

**6.11 NATALIZUMAB,  
Solution concentrate for I.V. infusion 300 mg in  
15 mL,  
Tysabri®,  
Biogen Australia Pty Ltd**

**1 Purpose of Submission**

- 1.1 The Committee secretariat submission requested to remove the prescribing instructions ‘Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program’ of natalizumab (Tysabri®) for the treatment of clinically definite relapsing-remitting multiple sclerosis (MS).

**2 Background**

***Registration status***

- 2.1 Natalizumab was registered in the Australian Register of Therapeutic Goods (ARTG) on 1 November 2006 as a monotherapy for the treatment of patients with relapsing-remitting MS to delay the progression of physical disability and to reduce the frequency of relapse.
- 2.2 On 31 August 2020 the Therapeutic Goods Administration (TGA) approved the removal of following specific condition on the registration of natalizumab:
- ‘Prescribing neurologists must undergo mandatory training on use of the medicine (with emphasis on key requirements described in the Product Information) and the clinical features of Progressive Multifocal Leukoencephalopathy. The names of these neurologists are to be kept on a central registry to be held by Biogen Idec Australia Pty Ltd,’
- 2.3 Further, on 7 September 2021 the TGA approved the revised Tysabri Australian Specific Annex (ASA). The main impact of this was:
- Healthcare professionals no longer need to be trained by the Tysabri Australian Prescribing Program (TAPP). As per the ASA, healthcare professional training by use of the Physician Information and Management Guideline and Product Information (PI) is sufficient.

***Current status***

- 2.4 Natalizumab (Tysabri) is currently listed on the PBS as a Section 100 Highly Specialised Drug program (S100 HSD) Authority Required (STREAMLINED) listing for the treatment of clinically definite relapsing-remitting multiple sclerosis.

### 3 Requested listing

3.1 The submission requested the following changes to the existing listings. Suggested additions are in italics and deletions are in strikethrough.

Amend restriction as follows:

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 9624M	1	1	5	Tysabri
<b>Restriction Summary 9830 / Treatment of Concept: 9818</b>					
	<b>Category / Program:</b> Section 100 – Highly Specialised Drugs Program (HB)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
	<b>Indication:</b> clinically definite relapsing-remitting multiple sclerosis				
	<b>Treatment criteria:</b>				
	Must be treated by a neurologist				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	The treatment must be the sole PBS-subsidised disease modifying therapy for this condition				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	Patient must be ambulatory (without assistance or support)				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	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				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; or Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient				
	<b>Caution:</b> Progressive multifocal leukoencephalopathy has been reported with this drug.				
	<b>Prescribing Instructions:</b> The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.				
	<b>Prescribing Instructions:</b> Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.				
	<b>Prescribing Instructions:</b> For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.				
Remove	<del><b>Prescribing Instructions:</b> Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.</del>				
<b>Restriction Summary 9795 / Treatment of Concept: 9744</b>					
	<b>Category / Program:</b> Section 100 – Highly Specialised Drugs Program (HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – Streamlined				

	<b>Indication:</b> clinically definite relapsing-remitting multiple sclerosis
	<b>Treatment criteria:</b>
	Must be treated by a neurologist
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised disease modifying therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must be ambulatory (without assistance or support)
	<b>AND</b>
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; or Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient
	<b>Caution:</b> Progressive multifocal leukoencephalopathy has been reported with this drug.
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	<b>Prescribing Instructions:</b> For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.
Remove	<del><b>Prescribing Instructions:</b> Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.</del>

For more detail on PBAC's view, see section 5 PBAC outcome.

## 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.

### **Estimated PBS utilisation and financial implications**

4.3 The submission states that healthcare professionals (HCP) are no longer required to be trained by the TAPP. The submission also stated the proposed change to the prescribing instructions will not impact patient safety of the current listing. The submission considers Physician Information and Management Guideline, and the PI are sufficient for HCP training.

- 4.4 The submission stated there is no financial implication with the proposed change and would result in a nil cost to Government.

*For more detail on PBAC’s view, see section 5 PBAC outcome.*

## 5 PBAC Outcome

- 5.1 The PBAC recommended removing the prescribing instruction ‘Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program’ from the circumstances under which natalizumab (Tysabri®) is available on the PBS for the treatment of clinically definite relapsing-remitting MS.
- 5.2 The PBAC noted that the TGA had approved the revised Tysabri ASA, confirming that healthcare professional training by use of the Physician Information and Management Guideline, and PI is sufficient.
- 5.3 The PBAC noted the change in restrictions would have nil financial implication.
- 5.4 The PBAC noted the change in natalizumab restrictions is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, or not expected to address a high and urgent unmet clinical need, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.5 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 Amend existing listing as follows:

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	The treatment must be the sole PBS-subsidised disease modifying therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must be ambulatory (without assistance or support)
	<b>AND</b>
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Remove	<del><b>Prescribing Instructions:</b> Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.</del>

***This restriction 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.