

## 5.8 PEGINTERFERON BETA-1A

**63 microgram/0.5 ml injection, 0.5 ml syringe + 94 microgram/0.5 ml injection, 0.5 ml syringe, 63 microgram/0.5 ml injection, 0.5 ml injection device + 94 microgram/0.5 ml injection, 0.5 ml injection device, 125 microgram/0.5 ml injection, 2 x 0.5 ml syringes, 125 microgram/0.5 ml injection, 2 x 0.5 ml injection devices;  
Plegridy®; Biogen Idec Australia Pty Ltd.**

### 1 Purpose of Application

- 1.1 The submission sought an Authority Required listing for peginterferon beta-1a for the first line treatment of patients with remitting, relapsing multiple sclerosis.

### 2 Requested listing

- 2.1 Suggestions and additions proposed by the Secretariat to the requested listing are added and suggested deletions are crossed out with strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	No. of Rpts	Proprietary Name and Manufacturer
PEGINTERFERON BETA-1A peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL syringe] (& peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL syringe], 1 pack	1	0	Plegridy Biogen Idec
peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (& peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack	1	0	
peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL syringes	1	4	
peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices	1	4	

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	-
<b>Severity:</b>	-
<b>Condition:</b>	Multiple sclerosis
<b>PBS Indication:</b>	Multiple sclerosis
<b>Treatment phase:</b>	Initial

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<b>Restriction:</b>	Authority Required ( <del>STREAMLINED</del> )
<b>Clinical criteria:</b>	<p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR</p> <p>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.</p> <p>AND</p> <p>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years</p> <p>AND</p> <p>Patient must be ambulatory (without assistance or support)</p>
<b>Prescriber Instructions</b>	Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.
<b>Administrative Advice</b>	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p>

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	No. of Rpts	Proprietary Manufacturer	Name and Manufacturer
PEGINTERFERON BETA-1A			Plegridy	Biogen Idec
peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL syringes	1	5		
peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices	1	5		

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
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<b>Episodicity:</b>	-
<b>Severity:</b>	-
<b>Condition:</b>	Multiple sclerosis
<b>PBS Indication:</b>	Multiple sclerosis
<b>Treatment phase:</b>	Continuing
<b>Restriction:</b>	Authority Required ( <del>STREAMLINED</del> )

<b>Clinical criteria:</b>	Patient must have previously been issued with an authority prescription for this drug  AND  Patient must not show continuing progression of disability while on treatment with this drug  AND  Patient must have demonstrated compliance with, and an ability to tolerate, this therapy
<b>Administrative Advice</b>	No increase in the maximum quantity or number of units may be authorised.  No increase in the maximum number of repeats may be authorised.

2.2 Listing was sought on a cost minimisation basis with INFB-1a as the main comparator.

### 3 Background

3.1 The submission was made under TGA/PBAC Parallel Process. At the time of PBAC consideration, the TGA approval letter was available.

3.2 This application has not been considered by PBAC previously.

### 4 Clinical place for the proposed therapy

4.1 Peginterferon beta-1a (peg(INF)) is an immunomodulatory agent in which the principal pharmacological action operates to reduce inflammation through cytokine production, promote nerve growth factor and natural killer cells and prevent leukocyte migration across the blood borne barrier.

4.2 The submission proposes peg(INF) as an alternative first line treatment for patients with remitting, relapsing MS. The submission suggests that pegylation of IFNB-1a by attaching a 20 kDa methoxy-PEG-O-2-methyl-propionaldehyde group to the N-terminus of IFN $\beta$ -1a, (pegINF) would improve stability and biological activity, compared with INFB-1a.

### 5 Comparator

5.1 The submission nominated INFB-1a as the comparator. The ESC agreed that this was an appropriate comparator, noting that other drugs for MS such as interferon beta-1b and glatiramer may also be replaced.

