OOS EDARAVONE, Solution concentrate for I.V. infusion 30 mg in 20 mL, Radicava®, Teva Pharma Australia Pty Ltd

1 Purpose of Submission

1.1 The submission sought to amend the current Section 100 (Highly Specialised Drug Program (HSD)) Authority Required (telephone/online PBS Authorities system) listings of edaravone (Radicava®) for the treatment of amyotrophic lateral sclerosis (ALS) to:

- Add a Section 100 HSD Community Access (CA) listing for initial treatment, in addition to the existing Section 100 HSD listings for Public and Private hospitals, allowing community-based neurologists to prescribe edaravone for initiation; and
- Amend the clinical criteria to ensure that ALS patients who have initiated treatment with edaravone and meet the requirements for continuing therapy, regardless of whether treatment commenced privately, are eligible to receive PBS-subsidised continuation therapy.

2 Background

2.1 At its March 2024 meeting, the PBAC considered it would be appropriate for HSD CA arrangements to apply to edaravone for the continuing treatment of ALS, without requiring additional accreditation for prescribers (paragraph 3.8, edaravone Public Summary Document [PSD], March 2024 PBAC meeting). The PBAC recommended listing edaravone for the treatment of ALS under Section 100 HSD arrangements, where CA on the HSD program applies only for continuing treatment (paragraph 5.1, edaravone PSD, March 2024 PBAC meeting).

2.2 The submission was originally lodged for the March 2026 PBAC meeting. However, the sponsor requested out-of-session consideration due to the urgent clinical need and time-critical nature of initiating treatment for ALS. The sponsor considered that the current restrictions, which limit initiation to hospital-based neurologists, are causing unnecessary delays and difficulties in accessing edaravone treatment for ALS patients who would otherwise be eligible for treatment, primarily due to administrative limitations associated with the existing listings.

2.3 Edaravone solution for intravenous (IV) infusion was registered by the Therapeutic Goods Administration (TGA) on 15 February 2023 for use in adults diagnosed with ALS who are independent in activities of daily living, have normal respiratory function, and where treatment is initiated within two years of disease onset.

2.4 The recommended dosage of edaravone, as per TGA-approved product information, is 60 mg (two ampoules) diluted with 100 mL of 0.9% sodium chloride and administered as an IV infusion over 60-minutes period:

- Initial treatment cycle: daily dosing for 14 days, followed by a 14-day drug-free period.
- Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

3 Requested listing

3.1 The submission requested the addition of a new Section 100 HSD CA listing for initial treatment. The submission's proposed additions are in italics and deletions in strikethrough, while Secretariat additions and deletions are shown in bold text.

MEDICINAL PRODUCT medicinal product pack		**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EDARAVONE						
edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules		NEW	2.8	28	0	Radicava
Concept ID (for internal Dept. use)		☒ *Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)*				
		Prescriber type: ☒Medical Practitioners				
		Restriction type: ☒Authority Required (telephone/online PBS Authorities system)				
		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: The ALS Functional Rating Scale - Revised (ALSFRS-R) can be accessed online at: www.mdcalc.com/calc/10166/revised-amyotrophic-lateral-sclerosis-functional-rating-scale-alsfrs-r or https://neurotoolkit.com/alsfrs-r/				
		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.				
		Caution: Hypersensitivity reactions and cases of anaphylaxis have been reported following the administration of edaravone. Patients should be monitored carefully for hypersensitivity reactions following administration. For more information on administration schedule, refer to the approved Therapeutic Goods Administration product Information.				
		Indication: Amyotrophic lateral sclerosis				
		Treatment Phase: Initial treatment				
		Clinical criteria:				
		The condition must be/have been diagnosed by a neurologist				
		AND				
		Clinical criteria:				
		Patient must not have had symptoms for more than 2 years prior to commencing therapy with this drug				
		AND				
		Clinical criteria:				

	Patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months prior to commencing therapy with this drug
	AND
	Clinical criteria:
	Patient must not require assistance with eating or ambulation
	AND
	Clinical criteria:
	Patient must have at least two points on each individual item of the ALS Functional Rating Scale - Revised (ALSFRS-R) score prior to commencing therapy with this drug
	AND
	Clinical criteria:
	Patient must not have undergone a tracheostomy
	AND
	Clinical criteria:
	Patient must not have experienced respiratory failure
	Prescribing Instructions: The date of diagnosis, the date and results of spirometry (in terms of percent of predicted forced vital capacity or slow vital capacity) must be supplied with the initial authority application.

