1: People 0 - 100 yrs inclusive (2021-2026) - (Incidence): Full year

Figure 55 MBS calculation – per patient

3. Relate the MBS Item to the proposed medicines

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

Figure 56 Relating MBS Items to patients

2. Estimate volume INCREASES to the MBS

List all the MBS items that will INCREASE as a result of the listing of the proposed 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 Descriptor	Proportion of public hospital use	Proportion of private hospital use	Proportion of in-patient services	Proportion of out-patient services	Co-payment group	Delivery basis	Number of services / patient / year	Number of services / script	Scheduled fee (100%)	Treatment phase	Population split	Duration of treatment group
23	Professional attendance by a general practitioner at consulting rooms	45.79%	54.21%	0.00%	100.00%	1	Per script		1.00	\$38.20			

Figure 57 MBS calculation – per script

3. Relate the MBS Item to the proposed medicines

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

Figure 58 Relating MBS Items to all scripts

3. Relate the MBS Item to the proposed medicines

MBS Item	Medicine / Molecule - Proposed	Calculation basis
23 - Professional attendance by a general practitioner at consulting rooms	Allegorimb 200mg tablet, 56 - Initiating	Specific medicine

Figure 59 Relating MBS Item to a specific script



13.1.1.4 Estimated services and financial impact of an MBS Item

For each item you identify in Section 2, there will be a pair of tables that show the indicative cost and service volumes for the PBS and RPBS.

23 - Professional attendance by a general practitioner at consulting rooms						Co-payment group 1
PBS	2021	2022	2023	2024	2025	2026
Indicative costs	\$66,273	\$67,356	\$68,423	\$69,475	\$70,508	\$71,522
Total services	2,169	2,204	2,239	2,273	2,307	2,340
In hospital - private	0	0	0	0	0	0
In hospital - public	0	0	0	0	0	0
Out of hospital	2,169	2,204	2,239	2,273	2,307	2,340

Figure 60 MBS Item details

The worksheet provides the following details for both the PBS and RPBS:

- Indicative costs – the Total Services multiplied by 80% of the scheduled fee
- Total services – the sum of all in and out of hospital services
- In hospital – private – the services provided to private hospital patients
- In hospital – public – the services provided to public hospital patients
- Out of hospital – the services provided to patients out of hospital

13.1.1.5 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 13.1.1.2.

13.1.1.6 Relate the MBS Item to the affected medicines

Part 5 allows you to relate all the MBS Items identified in Part 4 of the worksheet 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 of the worksheet to *per patient*, then this option will not be available. This information is used to determine the MBS Item volumes and hence the cost.



13.1.1.7 Estimated services and financial impact of an MBS Item

For each item you identify in Section 4, there will be a pair of tables that show the indicative cost and service volumes for the PBS and RPBS.

13.1.1.8 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.

14 Justification of data sources

Overview

☐ Worksheet 12. Copies of data

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

14.1 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 2e. 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

14.2 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.