# 5.16 AFLIBERCEPT

## Solution for intravitreal injection 6.6 mg in 165 microlitres (40mg per mL) pre-filled syringe
## Solution for intravitreal injection 11.32 mg in 283 microlitres (40 mg per mL),
## Eydenzelt®,
## Celltrion Healthcare Australia Pty Ltd

## 1 Purpose of Submission

1.1 The Category 3 submission requested to add four new indications to the existing PBAC recommendation for aflibercept (Eydenzelt®) 2 mg/0.05 mL vial (vial) and pre-filled syringe (PFS) for intravitreal injection for the treatment of:

- Subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD)
- Diabetic macular oedema (DMO)
- Branch retinal vein occlusion (BRVO) with macular oedema (MO)
- Central retinal vein occlusion (CRVO) with macular oedema (MO)

1.2 Listing for Eydenzelt was requested on a cost-minimisation basis under the same conditions as the reference biologic Eylea®.

## 2 Background

2.1 At the November 2025 PBAC meeting, Eydenzelt 2 mg/0.05 mL injection, 0.05 mL PFS and vial were recommended for the treatment of subfoveal CNV due to pathologic myopia (PM).

### *Registration status*

2.2 Aflibercept (Eydenzelt) was Therapeutic Goods Administration (TGA) registered on 31 March 2025 for "visual impairment due to myopic choroidal neovascularisation (myopic CNV)".

2.3 A positive Delegate's Overview (DO) was provided on 5 January 2026. The TGA DO determined Eydenzelt 2 mg to be bioequivalent to the reference biologic Eylea 2 mg. On 19 May 2026 the TGA approved registration for the following additional indications:

- Neovascular (wet) age-related macular degeneration (wet AMD)

- Visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)
- Visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO)
- Diabetic macular oedema (DMO)

2.4 Eylea was TGA registered on 7 March 2012.

2.5 Afqlir® and Enzeevu® were TGA registered on 27 May 2025 and were determined to be biosimilars to the reference brand, Eylea.

## *Previous PBAC recommendations*

2.6 The PBAC has previously considered aflibercept originator Eylea, and three subsequent generic brands Afqlir®, Enzeevu® and Eydenzelt. A summary of previous PBAC recommendations is outlined in Table 1.

**Table 1: Previous PBAC recommendations**

| PBAC meeting | CNV due to AMD | DMO | CRVO with MO | BRVO with MO | CNV due to PM | Neovascular AMD |
|---|---|---|---|---|---|---|
| March 2012 | Eylea 4mg/0.1mL | | | | | |
| November 2014 | | Eylea 4mg/0.1mL | Eylea 4mg/0.1mL | | | |
| November 2015 | | | | Eylea 4mg/0.1mL | | |
| July 2019 | | | | | Eylea 4mg/0.1mL | |
| May 2024 | | Eylea 8mg/0.07mL | | | | Eylea 8mg/0.07mL |
| November 2024 | Eylea 8mg/0.07mL | Eylea 8mg/0.07mL | | | | |
| July 2025 | Afqlir & Enzeevu 4mg/0.1mL | Afqlir & Enzeevu 4mg/0.1mL | Afqlir & Enzeevu 4mg/0.1mL | Afqlir & Enzeevu 4mg/0.1mL | Afqlir & Enzeevu 4mg/0.1mL | |
| November 2025 | | | | | Eydenzelt 4mg/0.1mL | |

## *Current listings - originator and subsequent brands*

2.7 Aflibercept 2 mg/0.05 mL PFS (Eylea and Afqlir) and 2 mg/0.05 mL vial (Eylea) are currently listed for the treatment of:

- Subfoveal CNV due to AMD
- Subfoveal CNV due to PM
- DMO
- BRVO with MO
- CRVO with MO

2.8 Aflibercept 8 mg/0.07 mL PFS (Eylea) is currently listed for the treatment of:

- Subfoveal CNV due to AMD
- DMO

2.9 The PBAC noted that although the AMT preferred terms of '2 mg/0.05 mL' are aligned and reference the usable amount across the brands Eylea, Afqlir and Eydenzelt, the extractable volume is different. As a result, each brand and form require separate PBS items because they are different pharmaceutical items on the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*. All 2 mg/0.05 mL forms and brands of aflibercept are 'a flagged' across their individual item codes for each indication.

# 3 Requested listing

3.1 The submission requested listing Eydenzelt under the same circumstances as Eylea for the treatment of subfoveal CNV due to AMD, DMO, BRVO with MO and CRVO with MO. As the submission requested the same restrictions as the reference brand Eylea, the full restrictions have not been reproduced here.

3.2 The submission requested that the four additional indications for Eydenzelt 2 mg/0.05 mL be considered equivalent ('a' flagged) to Eylea and Afqlir 2 mg/0.05 mL for the purpose of substitution.