3.2 The submission also proposed two alternative options to allow grandfathering of patients who commenced edaravone therapy privately prior to PBS listing, ensuring their continued access to subsidised treatment.

a. Amend the existing Section 100 HSD CA listing for continuing treatment as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
EDARAVONE					
edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules	14806G	2	20	2	Radicava

Concept ID (for internal Dept. use)		☒ Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (telephone/online PBS Authorities system)
		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: 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.
		Indication: Amyotrophic lateral 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 have undergone a tracheostomy
		AND
		Clinical criteria:
		Patient must not have experienced respiratory failure

b. Add a new Section 100 HSD CA grandfather arrangement as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
EDARAVONE					
edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules	***NEW***	***2***	***20***	***2***	Radicava

Concept ID (for internal Dept. use)	☒ Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (telephone/online PBS Authorities system)
	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: 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.
	Indication: Amyotrophic lateral sclerosis
	***Treatment Phase*:** *Continuing treatment*
	Clinical criteria:
	Patient must have previously received treatment with this drug for this condition
	AND
	Clinical criteria:
	The condition must have been diagnosed by a neurologist
	AND
	Clinical criteria:
	At the time of starting therapy the patient must not have had the disease for more than 2 years
	AND
	Clinical criteria:
	At the time of starting therapy the patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months before commencing therapy with this drug
	AND
	Clinical criteria:
	At the time of starting therapy the patient was ambulatory and able to use upper limbs
	AND
	Clinical criteria:
	Patient must not have undergone a tracheostomy
	AND
	Clinical criteria:
	Patient must not have experienced respiratory failure

Community Access under the HSD program for initiation

3.3 The restriction for the proposed Section 100 HSD CA for initial treatment is the same as that for the Section 100 HSD Public and Private hospital listings, except for the HSD access type, where the CA arrangements allow community-based neurologists to prescribe edaravone without the need to be affiliated with a hospital.

3.4 The evaluation noted that the purpose of the submission is to enable initiation of edaravone treatment by treating neurologists without limiting prescribing to hospital-affiliated neurologists and to provide the option for dispensing and administration of initial doses in the community setting. It did not seek to expand the types of prescribers (e.g., GPs with additional accreditation) authorised to initiate treatment. As such, the evaluation suggested removing the current Section 100 HSD Public and Private hospital listings should the PBAC recommend a Section 100 HSD CA listing for initiation, to avoid multiple PBS item codes, as a CA listing can be accessed in a hospital setting. The PBAC supported a single CA listing for initiation and advised that the existing HSD Public and Private PBS item codes be delisted.

Eligibility criteria for grandfathered patients

3.5 The submission stated that, prior to PBS listing, a small number of patients were importing edaravone for treatment. The proposed listing would enable these grandfathered patients (estimated at < 500) to transition to PBS-subsidised therapy. The evaluation noted that the existing initial treatment criteria are intended to ensure grandfathered patients can access PBS-subsidised edaravone regardless of their treatment stage, whether initial or continuing cycles. Eligibility for initial access is determined by the patient's status prior to commencing edaravone therapy, rather than before starting PBS-subsidised treatment. Patients who met the criteria at the time of treatment initiation, whether PBS or non-PBS subsidised, are entitled to receive their first PBS supply under the initial treatment restriction. These patients may then continue therapy under the continuing treatment restriction, provided they meet the ongoing eligibility requirements for continuing treatment.

3.6 The pre-PBAC response argued that in-market experience indicates prescribers interpret the current PBS initiation criteria as excluding patients who commenced edaravone privately. Requirements such as "Patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months prior to commencing therapy with this drug" and "Patient must not require assistance with eating or ambulation" prevent grandfathered patients from accessing PBS-subsidised treatment. Given the degenerative nature of ALS, these patients may no longer meet these criteria at the time of PBS application. Furthermore, the pre-PBAC response stated that the PBS continuation restriction also precludes access, as patients must have previously received PBS-subsidised edaravone for ALS. This requirement prevents those who initiated treatment privately prior to PBS listing from transitioning to PBS-subsidised continuation therapy.

