

5.24 ATEZOLIZUMAB

**Solution for subcutaneous injection 1875 mg in 15 mL vial,
Tecentriq®SC,
Roche Products Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 4 submission requested a Section 100 (Highly Specialised Drugs (HSD)) Authority Required (STREAMLINED) listing of a subcutaneous (SC) injection of atezolizumab 1875 mg/15 mL (Tecentriq®SC) (atezolizumab SC from herein) under the same circumstances as the currently listed intravenous (IV) infusion of atezolizumab 1200 mg/20 mL (atezolizumab IV from herein).

2 Background

Registration status

- 2.1 Atezolizumab IV and atezolizumab SC were Therapeutic Goods Administration (TGA) registered on 27 July 2017 and 29 February 2024, respectively, for the following indications:
- Early-stage non-small cell lung cancer (NSCLC)
 - Metastatic NSCLC
 - Small cell lung cancer
 - Urothelial carcinoma
 - Hepatocellular carcinoma (HCC)

Previous PBAC consideration

- 2.2 Atezolizumab SC has not been previously considered by the PBAC.
- 2.3 Atezolizumab IV is currently PBS-listed as Section 100 (Efficient Funding of Chemotherapy, (EFC)) Authority Required (STREAMLINED) for the following indications:
- Locally advanced or metastatic NSCLC
 - Stage IV (metastatic) NSCLC
 - Extensive-stage small cell lung cancer (ES-SCLC)
 - Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C HCC

- Resected early stage (Stage II to IIIA) NSCLC (eNSCLC)

3 Requested listing

3.1 The submission requested a Section 100 (HSD) Authority Required (STREAMLINED) listing of atezolizumab SC under the same restrictions as the PBS-listed atezolizumab IV. A shortened version of the requested listing is presented below. Suggested additions are in italics.

3.2 The PBAC recalled its previous recommendations for dual General Schedule and Section 100 (EFC – Related Benefits) Schedule 2, Authority Required listing of rituximab SC (November 2014 PBAC meeting), trastuzumab SC (July 2015 PBAC meeting) and daratumumab SC (July 2021 PBAC meeting). In recommending the listing of daratumumab at its July 2021 meeting, the PBAC recalled that, when considering the SC forms of rituximab and trastuzumab, for which IV forms of these agents were listed on the PBS under the Section 100 (EFC) Schedule 1, it had recommended a dual listing for the SC forms under the General Schedule and the Section 100 (EFC – Related Benefits) Schedule 2. The PBAC could not see any differences in the circumstances of listing SC daratumumab to those which led to the listing of SC rituximab and SC trastuzumab in two separate sections of the PBS Schedule. Therefore, for consistency, the PBAC considered that the listing of the SC form of daratumumab should follow the examples of SC rituximab and SC trastuzumab (para 3.2, daratumumab Public Summary Document (PSD), July 2021 PBAC meeting).

For more detail on PBAC’s view, see section 6 PBAC outcome.

Locally advanced or metastatic NSCLC

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Brand
ATEZOLIZUMAB					
<i>atezolizumab 1875 mg/15mL injection, 15 mL vial</i>	<i>NEW (HS)</i>	<i>1</i>	<i>1</i>	<i>5 (Initial) 7 (Continuing)</i>	<i>Tecentriq SC</i>
<i>atezolizumab 1875 mg/15 mL injection, 15 mL vial</i>	<i>NEW (HS)</i>	<i>1</i>	<i>1</i>	<i>5 (Initial) 7 (Continuing)</i>	<i>Tecentriq SC</i>
Restriction Summary [NEW] / Treatment of Concept: [NEW]					
Category / Program: Section 100 – Highly Specialised Drugs Program					

Stage IV (metastatic) NSCLC

MEDICINAL PRODUCT Medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Brand
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	5 (Initial) 7 (Continuing)	Tecentriq SC
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	5 (Initial) 7 (Continuing)	Tecentriq SC
Restriction Summary [NEW] / Treatment of Concept: [NEW]					
Category / Program: Section 100 – Highly Specialised Drugs Program					

ES-SCLC

MEDICINAL PRODUCT Form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Brand
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	3 (Initial) 4 (Continuing)	Tecentriq SC
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	3 (Initial) 4 (Continuing)	Tecentriq SC
Restriction Summary [NEW] / Treatment of Concept: [NEW]					
Category / Program: Section 100 – Highly Specialised Drugs Program					

HCC

MEDICINAL PRODUCT Form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Brand
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	3 (Initial) 8 (Continuing)	Tecentriq SC
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	3 (Initial) 8 (Continuing)	Tecentriq SC
Restriction Summary [NEW] / Treatment of Concept: [NEW]					
Category / Program: Section 100 – Highly Specialised Drugs Program					

Resected eNSCLC

MEDICINAL PRODUCT Form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Brand
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	7	Tecentriq SC
atezolizumab 1875 mg/15 mL injection, 15 mL vial	NEW (HS)	1	1	7	Tecentriq SC
Restriction Summary [NEW] / Treatment of Concept: [NEW]					
Category / Program: Section 100 – Highly Specialised Drugs Program					

4 Comparator

- 4.1 The submission nominated atezolizumab IV as the comparator. However, the PBAC noted that for each of the indication that atezolizumab is listed for, there may be other relevant alternative therapies, including other medicines that have been recommended on a cost-minimisation basis with atezolizumab.
- 4.3 Under Section 101(3B) of the *National Health Act 1953*, the PBAC could only recommend listing atezolizumab SC at a higher price than the alternative therapy or therapies if it is satisfied that it provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy.

