biogen idec

Post-market Review of Authority Required PBS Listings: Public Consultation

Submission from Biogen Idec (Australia) Pty Ltd regarding disease-modifying therapies for Multiple Sclerosis (first tranche of reviews)

Dear PBAC

Biogen Idec Australia Pty Ltd is pleased to provide input into the public consultation regarding the post-market review of Authority Required PBS listings- specifically with a focus on the review of disease-modifying therapies for relapsing-remitting multiple sclerosis.

As a manufacturer of therapies for people living with multiple sclerosis, our staff is committed to ensuring that Australians are able to access the medicines we provide, at the earliest possible opportunity. The Pharmaceutical Benefits Scheme does serve the needs of the MS community well, providing broad access to a range of therapies. Our products currently funded on the Pharmaceutical Benefits Scheme- Tysabri® (natalizumab), Tecfidera® (dimethyl fumarate), Avonex® (interferon beta-1a)- all serve the purpose of reducing the relapses associated with multiple sclerosis, and delaying the progression of disability. These products sit alongside a number of other disease-modifying therapies that also serve to benefit the MS community. In the main, all of these products are well-characterised and have similar criteria for prescribing, as well as providing expectations for doctors and people living with MS that a reduction in relapses and a delay in disease progression are possible through therapy.

Biogen Idec would welcome the broadening from the current Authority Required criteria to an Authority Required (Streamlined) criteria for all current disease-modifying therapies for multiple sclerosis, and to allow future listings of disease-modifying therapies to be immediately listed on a similar basis following recommendation by the PBAC. In March 2014, the PBAC recommended both Avonex® (interferon beta-1a) and Tysabri ® (natalizumab [Section 100HSD Private]) for Authority Required [Streamlined], but further recommended that the Department review the administrative requirements for all PBS-listed treatments for RRMS in a consolidated fashion, as it would be problematic to amend some listings before others had been considered for Streamlining. The actions being taken in this Post Market Review will provide the mechanism for that consolidated review, in the first tranche of therapies to be considered at the November 2014 PBAC meeting.

The recommendation of an Authority Required (Streamlined) listing for all disease-modifying therapies for RRMS presents a very beneficial opportunity to reduce a considerable administrative burden for DHS, a clear benefit to patients and doctors in terms of the value of the consultation, and a clear and consistent approach across MS therapies for neurologists. It will also provide consistency to the current recommendations by the PBAC for Avonex and Tysabri, and would allow all products to join the only current Streamlined listing- Tysabri Section 100HSD Public- as items with a lower administrative burden to prescribe.

Please find attached our submission for the review. Many thanks for your consideration.

Yours sincerely

Sean Lybrand
Head, Market Access

Post-market Review of Authority Required PBS Listings: Public Consultation

Scope of the current Review

This Review will consider criteria to determine Authority Required listings, and review all Authority Required listings with the objective of reducing the administrative burden on prescribers and dispensers of PBS listed medicines. The Authority Required listings will be identified and reviewed in groups targeting those that create the greatest regulatory burden.

Disease modifying therapies (DMTs) for multiple sclerosis are to be considered in the first tranche of items, along with other therapeutic areas that represent the greatest regulatory burden. The criteria for review of the DMTs are the same as that for all products under consideration for eligibility to be moved to Authority Required (Streamlined) items; that is:

Criteria for review of DMTs:

1. *Review the criteria used by the PBAC to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS including the advantages and disadvantages of an Authority Required or Authority Required (Streamlined) listing.*

2. *Systematically review the current Authority Required listings according to the proposed criteria to ensure this is applied consistently to all PBS Authority listed medicines.*

3. *Use the review to explore how to best use available secondary health data sources to provide information on the utilisation of Authority Required and/or Authority Required (Streamlined) PBS items.*

Biogen Idec welcomes the opportunity to provide commentary in a broad manner regarding the eligibility of DMTs for movement to Authority Required (Streamlined) criteria, and believe the MS community (incorporating both prescribing doctors and people living with MS) would be best served by the PBAC recommending that Authority Required (Streamlined) criteria be allowed for all current DMTs, and to also recommend that future reimbursement submissions for disease-modifying therapies be listed on a similar basis.

Summary of Streamlined Authority history, and actions related to medicines for multiple sclerosis

As part of a package of reforms to the Pharmaceutical Benefits Scheme (PBS) announced by the Commonwealth Minister for Health and Ageing in November 2006, a new streamlined authority process was instituted from 1 July 2007 for almost half of the medicines then listed as Authority Required. The aim of introducing a Streamlined Authority was to reduce the administrative burden for prescribers (and by proxy, for the teams responsible for the administration of the Authority line). The Review noted "*no substantial changes relative to historical growth trends observed in either total script volume or total PBS outlays for streamlined authority medicines for the first year of operation*" (p2).

A number of previous submissions or actions have been taken with respect to the disease-modifying therapies for multiple sclerosis. A summary of those actions is described in the points below.

