

Restriction templates for PBS listings:

Font: Arial Narrow Size: 9

Paragraph \ Line Spacing = single \ Spacing: before = 0 pt after = 0 pt

for Efficient Funding of Chemotherapy items use:

Category/Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals				
MEDICINAL PRODUCT	PBS item code	Max. Amount	No. of Rpts	Manufacturer
MEDICINAL PRODUCT (use Australian Medicines Terminology) Injection	1234Z NEW (Public) NEW (Private) MP	(must be a whole number – no decimals)		XYZ Pty Ltd
Available brands				
Brand name (medicinal product pack – use Australian Medicines Terminology)				
Add more rows if required				
Restriction Summary [number – For. Dept. use] / Treatment of Concept: [number – For. Dept. use]: Restricted Benefit / Authority Required / Authority Required (STREAMLINED)				
This column – for Dept. use	Indication: Episodicity + severity + condition <i>[blank if unrestricted benefit]</i>			
	Treatment Phase: Free text (optional)			
	Clinical criteria:			
	Use the following set prefixes: <i>The condition must/must not... ; OR</i> <i>Patient must/must not...</i> <i>The treatment must/must not...</i>			
	AND			
	Clinical criteria:			
	Parameter 1; or			
	Parameter 2; or			
	Parameter 3			
	Add more rows if needed			
	AND			
	Clinical criteria:			
	Treatment criteria:			
	Use the following set prefixes: For care type: Patient must/must not be undergoing... For location: Must/must not be treated in a(n)... For prescriber: Must/must not be treated by a(n)...			
	Population criteria:			
	Use the following set prefixes: For age, gender, other parameters: Patient must/must not...			
	Prescribing Instructions: Free text here. No set prefixes. Can incorporate definitions here. Avoid references to organisations and websites in this field.			
	Administrative Advice: Free text here. No set prefixes.			
	Caution: Free text here. No set prefixes.			

2 spaces between additional Restriction summaries	
Restriction Summary [number – For. Dept. use] / Treatment of Concept: [number – For. Dept. use]: Restricted Benefit / Authority Required / Authority Required (STREAMLINED)	
This column – for Dept. use	Indication:

for non-Chemotherapy items use:

Category/Program: GENERAL – General Schedule (Code GE) / GENERAL – General Schedule Palliative Care (Code PL), Section 100 – Highly Specialised Drugs Program {Community Access (CA) - delete CA if not an antiretroviral drug treating HIV or hepatitis related infections or if not clozapine}, Section 100 – IVF Program, Section 100 – Botulinum Toxin Program Section 100 – Chemotherapy Related Benefits – e.g. anti-nauseants/pre-medications}					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
MEDICINAL PRODUCT (capital letters; use Australian Medicines Terminology)					
medicinal product pack (lower case; use Australian Medicines Terminology)	123X /NEW MP NP OP Dental	1	30	5	Brand
medicinal product pack (lower case; use Australian Medicines Terminology)	456Y /NEW MP NP OP Dental	1	30	5	Brand
Add more rows if required					
Restriction Summary [number – For. Dept. use] / Treatment of Concept: [number – For. Dept. use]: Restricted Benefit / Authority Required / Authority Required (STREAMLINED)					
This column – for Dept. use	Indication: Episodicity + severity + condition <i>[blank if unrestricted benefit]</i>				
	Treatment Phase: Free text (optional)				
	Clinical criteria:				
	Use the following set prefixes: <i>The condition must/must not... ; OR</i> <i>Patient must/must not...</i> <i>The treatment must/must not...</i>				
	AND				
	Clinical criteria:				
	Parameter 1; or				
	Parameter 2; or				
	Parameter 3				
	Add more rows if needed				
	AND				
	Clinical criteria:				
	Treatment criteria:				
	Use the following set prefixes: For care type: Patient must/must not be undergoing... For location: Must/must not be treated in a(n)... For prescriber: Must/must not be treated by a(n)...				
	Population criteria:				
	Use the following set prefixes: For age, gender, other parameters: Patient must/must not...				

