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5.01 AMIVANTAMAB,
Solution for subcutaneous injection 1,600 mg in 10 mL
Solution for subcutaneous injection 2,240 mg in 14 mL
Solution for subcutaneous injection 2,400 mg in 15 mL
Solution for subcutaneous injection 3,520 mg in 22 mL
Rybrevant SC®,
JANSSEN-CILAG PTY LTD.

1 Purpose of submission

1.1 The Category 2 submission requested Section 100 Efficient Funding of Chemotherapy (EFC) Related Benefits and Section 85 General Schedule listing of a subcutaneous (SC) injection of amivantamab for the treatment of locally-advanced/metastatic epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) positive non-small cell lung cancer (NSCLC). The submission requested the same restrictions as the currently listed intravenous (IV) infusion of amivantamab (350 mg/7 mL).

1.2 Listing was requested on the basis of a cost-minimisation approach (CMA) against amivantamab IV.

Table 1: Key components of the clinical issue addressed by the submission (as stated in the submission)

Component	Description
Population	Patients with locally advanced or metastatic NSCLC with evidence of an EGFR ex20ins mutation who are treatment naïve (i.e. first-line setting) or have progressed following treatment with platinum-based chemotherapy (i.e. second-line setting).
Intervention	First-line setting: Amivantamab administered as a SC injection in combination with PBC until disease progression. Second-line setting: Amivantamab SC injection as monotherapy until disease progression.
Comparator	First-line setting: Amivantamab administered as an IV infusion in combination with PBC until disease progression. Second-line setting: Amivantamab IV infusion as monotherapy until disease progression.
Outcomes	Efficacy (objective response rate, overall survival, progression-free survival), pharmacokinetics and safety/tolerability.
Clinical claim	The pivotal PALOMA-3 trial demonstrates that amivantamab SC provides non-inferior pharmacokinetics, efficacy and safety/tolerability compared to amivantamab IV.

Source: Table 1.1, p15 of the submission
Abbreviations: EGFR=epidermal growth factor receptor; ex20ins=Exon 20 insertion; IV=intravenous; NSCLC=non-small cell lung cancer; PBC=platinum-based chemotherapy; SC=subcutaneous.

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2 Background

Registration status

2.1 Amivantamab IV and amivantamab SC (1,600 mg/10 mL, 2,240 mg/14 mL) were TGA approved on 3 February 2025 and 3 October 2025, respectively, for the following indications:

- in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR exon 20 insertion mutations.
- as monotherapy for the treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.
- in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor (TKI).
- in combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations.

2.2 The approved product information (PI) for amivantamab SC (1,600 mg/10 mL, 2,240 mg/14 mL) indicated that non-inferiority of amivantamab SC and amivantamab IV was established in a randomised, open-label Phase 3 study (PALOMA-3) (p8 of amivantamab SC PI). The TGA Delegate considered there was sufficient evidence that the clinical efficacy of the SC formulation can be expected to be the same as that described for the IV formulation based on the pharmacokinetics data (PALOMA-3) together with the descriptive analyses of clinical efficacy endpoints (PALOMA-2) to allow bridging from the SC formulation studies to studies conducted using the original IV formulation (TGA Delegate's Overview, September 2025).

2.3 At the time of evaluation, a TGA application for the registration of amivantamab SC 2,400 mg and 3,520 mg formulations was submitted in August 2025 and the TGA Delegate's Overview was available prior to PBAC consideration. In addition to the two new formulations, the Delegate was supportive of registering a four weekly dosing regimen when amivantamab is used in combination with lazertinib or as monotherapy.

Previous PBAC consideration

2.4 Amivantamab SC has not previously been considered by the PBAC.

2.5 Amivantamab IV was recommended for the treatment of locally advanced or metastatic ex20ins NSCLC in the first- and second-line setting by the PBAC at its November 2024 meeting and has been listed on the PBS since May 2025.

2.6 There have been two subsequent considerations for amivantamab IV.

- Amivantamab in combination with lazertinib for the first-line treatment of patients with locally advanced or metastatic NSCLC with evidence in tumour material of an activating epidermal growth factor receptor mutation (EGFRm) known to confer sensitivity to EGFR TKIs was not recommended at the March 2025 PBAC meeting.
- Amivantamab in combination with platinum-based chemotherapy (PBC) for the treatment of locally advanced or metastatic EGFRm NSCLC where the condition has progressed on or after osimertinib was recommended at the March 2026 meeting.

For more detail on PBAC's view, see section 7 PBAC outcome.

3 Requested listing

3.1 The PSCR provided a revised restriction criteria (presented below, edits in italics and strikethrough) that (i) removed the grandfather (GF) criterion as it was not required and (ii) included revised wording proposed by Secretariat to the clinical criteria to enable switching between the two amivantamab formulations.

MEDICINAL PRODUCT Form	Dispensed Price Max Amt		Max. Amount	№.of Rpts
AMIVANTAMAB				
Amivantamab 1,600 mg / 10 mL vial	**General:** Published: $6,946.93 Effective: $[redacted]	**EFC Related:** Published: $6,784.00 Effective: $[redacted]	1,600 mg	0 (Initial *1*)
Amivantamab 2,240 mg / 14 mL vial	**General:** Published: $9,660.53 Effective: $[redacted]	**EFC Related:** Published: $9,497.60 Effective: $[redacted]	2,240 mg	0 (Initial *1*)
Amivantamab 2,400 mg / 15 mL vial	**General:** Published: $10,338.93 Effective: $[redacted]	**EFC Related:** Published: $10,176.00 Effective: $[redacted]	2,400 mg	4 (Initial *2*)
Amivantamab 3,520 mg / 22 mL vial	**General:** Published: $15,087.73 Effective: $[redacted]	**EFC Related:** Published: $14,924.80 Effective: $[redacted]	3,520 mg	4 (Initial *2*)
Amivantamab 2,400 mg / 15 mL vial	**General:** Published: $10,338.93 Effective: $[redacted]	**EFC Related:** Published: $10,176.00 Effective: $[redacted]	2,400 mg	7 (Continuing)
Amivantamab 3,520 mg / 22 mL vial	**General:** Published: $15,087.73 Effective: $[redacted]	**EFC Related:** Published: $14,924.80 Effective: $[redacted]	3,520 mg	7 (Continuing)
	Available brands			
	Rybrevant Amivantamab 1,600 mg/10 mL, 2,240 mg/14 mL, 2,400 mg/15 mL and 3,520 mg/22 mL, solution for subcutaneous injection			

Note: General prices presented were based on S85 community pharmacy dispensing fees and EFC related prices were based on public hospital dispensing fees.