### 6 Consideration of the evidence

## Sponsor hearing

6.1 There was no hearing for this item.

## Consumer comments

6.2 The PBAC noted and welcomed the input from organisations (2) via the Consumer Comments facility on the PBS website. The comments described the perceived benefit to patients of having another treatment option for MS.

## Clinical trials

6.3 The submission was based on an indirect comparison of two trials comparing peg(INF) (n=1012) to INFB-1a (n=897) with placebo being the common comparator.

6.4 Details of the trials presented in the submission are provided below.

### Trials and associated reports presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
ADVANCE (105-MS-301)	A Multicenter, Randomised, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy and Safety of PEGylated Interferon Beta-1a (BIIB017) in Subjects with Relapsing Multiple Sclerosis	Clinical Study Report. 18 April 2013
ATTAIN (105-MS-302)	A Dose-Frequency Blinded, Multicenter, Extension Study to Determine the Long-Term Safety and Efficacy of PEGylated Interferon Beta-1a (BIIB017) in Subjects with Relapsing Multiple Sclerosis	Clinical Study Report. 23 April 2013
BRAVO	Vollmer et al. A randomised placebo-controlled phase III trial of oral laquinimod for multiple sclerosis.	J Neurol (2014), 261:773-783

Source: Table B.2.5, Section B p 45 of the submission.

6.5 The key features of the direct randomised trials are summarised below. The common comparator is placebo. The risk of bias is high in the BRAVO trial as patients were not blinded to treatment with INFB-1a but blinded to the oral treatment (laquinimod vs placebo).

### Key features of the included evidence – indirect comparison

Trial	N	Design/ duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
<b>Peg(INF) vs placebo</b>						
ADVANCE	1015	R DB PG PC 48 weeks	Low	Relapsed remitting	Annualised relapse rate (ARR)	N/A
<b>INF b-1a vs placebo</b>						
BRAVO	897	R PB PG PC 2 years	High	Relapsed remitting	Annualised relapse rate (ARR)	N/A

DB=double blind; PB; partially blinded MC=multi-centre; OL=open label; PC=placebo controlled; PG=parallel group  
R=randomised

Source: compiled during the evaluation

## Comparative effectiveness

**Results of annualised relapse rate (ARR) across the direct randomised trials**

	ADVANCE 1 year		ADVANCE 2 years	BRAVO* 2 years	
	Placebo	peg(INF) Q2W	peg(INF) Q2W	Placebo	INFB-1a
Number of subjects in ITT population	500	512	438	450	447
Total number of relapses	181	116	95	NR	NR
Absolute difference RD± NNT [or mean difference] (95% CI)	13.54 (7.9,19.1)			NR	
Total number of subject-years followed	445.25	435.74	402.33	–	–
Unadjusted annualised relapse rate (a)	0.407	0.266	0.236	–	–
Adjusted annualised relapse rate	0.397	0.256	0.230	0.3474	0.26
95% CI (b)	0.328,0.481	0.206,0.318	0.183, 0.291	–	–
Rate ratio (active/placebo)	–	0.644		–	0.74
95% CI (b)	–	0.500,0.831		–	0.60, 0.92
p-value (compared to placebo)	–	0.0007	–	–	0.007
Indirect rate ratio (95% CI) p value Result < 1 favours peg(INF)	0.87 (0.62, 1.21) p=0.412				

NOTE 1: Only relapses confirmed by INEC are included in the analysis.

2: Data after subjects switched to alternative MS medications are excluded.

3: Numbers in parentheses are percentages.

\* BRAVO reported ARR over 2 years

(a) The annualised relapse rate is calculated as the total number of relapses occurred during year 1 for all subjects, divided by the total number of subject-years followed in year 1.

(b) Based on negative binomial regression, with adjustment for baseline EDSS (<4 vs. >=4), baseline relapse rate, age (<40 vs. >=40).

(c) The number of relapses for each subject divided by the number of years followed in year 1 for that subject. Summary statistics across all subjects are presented.

