5.26 OCRELIZUMAB, Solution for subcutaneous injection 920 mg in 23 mL, Ocrevus®, Roche Products Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission requested Section 100 (Highly Specialised Drugs Program) (S100 HSD) Authority Required (STREAMLINED) listing of a new form of ocrelizumab (solution for subcutaneous injection 920 mg in 23 mL; herein referred to as ocrelizumab SC), under the same circumstances as the Pharmaceutical Benefits Scheme (PBS)-listed ocrelizumab solution concentrate for intravenous infusion 300 mg in 10 mL (herein referred to as ocrelizumab IV), for the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS).

1.2 Listing was requested on a cost-minimisation basis versus ocrelizumab IV.

2 Background

2.1 Ocrelizumab IV is currently listed on the PBS as Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings (S100 HSD Private and S100 HSD Public) for multiple sclerosis.

2.2 The submission stated ocrelizumab SC provides an alternative manner of administration for ocrelizumab. It claimed that ocrelizumab SC has the following advantages compared to ocrelizumab IV:

- Reduced administration time (ocrelizumab SC is administered over approximately 10 minutes compared to 2-3.5 hours for the infusion).
- Increased patient satisfaction and convenience, and reduced time away from work.
- Lower use of resources due to less time spent by the patient in hospital, less time spent by healthcare professionals administering and monitoring treatment, reduced use of consumables and time associated with preparing and administering ocrelizumab IV (the SC form is available ready-to-use versus the IV form which requires preparation before administration).

2.3 The submission further claimed that if ocrelizumab SC was well-tolerated and the prescriber planned to continue treatment, the injection could be administered during the medical review (i.e. only one appointment would be required without a follow-up appointment for administration), thereby improving convenience for patients and reducing use of healthcare resources.

Registration status

2.4 Ocrelizumab SC was Therapeutic Goods Administration (TGA) registered on 27 March 2025 for:

- the treatment of patients with relapsing forms of multiple sclerosis to delay the progression of physical disability and to reduce the frequency of relapse.
- the treatment of patients with primary progressive multiple sclerosis (PPMS) to delay the progression of physical disability.

2.5 Ocrelizumab IV is TGA registered for the same indications.

Previous PBAC consideration

2.6 Ocrelizumab SC has not been considered by the Pharmaceutical Benefits Advisory Committee (PBAC) previously.

2.7 At its July 2017 meeting, the PBAC recommended listing ocrelizumab IV on the PBS for the treatment of RRMS on a cost-minimisation basis with fingolimod (paragraph 7.1, ocrelizumab, Public Summary Document (PSD), July 2017 PBAC meeting).

2.8 At its November 2017 and July 2020 meetings, the PBAC did not recommend listing ocrelizumab IV on the PBS for the treatment of patients with PPMS. At its November 2017 meeting, the PBAC did not recommend listing on the basis of modest clinical benefit and the resulting high and uncertain incremental cost-effectiveness ratio (paragraph 7.1, ocrelizumab, PSD, November 2017 PBAC meeting). At its July 2020 meeting, the PBAC considered that the key subgroup analysis that was relied on in the submission was inconsistent with the requested PBS population, which led to difficulties in assessing the cost-effectiveness (paragraph 7.1, ocrelizumab, PSD, July 2020 PBAC meeting).

3 Requested listing

3.1 The submission requested the following new listing:

Add new medicinal product pack as follows:

3.2 Suggested additions proposed by the Secretariat are in italics.

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
OCRELIZUMAB					
ocrelizumab 920 mg/23 mL injection, 23 mL vial	NEW (HSD Public)	1	1	0	Ocrevus SC
Restriction Summary 7713 / Treatment of Concept: 7699					
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB)				