For more detail on PBAC's view, see section 6 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from consumer group/organisations (2) via the Consumer Comments facility on the PBS website. Rare Cancers Australia emphasised several benefits of atezolizumab SC compared to atezolizumab IV, including reduced administration time, fewer hospital visits particularly for patients in rural and regional areas, reduced discomfort and thus improved quality of life. The PBAC also noted input from Lung Foundation Australia which highlighted atezolizumab SC as an important immunotherapy for NSCLC as an additional treatment option for NSCLC patients who cannot tolerate atezolizumab IV.

Clinical trials

- 5.3 The submission's request was based on evidence from a phase Ib/III randomised clinical trial (IMscin001) to demonstrate that atezolizumab SC is non-inferior to atezolizumab IV administered every three weeks (Q3W) in terms of pharmacokinetics, effectiveness and safety (Clinical Study Report for IMscin001; Burotto et al., 2023).
- 5.4 The submission also stated that pharmacokinetics evidence from the trial supported the use of atezolizumab SC in all the indications for which atezolizumab IV is currently approved. Details of the trials are summarised in Table 1 below.

Table 1: Trial presented in the submission

Trial ID	Protocol title/ Publication title	Study dates/Presentation
IMscin001 NCT03735121	<p>A randomized, multicenter, Phase Ib/III study to investigate the pharmacokinetics, efficacy, and safety of atezolizumab subcutaneous compared with atezolizumab intravenous in patients with previously treated locally advanced or metastatic non—small cell lung cancer.</p> <p>Dr. Enriqueta Felip, Head, Thoracic and Head and Neck Oncology Units, Vail d'Hebron University Hospital, Vail d'Hebron Institute of Oncology (VHIO) Passeig de la Vail d'Hebron, 119, 08035 Barcelona, Spain.</p>	<p>First Patient Enrolled (Part 1): 21-Dec-2018 Data cut-off (Part 1): 10-Mar-2020 First Patient Enrolled (Part 2): 02-Dec-2020 Data cut-off (Part 2): 26-Apr-2022 Part 2 of the study is ongoing.</p>
Burotto et al., 2023	<p>IMscin001 Part 2 updated results: Efficacy, safety, immunogenicity, healthcare provider perspectives and patient-reported outcomes from the randomised Phase III study of atezolizumab subcutaneous vs intravenous in patients with locally advanced or metastatic non-small-cell lung cancer.</p>	<p>Poster presented at European Society for Medical Oncology Congress 2023; 20-24 October; Madrid, Spain.</p>

Source: Pg 1, Clinical Study Report for IMscin001 and Burrotto 2023 reference provided with submission.

5.5 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

5.6 The submission claimed that atezolizumab SC is non-inferior to atezolizumab IV in terms of effectiveness and safety. The TGA CER stated the evaluator was satisfied that atezolizumab SC demonstrated similar pharmacokinetics, efficacy and safety assessments to atezolizumab IV.

5.7 The PBAC considered that the claim of non-inferior comparative effectiveness and safety was reasonable.

Economic analysis

5.8 The submission presented a cost-minimisation approach (CMA) of atezolizumab SC compared with atezolizumab IV for its five proposed PBS-listed indications. The CMA specifically examined the drug acquisition costs, fees and mark-ups, and administration costs over a month period for both the atezolizumab SC and IV administration formulations under the HSD and EFC programs in the public and private hospital settings. However, the PBAC considered it would be more appropriate to calculate the CMA using the ex-manufacturer price.

5.9 The submission proposed the equi-effective doses of atezolizumab SC 1875 mg Q3W to be equal to atezolizumab IV 1200 mg Q3W and estimated that 1.45 administrations will be required per average calendar month (30.4375 days).

5.10 The submission requested the same published approved ex-manufacturer price (AEMP) of \$6,747.37 and effective AEMP (Tables 2-6) for atezolizumab SC as that of atezolizumab IV. As per the existing PBS listings of atezolizumab IV, special pricing arrangements (SPAs) were requested for atezolizumab SC.

- 5.11 The submission stated that both atezolizumab SC and IV administrations are captured within the Medicare Benefits Schedule (MBS) parenteral classification (item number: 13950) with a fee of \$118.90 respectively across all the five proposed PBS-listed indications. The Department notes that the MBS fee of \$118.90 (item number: 13950) would not be applicable for atezolizumab SC because it is not administered intravenously. The pre-PBAC response disagreed with the Department and argued that since 1 November 2020, the structure to the chemotherapeutic procedures listed on the MBS has changed. The pre-PBAC responses further stated that the current definition of parenteral administration (item number: 13950) includes subcutaneous therapies, therefore the MBS fee of \$118.90 would be captured in the atezolizumab SC administrations.
- 5.12 The submission stated that as atezolizumab SC is requested under the HSD program, the mark-up fee of \$40 and a ready-prepared fee of \$8.37 will only be required in the private hospital setting. There will be no fee in the public hospital setting.