	Prescribing Instructions: Free text here. No set prefixes. Can incorporate definitions here. Avoid references to organisations and websites in this field.
	Administrative Advice: Free text here. No set prefixes.
	Caution: Free text here. No set prefixes.
2 spaces between additional Restriction summaries	
Restriction Summary [number – For. Dept. use] / Treatment of Concept: [number – For. Dept. use]: Restricted Benefit / Authority Required / Authority Required (STREAMLINED)	
This column – for Dept. use	Indication:

Style conventions:

- 1) If creating new concepts or editing existing concepts, reserve use of ‘or’, ‘and’ for use as Boolean operators only; avoid use mid-sentence;
 - Where an ‘or’ might be used, consider a forward slash ‘/’, the words: at least one of... no greater than.... Either of..., Each of....only one of...
 - Where an ‘and’ might be used, consider repeating the line and use of a Boolean ‘AND’ operator, the words ‘in combination with...’ ‘together with...’ ‘both of ...’, ‘at least one of:./ / / /’

- 2) Treatment phase description:
 - Consider if separate phases are really needed; can continuing or grandfather treatment be combined into a single phase with initial treatment?
 - Consider consistency with Product Information language – is Initial treatment meant to be mean Induction treatment? Continuing treatment vs. Maintenance treatment
 - Consider non-linear dosing regimens – do the treatment phase descriptions align with those specified in the dosing section of the Product Information?
 - Consider if there are multiple listings and therefore multiple treatment phase descriptions for the one drug; can a prescriber quickly identify if a treatment phase relates to use in 1st line or 2nd line treatment?

Documents Incorporated by Reference:

What are 'Documents Incorporated by Reference'?

A document incorporated by reference is written information located externally to the Pharmaceutical Benefits Scheme (PBS) restriction (i.e. written set of criteria). The written information must be consulted in order to fully understand whether PBS eligibility is met.

Examples are:

- Product Information
- Optometry Board Guidelines
- The Modified Monash Model
- Instructions on the correct use of a certain instrument/index/scale (e.g. WHO performance status)

In most cases, such documents are neither authored by the Pharmaceutical Benefits Advisory Committee (PBAC) nor the Department of Health and Aged Care. As such, document(s) incorporated by reference have the potential effect of allowing a person/organisation other than the rule-maker to determine PBS eligibility.

Careful consideration should be given to whether PBS eligibility can be communicated clearly without relying on a document incorporated by reference.

Where the PBAC recommends incorporation of such a document(s), these documents are to be sufficiently certain and ascertainable by prescribers, the Australian Government and anybody who may read the restriction on www.pbs.gov.au. This is with respect to the name of the document, the version/edition (if applicable), any requirement to obtain a licence or copyright permission to use the document, and the source/author(s).

How to incorporate 'Documents Incorporated by Reference' into the Restriction Template

1. Identify any document(s) incorporated by reference within the restriction text and complete the following table. Display this immediately after the last restriction table above:

Document incorporated by reference	Listed drug	Description of document	Document access

2. Describe the nature and purpose of the document incorporated by reference.
3. State where the document may be **freely** (i.e. at no cost) accessed and used by the prescriber, members of the public and public service administrators. There may be instances where a website link is the only available access location, however it is the Department's preference to avoid website links, as these may change/update/stop working over time without stakeholder knowledge (the Department, sponsor, prescribers, the public).
4. Identify the version that is intended to be incorporated where there are multiple versions (e.g. Edition 1, Edition 2, Edition 3, latest version/edition, etc).

Examples of a completed table is below:

Document incorporated by reference	Listed drug	Description of document	Document access (include organisation/body responsible for the document)

Therapeutic Goods Administration (TGA)-approved Product Information – latest version.	Insert the generic drug name here	This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of this drug.	TGA-approved Product Information is available from the following sources: - Therapeutic Goods Administration; - Links contained next to the drug description on www.pbs.gov.au
Modified Monash Model	Nirmatrelvir and ritonavir	The Modified Monash Model is used to define whether a location where a person lives is a city, rural, remote, or very remote.	The Modified Monash Model is available from the Department of Health and Aged Care, Australian Commonwealth Government:: https://www.health.gov.au/topics/rural-health-workforce/classifications/mmm
World Health Organization (WHO) performance status grading	Insert the generic drug name here	Performance status quantifies the general well-being and ability to perform activities of daily life of a patient affected by cancer. The grading runs in whole numbers from 0 to 5, with grade 0 representing perfect health and 5 representing death. It is also known as the Eastern Cooperative Oncology Group (ECOG) score, or as the Zubrod score.	Medical text books and literature. Scientific journals that reference: Oken MM et al. 1982. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655 The ECOG-ACRIN Cancer Research Group publishes the scale on the following website: https://ecog-acrin.org/resources/ecog-performance-status/