Concept ID (for internal Dept. use)		**Prescriber type:** ☒Medical Practitioners
		Restriction type: ☒Authority Required (Streamlined) [7699]
		Authority type: ☒ Non-complex Authority Required (non-CAR)
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 Arrangements apply.*
		Indication: Multiple sclerosis
		Treatment Phase: Initial treatment
		Clinical criteria:
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,
		AND
		Clinical criteria:
		The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must be ambulatory (without assistance or support).
		Treatment criteria:
		Must be treated by a neurologist.
		Prescribing Instructions: Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.
Restriction Summary 7396 / Treatment of Concept: 7386		
Concept ID (for internal Dept. use)		**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (Streamlined) [7386]
		Authority type: ☒ Non-complex Authority Required (non-CAR)
		Indication: Multiple sclerosis
		Treatment Phase: Continuing treatment
		Clinical criteria:
		Patient must have previously received PBS-subsidised treatment with this drug for this condition,
		AND
		Clinical criteria:
		Patient must not show continuing progression of disability while on treatment with this drug,
		AND
		Clinical criteria:
		The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
		AND

	Clinical criteria:
	Patient must have demonstrated compliance with, and an ability to tolerate this therapy.
	Treatment criteria:
	Must be treated by a neurologist.

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
OCRELIZUMAB					
ocrelizumab 920 mg/23 mL injection, 23 mL vial	NEW (HSD Private)	1	1	0	Ocrevus SC

Restriction Summary 9523 / Treatment of Concept: 9523		
Concept ID (for internal Dept. use)		**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Private (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (Streamlined) [9523]
		Authority type: ☒ Non-complex Authority Required (non-CAR)
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 Arrangements apply.*
		Indication: Multiple sclerosis
		Treatment Phase: Initial treatment
		Clinical criteria:
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,
		AND
		Clinical criteria:
		The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must be ambulatory (without assistance or support).
		Treatment criteria:
		Must be treated by a neurologist.
		Prescribing Instructions: Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Restriction Summary 9635 / Treatment of Concept: 9635	
Concept ID (for internal Dept. use)	**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Private (Code HS)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Streamlined) [9635]
	Authority type: ☒ Non-complex Authority Required (non-CAR)
	Indication: Multiple sclerosis
	Treatment Phase: Continuing treatment
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition,
	AND
	Clinical criteria:
	Patient must not show continuing progression of disability while on treatment with this drug,
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
	AND
	Clinical criteria:
	Patient must have demonstrated compliance with, and an ability to tolerate this therapy.
	Treatment criteria:
	Must be treated by a neurologist.

3.3 The submission requested ocrelizumab SC be listed on the PBS under the same circumstances as the current PBS listings for ocrelizumab IV.

3.4 The submission referred to the PBAC's recommendation at its November 2024 meeting to amend the listings of a number of medicines for multiple sclerosis to allow nurse practitioners to prescribe treatment in consultation with a specialist physician (paragraph 5.1, fingolimod, ofatumumab and siponimod, PSD, November 2024 PBAC meeting). At this meeting the PBAC noted that flow-on recommendations to ocrelizumab would not be feasible as it is listed under Section 100 Highly Specialised Drugs arrangements which currently exclude nurse practitioners from prescribing these benefits (paragraph 5.5, fingolimod, ofatumumab and siponimod, PSD, November 2024 PBAC meeting). The submission stated that allowing nurse practitioners, in consultation with a specialist physician, to initiate and continue treatment with all PBS-listed disease-modifying treatments would streamline the patient journey and reduce the burden on the healthcare system for all patients with multiple sclerosis. The requested listing includes the treatment criteria 'Must be treated by a neurologist' for both initial and continuing treatment, limiting prescribing to neurologists.

4 Comparator

4.1 The submission nominated the currently listed ocrelizumab IV, 2 x 300 mg (600 mg) as the main comparator.

4.2 At the July 2017 meeting in its consideration of ocrelizumab IV, the PBAC agreed that the nominated comparators of fingolimod, natalizumab and alemtuzumab were appropriate clinical comparators; however, considered that in practice, ocrelizumab would substitute for all PBS-subsidised medicines for RRMS (paragraph 7.4, ocrelizumab, PSD, July 2017 PBAC meeting).