Avonex (interferon beta-1a): July 2011 PBAC meeting

Biogen Idec originally sought an Authority (Streamlined) recommendation as a minor submission at the July 2011 PBAC meeting. The submission was rejected at that time on the following basis:

- The PBAC believed that relapsing-remitting multiple sclerosis (RRMS) is not a chronic and stable long-term condition
- The PBAC considered that there would be potential for use outside of the restriction criteria

Tysabri (natalizumab) (S100 HSD Public)- 2010

The restriction for Tysabri in public hospitals was changed to an Authority Required (Streamlined) listing in 2010, as a result of a departmental review of Authority required listings. The purpose of that review was to reduce the administrative burden on public hospitals. This change was not precipitated by a submission from Biogen Idec Australia Pty Ltd, but rather a Departmental initiative.

Avonex (interferon beta-1a) and Tysabri (natalizumab) (S100 HSD Private)- March 2014 PBAC meeting

Biogen Idec sought a new review of the circumstances in favour of an Authority (Streamlined) recommendation at the March 2014 PBAC meeting for both Avonex and Tysabri (Private). At this meeting, the PBAC decided to recommend a change to the circumstances under which interferon beta-1a and natalizumab are made available as pharmaceutical benefits.

In summarising the recommendation for Avonex and Tysabri at the March 2014 meeting, the PBAC accepted that:

- RRMS is a chronic and stable long-term condition;
- Interferon beta-1a and natalizumab have a stable dosage regime in RRMS;
- Interferon beta-1a and natalizumab are not susceptible to misuse;
- PBS expenditure is unlikely to be jeopardised with streamlining with either product;
- Patient safety is unlikely to be jeopardised with streamlining for either product; and
- Patients are unlikely to continue with treatment with either agent if they do not respond to therapy, as new oral agents have since become listed on the PBS for RRMS

However, the PBAC recommended that the Department review the administrative requirements for all PBS listed treatments for RRMS in a consolidated fashion, rather than considering the individual listings in a piecemeal approach. The PBAC considered that it would be problematic for any one listing to be amended before other RRMS listings had been reviewed for suitability for Streamlining. The position of the PBAC is reflected in the current review of the DMTs in the first tranche of items to be reviewed for at the November 2014 PBAC meeting.

Biogen Idec recommendations for the Post Market Review of Authority Required PBS Listings

Given the positive recommendation for Avonex and Tysabri, Biogen Idec considers it appropriate to amend the PBS listings for all MS therapies to become Authority Required (Streamlined) listings. It is important to note that all other DMTs temporally fit the model established by the PBAC when considering their recommendation for Avonex and Tysabri, and there is little reason to suggest that any aspect of the physician/ patient interaction would be compromised by a universal Authority Required (Streamlined) recommendation being made for all of the DMTs. There are important

benefits to allowing for a universal Authority Required (Streamlined) recommendation to be made.

This submission makes the following arguments in favour of a Streamlined Authority listing being applied broadly for all current DMTs for RRMS, and to be allowable for new DMT listings in the future:

- This proposed change from Authority Required to Authority Required (Streamlined) for all disease-modifying MS therapies will present a beneficial opportunity to reduce a considerable administrative burden for the DHS, a clear benefit to patients and doctors in terms of the value of the consultation, and a clear and consistent approach across MS therapies for neurologists.
- It would provide a considerably improved encounter for the patient and the doctor, by reducing the amount of time taken to wait for the Authority line to answer the call and address the Authority criteria
- It would provide a dramatic reduction in the number of calls taken by the Authority line for DMTs- if 14,000 patients are currently on therapy with DMTs, with two calls being needed per year at the minimum (renewal of script), and further calls needing to be made either for patients switching medication or other reasons, then there may be 28,000-32,000 calls being made for DMTs alone.
- If each call takes an average of 5 minutes, then over 2330 hours of operator time could be avoided, and over 2330 hours of patient consultations could be better spent talking about treatments and patient outcomes.
- The overall Authority process could be made equitable across all DMTs, will provide consistency with the sole current Streamlined listing for Tysabri (PUBLIC), and will be consistent with the recommendations made by the PBAC in March 2014 for the move to Streamlined Authority listings for Avonex and Tysabri.
- There is no further question of favouring one commercial product over another if the Authority Required (Streamlined) recommendation is made simultaneously
- As accepted by the PBAC in March 2014, RRMS is a chronic and stable long-term condition. This applies equally to all patients who receive therapy with any of the listed DMTs for relapsing-remitting multiple sclerosis, as the restrictions require that only stable patients are permitted to remain on therapy.
- Tysabri has had an Authority Required (Streamlined) listing for public hospitals since 2010. This change was made to reduce the administrative burden on public hospitals. An identical change can be made for the current prescribing of DMTs outside of the public hospital system to reduce the administrative burden on private practitioners.
- The recommendation for amending the listings of Avonex and Tysabri to Authority Required (Streamlined) items at the March 2014 PBAC meeting establishes a precedent for all other DMTs, given the claims that were accepted for Avonex and Tysabri are identical for all other DMTs. Given this fact, it is appropriate to consider the eligibility of all other DMTs against the criteria that the PBAC adjudicated against listed for both Avonex and Tysabri. **Table 1** establishes the relevance of each question against each product available for RRMS.

