

5.24 RILUZOLE

50 mg/10 mL oral liquid, 300 mL, Teglutik®, Seqirus (Australia) Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought listing of a new oral liquid formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS).

2 Requested listing

- 2.1 The submission requested the same restriction as the current riluzole tablet formulation. The requested listing is presented below.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
RILUZOLE 50 mg/10 mL oral liquid, 300 mL	2	5	\$ [REDACTED]	Teglutik® Seqirus (Australia) Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Amyotrophic lateral sclerosis
PBS Indication:	Amyotrophic lateral sclerosis
Treatment phase:	Initial treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

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Clinical criteria:	The condition must be diagnosed by a neurologist, AND Patient must not have had the disease for more than 5 years, AND Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, AND Patient must be ambulatory; OR Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure.
Prescriber Instructions	The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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Treatment phase:	Continuing treatment
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Clinical criteria:	Patient must have previously been issued with an authority prescription for this drug, AND Patient must be ambulatory; OR Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure.

Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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Secretariat comments on the restriction

2.2 The submission requested listing at a higher price than the tablet formulation of riluzole. Given the liquid formulation may be suitable for patients who cannot use riluzole tablets, the PBAC may wish to consider restricting the liquid form to these patients as part of its consideration of the cost-effectiveness of riluzole liquid.

National Health Act considerations

2.3 If the submission is rejected by the PBAC, it would not meet the criteria for an Independent Review as the request is not for an entirely different disease, objectively different subtype of the same disease or targeting a different disease stage.

2.4 The requested restriction is considered to be simple as the submission requested the same restriction as the current riluzole listings.

Early Supply Rule

2.5 The Secretariat noted the Early Supply Rule applies to the tablet listing of riluzole. However, the Secretariat also notes at its April 2015 special meeting, the PBAC advised that circumstances that may support an exemption from the Safety Net Early Supply Rule could include oral liquid preparations. As such, it may be reasonable for the oral liquid formulation of riluzole to also be exempt.

Nurse Practitioner Prescribing

2.6 The Secretariat noted the current listing of riluzole is able to be prescribed by nurse practitioners as continuing therapy only.

PBS Reform issues

Section 101(3BA)

2.7 If recommended for listing, the PBAC must make a recommendation as to whether, under Section 101(3BA) of the National Health Act, 1953 riluzole should be treated as interchangeable with any other drugs on an individual patient basis. The Secretariat noted that riluzole was originally recommended prior to the requirement to provide advice under this section of the Act. The Secretariat also noted riluzole is currently the only treatment PBS-subsidised for ALS.

Suggested wording for the restriction:

2.8 The request to align the listing of the liquid form of riluzole with the current tablet listings is reasonable, therefore a Secretariat suggested wording has not been proposed.

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

3 Background

- 3.1 Riluzole is TGA registered for the treatment of patients with ALS. The 50 mg tablet was first registered on 13 May 2002, branded as Rilutek[®] (sponsored by Sanofi-Aventis Australia Pty Ltd). Generics of the 50 mg tablet are TGA-registered and listed on the PBS. The liquid formulation of riluzole was TGA-registered on 21 August 2018.
- 3.2 Riluzole was first considered by the PBAC at its June 2002 meeting. The initial submission was rejected on the basis of a meta-analysis of four trials which suggested a lack of significant differences in outcomes between placebo and riluzole-treated groups. At the time, the PBAC considered it was likely that some patients with ALS would benefit, however the submission provided no basis upon which to identify such patients or the magnitude of any benefit gained by such patients. A subsequent resubmission to the December 2002 meeting was also rejected.
- 3.3 At its March 2003 meeting, the PBAC considered a request that the Rule of Rescue¹ should apply to riluzole. The PBAC recommended riluzole at a revised price, stating that whilst uncertainty remained about the clinical benefit of riluzole, the resubmission proposed restriction to a smaller patient group that was expected to benefit most, and considered the Rule of Rescue should apply in the case of riluzole in support of a positive recommendation.