Category / Program: Section 100 – Chemotherapy Related Benefits (Code CT) Section 85 – General Schedule (Code GE)
Prescriber type: Medical Practitioners
Restriction Level: Authority Required (immediate assessment- telephone/online application avenues)
Indication: Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment
Clinical criteria:
Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation,
AND

Clinical criteria:
Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition.
AND
Clinical criteria:
Patient must not have previously received this drug for this condition; OR
~~If the patient is currently receiving the intravenous form of this drug for this condition, the patient can switch to receive the subcutaneous form of this drug for this condition~~ *Patient must be each of: (i) previously received the intravenous form of this drug for this condition (ii) switching to receive the subcutaneous form of this drug for this condition while being free of disease progression since commencing treatment with this drug; OR*
~~Patient must be each of: (i) currently receiving non-PBS subsidised supply for this drug for this PBS indication, (ii) free of disease progression since commencing non-PBS subsidised supply.~~
AND
Clinical criteria:
The treatment must be/have been in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting, (i.e. used in combination with PBC in the first line setting) OR
The treatment must be the sole PBS subsidised therapy where the condition has progressed following treatment with platinum-based chemotherapy, (i.e. used as monotherapy in the second line setting).
Administrative Advice: No increase in the maximum amount or number of units may be authorised.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Special Pricing Arrangement apply.
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Treatment Phase: Continuing treatment
Clinical criteria
Patient must have previously received PBS-subsidised treatment with this drug for this condition OR
Patient must have previously received PBS-subsidised treatment with this drug for this condition in any form.
AND
Clinical criteria
Patient must not have developed disease progression while receiving treatment with this drug for this condition
Administrative Advice: No increase in the maximum amount or number of units may be authorised.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Special Pricing Arrangement apply.
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

3.2 The submission requested a dual Section 100 (EFC – Related Benefits) and Section 85 General Schedule listing for amivantamab SC under the same restrictions as the PBS-listed amivantamab IV. The request for dual listings is consistent with PBAC's previous considerations of atezolizumab (March 2024 PBAC meeting), daratumumab (July 2021 PBAC meeting), rituximab (November 2014 PBAC meeting) and trastuzumab (July

2015 PBAC meeting), for which IV forms of these agents were listed under Section 100 (Efficient Funding of Chemotherapy) and dual listings for the SC forms were recommended.

3.3 The proposed PBS restrictions for amivantamab SC are intended to target the same populations as the currently listed indication for amivantamab IV (paragraph 2.5), thus remain largely the same except for the proposal to include an additional clinical criteria to allow patients to switch from the IV to SC formulations. The proposed wording for this is "If the patient is currently receiving the intravenous form of this drug for this condition, the patient can switch to receive the subcutaneous form of this drug for this condition". The PSCR accepted the following amended wording for this criterion (as proposed by the Secretariat): "Patient must be each of: (i) previously received the intravenous form of this drug for this condition (ii) switching to receive the subcutaneous form of this drug for this condition while being free of disease progression since commencing treatment with this drug;".

3.4 The submission also proposed the following change to the treatment criteria of amivantamab IV listing as a possible flow-on change. The change would involve replacing the criterion "Patient must not have previously received this drug for this condition" with "Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time for this PBS indication, (ii) changing the drug's form (intravenous/subcutaneous)." The ESC considered it was likely switching would occur, with most occurring from IV to SC but a small amount of switch would be from SC to IV.

3.5 The submission requested that the initial treatment covers the first four weekly doses of amivantamab SC, followed by two doses every 3 weeks (Q3W) (up to Week 10). The continuing treatment period also allows for a further eight Q3W doses (starting at Week 13) which equates to approximately 6 months of therapy. This is consistent with the PBS listing for amivantamab IV in ex20ins NSCLC; however, the IV listing caters for the use of monotherapy in the second line setting where the maximum amount of the drug is sufficient for all dosing regimens. According to the draft TGA Product information, the dosage regimen for amivantamab SC in combination with platinum-based chemotherapy (PBC), used every 3 weeks (Q3W), differs from the dosing regimen for amivantamab SC monotherapy, used every 2 weeks (Q2W) or every 4 weeks (Q4W). The current listing for amivantamab IV allows for Q2W dosing within the maximum amount of 2,100 mg. However, amivantamab SC is supplied in single-dose vials providing specific doses and the lower dose strengths (used for Q2W dosing) will not be listed for continuing treatment. The pre-subcommittee response (PSCR) reiterated its request to list the SC presentation based on Q3W dosing. The ESC noted a majority of patients will be treated in the first line treatment setting with Q3W dosing.

3.6 The submission proposed a special pricing arrangement. The effective approved ex-manufacturer prices (AEMPs) for each of the amivantamab SC vials are: 1,600 mg = $[redacted], 2,240 mg = $[redacted], 2,400 mg = $[redacted] and 3,520 mg = $[redacted].

For more detail on PBAC's view, see section 7 PBAC outcome.

4 Population and disease

4.1 Lung cancer is the fourth most commonly diagnosed cancer for Australian men and women, with an estimated 15,100 people diagnosed in 2025.[1] Lung cancer is the leading cause of cancer mortality, with an estimated 9,000 people expected to die from the disease in 2025. Of the five most common cancers in Australia, survival rates for lung cancer have been the lowest with a 5-year survival of 27% in 2017-2021.

4.2 EGFR mutations are the most common type of mutation in NSCLC, with approximately 30% of NSCLC patients carrying EGFR mutations.[2] Among these patients, approximately 4−15% of patients have EGFR ex20ins mutations, making it less common than EGFR exon 19 deletion (ex19del) mutations (46%) and EGFR L858R point mutation (38%).[3,4,5] Patients with EGFR 20ins mutations have poorer prognosis and outcomes compared to patients with more common forms of EGFR mutations.