Cost-minimisation approach and net cost for locally advanced or metastatic NSCLC

- 5.13 The CMA summary for locally advanced or metastatic NSCLC indication is presented below and the proposed effective AEMP for atezolizumab SC is \$1 (1% rebate on the published AEMP). The submission determined the proportion of patients treated in the public (25.7%) and private (74.3%) setting using the 2023 PBS utilisation data for atezolizumab IV (PBS items 11284X, 11277M, 11309F and 11297N).

Table 2: CMA summary in locally advanced or metastatic NSCLC (effective price)

	1200 mg atezolizumab IV Q3W		1875 mg atezolizumab SC Q3W	
Effective AEMP per administration	\$1		\$1	
Effective AEMP per month	\$1		\$1	
Setting	Public	Private	Public	Private
Split	25.7%	74.3%	25.7%	74.3%
Fees	\$88.62	\$131.91	\$0.00	\$48.37
Pharmacy mark-up	\$0.00	\$1	\$0.00	\$0.00
DPMA/DPMQ per administration	\$ ^a	\$ ^a	\$ ^b	\$ ^b
Weighted DPMA/DPMQ per administration	\$ ^a		\$ ^b	
Weighted DPMA/DPMQ per month	\$ ^a		\$ ^b	
Cost of administration (MBS Item 13950)	\$118.90		\$118.90	
Cost of administration per month	\$172.33		\$172.33	
Total cost per administration	\$1		\$1	
Total cost per month	\$1		\$1	

Source: Table 3.1 of the submission.

^a DPMA; ^b DPMQ

Abbreviations: DPMA = dispensed price at maximum amount; DPMQ = dispensed price at maximum quantity; AEMP = approved ex-manufacturer price; IV = intravenous; MBS = Medicare Benefits Schedule; SC = subcutaneous.

Cost-minimisation approach and net cost for Stage IV (metastatic) NSCLC

5.14 The CMA summary for Stage IV (metastatic) NSCLC indication is presented below and the proposed effective AEMP for atezolizumab SC is \$█ (█% rebate on the published AEMP). The submission determined the proportion of patients treated in the public (27.6%) and private (72.4%) setting using the 2023 PBS utilisation data for atezolizumab IV (PBS items 11807K, 11792P, 11802E and 11801).

Table 3: CMA summary in Stage IV (metastatic) NSCLC (effective price)

	1200 mg atezolizumab IV Q3W		1875 mg atezolizumab SC Q3W	
Effective AEMP per administration	\$█		\$█	
Effective AEMP per month	\$█		\$█	
Setting	Public	Private	Public	Private
Split	27.6%	72.4%	27.6%	72.4%
Fees	\$88.62	\$131.91	\$0.00	\$48.37
Pharmacy mark-up	\$0.00	\$█	\$0.00	\$0.00
DPMA/DPMQ per administration	█ ^a	█ ^b	█ ^b	█ ^b
Weighted DPMA/DPMQ per administration	█ ^a		█ ^b	
Weighted DPMA/DPMQ per month	█ ^a		█ ^b	
Cost of administration (MBS Item 13950)	\$118.90		\$118.90	
Cost of administration per month	\$172.33		\$172.33	
Total cost per administration	\$█		\$█	
Total cost per month	\$█		\$█	

Sources: Table 3.2 of the submission.

Abbreviations: DPMA = dispensed price at maximum amount; DPMQ = dispensed price at maximum quantity; AEMP = approved ex-manufacturer price; IV = intravenous; MBS = Medicare Benefits Schedule; SC = subcutaneous.

Cost-minimisation approach and net cost for ES-SCLC

5.15 The CMA summary for ES-SCLC indication is presented below and the proposed effective AEMP for atezolizumab SC is \$█ (█% rebate on the published AEMP). The submission determined the proportion of patients treated in the public (42.0%) and private (58.0%) setting using the 2023 PBS utilisation data for atezolizumab IV (PBS items 11926Q, 11929W, 11927R and 11928T).

Table 4: CMA summary in ES-SCLC (effective price)

	1200 mg atezolizumab IV Q3W		1875 mg atezolizumab SC Q3W	
Effective AEMP per administration	\$		\$	
Effective AEMP per month	\$		\$	
Setting	Public	Private	Public	Private
Split	42.0%	58.0%	42.0%	58.0%
Fees	\$88.62	\$131.91	\$0.00	\$48.37
Pharmacy mark-up	\$0.00	\$	\$0.00	\$0.00
DPMA/DPMQ per administration	^a	^b	^b	^b
Weighted DPMA/DPMQ per administration	^a		^b	
Weighted DPMA/DPMQ per month	^a		^b	
Cost of administration (MBS Item 13950)	\$118.90		\$118.90	
Cost of administration per month	\$172.33		\$172.33	
Total cost per administration	\$		\$	
Total cost per month	\$		\$	

Source: Table 3.3 of the submission.