4 Population and disease

- 4.1 ALS is a collective term for a number of rare motor neurone diseases (MND) which affect both upper and lower motor neurons in the brain. As these neurons degenerate and die, motor nerve signals cannot be sent to the rest of the body, and over time muscles weaken and atrophy. As the disease progresses, ALS sufferers gradually lose voluntary muscle control, and eventually lose the ability to speak, eat and move. Most people with ALS die from respiratory failure associated with the disease. There are limited treatment options for ALS, and most patients survive between 3 and 5 years from the onset of symptoms.
- 4.2 Riluzole is a synthetic aryl-substituted benzothiazolamine (2-amino-6-[trifluoromethoxy] benzothiazole) and is the only disease-modifying agent for ALS currently TGA registered and PBS listed in Australia. The exact mechanism by which riluzole exerts its disease-modifying effect is unclear; however it is thought to operate by multiple mechanisms of action, including inhibition of glutamate through inhibition of voltage-gated sodium channels and P/Q-type calcium channels, enhancement of glutamate reuptake and up-regulation of AMPA (α -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptors.

¹ PBAC Guidelines: Section 5.4 Basis for any claim for the 'rule of rescue' procedural guidance, available online at [PBAC website](#).

- 4.3 As a new liquid dose form of riluzole, the submission contends this dose form is suitable for all eligible ALS-patients, but has particular benefits for patients with dysphagia (problems swallowing) which is common in ALS, and is suitable for patients with a percutaneous endoscopic gastrostomy (PEG). The submission contends the current tablet formulation of riluzole is less suitable for these patients, as crushing of tablets for swallowing or PEG use is suboptimal and may affect the bioavailability of the drug, lead to micro-aspiration of particles and increased risk of respiratory infections, or blockage of PEG tubes with crushed particulates.

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

5 Comparator

- 5.1 The minor submission nominated riluzole tablets as the main comparator.

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 as it was a minor submission.

Consumer comments

- 6.2 The PBAC noted and welcomed the input from one organisation via the Consumer Comments facility on the PBS website. The advice from Motor Neurone Disease Australia noted that as ALS progresses the majority of patients experience difficulty swallowing, a situation which for many results in the insertion of a PEG. For both these populations, MND Australia was supportive of the listing of a liquid form of riluzole as many of these patients would otherwise have suboptimal therapy or would have to cease treatment entirely.

Clinical trials

- 6.3 The submission presented one study (CRO-PK-11-251) to demonstrate the comparative bioavailability of a single dose of riluzole oral liquid or tablets in healthy participants [N = 30].

Trials and associated reports presented in the submission

Trial ID/First Author	Protocol title/ Publication title	Publication citation
Direct randomised trial(s)		
CRO-PK-11-251 Radicioni M	A pharmacokinetic comparison of riluzole 50 mg/10 mL oral suspension vs. Rilutek® 50 mg tablets after single dose in healthy volunteers. A single centre, single dose, open label, randomised two-way cross-over study. Radicioni M, Rusca A (2011) – unpublished pharmacokinetic trial.	Unpublished

Source: Appendix 3 to the submission, Study Report CRO-PK-11-251

Comparative effectiveness

- 6.4 The pivotal pharmacokinetic (PK) trial measured a range of PK endpoints, with the primary endpoint being extent of plasma absorption of riluzole after a single dose (AUC_{0-t}). Secondary endpoints included mean peak plasma concentration (C_{max}), overall PK profile and safety and tolerability data after a single dose of either riluzole liquid or tablets.

Table 1: Results of the pivotal pharmacokinetic study (CRO-PK-11-251)

PK parameter	Oral suspension (Test)	Tablets (Reference)	Geometric mean ratio	
			PE%	90% CI
C_{max} (ng/mL)	393.67 ± 208.02	321.12 ± 163.49	122.32%	103.28 – 144.88%
AUC_{0-t} (ng/mL×h)	1189.74 ± 516.98	1138.66 ± 483.42	106.84%	96.98 – 117.71%
$AUC_{0-∞}$ (ng/mL×h)	1297.37 ± 573.26	1250.59 ± 557.25	106.46%	96.68 – 117.23%
T_{max} (h)	0.50 (0.25–2.00)	0.75 (0.50-2.00)	n/a	n/a
$t_{1/2}$ (h)	8.02 ± 1.64	8.11 ± 1.40	n/a	n/a