4.3 For patients with advanced or metastatic non-squamous EGFR exon 20 insertion mutation-positive NSCLC, the preferred first-line treatment is amivantamab in combination with PBC.[6,7] The National Comprehensive Cancer Network (NCCN) clinical NSCLC guidelines were recently updated to note that amivantamab SC injection may be substituted for amivantamab IV.[6]

4.4 Amivantamab is a fully human, immunoglobulin G1 (IgG1) bispecific antibody with high affinity for both EGFR and mesenchymal-epidermal transition (MET) receptors, thus enabling treatment advantage over other EGFR therapies.

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[1] Australian Institute of Health and Welfare (AIHW), 2025. Overview of cancer in Australia. https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/overview#lung

[2] Jordan et al, (2017), 'Prospective comprehensive molecular characterization of lung adenocarcinomas for efficient patient matching to approved and emerging therapies', Cancer discovery 7.6: 596-609.

[3] Lea et al, (2021), 'EGFR Exon 20 Insertion Mutations: Clinicopathological Characteristics and Treatment Outcomes in Advanced Non–Small Cell Lung Cancer', Clinical lung cancer 22.6: e859-e869.

[4] Arcila et al, (2013), 'EGFR exon 20 insertion mutations in lung adenocarcinomas: prevalence, molecular heterogeneity, and clinicopathologic characteristics', Molecular cancer therapeutics 12.2: 220-229.

[5] Gazdar, (2009), 'Activating and resistance mutations of EGFR in non-small-cell lung cancer: role in clinical response to EGFR tyrosine kinase inhibitors', *Oncogene* 28.1: S24-S31.

[6] NCCN Clinical Practice Guidelines in Oncology. Non-small cell lung cancer, version 5.2026 (published March 13, 2026)

[7] ESMO Oncogene-Addicted Non-Small Cell Lung Cancer Living Guideline v1.3, February 2026

5 Comparator

5.1 The submission nominated amivantamab IV as the comparator as it is the treatment most likely to be replaced by amivantamab SC, given the same active ingredient for the same PBS-subsidised population.

5.2 The submission stated that both formulations will continue to be available.

For more detail on PBAC's view, see section 7 PBAC outcome.

6 Consideration of the evidence

Sponsor hearing

6.1 There was no hearing for this item.

Consumer inputs

6.2 The PBAC noted and welcomed the input from a health care professional and organisations (3) via the Office of Health Technology Assessment Consultation Hub. The health care professional stated having a subcutaneous presentation of amivantamab will provide a benefit to patients (in terms of improved injection site reaction) and reduce cancer centre resources. The Lung Foundation Australia noted the significant burden lung cancer has on patients and society and supported the PBS listing of the subcutaneous form of amivantamab, noting it may help reduce barriers to care and support better health and quality of life for patients. Rare Cancers Australia noted a subcutaneous presentation may reduce hospital visits and the amount of time patients spend in a clinical setting.

6.3 The Medical Oncology Group of Australia (MOGA) also expressed its support for the amivantamab submission.

Clinical studies

6.4 The submission presented one phase 3 head-to-head clinical trial, PALOMA-3, to demonstrate that amivantamab SC is non-inferior to amivantamab IV (both in combination with lazertinib) in terms of pharmacokinetic and efficacy outcomes in patients with EGFRm locally advanced or metastatic NSCLC who have progressed following treatment with a third-generation TKI and platinum-based chemotherapy (n=418).

6.5 The submission also included one phase 2 study (PALOMA-2) conducted as a bridging study as supportive evidence to support the efficacy and safety of amivantamab SC in regimens and populations for which the IV formulation of amivantamab is indicated. Cohort 2 of the study was most relevant to the proposed population as it assessed the combination of amivantamab SC (administered every three weeks) with carboplatin and pemetrexed in first-line locally advanced/metastatic EGFR ex20ins NSCLC patients.

6.6 Details of the study presented in the submission are provided in Table 2.

Table 2: Studies and associated reports presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
PALOMA-3 NCT05388669	Clinical Study Report A Phase 3, Open-label, Randomized Study of Lazertinib with Subcutaneous Amivantamab Compared with Intravenous Amivantamab in Patients with EGFR-mutated Advanced or Metastatic Non-small Cell Lung Cancer After Progression on Osimertinib and Chemotherapy: PALOMA-3. Publications Leighl et al. Subcutaneous Versus Intravenous Amivantamab, Both in Combination With Lazertinib, in Refractory Epidermal Growth Factor Receptor-Mutated Non-Small Cell Lung Cancer: Primary Results From the Phase III PALOMA-3 Study. Alexander et al. Subcutaneous versus intravenous amivantamab, both in combination with lazertinib, in refractory EGFR-mutated non-small cell lung cancer: Patient satisfaction and resource utilization results from the PALOMA-3 study Conference presentation Leighl et al. Subcutaneous amivantamab vs intravenous amivantamab, both in combination with lazertinib, in refractory EGFR-mutated, advanced non-small cell lung cancer	3 January 2024 J Clin Oncol. 2024 Oct 20;42(30):3593-3605. Eur J Cancer. 2025 Sep 9:227:115624. American Society of Clinical Oncology (ASCO); May 31 – June 4, 2024
PALOMA-2	Clinical Study Report A Phase 2, Open-Label, Parallel Cohort Study of Subcutaneous Amivantamab in Multiple Regimens in Patients with Advanced or Metastatic Solid Tumors including EGFR-mutated Non-Small Cell Lung Cancer – PALOMA-2	5 November 2025

Source: Table 2.4, p37 of the submission and added to during the evaluation
Abbreviations: ASCO= American Society of Clinical Oncology; CCO=clinical cut-off; EGFR= epidermal growth factor receptor tyrosine kinase.

