

**POST-MARKET REVIEW OF
AUTHORITY REQUIRED PHARMACEUTICAL
BENEFITS SCHEME LISTINGS**

Submission to Request
Streamlined Authority Arrangements

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Introduction

Bayer Australia Ltd (herein Bayer) understands that the main objective of the review is to improve patient safety and care by reducing red tape and administrative burden for health professionals¹. As such, Bayer supports this initiative and appreciates the opportunity to provide comments related to specific products.

Three medicines are addressed within this submission, namely interferon beta-1b, iloprost and aflibercept. These medicines correspond to four PBS item codes, and fall into three separate tranches of the review, as shown in Table 1. Bayer requests that these four Authority Required listings be considered for movement to Authority Required (Streamlined) listings. Supporting rationale for each medicine is provided below. Bayer understands that the PBAC will consider the full list of Authority Required items over the next three meetings.

Table 1 Medicines addressed

Medicine	Review	Item Code	Schedule
Interferon beta-1b	Tranche 1	8101J	General (Section 85)
Iloprost	Tranche 2	5751Q	Highly Specialised Drugs (Section 100) –Public
		6456T	Highly Specialised Drugs (Section 100) –Private
Aflibercept	Tranche 3	2168D	General (Section 85)

Source: Schedule of Pharmaceutical Benefits October 2014; <http://www.pbs.gov.au/info/reviews/authority-required-medicines-public-consultation> accessed 03-Oct-2014.

Bayer understands that there may be several reasons for a medicine or medicinal form to be considered for restricted benefit or authority required status as noted in the PBAC Guidelines², however the importance of monitoring specific items may diminish over time. Bayer supports the quality use of medicines and believes that Authority Required (Streamlined) listings provide a preferred solution where monitoring of drug use is required, but with reduced administrative burden.

In addition to the request for consideration of specific Authority Required (Streamlined) listings, Bayer requests that the review consider other aspects related to the efficiency of the current process for all PBS Authority Required listings. For example, if prior approval is still required, Bayer requests greater use of technology, such as an online approval system, particularly for listings with complex requirements. This could save considerable prescriber time through alleviation of the time spent on the telephone. An online approval system would also allow considerably faster approvals, because the time lag due to documentation in the mail would be eliminated. A further benefit is that it would provide an equitable service throughout Australia, whereas the current system disadvantages prescribers in Western Australia due to differing time zones. A further advantage of an online system is that records would be retained electronically, and this may save time and resources associated with filing of paper records within the medical practice.

¹ Department of Health (2014). Post-market Review of Authority Required PBS Listings. <http://www.pbs.gov.au/info/reviews/authority-required-listings> accessed 03-Oct-2014.

² PBAC (2013). Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.4). <http://www.pbac.pbs.gov.au/content/information/printable-files/pbacg-book.pdf> accessed 03-Oct-2014.

Interferon beta-1b

Interferon beta-1b (BETAFERON[®]) is PBS listed for the treatment of patients with clinically definite relapsing-remitting multiple sclerosis. Separate restriction criteria apply for initial treatment and continuing treatment as noted in Table 2.

Table 2 Summary of PBS item code 8101J (interferon beta-1b)

Item	Schedule	Drug	Form	Overview of Restriction	Review
8101J	General (Section 85)	Interferon beta-1b	Injection set including 1 vial powder for injection 8,000,000 I.U. (250 micrograms) and solvent	For the treatment of patients with clinically definite relapsing-remitting multiple sclerosis, meeting PBS authority requirements for: <ul style="list-style-type: none"> • Initial treatment; or • Continuing treatment. 	Tranche 1

Source: Schedule of Pharmaceutical Benefits October 2014; <http://www.pbs.gov.au/info/reviews/authority-required-medicines-public-consultation> accessed 03-Oct-2014.

A copy of the PBS restriction text is provided in Text Box 1.

Text Box 1 PBS restriction text corresponding to Item Code 8101J (interferon beta-1b)

INTERFERON BETA-1B

Authority required

Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule

Authority required

Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule

Source: Schedule of Pharmaceutical Benefits October 2014; <http://www.pbs.gov.au/info/reviews/authority-required-medicines-public-consultation> accessed 03-Oct-2014.