4.3 The pre-PBAC response maintained that ocrelizumab IV was an appropriate comparator, and claimed the choice to prescribe ocrelizumab is primarily due to its mechanism of action, efficacy and safety profile, and administration schedule, which applies equally to both ocrelizumab IV and ocrelizumab SC.

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 individuals (14), health care professionals (1) and organisations (2) via the Consumer Comments facility on the PBS website. The comments from individuals described the treatment burden associated with ocrelizumab IV administration, including lengthy treatment sessions, disrupted work and personal lives for both the individual and carer, and fatigue from the onerous nature of accessing treatment. Benefits from ocrelizumab SC highlighted include benefits on quality of life for both individuals and carers due to simpler administration (e.g. more time for other daily activities, less disruption to daily life, less time spent travelling to access treatment), reduced stress and pain associated with difficult venous access, and the potential to increase accessibility for individuals living in rural and remote areas and those with difficult venous access. One individual raised concerns about potential out-of-pocket costs that may be incurred due to appointments for administration.

5.3 Health professional input described the comparable pharmacokinetics and clinical efficacy of ocrelizumab IV and ocrelizumab SC, and potential benefits of ocrelizumab SC, including greater convenience for patients, the potential to facilitate better access for individuals who currently face barriers to accessing ocrelizumab IV (i.e. geographic, logistical and medical constraints), and the potential for improved treatment adherence and patient outcomes due to increased accessibility.

5.4 The PBAC noted input received from MS Australia highlighting that due to the varied nature of multiple sclerosis, no single medication is suitable for every patient, and including ocrelizumab SC on the PBS will provide an additional treatment option for individuals, and help to alleviate economic costs to individuals, their families and the broader community.

5.5 Input from the MS & Neuroimmunology Group of the Australian & New Zealand

Association of Neurologists highlighted that having ocrelizumab SC on the PBS would reduce the burden on infusion centres where waiting lists to receive infusions can impact negatively on patient care.

Clinical trials

5.6 The submission cited the OCARINA II (CN42097) study, a phase III, non-inferiority, open-label, parallel-group, multicentre, randomised study which assessed the pharmacokinetics (PK), pharmacodynamics (PD), safety, and radiological and clinical effects of SC administration of ocrelizumab compared to ocrelizumab IV infusion in patients with either RRMS or PPMS.

5.7 The dose of ocrelizumab SC in CN42097 was based on the findings of the CN41144 (OCARINA I) study, where the PK, safety, immunogenicity and biomarker data supported ocrelizumab SC at a dose of 920 mg to be evaluated in the Phase III OCARINA II trial (Newsome et al, 2024).

Table 1: Trials/studies and associated reports presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
NCT03972306 NC41144	OCARINA I	
	Newsome S.D., Goldstick L., Robertson D.S., et al. Subcutaneous ocrelizumab in multiple sclerosis: Results of the Phase 1b OCARINA I study.	Ann Clin Transl Neurol 2024; 11(12): 3215-26.
NCT05232825 CN42097	OCARINA II	2022
	Protocol: A Phase III, non-inferiority, randomized, open-label, parallel group, multicenter study to investigate the pharmacokinetics, pharmacodynamics, safety and radiological and clinical effects of subcutaneous ocrelizumab versus intravenous ocrelizumab in patients with multiple sclerosis.	Feb 2022.
	Primary CSR – Study CN42097GO39869 (OCARINA II)	Report No.: 1121154; Aug 2023.

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

Comparative effectiveness

5.9 The submission stated that the OCARINA II trial demonstrated that ocrelizumab SC has a non-inferior PK profile and comparable efficacy and safety to ocrelizumab IV in a patient population with multiple sclerosis (comprising of mostly patients with RRMS). The submission stated that OCARINA II trial participants reported higher satisfaction and convenience with the SC form compared to the IV form.