- While usage of injectable DMTs are clearly decreasing with the introduction of new oral treatments to the PBS, and usage of Tysabri (natalizumab) has plateaued in recent years despite amending the PBS listing for public hospitals to Authority Required (Streamlined), a concomitant increase in usage of the oral agents for MS (Tecfidera, Gilenya, Aubagio) is evident. However, the increase in prescribing of oral DMTs occurs at the expense of a reduction in usage of injectable DMTs. Overall, the market has demonstrated steady growth year on year, despite the introduction of the oral agents. As can be seen from IMS Pharmacy Dispensing data for all MS DMTs in **Figure 1**, annual growth in this therapeutic area has returned to the approximate level before the first oral DMT, Gilenya® (fingolimod), was PBS listed. Note, that the decline at the beginning of 2011 and end of 2013 is assumed to be due to patients being enrolled in the Gilenya (fingolimod) and Tecfidera (dimethyl fumarate) Product Familiarisation Programs (PFP), respectively. This was considered a reasonable explanation for the dip in growth prior to the market entry of fingolimod in the DUSC Review of MS Therapies (*June 2013 DUSC meeting, p4/7 Sponsor's copy of Minutes extract, 13 August 2013*).

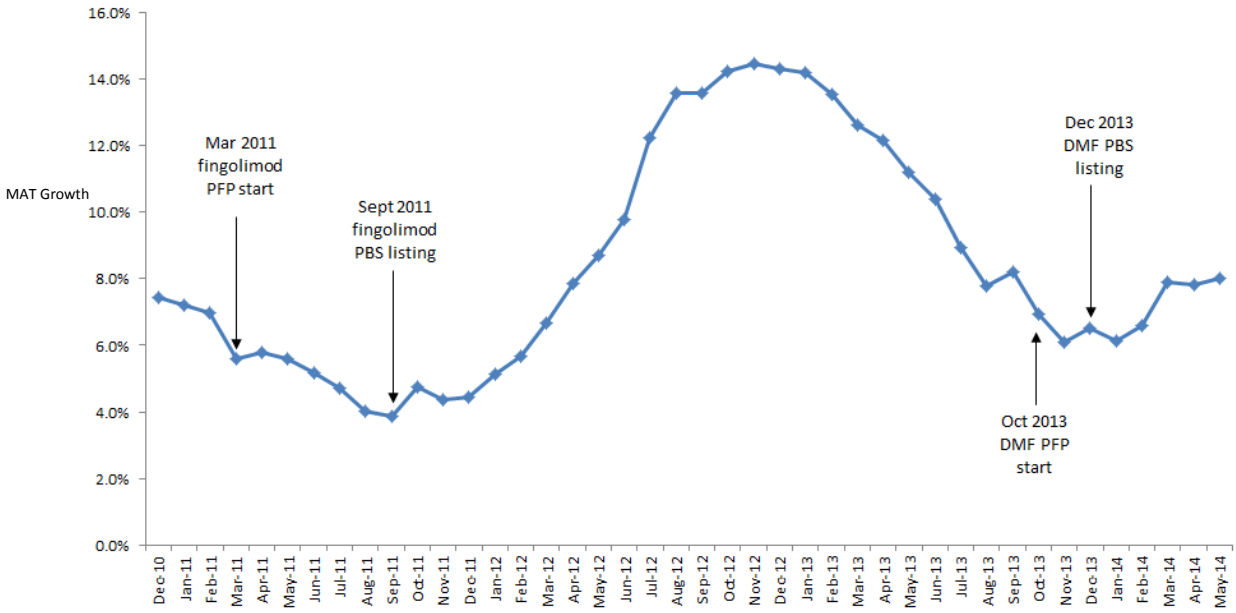

Figure 1: IMS Pharmacy Dispensing data for all MS DMTs, December 2010 – May 2014

Table 1: Summary of remaining DMTs against the PBAC criteria used for recommendation of an Authority Required (Streamlined) listing for Avonex and Tysabri, March 2014 PBAC meeting

	Avonex	Tysabri	Aubagio	Betaferon Extavia	Copaxone	Gilenya	Rebif	Tecfidera	Lemtrada*
	(March 2014 PBAC)		Correlation with March 2014 PBAC recommendations for Avonex + Tysabri						
Does the product treat RRMS?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Does the product have a stable dosage regime?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Is the product susceptible to misuse?	N	N	N	N	N	N	N	N	N
Would PBS expenditure be jeopardised with streamlining?	N	N	N	N	N	N	N	N	N
Would patient safety be jeopardised with streamlining?	N	N	N	N	N	N	N	N	N
Would patients continue with treatment if they do not respond to therapy?	N	N	N	N	N	N	N	N	N

* Recommended by PBAC July 2014; not yet listed on Pharmaceutical Benefits Scheme