^a DPMQ; ^b DPMQ

Abbreviations: DPMA = dispensed price at maximum amount; DPMQ = dispensed price at maximum quantity; AEMP = approved = ex-manufacturer price; IV = intravenous; MBS = Medicare Benefits Schedule; NSCLC=non-small cell lung cancer; SC = subcutaneous.

Cost minimisation approach and net cost for HCC


5.16 The CMA summary for HCC indication is presented below and the proposed effective AEMP for atezolizumab SC . The submission determined the proportion of patients treated in the public (41.4%) and private (58.6%) setting using the 2023 PBS utilisation data for atezolizumab (PBS items 12171N, 12168K, 12167J and 12155R).

Table 5: CMA summary in HCC (effective price)

	1200 mg atezolizumab IV Q3W		1875 mg atezolizumab SC Q3W	
Effective AEMP per administration	\$		\$	
Effective AEMP per month	\$		\$	
Setting	Public	Private	Public	Private
Split	41.4%	58.6%	41.4%	58.6%
Fees	\$88.62	\$131.91	\$0.00	\$48.37
Pharmacy mark-up	\$0.00	\$	\$0.00	\$0.00
DPMA/DPMQ per administration	^a	^a	^a	^a
Weighted DPMA/DPMQ per administration	^a		^b	
Weighted DPMA/DPMQ per month	^a		^b	
Cost of administration (MBS Item 13950)	\$118.90		\$118.90	
Cost of administration per month	\$172.33		\$172.33	
Total cost per administration	\$		\$	
Total cost per month	\$ 		\$ 	

Source: Table 3.4 of the submission.

^aDPMA; ^bDPMQ

Abbreviations: DPMA = dispensed price at maximum amount; DPMQ = dispensed price at maximum quantity; EEMP = effective ex-manufacturer price; IV = intravenous; MBS = Medicare Benefits Schedule; NSCLC = non-small cell lung cancer; SC = subcutaneous.

Cost minimisation approach and net cost for resected eNSCLC

5.17 The CMA summary for resected eNSCLC indication is presented below and the proposed effective AEMP is \$| (|% rebate on the published AEMP) for atezolizumab SC. The submission determined the proportion of patients treated in the public (25.7%) and private (74.3%) setting using the 2023 PBS utilisation data for atezolizumab IV (PBS items 13174J and 13172G).

Table 6: CMA summary in resected eNSCLC (effective price)

	1200 mg atezolizumab IV Q3W		1875 mg atezolizumab SC Q3W	
Effective AEMP per administration	\$		\$	
Effective AEMP per month	\$		\$	
Setting	Public	Private	Public	Private
Split	25.7%	74.3%	25.7%	74.3%
Fees	\$88.62	\$131.91	\$0.00	\$48.37
Pharmacy mark-up	\$0.00	\$	\$0.00	\$0.00
DPMA/DPMQ per administration	^a	^a	^a	^a
Weighted DPMA/DPMQ per administration	^a		^b	
Weighted DPMA/DPMQ per month	^a		^b	
Cost of administration (MBS Item 13950)	\$118.90		\$118.90	
Cost of administration per month	\$172.33		\$172.33	
Total cost per administration	\$		\$	
Total cost per month	\$		\$	

Sources: Table 3.4 of the submission.

^aDPMA; ^bDPMQ

Abbreviations: DPMA = dispensed price at maximum amount; DPMQ = dispensed price at maximum quantity; EEMP = effective ex-manufacturer price; IV = intravenous; MBS = Medicare Benefits Schedule; NSCLC = non-small cell lung cancer; SC = subcutaneous.

5.18 As a Category 4 submission, the economic analysis has not been independently evaluated.

Estimated PBS usage and financial implications.

5.19 The submission adopted a market share approach to estimate the net financial impact of listing atezolizumab SC. The submission assumed that atezolizumab SC is expected to directly substitute for atezolizumab IV on a 1:1 basis at the same published and effective prices across all five indications (100% substitution rate). As such, the submission estimated that the requested listing of atezolizumab SC to be cost neutral to the PBS/RPBS.

5.20 The submission assumed a 70% uptake rate of atezolizumab SC for indications where atezolizumab can be administered as monotherapy (i.e. locally advanced or metastatic NSCLC, ES-SCLC and resected eNSCLC) and a 30% uptake rate of atezolizumab SC for Stage IV (metastatic) NSCLC and HCC. The submission stated that the assumed uptake rates were based on Australian clinician feedback from the Roche Lung Cancer Advisory Board.

5.21 The submission estimated the units dispensed using the 2023 PBS utilisation data for atezolizumab IV.

Estimated rate of growth in the next six years of listing

5.22 The submission estimated the annual growth rates for the five indications based on the 2012 to 2017 incidence data from the 2021 Australian Cancer Incidence and Mortality (ACIM) book for lung cancer (ICD-10 codes C33-C34) produced by the

Australian Institute of Health and Welfare (AIHW; AIHW, 2021). The growth rates for HCC were estimated based on the 2010 to 2015 incidence data from the 2018 ACIM book for liver cancer (ICD-10 codes C22).