Request

Bayer requests that Item 8101J (interferon beta-1b) be considered for movement to an Authority Required (Streamlined) listing on the basis that it is a well-established medicine, and has been PBS listed since November 1996. Further, since the product is administered by injection, it is not likely to be over-used.

The streamlining of the listing would simplify the process of prescribing interferon beta-1b for the treatment of patients with clinically definite relapsing-remitting multiple sclerosis, and reduce the administration involved. At the same time, adherence to PBS requirements would still be maintained through the existing procedure for streamlined authority codes, which involves prescriber review of the restriction and recording of the appropriate four digit streamlined authority code on the authority prescription form.

Iloprost

Iloprost (VENTAVIS[®]) is PBS listed for the treatment of patients with pulmonary arterial hypertension (PAH). Separate restriction criteria apply for initial treatment and continuing treatment as noted in Table 3. The restrictions for use of iloprost, are complex, as are those of the other PAH agents³, which each span several pages of the printed PBS schedule.

Table 3 Summary of PBS item code 5751Q and 6456T (Iloprost)

Item	Schedule	Drug	Form	Overview of Restriction	Review
5751Q	Highly Specialised Drugs (Section 100) – Public	Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	For the treatment of patients with pulmonary arterial hypertension (PAH) meeting PBS authority requirements ^a for: <ul style="list-style-type: none"> • Initial treatment 1; or • Initial treatment 2; or • Initial treatment 3; or • Continuing treatment 	Tranche 2
6456T	Highly Specialised Drugs (Section 100) – Private				

- a. To gain approval for PBS subsidised treatment, the treating physician is required to submit the corresponding supporting information form (either PAH initial authority application PB070.140905 (formerly 4138) or PAH continuing authority application PB071.1409 (formerly 4146)).

Source: Schedule of Pharmaceutical Benefits October 2014; <http://www.pbs.gov.au/info/reviews/authority-required-medicines-public-consultation> accessed 03-Oct-2014.

Request

Bayer requests that Items 5751Q and 6456T (Iloprost) be considered for movement to an Authority Required (Streamlined) listing on the basis that the treatment of patients with PAH is extremely specialised, and as such, the PBS prescribing of PAH agents is strictly limited to expert physicians from approved designated centres. Further, since the product is administered by nebuliser, it is not likely to be over-used.

The streamlining of the listings would simplify the process of prescribing iloprost in accordance with the PBS restriction criteria. Confirmation of eligibility for PBS subsidised treatment would still be maintained through the existing procedure for streamlined authority codes, which involves prescriber review of the restriction and recording of the appropriate four digit streamlined authority code on the authority prescription form. Further, appropriate record keeping could be maintained at each prescriber's office following the existing procedure for streamlined authority codes, which requires the prescriber to store the prescriber's copy of the Authority PBS/RPBS Prescription Form for 12 months, recording data such as daily dose, details of the disease, clinical justification for using the item and whether the patient has previously received an authority for this pharmaceutical benefit. A modified version of the existing supporting information forms could be used to ensure that the required information to assess eligibility is recorded and stored by prescribers.

³ The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan (Schedule of Pharmaceutical Benefits October 2014).

Aflibercept

Aflibercept (EYLEA[®]) is an ophthalmic solution administered by intravitreal injection, and is PBS listed for the treatment of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD). Separate restriction criteria apply for initial treatment and continuing treatment as noted in Table 4.

Table 4 Summary of PBS item code 2168D (aflibercept)

Item	Schedule	Drug	Form	Overview of Restriction	Review
2168D	General (Section 85)	Aflibercept	Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL)	For the treatment of patients with subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), meeting PBS authority requirements for: <ul style="list-style-type: none"> • Initial treatment^a; or • Continuing treatment 	Tranche 3

- a. To gain approval for initial PBS subsidised treatment, the treating ophthalmologist is required to submit the Subfoveal choroidal neovascularisation initial PBS authority application supporting information PB072.1409 (formerly 4187).

Source: Schedule of Pharmaceutical Benefits October 2014; <http://www.pbs.gov.au/info/reviews/authority-required-medicines-public-consultation> accessed 03-Oct-2014.

Request

Bayer requests that Item 2168D (aflibercept) be considered for movement to an Authority Required (Streamlined) listing on the basis of clinical benefits associated with timely access to PBS treatment, equity reasons associated with providing access to PBS treatment across Australia, as well as efficiency benefits associated with reduce administrative burden. The obligation and accountability for ensuring PBS eligibility is essentially unchanged since the prescriber is responsible for the diagnostic tests and clinical decisions that determine eligibility, both under the current situation and under a streamlined listing.

