6.08 AFLIBERCEPT
4 mg/0.1 mL injection, 1 x 0.1 mL vial, 4 mg/0.1 mL injection, 1 x 0.09 mL syringe;
Eylea®; Bayer Australia Ltd

1 Purpose of Application

1.1 The minor submission requested PBAC advise the Minister that aflibercept pre-filled syringe and vial presentations be 'a' flagged for the treatment of wet age-related macular degeneration (AMD), central retinal vein occlusion (CRVO), and diabetic macular oedema (DME).

2 Requested listing

2.1 The submission proposed to maintain the current existing General Schedule listing of aflibercept injection for the vial and, when listed, the pre-filled syringe presentations with an added 'a' flag between the two formulations to enable pharmacists to substitute presentations without reference to the prescriber.

3 Background

3.1 At the March 2012 meeting, the PBAC recommended listing aflibercept vial and pre-filled syringe on the PBS as an Authority Required benefit for treatment of subfoveal choroidal neovascularisation (CNV) due to age related macular degeneration (AMD). At the time of listing, [redacted] only the vial was listed.

3.2 At the November 2014 PBAC meeting, aflibercept vial and pre-filled syringe were recommended under Section 85 to extend the listing to include patients with DME and CRVO. The PBAC considered that authority applications through the PBS and Specialised Drugs Branch of the Department of Human Services would be appropriate for aflibercept, similar to administrative arrangements for ranibizumab and aflibercept in AMD.

4 Current situation

4.1 Vial
Aflibercept vial contains 100µL of extractable volume to ensure a single 50µL injectable dose containing 2mg of aflibercept is delivered.

4.2 Pre-filled syringe (PFS)
Aflibercept PFS is supplied in a glass 1mL syringe. The target fill volume for each syringe is 90µL of extractable volume. The PFS can deliver a single 50µL injectable dose containing 2mg of aflibercept.

4.3 While the extractable volume for the vial differs slightly for the PFS, both the vial and PFS provides a usable amount to deliver a single dose of 50µL. It must only be administered by an ophthalmologist experienced in administering intravitreal injections.

4.4 The Sponsor proposed that 'a' flagging of the two presentations will provide greater flexibility in supply of aflibercept upon launching of the pre-filled syringe in order to ensure continuity of treatment in the event that demand for either vial or pre-filled syringe exceeds the forecast volume.

4.5 The Sponsor requested that the same Special Pricing Arrangements apply for both forms of aflibercept.

4.6 Consistent with existing practices, the prescriber can choose to mark the prescription with "Substitution not permitted" if they have a strict preference for either the vial or pre-filled syringe.

5 Consideration of evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

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

Clinical trials

5.3 As a minor submission, no new clinical evidence was presented.

Estimated PBS usage & financial implications

5.4 The minor submission estimated no incremental cost to the PBS or the government if an 'a' flag was to be applied. The submission indicated there was no change in price.

5.5 The minor submission stated that the pre-filled syringe should not be treated as a generic competitor of the vial and therefore a price reduction cannot be applied in this case. The PBAC noted that the applicability of a statutory price reduction under Section 99 ACB of the National Health Act is a matter for the Minister and Department.

6 PBAC Outcome

6.1 The PBAC advised the Minister that aflibercept vial could be considered equivalent for the purposes of substitution at the point of dispensing ('a' flagged in the schedule) with aflibercept pre-filled syringe at the commencement of listing of the pre-filled syringe for all recommended indications. The PBAC noted that a smaller amount of drug is presented in a pre-filled syringe compared to a vial.

Outcome:
Recommended

7 Recommended listing

7.1 Amend listing as follows:

Add NOTE to PBS Item 2168D and to PBS restrictions for macular oedema secondary to central retinal vein occlusion (CRVO) and diabetic macular oedema (DME) recommended by the PBAC in November 2014 PBAC meeting as follows:

Note
Pharmaceutical benefits that have the form aflibercept 0.1mL injection vial and pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe are equivalent for the purposes of substitution.

8 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.

9 Sponsor's Comment

The Sponsor had no comment.