5.23 A linear trend using the method of least squares was applied to the cancer incidence data to extrapolate projected annual growth rates of lung and liver cancer across the six-year forward estimates from 2024 to 2029. The submission claimed that this methodological approach for estimating annual growth rates was previously accepted by the PBAC in its consideration of atezolizumab for resected NSCLC (atezolizumab PSD, July 2022 PBAC meeting) and HCC (atezolizumab PSD, July 2020 PBAC meeting).

5.24 The submission’s estimated annual rate of growth for each of the five proposed PBS indications from 2023 to 2029 is presented below.

Table 7: Estimated annual rate of growth in the market for each PBS indication

	2023	2024	2025	2026	2027	2028	2029	Source
2L NSCLC	2.50%	2.23%	2.06%	2.06%	2.07%	2.07%	1.92%	2021 ACIM book for lung cancer
1L NSCLC	2.50%	2.23%	2.06%	2.06%	2.07%	2.07%	1.92%	2021 ACIM book for lung cancer
1L ES-SCLC	2.50%	2.23%	2.06%	2.06%	2.07%	2.07%	1.92%	2021 ACIM book for lung cancer
HCC	3.87%	3.90%	3.86%	3.52%	3.31%	3.41%	3.24%	2018 ACIM book for liver cancer
Resected eNSCLC	2.50%	2.23%	2.06%	2.06%	2.07%	2.07%	1.92%	2021 ACIM book for lung cancer

Source: Section 4 Workbook.xlsx, spreadsheets 'Incidence of lung cancer' and ' Incidence of liver cancer'.

Overall cost to the PBS/RPBS

5.25 As a Category 4 submission, the financial estimates analysis has not been independently evaluated.

5.26 Table 8 shows the estimated extent of use, cost of listing atezolizumab SC and the net financial implications to the PBS/RPBS and MBS.

Table 8: Estimated use and financial implications for atezolizumab SC as Section 100 (HSD)

Year	2024	2025	2026	2027	2028	2029
Estimated extent of use						
Total number of prescriptions	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Estimated financial implications of atezolizumab SC (published price)						
Cost to PBS less co-payment (new listing)	█ ²	█ ²	█ ²	█ ²	█ ³	█ ³
Changed listing	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Net cost to PBS	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Cost to RPBS less co-payment (new listing)	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵
Changed listing	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Net cost to RPBS	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Net cost to MBS	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵
Total net cost to PBS/RPBS	█⁴	█⁴	█⁴	█⁴	█⁴	█⁴
Estimated financial implications of atezolizumab SC (effective price)						
Cost to PBS less co-payment (new listing)	█ ⁶	█ ⁶	█ ⁶	█ ⁷	█ ⁷	█ ⁷
Changed listing	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Net cost to PBS	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Cost to RPBS less co-payment (new listing)	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵
Changed listing	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Net cost to RPBS	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Net cost to MBS	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁵
Total net cost to PBS/RPBS	█⁴	█⁴	█⁴	█⁴	█⁴	█⁴

Source: Table 4.2, pp. 37; Table 4.3, pp. 38 of the submission.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; MBS = Medical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ 5000 to < 10,000

² \$50 million to < \$60 million

³ \$60 million to < \$70 million

⁴ net cost saving

⁵ \$0 to < \$10 million

⁶ \$10 million to < \$20 million

⁷ \$20 million to < \$30 million

5.27 As per the submission, if atezolizumab SC was listed as Section 100 (HSD), the submission estimated that the net financial impact to the PBS/RPBS for the listing of atezolizumab SC is net cost saving (at published price level) and net cost saving (at effective price level) over the six years. The submission expected no change to MBS following the proposed listing of atezolizumab SC.

5.28 The net financial implication to the Commonwealth for all five indications if atezolizumab SC was listed as Section 100 (EFC-Related Benefits) and Section 85 General Schedule is presented in Tables 9-14.

Table 9: Estimated financial implications for atezolizumab SC as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for locally advanced or metastatic NSCLC

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated financial implications of atezolizumab SC (published price)						
Cost to PBS/RPBS less co-payment	¹	¹	¹	¹	¹	²
Estimated financial implications of atezolizumab IV (published price)						
Cost to PBS/RPBS less co-payment	³	³	³	³	³	³
Net cost to PBS/RPBS	³	³	³	³	³	³
Estimated financial implications of atezolizumab SC (effective price)						
Cost to PBS/RPBS less co-payment	¹	¹	¹	¹	¹	¹
Estimated financial implications of atezolizumab IV (effective price)						
Cost to PBS/RPBS less co-payment	³	³	³	³	³	³
Net cost to PBS/RPBS	³	³	³	³	³	³
Net cost to MBS	¹	¹	¹	¹	¹	¹

Source: Table provided by PBS estimates.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; MBS = Medical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² \$10 million to < \$20 million

³ net cost saving

5.29 If atezolizumab SC was listed as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for locally advanced or metastatic NSCLC, the total financial implication of listing atezolizumab SC is expected to be net cost saving to the PBS/RPBS (at published price level) and net cost saving to the PBS/RPBS (at effective price level).