Source: Table B.6.2 Section B, p 69 of the submission.

- 6.6 The annualised relapse rate (ARR) was calculated based on 48 weeks in the ADVANCE trial and 2 years in the BRAVO trial. No difference in reducing ARR was observed between peg(INF) and INFB-1a treatment.

**Time to sustained progression of disability as measured by increase in EDSS (confirmed at 3 months)**

	ADVANCE		BRAVO	
	Placebo	Peg(IFN) Every 2 weeks	Placebo	INFB-1a
Number of subjects in ITT population	500 (100)	512 (100)	450	447
Number of subjects progressed, n (%)	50 ( 10)	31 (6)	60 (13)	47 (11)
Estimated proportion of subjects progressed at (a)				
12 weeks	0.023	0.004	–	–
24 weeks	0.052	0.038	–	–
36 weeks	0.071	0.056	–	–
48 weeks	0.105	0.068	–	–
Hazard ratio (active/placebo)	–	0.62	–	0.74
95% CI (b)	–	0.40, 0.97	–	0.51, 1.09
p-value (compared to placebo) (b)	–	0.0383	–	0.13
Indirect hazard ratio (95% CI) p value Result < 1 favours peg(INF)	0.84 (0.46, 1.50) p=0.552			

NOTE 1: Sustained progression of disability is defined as at least a 1.0 point increase on the EDSS from a baseline EDSS  $\geq$ 1.0 sustained for 12 weeks or at least a 1.5 point increase on the EDSS from a baseline EDSS of 0 sustained for 12 weeks.

2: Subjects are censored at the time of withdrawal/switch if they withdrew from study or switched to alternative MS medication without a progression.

3: Numbers in parentheses are percentages.

(a) Estimated time to progression and proportion of patients with progression based on the Kaplan-Meier product limit method.

(b) Based on Cox Proportional Hazards model, adjusted for baseline EDSS and age (<40 vs.  $\geq$ 40).

Abbreviations: NA = not available since the proportion of subjects with progression within the 48 weeks follow-up is less than the specified percentage. Source: Table B.6.6, Section B, p 73 of the submission.

- 6.7 No difference is observed in reducing the risk of progression of disability between peg(IFN) and INF B-1a treatment.

### Comparative harms

- 6.8 Based on the trials, the incidence of treatment related adverse events was significantly more common in INFB1-a treatment, than peg(INF). However, the incidence of adverse events causing discontinuation and serious adverse events were similar between peg(INF) and INFB-1a. There are limitations to the indirect comparison as trial duration differed and the BRAVO trial was unblinded. Longer term safety data suggested that the benefit-risk profile of peg(INF) remains favourable.

### Benefits/harms

- 6.9 A summary of the comparative benefits and harms for peg (INF) versus INFB-1a is presented below.

**Summary of comparative benefits and harms for Peg(INF) and INF b-1a /PBO**

Trial	Peg(INF)	INF b-1a /PBO	RR (95% CI)	Event rate/100 patients*			RD (95% CI)	
				Peg(INF)	INF b-1a / PBO			
<b>Benefits</b>								
<b>Dichotomous Outcome I: indirect comparison</b>								
	Peg(INF)	PBO	INF b-1a	Annualised rate ratio (95% CI)	Event rate/100 patients**^			RD^ (95% CI)
					Peg(INF)	PBO	Comparator	
ADVANCE (1 year)	116/512	181/500	-	0.644 (0.500,0.831)	22.66	36.2	-	-13.54 (-19.1, -7.98)
BRAVO (2 years)		NR	NR	0.74 (0.60,0.92)	-	NR	NR	NR
Indirect comparison: ADVANCE vs BRAVO				0.87 (0.62, 1.21)	-			-
<b>Harms</b>								
	Peg(INF)	INF b-1a		RR (95% CI)	Event rate/100 patients**^			RD^ (95% CI)
					Peg(INF)	INF b-1a		
Number of subjects with an event related to study treatment								
ADVANCE (1 year)/ BRAVO (2 years)	459/512	296/442		0.56 (0.45,0.68) P<0.00001	89.6	66.97		0.227 (0.175,0.277)
Number of subjects with a serious event								
ADVANCE (1 year)/ BRAVO (2 years)	55/512	34/442		1.10^ (0.66, 1.86)	10.74	7.69		0.035 (0.0068,0.067)
Number of subjects discontinuing study treatment due to an event								
ADVANCE (1 year)/ BRAVO (2 years)	25/512	26/442		2.51^ (0.91, 6.89)	4.88	5.88		-0.01 (-0.04, 0.02)