3.3 The submission requested that listings for Eydenzelt be consistent with the biosimilar uptake driver policy. The Secretariat drafted administrative advice reflecting the biosimilar uptake policy (i.e. encouraging biosimilar prescribing for treatment-naïve patients). The PBAC noted that lowering the Authority Required level for Eydenzelt for the continuing treatment (second biosimilar uptake driver) will not apply as the existing PBS listings of Aflibercept for the requested indications (including the reference biologic) are already Streamlined Authority Required for the continuing treatment phase restrictions.

# 4 Consideration of the evidence

## *Sponsor hearing*

4.1 There was no hearing for this item.

## *Consumer inputs*

4.2 The PBAC noted that no consumer inputs were received for this item.

## *Clinical trials*

4.3 This submission provided the same clinical data that the PBAC reviewed in their November 2025 consideration of Eydenzelt. The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of Eydenzelt compared with Eylea.

4.4 The TGA DO determined Eydenzelt to be bioequivalent to Eylea.

4.5 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.

4.6 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

4.7 The PBAC considered the equi-effective dose to be 1 mg Eydenzelt = 1 mg Eylea.

# 5 Estimated PBS usage and financial implications

5.1 Listing of biosimilar brands does not change overall utilisation of the drug.

5.2 Eydenzelt is expected to substitute for Eylea and, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

# 6 PBAC Outcome

6.1 The PBAC was in favour of extending the existing recommendation of aflibercept (Eydenzelt) 2 mg/0.05 mL vial (vial) and pre-filled syringe (PFS) for intravitreal injection. The PBAC recommended the addition of four treatment indications under the same conditions as the reference biologic aflibercept (Eylea);

- Subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD)
- Diabetic macular oedema (DMO)
- Branch retinal vein occlusion (BRVO) with macular oedema (MO)
- Central retinal vein occlusion (CRVO) with macular oedema (MO)

6.2 The PBAC considered the nominated comparator of Eylea was appropriate and noted the opinion of the TGA that Eydenzelt is a biosimilar medicine to Eylea.

6.3 The PBAC advised the equi-effective dose to be 1 mg Eydenzelt = 1 mg Eylea and all other biosimilar brands of aflibercept.

6.4 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable. The PBAC considered that the claim of non-inferior comparative safety was reasonable.

6.5 The PBAC considered that the listing of Eydenzelt would not result in a net cost to the PBS as it would likely substitute for Eylea and not increase the overall market utilisation.

6.6 The PBAC advised, under Section 101 (4AACD) of the *National Health Act*, that aflibercept (Eydenzelt), aflibercept (Eylea) and aflibercept (Afqlir) should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule with a NOTE stating PBS of one form and PBS of another form are equivalent for the purposes of substitution).

6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because aflibercept (Eydenzelt) is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over

aflibercept (Eylea), and not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

6.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**
Recommended

# 7 Recommended listing

7.1 As the PBAC recommended the same restrictions as the reference brand Eylea, the full restrictions for Eydenzelt have not been reproduced here. Additions are in italics and deletions are in strikethrough.

*Add new listings as follows:*

**Subfoveal CNV due to AMD initial treatment:**

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 2 | Eydenzelt |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 2 | Eydenzelt |

| | |
|---|---|
| **Restriction Summary / Treatment of Concept** | |
| | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) |
| | **Prescriber type:** ☒ Medical Practitioners |
| | **Restriction type:** ☒ Authority Required (Streamlined) [new code] |
| | **Indication:** Subfoveal choroidal neovascularisation (CNV) |
| | **Treatment Phase:** Initial treatment |
| Prescribing rule | ***Administrative Advice:***<br>***Biosimilar prescribing policy***<br>*Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.* |
| | ***Administrative Advice***<br>*Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).* |
| | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| | ~~**Administrative Advice:**~~ |

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|---|---|---|
| | | ~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

**Subfoveal CNV due to AMD continuing treatment:**

| **MEDICINAL PRODUCT medicinal product pack** | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 2 | Eydenzelt |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 2 | Eydenzelt |

| | | |
|---|---|---|
| **Restriction Summary / Treatment of Concept** | | |
| | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) | |
| | **Prescriber type:** ☒ Medical Practitioners | |
| | **Restriction type:** ☒ Authority Required (Streamlined) [new code] | |
| | | |
| | **Indication:** Subfoveal choroidal neovascularisation (CNV) | |
| | **Treatment Phase:** Continuing treatment | |
| Prescribing rule | | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| | | ~~**Administrative Advice:**~~<br>~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

**DMO initial treatment:**

| **MEDICINAL PRODUCT medicinal product pack** | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 5 | Eydenzelt[a] |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 5 | Eydenzelt[a] |

| | | |
|---|---|---|
| **Restriction Summary / Treatment of Concept:** | | |
| | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) | |
| | **Prescriber type:** ☒ Medical Practitioners | |
| | **Restriction type:** ☒ Authority Required (Streamlined) [new code] | |
| | | |
| | **Indication:** Diabetic macular oedema (DMO) | |
| | **Treatment Phase:** Initial treatment | |
| Prescribing rule | | ***Administrative Advice:***<br>***Biosimilar prescribing policy***<br>*Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.* |
| | | ***Administrative Advice*** |

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|---|---|---|
| | | *Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).* |
| | | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| | | ~~**Administrative Advice:**~~<br>~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