6.7 The key features of the studies are summarised in Table 3.

Table 3: Key features of the included evidence

Trial	N	Design/ duration	Risk of bias	Patient population	Outcomes
Amivantamab SC vs. Amivantamab IV					
PALOMA-3	418	R, DB, OL, MC 7 months	Low	EGFRm locally advanced or metastatic NSCLC who have progressed on or after both a third-generation TKI and platinum-based chemotherapy	Co-primary: C_{trough}, AUC Secondary: ORR, PFS
Amivantamab SC					
PALOMA-2	66 [a]	OL, parallel cohort 10.4 months	*High* [b]	EGFRm ex20ins locally advanced or metastatic NSCLC	Primary: ORR. Secondary: DOR, PFS, OS, TTR and safety

Source: Compiled during the evaluation using information from Section 2.2 and accompanying appendix of the submission
Abbreviations: AUC=area under the curve; C_{trough}=serum trough concentration; DB=double blind; DOR=duration of response; EGFRm=mutated epidermal growth, factor receptor; IV=intravenous; MC=multi-centre; NSCLC=non-small cell lung cancer; OL=open label; ORR-objective response rate; OS=overall survival; PFS=progression-free survival; Q3W=every three weeks; R=randomised; SC=subcutaneous; TKI=tyrosine kinase inhibitors; TTR=time to response
[a] Cohort 2 only, patients administered amivantamab SC Q3W + carboplatin and pemetrexed relevant to the proposed patient population and treatment regimen
[b] Assessed as high given that it is a single-arm, open label study.

6.8 The submission acknowledged that the patient population in PALOMA-3 is different to the population requested for listing. The PALOMA-3 trial included patients who had exon 19del or exon 21 L858R EGFR mutations rather than ex20ins mutations, were more heavily pretreated (more prior lines of therapy) and were administered amivantamab SC in combination with lazertinib, dosed every two weeks.

6.9 The TGA Delegate considered there was sufficient evidence that the clinical efficacy of the SC formulation can be expected to be the same as that described for the IV formulation based on the pharmacokinetics and clinical efficacy evidence from PALOMA-3 and PALOMA-2 studies for approved indications (see paragraph 2.2).

6.10 The submission stated that the safety profile of amivantamab SC is consistent with the known safety profile of amivantamab IV as the incidence of overall adverse events (AEs), Grade ≥3 AEs and serious AEs were similar in the amivantamab SC and IV arms. The TGA Delegate noted that safety was comparable between the two formulations, noting a lower rate of administration-related systemic reactions with the SC formulation (TGA Delegate's Overview, September 2025).

Clinical claim

6.11 The submission claimed that amivantamab SC was non-inferior in terms of pharmacokinetics, efficacy and safety compared to amivantamab IV in patients with locally advanced or metastatic NSCLC with evidence of an EGFR ex20ins mutation. The ESC considered the claim is reasonable based on TGA's advice that amivantamab given subcutaneously provides similar efficacy to amivantamab administered intravenously. The ESC acknowledged there is less time-toxicity and fewer administration-related systemic reactions with amivantamab administered subcutaneously.

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

Economic analysis

6.13 The submission presented a cost-minimisation approach of amivantamab SC compared with amivantamab IV. The approach and assumptions are shown in Table 4.

Table 4: Key components and assumptions of the cost-minimisation approach

Component	Claim or assumption
Therapeutic claim: effectiveness	Based on evidence presented in the submission, amivantamab SC provides non-inferior efficacy compared with amivantamab IV.
Therapeutic claim: safety	Based on evidence presented in the submission, amivantamab SC provides non-inferior safety compared with amivantamab IV.
Evidence base	Direct evidence (PALOMA-3) which compared the pharmacokinetics, efficacy and safety of amivantamab SC to amivantamab IV. Supplementary evidence from PALOMA-2 supported the extrapolation of the PALOMA-3 study conclusions to the proposed population relevant to this submission.
Equi-effective doses	Based on the recommended doses as per the PI over 67.265 weeks of treatment with a relative dose intensity of 80.4% *for the IV and the SC presentation*
Direct medicine costs	The direct costs of amivantamab SC are equivalent to amivantamab IV over the average duration of treatment in ex20ins NSCLC (per the economic model recommended by PBAC in November 2024).
Other costs or cost offsets	None requested.

Source: Table 3.1, p88 of the submission
Abbreviations: IV=intravenous; PBS=Pharmaceutical Benefit Scheme; PI=product information; SC=subcutaneous

6.14 The CMA presented in the submission was based on the effective AEMP of amivantamab IV of $[redacted] per 350 mg vial.

6.15 The submission proposed that the dosing regimen as described in Table 5 to be equi-effective doses for amivantamab SC to amivantamab IV. The submission stated that for amivantamab SC, the doses align with those used in Cohort 2 of the PALOMA-2 trial and match the dosing recommended in the TGA approved PI and for amivantamab IV, the doses correspond to doses applied in the PAPILLON trial [8] which supported the PBS listing of amivantamab IV for the first-line and second-line treatment of ex20ins NSCLC. The ESC noted the dose is lower when amivantamab is used as monotherapy Q2W (e.g., excluding loading doses, dose from Week 5 is 1,600 mg for patients < 80 kg and 2,240 mg for patients ≥ 80 kg) and higher when used as monotherapy Q4W (e.g., excluding loading doses, dose from Week 5 is 3,520 mg for patients < 80 kg and 4,460 mg for patients ≥ 80 kg). However, as discussed in paragraph 3.5, the ESC reiterated its consideration that a majority of patients would be treated Q3W.

[8] Zhou et al. "Amivantamab plus chemotherapy in NSCLC with EGFR exon 20 insertions." *New England Journal of Medicine* 389.22 (2023): 2039-2051.