Source: Table 2.1.1 of the submission (Appendix 3 – CRO-PK-11-251 Clinical Study Report, Tables 11.4.1.1/11.4.1.2, p 45)
 Abbreviations: PK = pharmacokinetics; PE = point estimate calculated as test/reference ratio of geometric means; CI = confidence interval; C_{max} = mean peak plasma concentration; AUC_{0-t} = mean area under curve to final measurement; $AUC_{0-∞}$ = mean area under curve to elimination (extrapolated); T_{max} = median time to maximum concentration; $t_{1/2}$ = mean half life

- 6.5 Outcomes for the primary endpoint (AUC_{0-t}) were very similar for both the liquid and tablet forms of riluzole. There was an approximately 22% difference in mean C_{max} outcomes, with a higher mean peak plasma concentration recorded in the patients who received the liquid presentation, and exceeded the bioequivalence 90% CI limit of 125%.
- 6.6 The submission argued this difference was unlikely to be of clinical significance because supplementary analyses, including a logistic regression analysis of potential safety implications of increased C_{max} , found only small differences in dose-related safety events. This is discussed further in the Comparative Harms section below.

Comparative harms

- 6.7 A summary of adverse events (AEs) in study CRO-PK-11-251 is presented in the table below.

Table 2: Summary of adverse events from study CRO-PK-11-251

Body system Preferred term	Oral suspension (N = 30)		Tablets (N = 30)	
	Adverse Events (N)	Subjects N (%)	Adverse Events (N)	Subjects N (%)
All body system	13	9 (30.0)	11	5 (16.7)
Nervous system disorders	6	6 (20.0)	4	4 (13.3)
Headache	3	3 (10.0)	3	3 (10.0)
Dizziness	1	1 (3.3)	1	1 (3.3)
Presyncope	2	2 (6.7)	0	0 (0.0)
Gastrointestinal disorders	5	4 (13.3)	7	4 (13.3)
Vomiting	1	1 (3.3)	4	4 (13.3)
Nausea	1	1 (3.3)	2	2 (6.7)
Paraesthesia oral	2	2 (6.7)	0	0 (0.0)
Dry mouth	1	1 (3.3)	0	0 (0.0)
Dyspepsia	0	0 (0.0)	1	1 (3.3)
Musculoskeletal and connective tissue disorders	1	1 (3.3)	0	0 (0.0)
Neck pain	1	1 (3.3)	0	0 (0.0)
Reproductive system and breast disorders	1	1 (3.3)	0	0 (0.0)
Dysmenorrhoea	1	1 (3.3)	0	0 (0.0)

Source: Table 2.1.2 of the submission (Appendix 3 - CRO-PK-11-251 Clinical Study Report, Table 12.2.2.2, p 49)

- 6.8 The submission argued that AE rates were comparable for the two treatments, and common AEs were consistent with the established profile of riluzole tablets. The study reported all AEs were mild or moderate, and no severe AEs were reported in either group. No statistical analysis of differences in AEs was carried out in the trial.
- 6.9 The submission noted a higher risk of adverse events due to the higher C_{max} observed in the trial could not be excluded, however as noted above, it was argued the difference was unlikely to be clinically significant. The approved Product Information also notes that a slightly increased risk of C_{max} related adverse events cannot be excluded.
- 6.10 The logistic regression undertaken to test the effects of this difference made a number of assumptions, including dose proportionality for riluzole based on clinical trials of the tablet form, and a conservative assumption that a direct relationship existed between C_{max} and probability of adverse events². Given the approximate ~20% difference C_{max} , the analysis assumed the probability of developing an adverse event with the liquid formulation was 20% higher than an equivalent tablet dose. Based on the original riluzole trials, the analysis focussed on adverse events that were identified as being dose-dependent, and found no increase in overall risk of anorexia with the higher C_{max} of the liquid formulation, and only slightly increased risk of diarrhoea, dizziness and increased alanine aminotransferase (ALT) compared to the tablet formulation. While not statistically evaluated, the submission argued the potential small increase in risk of these adverse events identified in the logistical analysis of

² Source: Appendix 1a to the submission, Clinical Overview of study CRO-PK-11-251, Section 2.5.2.3 pp 17-21

safety was not particularly clinically significant, given the potential disadvantages associated with crushing riluzole tablets, which is necessary for many ALS patients.