5.10 The TGA Clinical Evaluation Report stated that over the treatment phase and safety follow-up, no major differences in number of new or enlarging T2 lesions (from the previous scheduled available visit) and lesion rates were observed between the two arms at weeks 12 and 24. The numbers of new or enlarging T2 lesions and lesion rates were low in both arms and populations. The evaluator concluded that the numbers of MRI lesions and lesion rates were too low in both arms and populations for realistic comparison.

5.11 The TGA evaluator commented that both routes of administration were parenteral, bioavailability was estimated at 81.4%, the C_{max} for ocrelizumab SC 920 mg and

ocrelizumab IV 600 mg were similar, and the AUC at 12 and 24 weeks was greater for ocrelizumab SC versus ocrelizumab IV.

Comparative harms

5.12 In the TGA Clinical Evaluation Report, the evaluator's conclusions on clinical safety noted that in the controlled period of CN42097, 52.5% of patients receiving ocrelizumab SC experienced treatment-related adverse effects compared to 24.6% in the ocrelizumab IV arm. The most frequent were injection related reactions (46.6% in the ocrelizumab SC arm) and infusion related reactions (16.9% in the ocrelizumab IV arm).

Clinical claim

5.13 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of ocrelizumab SC 920 mg administered every 6 months compared with ocrelizumab IV 600 mg (2 x 300 mg) administered every 6 months for RRMS.

5.14 The submission cited the OCARINA II study to support the claim that ocrelizumab SC 920 mg administered every 6 months is equally effective and safe as ocrelizumab IV 600 mg administered every 6 months for patients with RRMS.

5.15 The TGA Delegate's Overview stated 'Efficacy, PK and PD data from the pivotal Phase III Study CN42097 (OCARINA II); and the safety from Pivotal Phase III Study CN42097 (OCARINA II) and the Study CN41144 establish the bioequivalence between intravenous and subcutaneous strengths of Ocrevus. No new safety concerns were reported'.

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

Economic analysis

5.17 As a Category 4 submission, the economic analysis was not independently evaluated.

5.18 The submission presented a cost-minimisation approach of ocrelizumab SC compared with ocrelizumab IV. The equi-effective doses were estimated as a single dose of ocrelizumab SC 920mg in 23 mL, to ocrelizumab IV 300mg in 10mL, two vials as a single infusion (600 mg), administered every six months.

Drug cost/patient/year: $[redacted] (S100 HSD Public), $[redacted] (S100 HSD Private)

5.19 The estimated drug cost/patient per year would be $[redacted] (S100 HSD Public listing) and $[redacted] (S100 HSD Private listing), based on one injection every 6 months, and an effective dispensed price for maximum quantity (DPMQ) of $[redacted] (S100 HSD Public) and $[redacted] (S100 HSD Private).

Estimated PBS usage and financial implications

5.20 The requested published price was based on the approved ex-manufacturer price (AEMP) of 2 vials of ocrelizumab IV, listed in the PBS as of June 2025 (i.e. the requested

published AEMP for ocrelizumab SC, 1 vial, is $16,656.36, the current published AEMP of ocrelizumab IV for 1 vial is $8,328.18).

5.21 The submission requested a Special Pricing Arrangement for ocrelizumab SC to align with the currently PBS-listed ocrelizumab IV. The submission requested an effective price of $[redacted] for ocrelizumab SC.

5.22 The submission adopted a market share approach to estimate the utilisation and financial impact of ocrelizumab SC over a six-year period. The submission assumed ocrelizumab SC would replace ocrelizumab IV at an uptake rate of [redacted]%, and that ocrelizumab SC would only replace ocrelizumab IV in practice. The submission assumed no incremental growth in the ocrelizumab market if ocrelizumab SC is PBS-listed. As the requested price for one prescription of ocrelizumab SC (1 vial) was equivalent to one prescription of ocrelizumab IV (2 vials), the submission estimated listing ocrelizumab SC on the PBS would be cost neutral to be PBS/RPBS.