Table 5: Proposed doses of amivantamab SC and IV in locally advanced/metastatic ex20ins NSCLC, in combination with platinum based chemotherapy

	Amivantamab SC		Amivantamab IV	
Timing	**Patients < 80 kg**	**Patients ≥ 80 kg**	**Patients < 80 kg**	**Patients ≥ 80 kg**
Week 1	1,600 mg	2,240 mg	1,400 mg [a]	1,750 mg [a]
Weekly from Weeks 2 to 4	2,400 mg	3,360 mg [b]	1,400 mg	1,750 mg
Subsequent weeks (Q3W starting Week 7 Day 1)	2,400 mg	3,360 mg [b]	1,750 mg	2,100 mg

Source: Table 3.2, p89 of the submission
Abbreviations: ex20ins=Exon 20 insertion; IV=intravenous; kg=kilograms; mg=milligrams; NSCLC= non-small cell lung cancer; Q3W=every three weeks; SC=subcutaneous
[a] As split dose across days 1 & 2
[b] 3,520 mg was applied in the cost-minimisation approach to correspond to the vial size. This accounts for wastage and is appropriate.

6.16 The results of the CMA presented in the submission are shown in Table 6.

Table 6: Results of the cost-minimisation approach presented in the submission

	Amivantamab SC	Amivantamab IV
Route of administration	Subcutaneous	Intravenous
Dosing schedule	Administered weekly for the first 4 weeks, then once every 3 weeks from Week 7 onwards until disease progression	
Effective AEMP per 350 mg vial of amivantamab IV	-	$[redacted]
Modelled total cost of treatment (which applies an RDI of 80.4%) [a]	-	$[redacted]
Modelled average treatment duration (weeks) [a]	-	67.265
Estimated number of 21-day treatment cycles	-	22.42
Estimated cost of amivantamab per cycle	-	$[redacted]
Weighted amount of amivantamab SC dispensed per cycle (mg) [b]	2,765.36	-
Weighted amount of amivantamab SC dispensed per cycle (mg) adjusted for dose intensity of 80.4%	2,223.35	-
Estimated effective AEMP per mg	$[redacted]	-
Requested effective AEMP for SC formulations		
1,600 mg/10 mL	$[redacted]	
2,240 mg/14 mL	$[redacted]	
2,400 mg/15 mL	$[redacted]	
3,520 mg/22 mL	$[redacted]	

Source: Table 3.7, p95 of the submission
Abbreviations: AEMP=Approved ex-manufacturer price, DPMQ=Dispensed ex-manufacturer price; IV=intravenous; mg=milligrams; mL=millilitres; RDI = relative dose intensity; SC=subcutaneous
[a] Extracted from the economic model of amivantamab IV from the PBAC's consideration at its November 2024 meeting. Costs included markups for private and public markets (DPMQ).
[b] Based on the actual dispensed amount (i.e. accounting for wastage), weighted by weight distribution of patients < 80 mg and those ≥ 80 kg (84.4%/15.6%)

6.17 Based on the assumptions applied in the CMA presented in Table 6, 49,851 mg of amivantamab delivered subcutaneously is equi-effective to 34,308 mg of amivantamab delivered by intravenous infusion.

6.18 To calculate the estimated cost of amivantamab IV per cycle, the submission used parameters extracted from the economic model of amivantamab IV from the PBAC's considerations at the November 2024 meeting. These include:

- Modelled average treatment duration of 67.265 weeks.
- Modelled total treatment cost for amivantamab ($[redacted]) based on the undiscounted total cost of amivantamab IV over a 7.5-year time horizon. The costs extracted from the model reflected prices at the DPMQ level. The PBAC noted it isn't necessary to use the modelled treatment cost and the calculation can be based on the equi-effective doses. This results in a cost per patient of $[redacted][9] using ex-manufacturer prices.
- The submission assumed a dose intensity of 80.4%, applied to both the amivantamab SC and IV treatment arms stating this was consistent with the dose intensity applied in the consideration of amivantamab IV at the November 2024 PBAC meeting. Based on data presented in the PALOMA-2 and PALOMA-3 studies, higher dose intensities have been reported for amivantamab SC. The PALOMA-3 trial reported a relative dose intensity in the amivantamab SC arm of 91.94% compared to 89.25% in the amivantamab IV arm, noting the differences between trial and proposed patient populations described in paragraph 6.8. The ESC considered it was reasonable to assume there would be no difference in dose intensity between the IV and SC presentation.

6.19 The PBAC noted that applying the equi-effective doses outlined in paragraph 6.17 and using the ex-manufacturer price, the price per mg of amivantamab SC is $[redacted][10], which results in EMPs of 1,600 mg = $[redacted]; 2,240 mg = $[redacted]; 2,400 mg = $[redacted] and 3,520 mg = $[redacted].

6.20 Should the PBAC accept the clinical claim of overall non-inferior effectiveness and safety, the cost-minimisation approach must establish that the cost per patient for treatment with amivantamab SC would be no more than the cost per patient of amivantamab IV. Where these cost per patient calculations are uncertain, the guiding principle is that the Australian Government should not bear the financial risk of this uncertainty because the Australian population already has access to therapy that is at least as effective and safe. In this case, the PBAC should consider the impacts of the following parameters in the cost minimisation approach: equi-effective doses.

Drug cost/patient/course

6.21 The submission estimated that the drug cost per patient would be $[redacted] per course of treatment with amivantamab SC as summarised in Table 6. This is the cost per patient in the first line setting (Q3W, in combination with PBC); it is uncertain what the cost per patient is in the second line setting (as monotherapy).

[9] 34,308/350 x $[redacted] = $[redacted]
[10] $[redacted]/49,851 = $[redacted]

Estimated PBS usage & financial implications

6.22 This submission was not considered by DUSC. The submission presented a market share approach to estimating the PBS usage and financial implications. Key inputs used in the estimates are summarised in Table 7.