Table 10: Estimated financial implications for atezolizumab SC as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for Stage IV (metastatic) NSCLC

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated financial implications of atezolizumab SC (published price)						
Cost to PBS/RPBS less co-payment	¹	¹	¹	¹	¹	¹
Estimated financial implications of atezolizumab IV (published price)						
Cost to PBS/RPBS less co-payment	²	²	²	²	²	²
Net cost to PBS/RPBS	²	²	²	²	²	²
Estimated financial implications of atezolizumab SC (effective price)						
Cost to PBS/RPBS less co-payment	¹	¹	¹	¹	¹	¹
Estimated financial implications of atezolizumab IV (effective price)						
Cost to PBS/RPBS less co-payment	²	²	²	²	²	²
Net cost to PBS/RPBS	²	²	²	²	²	²
Net cost to MBS	¹	¹	¹	¹	¹	¹

Source: Table provided by PBS estimates.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; MBS = Medical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

5.30 If atezolizumab SC was listed as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for stage IV (metastatic) NSCLC, the total financial implication of listing atezolizumab SC is expected to be net cost saving to the PBS/RPBS (at published price level) and net cost saving to the PBS/RPBS (at effective price level).

Table 11: Estimated financial implications for atezolizumab SC as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for ES-SCLC

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated financial implications of atezolizumab SC (published price)						
Cost to PBS/RPBS less co-payment	¹	²	²	²	²	²
Estimated financial implications of atezolizumab IV (published price)						
Cost to PBS/RPBS less co-payment	³	³	³	³	³	³
Net cost to PBS/RPBS	³	³	³	³	³	³
Estimated financial implications of atezolizumab SC (effective price)						
Cost to PBS/RPBS less co-payment	⁴	⁴	⁴	⁴	⁴	⁴
Estimated financial implications of atezolizumab IV (effective price)						
Cost to PBS/RPBS less co-payment	³	³	³	³	³	³
Net cost to PBS/RPBS	³	³	³	³	³	³
Net cost to MBS	⁴	⁴	⁴	⁴	⁴	⁴

Source: Table provided by PBS estimates.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; MBS = Medical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ \$20 million to < \$30 million

² \$30 million to < \$40 million

³ net cost saving

⁴ \$0 to < \$10 million

- 5.31 If atezolizumab SC were dual listed as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for ES-SCLC, the total financial implication of listing atezolizumab SC is expected to be net cost saving to the PBS/RPBS (at published price level) and net cost saving to the PBS/RPBS (at effective price level).

Table 12: Estimated financial implications for atezolizumab SC as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for HCC

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated financial implications of atezolizumab SC (published price)						
Cost to PBS/RPBS less co-payment	1	1	1	1	1	1
Estimated financial implications of atezolizumab IV (published price)						
Cost to PBS/RPBS less co-payment	2	2	2	2	2	2
Net cost to PBS/RPBS	2	2	2	2	2	2
Estimated financial implications of atezolizumab SC (effective price)						
Cost to PBS/RPBS less co-payment	3	3	3	3	3	3
Estimated financial implications of atezolizumab IV (effective price)						
Cost to PBS/RPBS less co-payment	2	2	2	2	2	2
Net cost to PBS/RPBS	2	2	2	2	2	2
Net cost to MBS	3	3	3	3	3	3

Source: Table provided by PBS estimates.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; MBS = Medical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ \$10 million to < \$20 million

² net cost saving

³ \$0 to < \$10 million

- 5.32 If atezolizumab SC was listed as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for HCC, the total financial implication of listing atezolizumab SC is expected to be net cost saving to the PBS/RPBS (at published price level) and net cost saving to the PBS/RPBS (at effective price level).

Table 13: Estimated financial implications for atezolizumab SC as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for resected eNSCLC

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated financial implications of atezolizumab SC (published price)						
Cost to PBS/RPBS less co-payment	¹	¹	¹	¹	¹	¹
Estimated financial implications of atezolizumab IV (published price)						
Cost to PBS/RPBS less co-payment	²	²	²	²	²	²
Net cost to PBS/RPBS	²	²	²	²	²	²
Estimated financial implications of atezolizumab SC (effective price)						
Cost to PBS/RPBS less co-payment	¹	¹	¹	¹	¹	¹
Estimated financial implications of atezolizumab IV (effective price)						
Cost to PBS/RPBS less co-payment	²	²	²	²	²	²
Net cost to PBS/RPBS	²	²	²	²	²	²
Net cost to MBS	¹	¹	¹	¹	¹	¹

Source: Table provided by PBS estimates.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; MBS = Medical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ \$0 to < \$20 million

² net cost saving

5.33 If atezolizumab SC was listed as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for resected eNSCLC, the total financial implication of listing atezolizumab SC is expected to be net cost saving to the PBS/RPBS (at published price level) and net cost saving to the PBS/RPBS (at effective price level).