5.23 The submission used 2024 PBS utilisation data for ocrelizumab IV to estimate the proportion of patients treated in the public (74.4%) and private (25.6%) settings.

5.24 The submission estimated listing ocrelizumab SC on the PBS would decrease use of IV infusions and shorten administration times. It estimated there would be a net save to the Medicare Benefits Schedule (MBS) and public hospitals due to less IV infusions.

5.25 Refer to Table 2 which presents the estimated extent of use, cost of ocrelizumab SC to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

5.26 The submission estimated that 20,000 to < 30,000 scripts would be supplied for ocrelizumab SC over the first six years of listing (500 to < 5,000 in Year 1 to 500 to < 5,000 in Year 6).

5.27 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of ocrelizumab SC is nil over six years (Year 1 $0 to < $10 million to Year 6 $0 to < $10 million).

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of ocrelizumab SC						
Cost to PBS/RPBS less co-payment	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][3]	$[redacted][3]
Estimated financial implications of ocrelizumab IV						
Cost to PBS/RPBS less co-payment	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][3]	-$[redacted][3]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]

Source: Utilisation and Cost Model Workbook.
Abbreviations: IV = intravenous; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; SC = subcutaneous.
The redacted values correspond to the following ranges:
[1]500 to < 5,000
[2]$20 million to < $30 million
[3]$30 million to < $40 million
[4] $0 to < $10 million

5.28 At year 6, the estimated number of scripts dispensed was 500 to < 5000 and the net cost to the PBS would be $0 to < $10 million).

6 PBAC Outcome

6.1 The PBAC recommended the listing of a new form of ocrelizumab (solution for subcutaneous injection 920 mg in 23 mL; ocrelizumab SC) under the same circumstances as the PBS-listed ocrelizumab solution concentrate for intravenous infusion 300 mg in 10 mL (ocrelizumab IV), for the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS), on the basis that it should be available only under special arrangements under Section 100 (S100), as S100 Highly Specialised Drugs (HSD) Private and S100 HSD Public listings.

6.2 The PBAC recommended listing ocrelizumab SC on a cost-minimisation basis to ocrelizumab IV. The PBAC considered ocrelizumab IV an appropriate comparator. The PBAC noted that ocrelizumab SC provides an alternative option to ocrelizumab IV currently listed on the PBS and that evidence demonstrated that ocrelizumab SC has non-inferior comparative effectiveness and safety compared to ocrelizumab IV. While there are other medicines listed on the PBS for RRMS, the PBAC considered these are not relevant comparators, as it is unlikely to be appropriate for patients stabilised on another RRMS treatment to switch to ocrelizumab, or to change prescriber choice of agent in new RRMS patients, because a subcutaneous form is available. The PBAC considered the most likely candidates to use ocrelizumab SC are patients who are already using, or would potentially have commenced, ocrelizumab IV. This was also consistent with the financial estimates presented which assumed replacement with

ocrelizumab IV only.

6.3 The PBAC advised the equi-effective doses to be a single dose of ocrelizumab SC 920 mg in 23 mL to ocrelizumab IV 300 mg in 10 mL, two vials as a single infusion (600 mg), administered every six months.

6.4 The PBAC advised that ocrelizumab SC is suitable for prescribing by medical practitioners only, consistent with the listing for ocrelizumab IV.

6.5 The PBAC recommended that the Early Supply Rule should not apply.

6.6 The PBAC considered the utilisation and financial estimates, and the estimated net financial impact to the PBS/RPBS over the first six years of listing, to be reasonable, based on the assumption that ocrelizumab SC is expected to only substitute for ocrelizumab IV.