Table 7: Key inputs for financial estimates

Parameter	Value	Source	Comment
Market:			
Existing Market	[redacted]1 scripts in 2025; [redacted]1scripts in 2026	Utilisation estimates (script volume) for amivantamab IV presented in Sponsor's pricing offer package.	Alternative sources such as Medicare Statistics may be more reasonable because this would reflect real-world utilisation. Across the nine-month period since the listing of amivantamab IV in May 2025, there has been a total of 468 scripts dispensed (no RPBS scripts).[a] This is lower than the projected scripts presented in the submission, noting that data was not for a full year.
% Growth Rate	Yr 1: -11.38% (initiating), -6.14% (continuing) Yr 2: 2.64% Yr 3: 2.64% Yr 4: 2.64% Yr 5: 1.58%	Calculated from submission's projected script volume for amivantamab IV	The submission noted the initial negative growth trend was due to inflated numbers in the initial years of listing due to prevalent and grandfathered patients. A compound annual growth rate of 1.58% was then applied to forecast for Years 5 and 6.
% Treatment Switch from IV to SC	Yr 1: [redacted]% Yr 2: [redacted]% Yrs 3 - 6: [redacted]%	Sponsor assumption	The ESC considered [redacted]% switch in Yr 1 was likely to be overestimated as switch was likely to be slower in patients already receiving IV.
Script Equivalence	1:1	Sponsor assumption	This is reasonable as the dosing regimen is similar for both amivantamab IV and SC.
Costs			
Amivantamab SC effective DPMQ	1,600 mg: $[redacted] 2,240 mg: $[redacted] 2,400 mg: $[redacted] 3,520 mg: $[redacted]	Calculated by submission based on a 91.5%/8.5% split for S85/S100 scripts from daratumumab scripts (PBS/RPBS items reported Jan-Dec 2025)	

Parameter	Value	Source	Comment
Patient co-payment	PBS: $13.03 RPBS: $7.20	Based on pembrolizumab and atezolizumab Services Australia data across January to December 2024	The model appears to have assumed a 50%/50% split between PBS and RPBS which has likely overestimated the RPBS population. This does not align with the PBS/RPBS split applied for amivantamab IV. The PSCR presented revised financial estimates with a split of 97% PBS/ 3% RPBS.
Public/Private split	Public: 39.7% Private: 60.3%	Source not provided	This was used by the submission to calculate the DPMQs for amivantamab IV. Using 2025 Services Australia PBS/RPBS dispensed script data for amivantamab IV indicated a split of 23.1%/76.9% which would result in a small increase in the weighted DPMQs.
MBS Impacts	Not included	Submission noted listing amivantamab SC it is not expected to result in significant changes in the use of any MBS items, including administration costs which are the same for IV and SC administration in the proposed population (see paragraph 6.26).	May have underestimated net financial implications to PBS/RPBS.

Source: Compiled during the evaluation using information presented in the submission
Abbreviations: DPMQ=dispensed price for maximum quantity; IV=intravenous; mg=milligrams; PBS=Pharmaceutical Benefit Scheme; RPBS= Repatriation Schedule of Pharmaceutical Benefits; SC=subcutaneous; Yr=year
[a] Based on PBS item reports for amivantamab IV (14807H, 14802C, 14801B, 14800Y) extracted during the evaluation for period May 2025 to Jan 2026.
The redacted values correspond to the following ranges:
[1] 500 to < 5,000

6.23 Table 8 shows the estimated financial impact of listing amivantamab SC over the next 6 years.

Table 8: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of initial scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Number of continuing scripts dispensed	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
Total number of scripts dispensed [a]	[redacted][2]	[redacted][2] [b]	[redacted][2] [b]	[redacted][2] [b]	[redacted][2] [b]	[redacted][2] [b]
Estimated financial implications of amivantamab SC						
Cost to PBS/RPBS less copayments	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]
Estimated financial implications for amivantamab IV						
Cost to PBS/RPBS less copayments	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]
Net cost to MBS	$0	$0	$0	$0	$0	$0

Source: Table 4.19, p108-109 of the submission

[a] Projected based on script volumes estimated for the Sponsor's submission for amivantamab IV at the PBAC November 2024 meeting.

[b] Script numbers used for financial calculations. Although some discrepancies were noted in the submission, the financial implications were based on the same script numbers for amivantamab SC and IV.

The redacted values correspond to the following ranges:

[1] *< 500*

[2] *500 to < 5,000*

[3] *$0 to < $10 million*

[4] *net cost saving*

6.24 The total cost of PBS/RPBS listing based on the effective prices of amivantamab SC was estimated to be $0 to < $10 million in Year 1 increasing to $0 to < $10 million in Year 6, totalling $20 million to < $30 million across six years. The submission estimated that there would a net cost of $0 to < $10 million to the PBS/RPBS over the first six years of listing.

6.25 There were several structural concerns identified with the financial model which may have affected the robustness of the results presented in the submission. These include incorrect calculation of script numbers from Year 2 onwards (e.g. incorrect referencing of script volumes and growth rate), overestimating the RPBS population by using a 50%/50% split for PBS and RPBS, incorrect allocation of the number of initiating and continuing scripts based on proposed repeats. The PSCR provided revised financial estimates addressing these issues (see Table 9) which resulted in a net cost to the PBS/RPBS of $0 to < $10 million over the first 6 years of listing. The PBAC noted some additional errors were identified[11] and correcting these resulted in a net cost of $0 to < $10 million over 6 years. Additionally, the PBAC noted applying the revised ex-

[11] Worksheet 2e, Rows 129 and 165, update to -6.14%, 2.64%, 2.64%, 2.64%, 1.58%, 1.58% in years 1-6 respectively. Worksheet 3b, Row 174 correct DPMQ calculation. Worksheet 4c, Rows 275 and 278, correct vial numbers.

manufacturer price of amivantamab SC (see paragraph 6.19), resulted in a small net savings over 6 years.

Table 9: Estimated use and financial implications, revised in PSCR

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Total number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of amivantamab SC						
Cost to PBS/RPBS less copayments	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Estimated financial implications for amivantamab IV						
Cost to PBS/RPBS less copayments	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Net cost to MBS	$0	$0	$0	$0	$0	$0
Additional errors corrected						
Estimated extent of use						
Total number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of amivantamab SC						
Cost to PBS/RPBS less copayments	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Estimated financial implications for amivantamab IV						
Cost to PBS/RPBS less copayments	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]
Net financial implications						
Net cost to PBS/RPBS	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]
Net cost to MBS	$0	$0	$0	$0	$0	$0

Source: Revised UCM provided with PSCR

The redacted values correspond to the following ranges:

[1] *500 to < 5,000*

[2] *$0 to < $10 million*

[3] *net cost saving*

6.26 The submission stated that the listing of amivantamab SC is not expected to result in significant changes in the use of any MBS items given administration costs which are the same for IV and SC administration in the proposed population. Although this is consistent with the submission's cost-minimisation approach, it is noted that SC administration would require one less administration compared to amivantamab IV (due to split Week 1 IV dosing). The PSCR acknowledged that SC administration would result in one less MBS administration (item 13950) per patient per treatment course compared with IV administration (due to split Week 1 dosing), which would further reduce overall cost to the Government Health Budget. However, it stated that because the UCM applies a market share based approach, modelling substitution of IV to SC utilisation at the script level rather than the patient level, the reduction in MBS administrations (which is at the patient level) cannot be directly captured within the

SC UCM model framework. The PSCR noted the cost saving from this offset was likely to be small.