Table 14: Overall estimated financial implication of listing atezolizumab SC as Section 100 (EFC-Related Benefits) and Section 85 General Schedule for all five indications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated financial implications of atezolizumab SC (published price)						
Cost to PBS/RPBS less co-payment (new listing)	█ ¹	█ ¹	█ ¹	█ ²	█ ²	█ ²
Changed listing	█ ³	█ ³	█ ³	█ ³	█ ³	█ ³
Total net cost to PBS/RPBS	█ ³	█ ³	█ ³	█ ³	█ ³	█ ³
Net cost to MBS	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Estimated financial implications of atezolizumab SC (effective price)						
Cost to PBS less co-payment (new listing)	█ ⁵	█ ⁶	█ ⁶	█ ⁶	█ ⁶	█ ⁶
Changed listing	█ ³	█ ³	█ ³	█ ³	█ ³	█ ³
Total net cost to PBS/RPBS	█ ³	█ ³	█ ³	█ ³	█ ³	█ ³
Net cost to MBS	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴

Source: Table provided by PBS estimates.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; MBS = Medical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ \$50 million to < \$60 million

² \$60 million to < \$70 million

³ net cost saving

⁴ \$0 to < \$10 million

⁵ \$10 million to < \$20 million

⁶ \$20 million to < \$30 million

5.34 The overall financial impact to the PBS/RPBS of listing atezolizumab SC for all five indications is expected to be net cost saving (at published price level) and net cost saving (at effective price level).

6 PBAC Outcome

6.1 The PBAC recommended the dual Section 85 General Schedule and Section 100 (Efficient Funding of Chemotherapy – Related Benefits) Authority Required listings of atezolizumab SC for locally advanced or metastatic non-small cell lung cancer (NSCLC), stage IV (metastatic) NSCLC, extensive-stage small cell lung cancer (ES-SCLC), advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma and resected early stage (Stage II to IIIA) NSCLC (eNSCLC) for which atezolizumab IV is currently listed. The PBAC’s recommendation for listing was based on, among other matters, its assessment that atezolizumab SC would be cost-effective if it were cost-minimised to the lowest cost comparator.

6.2 The PBAC considered that the claim of non-inferior comparative effectiveness and safety to atezolizumab IV was appropriate. The PBAC noted the TGA CER concluded that atezolizumab SC demonstrated similar pharmacokinetics, efficacy and safety assessments to atezolizumab IV.

6.3 The PBAC advised the equi-effective doses to be 1875 mg atezolizumab SC = 1200 mg

atezolizumab IV.

- 6.4 The PBAC noted that the submission calculated costs for a Section 100 Highly Specialised Drugs listing. The PBAC considered that although there would be minor differences from the submission estimates due to the differences in mark-ups between the schedules, dual listing of atezolizumab SC on Section 100 EFC (Related Benefits) and the General Schedule would likely still result in a modest cost saving to the PBS/RPBS.
- 6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because atezolizumab SC is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over atezolizumab IV, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.6 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new form as follows:

Locally advanced or metastatic non-small cell lung cancer

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	5	Tecentriq
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	5	Tecentriq
Restriction Summary [New] / Treatment of Concept: [New]					
Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined				
	Administrative Advice: In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Administrative Advice: Special Pricing Arrangements apply.				
	Indication: Locally advanced or metastatic non-small cell lung cancer				
	Treatment Phase: Initial treatment - 3 weekly treatment regimen				

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Clinical criteria:								
Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer								
AND								
Clinical criteria:								
Patient must have a WHO performance status of 0 or 1								
AND								
Clinical criteria:								
The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition								
AND								
Clinical criteria:								
The condition must have progressed on or after prior platinum based chemotherapy; or								
The condition must have progressed after treatment with tepotinib								
MEDICINAL PRODUCT				PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
medicinal product pack								
ATEZOLIZUMAB								
atezolizumab 1875 mg/15 mL solution for subcutaneous injection				NEW (CT)	1	1	7	Tecentriq
atezolizumab 1875 mg/15 mL solution for subcutaneous injection				NEW (GE)	1	1	7	Tecentriq
Restriction Summary [New] / Treatment of Concept: [New]								
Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)							
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners							
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined							
	Administrative Advice: No increase in the maximum number of repeats may be authorised.							
	Administrative Advice: Special Pricing Arrangements apply.							
	Indication: Locally advanced or metastatic non-small cell lung cancer							
	Treatment Phase: Continuing treatment - 3 weekly treatment regimen							
	Clinical criteria:							
	Patient must have previously received PBS-subsidised treatment with this drug for this condition							
	AND							
	Clinical criteria:							
	The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition							
	AND							
	Clinical criteria:							
	Patient must have stable or responding disease							

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	5	Tecentriq
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	5	Tecentriq

Restriction Summary [New] / Treatment of Concept: [New]

Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined
	Administrative Advice: In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Indication: Stage IV (metastatic) non-small cell lung cancer (NSCLC)
	Treatment Phase: Initial treatment 1
	Treatment criteria:
	Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy
	Clinical criteria:
	The condition must be non-squamous type non-small cell lung cancer (NSCLC)
	AND
	Clinical criteria:
	Patient must not have previously been treated for this condition in the metastatic setting; or
	The condition must have progressed after treatment with tepotinib
	AND
	Clinical criteria:
	Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer
	AND
	Clinical criteria:
	Patient must have a WHO performance status of 0 or 1
	AND
	Clinical criteria:
	The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material

Restriction Summary [New] / Treatment of Concept: [New]

Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined

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	Administrative Advice: In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.					
	Administrative Advice: No increase in the maximum number of repeats may be authorised.					
	Administrative Advice: Special Pricing Arrangements apply.					
	Indication: Stage IV (metastatic) non-small cell lung cancer (NSCLC)					
	Treatment Phase: Initial treatment 2					
	Treatment criteria:					
	Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy					
	Clinical criteria:					
	The condition must be non-squamous type non-small cell lung cancer (NSCLC)					
	AND					
	Clinical criteria:					
	Patient must have a WHO performance status of 0 or 1					
	AND					
	Clinical criteria:					
	Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material					
	AND					
	Clinical criteria:					
	Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI)					
	AND					
	Clinical criteria:					
	Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer					
	MEDICINAL PRODUCT	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
	medicinal product pack					
	ATEZOLIZUMAB					
	atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	7	Tecentriq
	atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	7	Tecentriq
	Restriction Summary [New] / Treatment of Concept: [New]					
Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined					
	Administrative Advice: No increase in the maximum number of repeats may be authorised.					
	Administrative Advice: Special Pricing Arrangements apply.					
	Indication: Stage IV (metastatic) non-small cell lung cancer (NSCLC)					
	Treatment Phase: Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen					

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	Treatment criteria:
	Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment
	AND
	Clinical criteria:
	Patient must have stable or responding disease

Extensive-stage small cell lung cancer

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	3	Tecentriq
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	3	Tecentriq
Restriction Summary [New] / Treatment of Concept: [New]					
Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined				
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Administrative Advice: Special Pricing Arrangements apply.				
	Indication: Extensive-stage small cell lung cancer				
	Treatment Phase: Initial treatment				
	Clinical criteria:				
	The condition must be previously untreated				
	AND				
	Clinical criteria:				
	Patient must have a WHO performance status of 0 or 1				
	AND				
	Clinical criteria:				
	The treatment must be in combination with etoposide and a platinum-based antineoplastic drug				

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	4	Tecentriq
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	4	Tecentriq
Restriction Summary [New] / Treatment of Concept: [New]					
Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined					
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
Administrative Advice: No increase in the maximum number of repeats may be authorised.					
Administrative Advice: Special Pricing Arrangements apply.					
Indication: Extensive-stage small cell lung cancer					
Treatment Phase: Continuing treatment - 3 weekly treatment regimen					
Clinical criteria:					
The treatment must be as monotherapy					
AND					
Clinical criteria:					
Patient must have previously received PBS-subsidised treatment with this drug for this condition					
AND					
Clinical criteria:					
Patient must not have developed disease progression while being treated with this drug for this condition					

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	3	Tecentriq
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	3	Tecentriq
Restriction Summary [New] / Treatment of Concept: [New]					
Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined					
Caution: The safety of atezolizumab in combination with bevacizumab has not been established in patients who have incompletely treated varices, variceal bleeding within the previous 6 months or who are at high risk of bleeding. Patients should be assessed for risk of variceal bleeding prior to treatment with this combination.					

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	Administrative Advice: In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.					
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
	Administrative Advice: No increase in the maximum number of repeats may be authorised.					
	Administrative Advice: Special Pricing Arrangements apply.					
	Indication: Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma					
	Treatment Phase: Initial treatment					
	Treatment criteria:					
	Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated					
	Clinical criteria:					
	Patient must have a WHO performance status of 0 or 1					
	AND					
	Clinical criteria:					
	Patient must not be suitable for transarterial chemoembolisation					
	AND					
	Clinical criteria:					
	Patient must have Child Pugh class A					
	AND					
	Clinical criteria:					
	The condition must be untreated with systemic therapy; or					
	Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal					
	MEDICINAL PRODUCT	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
	medicinal product pack					
	ATEZOLIZUMAB					
	atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	8	Tecentriq
	atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	8	Tecentriq
	Restriction Summary [New] / Treatment of Concept: [New]					
	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined					
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
	Administrative Advice: No increase in the maximum number of repeats may be authorised.					
	Administrative Advice: Special Pricing Arrangements apply.					
	Indication: Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma					

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	Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen
	Treatment criteria:
	Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	Patient must not have developed disease progression while being treated with this drug for this condition
	Prescribing Instructions:
	PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ATEZOLIZUMAB					
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (CT)	1	1	7	Tecentriq
atezolizumab 1875 mg/15 mL solution for subcutaneous injection	NEW (GE)	1	1	7	Tecentriq
Restriction Summary [New] / Treatment of Concept: [New]					
Concept ID	Category / Program: S100 Section 100 (Efficient Funding of Chemotherapy) – Related Benefits (Code CT) GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined				
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Administrative Advice: Special Pricing Arrangements apply.				
	Indication: Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)				
	Treatment Phase: 1,875 mg administered once every 3 weeks				
	Population criteria:				
	Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; or				
	Patient must be continuing existing PBS-subsidised treatment with this drug; or				
	Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated				
	Clinical criteria:				
	Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug				
	AND				
	Clinical criteria:				

	The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy
	AND
	Clinical criteria:
	The condition must have/have had at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement
	AND
	Clinical criteria:
	The condition must have/have had at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition
	Treatment criteria:
	Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.