4 Consideration of the evidence

Rationale for the requested changes

4.1 The submission stated that patients with ALS experience profound physical debilitation, including muscle weakness that limits mobility, speech and daily activities. As the disease progresses, attending hospital-based appointments or travelling to pharmacies becomes increasingly burdensome, placing significant physical and emotional strain on patients and carers. The submission emphasised that implementing a Section 100 HSD CA listing for initiation would allow community-based neurologists to commence edaravone treatment and provide patients with greater choice in accessing medicines through community or hospital pharmacies, facilitating at-home infusions. The proposed changes would address logistical and administrative barriers, particularly for rural and remote patients, and ensure equitable and timely access to edaravone while providing flexibility for patients, carers and healthcare providers, without expanding the market beyond clinically eligible patients.

4.2 The submission also stated that the proposed changes were supported by clinician and patient advocacy feedback, highlighting that current restrictions unintentionally delay access for eligible patients. Correspondence from Motor Neurone Disease (MND) Australia and neurologists (4) was included in support of this position. The submission noted that the PBAC recently recommended changes to the Section 100 HSD listings for lanreotide to allow CA for initiation, which would improve access for patients, particularly those in rural and remote areas (paragraphs 7.1 and 7.2, lanreotide PSD, July 2024 PBAC meeting).

4.3 The correspondence from the Australian and New Zealand Association of Neurologists (ANZAN) provided guidance that community-based initiation of intravenous edaravone for eligible ALS patients is appropriate under structured protocols (see paragraph 4.10 for further detail), supported by its favourable safety profile and international experience in the safe administration of edaravone within community infusion centres and home settings.

Estimated PBS usage and financial implications

4.4 The financial implications of adding a Section 100 HSD CA listing for initial treatment were estimated based on the current ex-manufacturer price (EMP) of $220 per ampoule. However, the dispensed price for maximum quantity (DPMQ) of $6,160.00 in the proposed listing was incorrectly calculated using the same value applied under the Section 100 HSD Public Hospital listing. Table 1 presents a comparison of DPMQ by access type on the HSD program.

Table 1 Comparison of EMP and DPMQ for initial treatment under Section 100 HSD access types

Value	Initiation			Continuation
	Private	Public	Community Access	Community Access
AEMP per ampule	$220.00			
Max Qty	28			20
Max Qty AEMP	$6,160.00			$4,400.00
DPMQ	$6,208.89	$6,160.00	$6,208.89	$4,448.88

Abbreviations: AEMP = Average Ex-Manufacturer Price; DPMQ = Dispensed Price for Maximum Quantity
Source: Compiled by the Secretariat based on page 14 of the submission.

4.5 Based on inputs from neurologists, the submission estimated that approximately < 500 patients currently experience delays or are unable to access edaravone due to the absence of a CA initiation restriction. Accordingly, forward estimates incorporated < 500 additional incident patients per year, without applying an annual growth rate. The submission also estimated that around < 500 patients who have previously imported edaravone independently may benefit from a grandfathering provision. The submission assumed that 100% of these incident and grandfathered patients would meet PBS eligibility criteria and elect to commence treatment, with financial estimates applying a 100% continuation rate for these patients.

4.6 The evaluation noted that the < 500 additional incident patients per year who currently experience delays are likely already eligible under the current restriction and were included in the previous forward estimates. In the previous consideration, it was noted that the prevalent patient population was expected to include any grandfathered patients within the model (paragraph 4.23, edaravone PSD, March 2024 PBAC meeting).

4.7 The submission did not anticipate displacement of any PBS-reimbursed medicines, as edaravone is proposed for use as adjunctive therapy to the current standard of care, with or without riluzole. However, given edaravone is expected to increase survival by approximately 0.52 years, the submission noted a likely increase in riluzole utilisation. It was assumed that around 85% of currently treated ALS patients also receive riluzole.

4.8 The submission estimated an additional net cost to the PBS/RPBS of $0 to < $10 million over the first six years of listing $0 to < $10 million in Year 1 to $0 to < $10 million in Year 6). The net financial impact of the requested changes is expected to be lower than this estimate. The evaluation considered the financial impact to be minor, given that the estimated increase in patient numbers was already incorporated into the original estimates. Furthermore, the submission did not propose any amendments to the current Risk Sharing Arrangement (RSA) and indicated that a substantial expansion of the market size is not expected. The existing RSA provides for [redacted]% reimbursement for use beyond the caps based on the original financial estimates, and any additional expenditure would potentially be mitigated under the existing RSA.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Additional incident population						
Incident population	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Proportion of patients eligible	100%	100%	100%	100%	100%	100%
Patients electing treatment	100%	100%	100%	100%	100%	100%
Total initiating patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Total continuing patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Grandfathered patients						
Total initiating patients	[redacted][1]					
Total continuing patients	[redacted][1]					
Total patients initiate edaravone	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Total patients continue edaravone	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of edaravone						
Cost to PBS/RPBS less co-payment	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Estimated financial implications of riluzole						
Additional scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Cost to PBS/RPBS less co-payment	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	[redacted][2]
Net cost to MBS for administration[b]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	[redacted][2]
Net cost to PBS/RPBS/MBS	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]