Quality Use of Medicines

6.27 The submission indicated that a quality use of medicines program is being developed and is expected to be implemented prior to PBS listing. This includes an education program on amivantamab SC formulation and dosing with reference materials to physicians and pharmacists.

For more detail on PBAC's view, see section 7 PBAC outcome.

7 PBAC Outcome

7.1 The PBAC recommended the Section 100 Efficient Funding of Chemotherapy Related Benefits and Section 85 General Schedule listing of a subcutaneous (SC) injection of amivantamab for the treatment of locally-advanced/metastatic epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) positive non-small cell lung cancer (NSCLC). The PBAC considered the amivantamab regimen delivered subcutaneously was non-inferior in terms of effectiveness and safety to the amivantamab regimen delivered intravenously. The PBAC considered amivantamab SC would be cost effective if it were cost minimised to amivantamab IV. The PBAC noted that, correcting errors in the financial estimates and using the revised effective price, listing amivantamab SC would result in a small cost saving to the PBS.

7.2 The PBAC noted the consumer input received and acknowledged a subcutaneous presentation of amivantamab may reduce the time-toxicity associated with cancer care.

7.3 The PBAC advised the restriction criteria proposed in the pre-subcommittee response (PSCR) that included amendments as proposed by the Secretariat (as provided in Section 3) was appropriate. The PBAC advised a flow on change to the amivantamab intravenous listing to allow eligible patients to switch from the subcutaneous to the intravenous form during initial or continuing treatment, by including the clinical criterion "Patient must be each of: (i) previously received the subcutaneous form of this drug for this condition (ii) switching to receive the intravenous form of this drug for this condition while being free of disease progression since commencing treatment with this drug".

7.4 The PBAC noted the proposed listing only accounted for the three weekly dosing regimen of amivantamab subcutaneous, despite the draft Product Information allowing for two weekly and four weekly dosing in the second line (monotherapy) treatment setting. The PBAC agreed with the ESC that the majority of patients will be treated with the amivantamab subcutaneous regimen three weekly (see paragraph 3.5). However, to facilitate the small proportion of patients that may be treated with amivantamab in the second line (monotherapy) treatment setting, either every 2

weeks or every 4 weeks, all strengths of amivantamab should be included in the Initial 2 and Continuing restriction criteria.

7.5 Based on the TGA assessment of the pharmacokinetic data, the PBAC considered the amivantamab regimen delivered subcutaneously was non-inferior in terms of effectiveness and safety compared to the amivantamab regimen delivered intravenously.

7.6 The PBAC considered the equi-effective doses were the amivantamab subcutaneous regimen and amivantamab intravenous regimen (based on the recommended doses in Table 5) administered weekly for the first 4 weeks, then once every 3 weeks from Week 7 onwards until disease progression. The PBAC considered the cost minimisation approach (CMA) should assume a relative dose intensity of 80.4% for both the subcutaneous and intravenous regimen with 84.4% of patients weighing less than 80 kg and 15.6% weighing 80 kg or more. The PBAC considered the CMA should be conducted over an average treatment duration of 67.26 weeks based on the modelled treatment duration for IV (as considered by the PBAC in November 2024). The PBAC noted this resulted in a total of 49,851 mg of amivantamab delivered subcutaneously and 34,308 mg of amivantamab delivered by intravenous infusion

7.7 The PBAC considered that, with corrections of errors (see paragraph 6.25), the estimated utilisation of amivantamab subcutaneous was reasonable. Overall, the PBAC considered the listing of the amivantamab subcutaneous presentation would not result in an increased cost to the PBS, based on the price calculated using the parameters outlined in paragraph 7.6.

7.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because amivantamab SC is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over amivantamab 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.

7.9 The PBAC noted that this submission is not eligible for an Independent Review as it was recommended.

Outcome:
Recommended

8 Recommended listing

8.1 Add new item:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
AMIVANTAMAB					
amivantamab 1.6 g/10 mL injection, 10 mL vial	NEW (CT) NEW (GE)	1	1	0	Rybrevant SC
amivantamab 2.24 g/14 mL injection, 14 mL vial	NEW (CT) NEW (GE)	1	1	0	

Concept ID	Category / Program:
	☒ Section 100 – Chemotherapy Related Benefits (CT) ☒ Section 85 - General Schedule (GE)
	Prescriber type: ☒Medical Practitioners
	Benefit type: ☒Authority Required (immediate assessment- telephone/online application avenues)
	Prescribing rule level:
	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 Arrangement apply.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Restriction Summary / Treatment of Concept
	Indication: Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
	Treatment Phase: Initial treatment 1
	Clinical criteria:
	Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation
	AND
	Clinical criteria:
	Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition.
	AND
	Clinical criteria:
	Patient must not have previously received this drug for this condition; **OR**
	Patient must be each of: (i) previously received the intravenous form of this drug for this condition (ii) switching to receive the subcutaneous form of this drug for this condition while being free of disease progression since commencing treatment with this drug;
	AND
	Clinical criteria:
	The treatment must be/have been in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting, (i.e. used in combination with PBC in the first line setting); **OR**
	The treatment must be the sole PBS-subsidised therapy where the condition has progressed following treatment with platinum-based chemotherapy, (i.e. used as monotherapy in the second line setting)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Repeats	Available brands
AMIVANTAMAB					
amivantamab 1.6 g/10 mL injection, 10 mL vial	NEW (CT) NEW (GE)	1	1	4	Rybrevant SC
amivantamab 2.24 g/14 mL injection, 14 mL vial	NEW (CT) NEW (GE)	1	1	4	
amivantamab 2.4 g/15 mL injection, 15 mL vial	NEW (CT) NEW (GE)	1	1	4	
amivantamab 3.52 g/22 mL injection, 22 mL vial	NEW (CT) NEW (GE)	1	1	4	