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

6.8 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 item:

<table>
<tr><th colspan="2">MEDICINAL PRODUCT
medicinal product pack</th><th>PBS item code</th><th>Max. qty packs</th><th>Max. qty units</th><th>№.of Rpts</th><th>Available brands</th></tr>
<tr><td colspan="7">OCRELIZUMAB</td></tr>
<tr><td colspan="2">ocrelizumab 920 mg/23 mL injection, 23 mL vial</td><td>NEW (HSD Public)</td><td>1</td><td>1</td><td>0</td><td>Ocrevus SC</td></tr>
<tr><td colspan="7"></td></tr>
<tr><td colspan="7">Restriction Summary 7713 / Treatment of Concept: 7699</td></tr>
<tr><td rowspan="4">Concept ID
(for internal Dept. use)</td><td colspan="6">Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB)</td></tr>
<tr><td colspan="6">Prescriber type: ☒Medical Practitioners</td></tr>
<tr><td colspan="6">Restriction type: ☒Authority Required (Streamlined) [7699]</td></tr>
<tr><td colspan="6">Authority type: ☒ Non-complex Authority Required (non-CAR)</td></tr>
<tr><td>Prescribing</td><td colspan="6">Administrative Advice:
No increase in the maximum quantity or number of units may be authorised.</td></tr>
</table>

		Administrative Advice: No increase in the maximum number of repeats may be authorised.
		Administrative Advice: Special Pricing Arrangements apply.
		Indication: Multiple sclerosis
		Treatment Phase: Initial treatment
		Clinical criteria:
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,
		AND
		Clinical criteria:
		The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must be ambulatory (without assistance or support)**.**
		Treatment criteria:
		Must be treated by a neurologist.
		Prescribing Instructions: Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.
Restriction Summary 7396 / Treatment of Concept: 7386		
Concept ID (for internal Dept. use)		**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (Streamlined) [7386]
		Authority type: ☒ Non-complex Authority Required (non-CAR)
		Indication: Multiple sclerosis
		Treatment Phase: Continuing treatment
		Clinical criteria:
		Patient must have previously received PBS-subsidised treatment with this drug for this condition,
		AND
		Clinical criteria:
		Patient must not show continuing progression of disability while on treatment with this drug,
		AND
		Clinical criteria:
		The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must have demonstrated compliance with, and an ability to tolerate this therapy.
		Treatment criteria:
		Must be treated by a neurologist.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
OCRELIZUMAB					
ocrelizumab 920 mg/23 mL injection, 23 mL vial	NEW (HSD Private)	1	1	0	Ocrevus SC

Restriction Summary 9523 / Treatment of Concept: 9523		
Concept ID (for internal Dept. use)		**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Private (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (Streamlined) [9523]
		Authority type: ☒ Non-complex Authority Required (non-CAR)
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 Arrangements apply.
		Indication: Multiple sclerosis
		Treatment Phase: Initial treatment
		Clinical criteria:
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
		The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,
		AND
		Clinical criteria:
		The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition,
		AND
		Clinical criteria:
		Patient must be ambulatory (without assistance or support).
		Treatment criteria:
		Must be treated by a neurologist.
		Prescribing Instructions: Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.
Restriction Summary 9635 / Treatment of Concept: 9635		
Concept ID (for internal Dept. use)		**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Private (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (Streamlined) [9635]
		Authority type: ☒ Non-complex Authority Required (non-CAR)

	Indication: Multiple sclerosis
	Treatment Phase: Continuing treatment
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition,
	AND
	Clinical criteria:
	Patient must not show continuing progression of disability while on treatment with this drug,
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised disease modifying therapy for this condition,
	AND
	Clinical criteria:
	Patient must have demonstrated compliance with, and an ability to tolerate this therapy.
	Treatment criteria:
	Must be treated by a neurologist.

These restrictions 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

Availability and accessibility to new routes of administration such as subcutaneously administered Ocrevus (ocrelizumab), is key to empowering patients and clinicians with treatment choice and personalising care.

While Roche is pleased with the recommendation, this case highlights an opportunity to further enhance Australia's HTA methods and processes. Beyond clinical outcomes, future frameworks must better capture and acknowledge real-world benefits like patient convenience, administration efficiency, and reduced healthcare resource use.

Roche is looking forward to working with the Department of Health, Disability and Ageing to bring this new treatment option to MS patients as soon as possible.