[a] Assuming the number of scripts per patient per year based on the estimated mean treatment duration of 7.8 cycles (one initiation cycle and 6.8 continuation cycles) as provided in the submission.
[b] MBS administration costs are included for all patients, applied to 100% of CA Initiating patients and 46.9% of grandfathered patients, with Porta-Cath installation and removal costed using MBS item 34528 ($317.80) and item 34530 ($238.20), respectively.
Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: utilisation and cost model workbook
The redacted values correspond to the following ranges:
[1] *< 500*
[2] *$0 to < $10 million*

Quality use of medicines

4.9 The correspondence from ANZAN (Attachment c(i)) stated its position was that community-based initiation of edaravone is appropriate when:

- The prescriber is a consultant neurologist
- A standardised safety protocol is followed to manage hypersensitivity or anaphylaxis if it occurs
- High risk individuals (e.g., those with significant asthma) are initiated in a hospital setting

4.10 ANZAN emphasised that community-based initiation of edaravone should be managed under structured protocols to ensure safe and effective administration. ANZAN noted rare but significant safety risks, primarily hypersensitivity and allergic-type reactions related to sulfite, including anaphylaxis and life-threatening or less severe asthmatic episodes in susceptible individuals. Key QUM considerations include appropriate screening for asthma, allergy history, and sulfite sensitivity, as well as

infusion safety, monitoring, and emergency preparedness. The evaluation has proposed a caution to be applied to the listing highlighting the risk of hypersensitivity and anaphylaxis and referring clinicians to consider the Product Information to address this.

4.11 ANZAN recommended implementing measures such as clear eligibility criteria, standardised infusion procedures, administration by trained nurses, and monitoring and emergency response plans. These safeguards are intended to mitigate potential risks in community settings and support timely access to treatment for eligible patients.

5 PBAC outcome

5.1 The PBAC recommended amending the Section 100 (Highly Specialised Drug Program (HSD)) Authority Required (telephone/online PBS Authorities system) listings of edaravone for the treatment of amyotrophic lateral sclerosis (ALS) by adding a Section 100 HSD Community Access (CA) listing for initial treatment to enable community-based neurologists to initiate edaravone therapy.

5.2 The PBAC considered that allowing CA initiation would provide greater flexibility for patients and ensure equitable, timely access to treatment through both community and hospital settings, particularly for those in rural and remote areas.

5.3 In recommending this change, the PBAC advised that the existing Section 100 HSD Public and Private hospital listings should be removed to avoid multiple PBS item codes, as the CA listing will allow access in hospital settings.

5.4 The PBAC noted advice from the Australian and New Zealand Association of Neurologists (ANZAN) regarding rare but clinically significant safety risks associated with edaravone, primarily hypersensitivity and allergic-type reactions related to sulfite, including anaphylaxis and severe asthmatic episodes in susceptible individuals. The PBAC considered it appropriate to include a caution in the listing to highlight these risks particularly in the context of administration outside the hospital setting:

"Hypersensitivity reactions and cases of anaphylaxis have been reported following the administration of edaravone. Patients should be monitored carefully for hypersensitivity reactions following administration. For more information on administration schedule, refer to the approved Therapeutic Goods Administration product Information."

5.5 The PBAC acknowledged concerns raised in the pre-PBAC response that current restrictions may be perceived to prevent patients who initiated edaravone treatment privately from transitioning to PBS-subsidised therapy. The PBAC noted these patients were intended to be permitted to transition to PBS-subsidised therapy under the existing restrictions. While the PBAC did not consider a separate grandfathering listing necessary, it agreed that clarifying the intended criteria would ensure these patients

are not disadvantaged if they meet eligibility requirements. Accordingly, the PBAC advised amending the initial treatment criterion from "Patient must not require assistance with eating or ambulation' to "Patient must not require assistance with eating or ambulation prior to commencing treatment with this drug".