Clinical benefits

The wet form of age-related macular degeneration (wAMD) makes up only 10% of all cases of AMD, however is responsible for 90% of all severe vision loss in those affected by it. It is characterised by the development of new blood vessels under the retina (the light sensitive tissue at the back of the eye responsible for vision) that are fragile and leak blood and fluid thus causing irreparable damage to the retina. If not treated early and timely a patient can lose vision in as little as 3 months following the presentation of first wAMD symptoms. Early detection, diagnosis and treatment of wAMD are vital in slowing down the vision loss in these patients. Many clinical studies (MARINA, ANCHOR, VIEW 1&2, PIER) demonstrated that with early detection and proactive treatment these patients can not only maintain their vision but also can obtain vision improvement of 3 lines or more on the vision chart.

The importance of timely treatment initiation is acknowledged in the supporting information form, which states for emergency treatments only: *“To avoid delay in starting treatment, the initial application, angiogram report and a copy of the prescription can be faxed to the Australian Government Department of Human Services on 1300 093 177”*. Similarly, the PBS restriction text indicates that the first authority application may be faxed to the DHS, however earlier this year prescribers were informed that faxes would no longer be routinely accepted, thereby delaying treatment initiation due to the time associated with movement of paper applications from each prescriber around Australia to the DHS in Tasmania. The supporting information form, refers to use of fax for “emergency treatments”, however for the

treatment of wAMD every patient meeting PBS eligibility criteria is at risk of developing blindness, and therefore Bayer considers that all approvals for treatment initiation should be processed with urgency.

Efficiency

The streamlining of the listing would simplify the process of prescribing aflibercept for the treatment of patients with AMD and reduce administrative burden for prescribers.

Streamlining could also produce additional cost savings for government, patients and their carers. If the patient was able to commence PBS treatment on the same day as diagnosis, this would mean that a second visit for the injection would not be required, thereby saving costs associated with the second medical consultation, patient out-of-pocket costs, as well as any travel-related costs and costs associated with a carer accompanying the patient.

PBS prescribing of aflibercept is limited to ophthalmologists and since aflibercept is administered by intravitreal injection, it is not likely to be over-used. Confirmation of eligibility for PBS subsidised treatment would still be maintained through the existing procedure for streamlined authority codes, which involves prescriber review of the restriction and recording of the appropriate four digit streamlined authority code on the authority prescription form. Further, appropriate record keeping could be maintained at each prescriber's office following the existing procedure for streamlined authority codes, which requires the prescriber to store the prescriber's copy of the Authority PBS/RPBS Prescription Form for 12 months, recording key information including details of the disease and clinical justification for using the item. A modified version of the existing supporting information form could be used to ensure that the required information to assess eligibility is recorded.

Given the ongoing nature of treatment, this could lead to a significant reduction in administrative burden for both prescribers and the Australian Government over time. Other options to reduce burden associated with ongoing approvals for continuing treatment could include permission to increase the number of repeats allowed for appropriate patients.

Equity

Adoption of a streamlined listing would help to minimise differences in access to aflibercept across the country. The current system relying on written applications means that initial treatment is delayed while papers are in transit. This transit time is likely to vary across Australia, based on the distance involved, and the frequency of mail services in the prescriber's location, with those in regional locations likely to experience more delay in initial treatment as compared with those in metropolitan areas. In addition, regional patients may be further disadvantaged by delays, since they may be required to travel significant distances from home to visit the ophthalmologist, thereby requiring considerable cost and effort to attend a second visit to commence treatment. A second visit may also be particularly burdensome for the wAMD patient population, given advanced age and vision impairment. Since the current system relies on telephone contact between the prescriber and the DHS, this is limited to 8.00 am to 5.00 pm Monday to Friday, Australian EST and may disadvantage those in W.A. due to time zone differences.

Conclusion

In summary, Bayer supports the introduction of an Authority Required (Streamlined) listing for aflibercept (EYLEA®). A streamlined listing would assist eligible patients to access PBS treatment in a timely manner and reduce the administrative burden associated with the current Authority Required listing.