\* Maximum duration of follow-up /Maximum duration of exposure: ADVANCE = 48 weeks; BRAVO = 2 years  
Abbreviations: PBO = placebo; RD = risk difference; RR = risk ratio. ^ calculated as part of the evaluation  
Source: Compiled during the evaluation/Table B.6.2 of the submission, Vollmer et al (2014), p 778

- 6.10 The comparison was based on an indirect comparison of 2 trials, with placebo as the common comparator. There were no statistically significant differences in the annualised relapse rate (primary outcome), number of subjects with a serious adverse event or number of subjects discontinuing due to a treatment related adverse event. There was a statistically significant difference in the number of subjects with a treatment related adverse event, which was in favour of peg(INF). There was a statistically significant difference between peg(INF) and INFB-1a for the secondary outcome of the number of new/enlarging T2 lesions, which was in favour of peg(INF). However, there are limitations to the indirect comparison of comparative harms and secondary outcomes due to 1) the BRAVO trial being unblinded and 2) different trial lengths (48 weeks vs. 2 years for ADVANCE and BRAVO respectively).

**Clinical claim**

- 6.11 The clinical claim was one of non-inferior efficacy and non-inferior safety. This claim was supported in terms of the primary efficacy outcome and all but one of the safety outcomes. Superiority was suggested in one secondary outcome and one safety outcome across the trials. However there are limitations to the indirect comparison due to the BRAVO trial being unblinded and due to different trial durations. Peg(INF) appears to be tolerated at least as well as INFB1-a.

- 6.12 The ESC considered that the claim of non-inferior efficacy and non-inferior safety compared to interferon beta-1a was reasonably well supported by the indirect comparison.

### Economic analysis

- 6.13 The equi-effective doses were estimated as peg(INF) 125 µg once every two weeks vs. INFB-1a IM 30 µg (once per week) or INFB-1a SC 44 µg (3 times per week). The estimates are based on the trials. This dose is consistent with the clinical claim of non-inferiority. The TGA delegate’s overview notes that the proposed Q2W dose of peg(INF) is benchmarked against the current weekly dose of INFb-1a.

### Drug cost/patient/year

- 6.14 The drug cost per patient per year is \$13,788.19. This is equal to the costs of the main comparator (INFB-1a). The treatment is ongoing.

### Estimated PBS usage & financial implications

- 6.15 This submission was not considered by DUSC. The submission used a market share approach based on the current PBS utilisation of other ABCR treatments. The submission assumed that there are no cost offsets for reducing the number of doses as patients self-administer. The estimated net cost was driven by small differences in the PBS price of peg(INF), INFb-1b and glatiramer acetate. The ESC considered that the estimates seem reasonable, despite the modest uncertainty regarding what doses of PEG interferon beta-1a will be used.

#### Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Estimated extent of use</b>					
Market share of ABCRE	■	■	■	■	■
Scripts <sup>a</sup>	■	■	■	■	■
<b>Estimated net cost to PBS/RPBS/MBS</b>					
Net cost to PBS/RPBS	■	■	■	■	■
Net cost to MBS					
<b>Estimated total net cost</b>					
<b>Net cost to PBS/RPBS/MBS</b>	■	■	■	■	■

<sup>a</sup> Assuming 13.04 per year as estimated by the submission. ABCRE = therapies include Avonex Rebif 44, Interferon beta-1b and Glatiramer acetate

Source: Table E.2-1, p 93 of the submission and E.4-1 Section E, p95 of the submission.