Concept ID	**Category / Program:** ☒ Section 100 – Chemotherapy Related Benefits (CT) ☒ Section 85 - General Schedule (GE)
	Prescriber type: ☒Medical Practitioners
	Benefit type: ☒Authority Required (immediate assessment- telephone/online application avenues)
	Prescribing rule level:
	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 Arrangement apply.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Restriction Summary / Treatment of Concept
	Indication: Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
	Treatment Phase: Initial treatment 2
	Clinical criteria
	Patient must have previously received PBS-subsidised treatment with this drug for this condition in the intravenous or subcutaneous form.
	AND
	Clinical criteria:
	The treatment must be/have been in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting, (i.e. used in combination with PBC in the first line setting); **OR**
	The treatment must be the sole PBS-subsidised therapy where the condition has progressed following treatment with platinum-based chemotherapy, (i.e. used as monotherapy in the second line setting)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
AMIVANTAMAB					
amivantamab 1.6 g/10 mL injection, 10 mL vial	NEW (CT) NEW (GE)	1	1	7	Rybrevant SC
amivantamab 2.24 g/14 mL injection, 14 mL vial	NEW (CT) NEW (GE)	1	1	7	
amivantamab 2.4 g/15 mL injection, 15 mL vial	NEW (CT) NEW (GE)	1	1	7	
amivantamab 3.52 g/22 mL injection, 22 mL vial	NEW (CT) NEW (GE)	1	1	7	

Concept ID	Category / Program:
	☒ Section 100 – Chemotherapy Related Benefits (CT) ☒ Section 85 - General Schedule (GE)
	Prescriber type: ☒Medical Practitioners
	Benefit type: ☒Authority Required (immediate assessment- telephone/online application avenues)
	Prescribing rule level:
	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 Arrangement apply.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Restriction Summary / Treatment of Concept
	Indication: Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
	Treatment Phase: Continuing treatment
	Clinical criteria
	Patient must have previously received PBS-subsidised treatment with this drug, either in the intravenous or subcutaneous form, for this condition.
	AND
	Clinical criteria
	Patient must not have developed disease progression while receiving treatment with this drug, either in the intravenous or subcutaneous form, for this condition

Flow-on changes:

Amend a clinical criterion for amivantamab IV to allow eligible patients to switch from the subcutaneous form to the intravenous form during either initial (PBS item codes: 14800Y and 14802C) or continuing treatment (PBS item codes: 14801B and 14807H) as follows:

Additions are in Italics and deletions are in strikethrough:

MEDICINAL PRODUCT		PBS item code	Max. Amount	№.of Rpts
AMIVANTAMAB		14800Y (Public) 14802C (Private)	2,100 mg	5
Available brands				
Rybrevant amivantamab 350 mg/7 mL injection, 7 mL vial				
Concept ID	**Program:** ☒ Section 100 – Efficient Funding of Chemotherapy – Public (IP)/ Private (IN)			
	Prescriber type: ☒Medical Practitioners			
	Benefit: ☒Authority Required (immediate assessment- telephone/online application avenues))			
	Prescribing rule level:			
	Administrative Advice: No increase in the maximum amount or number of units may be authorised.			
	Administrative Advice: No increase in the maximum number of repeats may be authorised.			
	Administrative Advice: Special Pricing Arrangement apply.			
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.			
	Edit Restriction Summary / ToC			
	Indication: Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)			
	Treatment Phase: Initial treatment			
	Clinical criteria:			
	Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation			
	AND			
	Clinical criteria:			
	Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition.			
	AND			
	Clinical criteria:			
	Patient must not have previously received this drug for this condition; OR			
	Patient must be each of: (i) currently receiving non-PBS subsidised supply for this drug for this PBS indication, (ii) free of disease progression since commencing non-PBS subsidised supply*; OR*			
	Patient must be each of: (i) previously received the subcutaneous form of this drug for this condition (ii) switching to receive the intravenous form of this drug for this condition while being free of disease progression since commencing treatment with this drug.			
	AND			
	Clinical criteria:			
	The treatment must be/have been in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting, (i.e. used in combination with PBC in the first line setting) **OR**			
	The treatment must be the sole PBS subsidised therapy where the condition has progressed following treatment with platinum-based chemotherapy, (i.e. used as monotherapy in the second line setting).			

	Administrative Advice: A patient may only qualify for PBS-subsidised treatment under this restriction once. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction.

MEDICINAL PRODUCT		**PBS item code**	**Max. Amount**	**№. of Rpts**
AMIVANTAMAB		14801B (Public) 14807H (Private)	2,100 mg	7
Available brands				
Rybrevant amivantamab 350 mg/7 mL injection, 7 mL vial				
Concept ID	**Program:** ☒ Section 100 – Efficient Funding of Chemotherapy – Public (HB)/ Private (HS)			
	Prescriber type: ☒Medical Practitioners			
	Benefit: ☒Authority Required (immediate assessment- telephone/online application avenues))			
	Prescribing rule level:			
	Administrative Advice: No increase in the maximum amount or number of units may be authorised.			
	Administrative Advice: No increase in the maximum number of repeats may be authorised.			
	Administrative Advice: Special Pricing Arrangement apply.			
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.			
	Edit Restriction Summary / ToC			
	Indication: Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)			
	Treatment Phase: Continuing treatment			
	Clinical criteria			
	Patient must have previously received PBS-subsidised treatment with this drug, *either in the intravenous or subcutaneous form,* for this condition.			
	AND			
	Clinical criteria			
	Patient must not have developed disease progression while receiving treatment with this drug, *either in the intravenous or subcutaneous form*, for this condition			

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

9 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

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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.

10 Sponsor's Comment

The sponsor had no comment.

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