Clinical claim

- 6.11 The submission described the oral liquid formulation of riluzole as an improved dosage form of riluzole for the treatment of ALS. For some patients, the alternative of a liquid formulation could be considered preferable, particularly for those with difficulty swallowing or who use a PEG or would otherwise require tablets to be crushed.

Economic analysis

- 6.12 The submission did not present an economic analysis, and requested a list price approximately █% higher than the current price of riluzole tablets. Pricing matters are further discussed in the estimated PBS usage and financial implications section below.

Drug cost/patient/year: \$█.

- 6.13 The sponsor requested a DPMQ of \$█ for two 300 mL bottles of riluzole liquid, equivalent to a one month (30 days) supply. The annual cost was derived at a monthly cost of \$█ x 12 [months] = \$█.

Estimated PBS usage & financial implications

- 6.14 The minor submission requested an AEMP of \$█ for 2 bottles, equivalent to 3,000 mg of riluzole, at a price of \$█ per mg. This is █% higher than the current riluzole tablet price on a per mg basis. Following the listing of generic brands, from 1 September 2018 the current DPMQ of riluzole is \$203.32 (AEMP \$178.40). The current riluzole tablet price is \$0.0637 per mg.
- 6.15 The sponsor claimed a higher price for the liquid formulation of riluzole was necessary due to a higher manufacturing cost and significant development cost of a stable oral suspension with a viscosity suitable for dysphasic patients and argued the liquid formulation of riluzole has advantages for a substantial proportion of the ALS population.
- 6.16 Recommending an alternative dose form with a modest premium where some patients may benefit from that form is not without precedent. At its March 2015 meeting, the PBAC recommended propranolol oral liquid (Hemangirol) at a modest price premium over hospital-supplied propranolol liquid (Ausman propranolol solution) in acknowledgement that Hemangirol is a commercially available product which is likely to have benefits for patients in terms of access. However, the PBAC rejected two subsequent re-submissions requesting a higher price based on the cost of extemporaneously compounded propranolol liquid.
- 6.17 The submission used historical riluzole prescription data from the publicly available Department of Human Services (DHS) PBS Statistics resource to determine the size of

the riluzole market annually from July 2013 to June 2018. Using this data, the submission derived an average annual market growth of 1.68%.

- 6.18 PBS/RPBS expenditure on riluzole has been in decline over the last five years. From July 2013 – June 2014, PBS expenditure was \$ [REDACTED] and from July 2015 – June 2016 it declined to \$ [REDACTED], and further declined to \$ [REDACTED] in the period July 2017 – June 2018. As the market for riluzole has been modestly increasing, the decrease in expenditure has been driven by the listing of generic brands of riluzole tablets and subsequent application of price disclosure. For consistency with the utilisation estimates, the DHS PBS Statistics resource was used to obtain PBS expenditure figures.
- 6.19 From the baseline of riluzole prescriptions processed from July 2017 to June 2018, the submission estimated a market share rising from 1% in year 1 to 40% in years 5 and 6. The submission estimates of utilisation and expenditure are presented in the table below.

Table 3: Estimated PBS usage and financial implications

	2019	2020	2021	2022	2023	2024
Total riluzole scripts	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Annual growth rate	1.68%	1.68%	1.68%	1.68%	1.68%	
Teglutik® liquid market share	1.00%	11.00%	22.50%	33.00%	40.00%	40.00%
Teglutik® PBS/RPBS scripts dispensed	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Estimated financial implications of Teglutik® oral liquid						
Drug cost to PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Less copayments	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]
Net cost to PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Estimated financial implications for riluzole tablets						
Riluzole tablet PBS/RPBS scripts replaced	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Replaced drug cost to PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Less copayments	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]
Net cost to PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net financial implications						
Net cost to PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

Source: Submission utilisation and financial estimates & Appendix 4 to the submission – utilisation and financial spreadsheets.

The redacted table shows that at Year 6 the estimated number of Teglutik® scripts dispensed was less than 10,000 per year, and the net cost to the PBS/RPBS (incorporating replaced tablet usage) would be substantially less than \$10 million per year.

- 6.20 As the riluzole liquid formulation provides 30 days' therapy compared to 28 days' therapy for riluzole tablets, the submission correctly estimated a slightly higher replaced number of tablet prescriptions than the estimated number of liquid formulation prescriptions. The submission noted there would be a small reduction in authority requests being processed due to differences in treatment duration per

authority (168 vs. 180 days), however did not consider this would result in any significant overall change in DHS processing costs.