The redacted table shows that the estimated net cost to the PBS/MBS is less than \$10 million per year.

- 6.16 It is possible that the market share of peg(INF) treatment could be higher than predicted, if patients consider it to be more convenient in terms of dosing frequency. However, the impact is largely cost neutral.

## 7 PBAC Outcome

- 7.1 The PBAC recommended peginterferon beta-1a as an Authority Required listing for the treatment of multiple sclerosis on a cost-minimisation basis compared with interferon beta-1a.
- 7.2 The PBAC agreed that the equi-effective doses from the trials were peginterferon beta-1a 125 µg fortnightly to interferon beta-1a IM 30 µg once a week or interferon beta-1a SC 44 µg three times per week.
- 7.3 The PBAC accepted that interferon beta-1a was an appropriate comparator, noting that peginterferon beta-1a may also replace other therapies such as interferon beta-1b and glatiramer.
- 7.4 The PBAC noted that the basis of the clinical evidence was an indirect comparison between ADVANCE and BRAVO trials. The PBAC considered that the two trials could inform an indirect comparison, given similar placebo event rates in both trials.
- 7.5 The PBAC considered that the claim of non-inferior comparative effectiveness to interferon beta-1a was reasonable.
- 7.6 The PBAC considered that the claim of non- inferior comparative safety to interferon beta-1a was reasonable. The Committee noted however that longer term safety data beyond the 2 year evaluation is unknown, and that MS treatment can involve decades of treatment.
- 7.7 The PBAC considered the claim that listing of peginterferon beta-1a on the PBS will be cost neutral to the Commonwealth to be reasonable.
- 7.8 The PBAC noted that injectable MS drugs were also being considered as part of the first tranche of the Post Market Review of PBS Authorities (item 9.2 refers). The PBAC advised that any recommendation to amend these listings to Streamlined Authorities as part of its consideration of that Review would also apply to this listing.
- 7.9 The PBAC recommended that peginterferon beta-1a should be treated as interchangeable on an individual patient basis with interferon beta-1a according to Section 101(3BA) advice.
- 7.10 The PBAC advised that peginterferon beta-1a is not suitable for prescribing by nurse practitioners.
- 7.11 The PBAC recommended that the Safety Net 20 Day Rule should not apply.
- 7.12 The PBAC noted that this submission is not eligible for an Independent Review.

**Outcome:**

Recommended

**8 Recommended listing**

- 8.1 Add new item:

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<b>Episodicity:</b>	-
<b>Severity:</b>	-
<b>Condition:</b>	Multiple sclerosis
<b>PBS Indication:</b>	Multiple sclerosis
<b>Treatment phase:</b>	Initial
<b>Restriction Level/ Method:</b>	<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
<b>Clinical criteria:</b>	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  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years  AND  Patient must be ambulatory (without assistance or support)
<b>Prescriber Instructions</b>	Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

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<b>Administrative Advice</b>	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.
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<b>Severity:</b>	-
<b>Condition:</b>	Multiple sclerosis
<b>PBS Indication:</b>	Multiple sclerosis
<b>Treatment phase:</b>	Continuing
<b>Restriction Level/ Method:</b>	<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
<b>Clinical criteria:</b>	Patient must have previously been issued with an authority prescription for this drug  AND  Patient must not show continuing progression of disability while on treatment with this drug  AND  Patient must have demonstrated compliance with, and an ability to tolerate, this therapy
<b>Administrative Advice</b>	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

## 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**

Biogen Idec welcomes this outcome that will provide MS patients with an additional treatment option that offers the lowest dose frequency among injectable treatments, allowing patients to reduce their administration burden without having to sacrifice efficacy.