## DMO continuing treatment:

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 5 | Eydenzelt[a] |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 5 | Eydenzelt[a] |

| | |
|---|---|
| **Restriction Summary / Treatment of Concept** | |
| | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) |
| | **Prescriber type:** ☒ Medical Practitioners |
| | **Restriction type:** ☒ Authority Required (Streamlined) [new code] |
| | |
| | **Indication:** Diabetic macular oedema (DMO) |
| | **Treatment Phase:** Continuing treatment |
| Prescribing rule | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| | ~~**Administrative Advice:**~~<br>~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

## BRVO with MO initial treatment:

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 2 | Eydenzelt[a] |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 2 | Eydenzelt[a] |

| | | |
|---|---|---|
| **Restriction Summary / Treatment of Concept:** | | |
| | | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) |
| | | **Prescriber type:** ☒ Medical Practitioners |
| | | **Restriction type:** ☒ Authority Required (Streamlined) [new code] |
| | | |
| | | **Indication:** Branch retinal vein occlusion with macular oedema |
| | | **Treatment Phase:** Initial treatment |
| | | ***Administrative Advice:***<br>***Biosimilar prescribing policy***<br>*Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.* |
| Prescribing rule | | ***Administrative Advice***<br>*Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).* |
| | | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| | | ~~**Administrative Advice:**~~<br>~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

**BRVO with MO continuing treatment:**

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 2 | Eydenzelt[a] |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 2 | Eydenzelt[a] |

| | | |
|---|---|---|
| **Restriction Summary / Treatment of Concept** | | |
| | | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) |
| | | **Prescriber type:** ☒ Medical Practitioners |
| | | **Restriction type:** ☒ Authority Required (Streamlined) [new code] |
| | | |
| | | **Indication:** Branch retinal vein occlusion with macular oedema |
| | | **Treatment Phase:** Continuing treatment |
| Prescribing rule | | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |

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| | | ~~**Administrative Advice:**~~<br>~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

## CRVO with MO initial treatment:

| **MEDICINAL PRODUCT**<br>**medicinal product pack** | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 2 | Eydenzelt[a] |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 2 | Eydenzelt[a] |

| | | |
|---|---|---|
| **Restriction Summary / Treatment of Concept** | | |
| | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) | |
| | **Prescriber type:** ☒ Medical Practitioners | |
| | **Restriction type:** ☒ Authority Required (Streamlined) [new code] | |
| | | |
| | **Indication:** Central retinal vein occlusion with macular oedema | |
| | **Treatment Phase:** Initial treatment | |
| Prescribing rule | | ***Administrative Advice:***<br>***Biosimilar prescribing policy***<br>*Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.* |
| | | ***Administrative Advice***<br>*Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).* |
| | | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| | | ~~**Administrative Advice:**~~<br>~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

## CRVO with MO continuing treatment:

| **MEDICINAL PRODUCT**<br>**medicinal product pack** | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|
| AFLIBERCEPT | | | | | |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe | New | 1 | 1 | 2 | Eydenzelt[a] |
| aflibercept 2 mg/0.05 mL injection, 0.05 mL vial | New | 1 | 1 | 2 | Eydenzelt[a] |

| Restriction Summary / Treatment of Concept | | |
|---|---|---|
| | | **Category / Program:** ☒ GENERAL - General Schedule (Code GE) |
| | | **Prescriber type:** ☒ Medical Practitioners |
| | | **Restriction type:** ☒ Authority Required (Streamlined) [new code] |
| | | |
| | | **Indication:** Central retinal vein occlusion with macular oedema |
| | | **Treatment Phase:** Continuing treatment |
| Prescribing rule | | ***Administrative Advice:***<br>*Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| | | ~~**Administrative Advice:**~~<br>~~Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution~~ |

**Proposed flow on changes to Eylea and Afqlir brands:**

| | |
|---|---|
| | **Replace Old Concept ID** |
| | **Administrative Advice:**<br>Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial are equivalent for the purposes of substitution |
| | **With New Concept ID** |
| | *Pharmaceutical benefits that have the form aflibercept 0.09 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.165 mL injection syringe, pharmaceutical benefits that have the form aflibercept 0.182 mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1 mL injection vial and pharmaceutical benefits that have the form aflibercept 0.283mL injection vial are equivalent for the purposes of substitution* |
| PBS Item Codes to be changed to new Concept: | |
| *12141B /aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Eylea)*<br>*12152N/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Eylea)*<br>*13139M/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Eylea)*<br>*13167B/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Eylea)*<br>*15213Q/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Afqlir)*<br>*15217X/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Afqlir)*<br>*15218Y/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Afqlir)*<br>*15219B/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Afqlir)*<br>*2168D/ aflibercept 2 mg/0.05 mL injection, 0.05 mL vial (Eylea)*<br>*12131L/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Afqlir)*<br>*13146X/ aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe (Afqlir)*<br>*13151E/ aflibercept 2 mg/0.05 mL injection, 0.05 mL vial (Eylea)* | |

***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

# 8 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.

# 9 Sponsor's Comment

The sponsor had no comment.