- 6.21 The submission estimates are based on the full PBS dataset (based on date of processing by DHS) which was used to establish an average overall growth trend in the use of riluzole.
- 6.22 The submission did not consider any potential growth in the market associated with increased duration of therapy if patients are able to continue using the oral liquid in circumstances where use of riluzole tablets is no longer possible. No data was available to evaluate comparative differences in ability to continue treatment (particularly as the disease progresses) between the liquid and tablet forms and the potential for any growth in the market is unclear.
- 6.23 There is some uncertainty regarding the projected uptake rate of the liquid formulation of riluzole (up to 40%). The submission presented sensitivity analyses to model differences in the net cost to the PBS if the maximum uptake rate was decreased to 20% (halving the uptake rate in all years) or increased to 60% (increasing the uptake rate by a factor of 1.5 in all years). Results of the sensitivity analyses are presented in the table below.

Table 4: Financial estimates sensitivity analyses with 20% and 60% maximum uptake rates

	2019	2020	2021	2022	2023	2024
Uptake rate (max 20%)	0.50%	5.50%	11.25%	16.50%	20.00%	20.00%
Net cost to PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Uptake rate (max 60%)	1.50%	16.50%	33.75%	49.50%	60.00%	60.00%
Net cost to PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

Source: Main body of the submission (sensitivity analyses)

Quality use of medicines

- 6.24 Due to differences in the liquid and tablet forms of riluzole, the submission explicitly requested that riluzole liquid not be considered interchangeable with riluzole tablets. The Secretariat assumed the request related to not marking riluzole liquid and tablets as equivalent for the purposes of substitution at the pharmacy level (i.e. ‘a’ flagged).

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

7 PBAC Outcome

- 7.1 The PBAC recommended the General Schedule, Authority Required listing of a new liquid formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS) on a cost minimisation basis with riluzole tablets, with a price premium as this form of riluzole offers an advantage to some patients with this disease. The PBAC considered that a price around 5-10% higher per ml for the liquid formulation over the tablet formulation may be considered reasonable.
- 7.2 The PBAC was satisfied that riluzole liquid provides the same clinical benefits as riluzole tablets, however considered there was a clinical need for an alternative form

which was likely to have advantages for patients with difficulty swallowing (dysphagia) or who use a percutaneous endoscopic gastrostomy (PEG), as tablets are often difficult to administer in these patients. Given the advantages in the manner of administration for some patients, the PBAC considered the requested price premium was reasonable.

- 7.3 The PBAC considered it was appropriate to align the restrictions for riluzole liquid with the current tablet restrictions.
- 7.4 The PBAC considered the comparator of riluzole tablets was appropriate.
- 7.5 The PBAC noted the single pharmacokinetic trial indicated some differences in the pharmacokinetic profile of riluzole liquid and tablets. The Committee noted there may be a slight increased risk of dose-related adverse events with riluzole liquid associated with higher peak plasma concentration. On balance, the PBAC did not consider this to be a major issue compared to the potential advantages of a liquid formulation for some patients.
- 7.6 The PBAC considered the utilisation and financial estimates were reasonable, however noted there was some uncertainty as to the expected uptake of the liquid form of riluzole.
- 7.7 The PBAC advised, under Section 101 (4AACD) of the National Health Act, that riluzole tablets and riluzole liquid should not be considered equivalent for the purposes of substitution (i.e. 'a' flagged) due to differences in the formulations.
- 7.8 The PBAC advised that riluzole liquid is suitable for prescribing by nurse practitioners, under the same circumstances as riluzole tablets.
- 7.9 The PBAC recommended that the Early Supply Rule should not apply as it has previously been of the view that oral liquid presentations should generally be exempt.
- 7.10 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

- 8.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
RILUZOLE 50 mg/10 mL oral liquid, 300 mL	2	5	Teglutik®	Seqirus (Australia) Pty Ltd

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Clinical criteria:	The condition must be diagnosed by a neurologist, AND Patient must not have had the disease for more than 5 years, AND Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, AND Patient must be ambulatory; OR Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure.
Prescriber Instructions	The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

10 Sponsor's Comment

The sponsor had no comment.