

## 5.26 NATALIZUMAB, Solution concentrate for I.V. infusion 300 mg in 15 mL, Tyruko<sup>®</sup>, Sandoz Pty Ltd

### 1 Purpose of Submission

- 1.1 The Category 3 submission requested the listing of a new biosimilar brand of natalizumab 300 mg in 15 mL vial for intravenous infusion (Tyruko<sup>®</sup>) as a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing under the same circumstances as the PBS-listed reference biologic Tysabri<sup>®</sup> for the treatment of clinically definite relapsing-remitting multiple sclerosis (RRMS).
- 1.2 Listing was requested on a cost-minimisation basis to Tysabri.

### 2 Background

- 2.1 Tyruko was approved on 11 September 2024 for registration in the Australian Register of Therapeutic Goods (ARTG) as monotherapy for the treatment of patients with RRMS to delay the progression of physical disability and reduce the frequency of relapse. The TGA approval of Tyruko as a biosimilar medicine to Tysabri was based on evidence demonstrating its comparability with Tysabri in physicochemical characteristics, efficacy, and safety outcomes.
- 2.2 Table 1 presents the key components of the current PBS listings for Tysabri and the requested listings in the submission.

Table 1: Current PBS listing of Tysabri versus requested listing for Tyruko

Tysabri (PBS item codes: 9505G, 9624M)			Tyruko		
Indication(s)	Form(s)	Restriction level	Indication(s)	Form(s)	Restriction level (Treatment Phase)
Clinically definite RRMS	300 mg/15 mL injection, 15mL vial	Authority Required (STREAMLINED)	Clinically definite RRMS	300 mg/15 mL injection, 15 mL vial	Authority Required (STREAMLINED)

Source: Compiled by the PBAC Secretariat during evaluation.

Abbreviations: RRMS = relapsing-remitting multiple sclerosis

- 2.3 Tyruko is the first biosimilar brand for natalizumab to request PBS listing and has not previously been considered by the PBAC.

### 3 Requested listing

- 3.1 The submission requested listing Tyruko under the same circumstances as the PBS-listed reference biologic, Tysabri (PBS item codes: 9505G, 9624M). As the submission

requested the same restrictions as the reference brand, the full restrictions have not been reproduced here.

*Add brand to existing items:*

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
NATALIZUMAB					
natalizumab 300 mg/15 mL injection, 15 mL vial	9505G (Public)	1	1	5	<sup>a</sup> Tysabri (reference biologic)
natalizumab 300 mg/15 mL injection, 15 mL vial	9624M (Private)	1	1	5	<sup>a</sup> Tyruko (proposed biosimilar brand)
<b>Restriction Summary 13470 / 13711/ Treatment of Concept: 13718/ 13625</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)				
Prescribing rule level	<b>Caution:</b> Progressive multifocal leukoencephalopathy has been reported with this drug.				
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>				
	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>				
<b>Indication:</b> Clinically definite relapsing-remitting multiple sclerosis					

- 3.2 The submission requested that Tyruko be considered equivalent (a-flagged) to Tysabri for the purpose of substitution.
- 3.3 The submission requested the addition of an administrative note to encourage the uptake of biosimilar prescribing for treatment-naïve patients. The Secretariat proposed the addition of two administrative notes reflecting the biosimilar uptake policy.

## 4 Consideration of the evidence

### *Sponsor hearing*

- 4.1 There was no hearing for this item.

### **Consumer comments**

4.2 The PBAC noted that no consumer comments were received for this item.

### **Clinical evidence**

4.3 The TGA has confirmed that, in equal dose, Tyruko is the same as Tysabri (TGA delegate's overview).

### **Estimated PBS usage and financial implications**

4.4 Listing the biosimilar brand Tyruko does not change the overall utilisation of natalizumab.

4.5 While not a matter for the PBAC, a 25% first new brand statutory price reduction (FNB SPR) is expected to apply to Tyruko, assuming it is the first biosimilar brand of natalizumab if recommended for listing as a biosimilar to Tysabri.

4.6 Tyruko has the same drug, form and manner of administration as the existing Tysabri brand and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as per Section 85C of the National Health Act 1953.

## **5 PBAC Outcome**

5.1 The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new biosimilar brand of natalizumab 300 mg in 15 mL vial for intravenous infusion (Tyruko®) on a cost-minimisation basis and under the same circumstances as the PBS-listed reference biologic, Tysabri®, for the treatment of clinically definite relapsing-remitting multiple sclerosis (RRMS).

5.2 The PBAC noted that the TGA has confirmed biosimilarity between Tyruko and the reference product Tysabri.

5.3 The PBAC considered that the inclusion of the 'Biosimilar prescribing policy' administrative note, encouraging use of the biosimilar brand (i.e., Tyruko) for treatment naïve patients, is clinically appropriate.

5.4 The PBAC advised that, under Section 101(4AACD) of the National Health Act 1953, Tysabri and Tyruko should be considered equivalent for substitution on the Schedule of Pharmaceutical Benefits.

5.5 The PBAC considered that the listing of Tyruko would not result in a net cost to the PBS as it would likely substitute for Tysabri and not increase the overall market utilisation.

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

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

**Outcome:**

Recommended

## 6 Recommended listing

- 6.1 As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here.

Add brand to existing items:

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<b>Restriction Summary 13470 / 13711/ Treatment of Concept: 13718/ 13625</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
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Prescribing rule level	<b>Caution:</b> Progressive multifocal leukoencephalopathy has been reported with this drug.				
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<b>Indication:</b> Clinically definite relapsing-remitting multiple sclerosis					

***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**

The sponsor had no comment.