5.6 The PBAC also advised including administrative advice and prescribing instruction to confirm that patients who accessed private supply (i.e., grandfathered patients) and met the eligibility criteria at the time of initiation may transition to PBS therapy. These patients may receive their first PBS supply under the initial treatment restriction and continue therapy under the continuing treatment restriction, provided they meet ongoing eligibility requirements. For these patients, prescribers should request quantities sufficient for one month per dispensing, aligned with the treatment cycle, and must request fewer vials than the maximum listed quantity if appropriate.

Administrative advice: Patients who are receiving non-PBS subsidised treatment with this drug (grandfathered patients) may transition to PBS-subsidised treatment through the initial treatment phase, provided they met the eligibility criteria at the time treatment was commenced. To continue PBS-subsidised treatment, after accessing the initial PBS-subsided therapy, a grandfathered patient must qualify under the continuing treatment restriction.
Prescribing instruction: Prescribers must request a quantity sufficient to cover one month per dispensing, in accordance with the patient's treatment cycle. Prescribers must request a smaller number of units than the listed maximum quantity units if it is adequate for the patient's needs.

5.7 The PBAC advised that the changes to the existing listings of edaravone would not affect the previously agreed patient population estimates, as the proposed incident patient numbers per year and grandfathered patients were likely already accounted for. Therefore, the PBAC considered the financial impact of adding CA initiation to be minor, with only a small additional cost to the PBS due to differences in fees and mark-ups between the Section 100 HSD Public hospital and CA programs, which would be mitigated by the existing Risk Sharing Arrangement.

5.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

6 Recommended listing:

6.1 Add a new initial treatment listing under Section 100 HSD Community Access as follows (additions in *italics* and deletions in ~~strikethrough~~):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
EDARAVONE					
edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules	NEW	2.8	28	0	Radicava

Concept ID (for internal Dept. use)		☒**Program:** *Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)*
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (telephone/online PBS Authorities system)
		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: The ALS Functional Rating Scale - Revised (ALSFRS-R) can be accessed online at: www.mdcalc.com/calc/10166/revised-amyotrophic-lateral-sclerosis-functional-rating-scale-alsfrs-r or https://neurotoolkit.com/alsfrs-r/
		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.
		Caution: *Hypersensitivity reactions and cases of anaphylaxis have been reported following the administration of edaravone. Patients should be monitored carefully for hypersensitivity reactions following administration. For more information on administration schedule, refer to the approved Therapeutic Goods Administration (TGA) Product Information.*
		Indication: Amyotrophic lateral sclerosis
		Treatment Phase: Initial treatment
		Clinical criteria:
		The condition must be/have been diagnosed by a neurologist
		AND
		Clinical criteria:
		Patient must not have had symptoms for more than 2 years prior to commencing therapy with this drug
		AND
		Clinical criteria:
		Patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months prior to commencing therapy with this drug
		AND
		Clinical criteria:
		Patient must not require assistance with eating or ambulation *prior to commencing treatment with this drug*
		AND
		Clinical criteria:
		Patient must have at least two points on each individual item of the ALS Functional Rating Scale - Revised (ALSFRS-R) score prior to commencing therapy with this drug
		AND
		Clinical criteria:
		Patient must not have undergone a tracheostomy
		AND
		Clinical criteria:
		Patient must not have experienced respiratory failure

	Prescribing Instructions: The date of diagnosis, the date and results of spirometry (in terms of percent of predicted forced vital capacity or slow vital capacity) must be supplied with the initial authority application.
	Prescribing instruction: *Prescribers must request a quantity sufficient to cover one month per dispensing, in accordance with the patient's treatment cycle. Prescribers must request a smaller number of units than the listed maximum quantity units if it is adequate for the patient's needs.*
	Administrative advice: *Patients who are receiving non-PBS subsidised treatment with this drug (grandfathered patients) may transition to PBS-subsidised treatment through the initial treatment phase, provided they met the eligibility criteria at the time treatment was commenced. To continue PBS-subsidised treatment, after accessing the initial PBS-subsided therapy, a grandfathered patient must qualify under the continuing treatment restriction.*

6.2 Remove edaravone listings for initial treatment under Section 100 HSD Public and Private hospitals - PBS item codes 14804E and 14805F.

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

7 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.

8 Sponsor's Comment

Teva welcomes the Committee's rapid out-of-session consideration given to the urgent clinical need. This change enables an important ease of access for patients diagnosed with ALS, where initiating treatment is of time-critical nature.