

**6.09 ADALIMUMAB,  
Injection 20 mg in 0.4 mL pre-filled syringe,  
Injection 40 mg in 0.8 mL pre-filled syringe,  
Injection 40 mg in 0.8 mL pre-filled pen,  
Abrilada,  
Pfizer Australia Pty Ltd**

**1 Purpose of Application**

- 1.1 The Category 3 submission sought Section 85 and Section 100 (Highly Specialised Drug Program – HSD) listings of a new brand of biosimilar medicine adalimumab (Abrilada®) in the form of 20 mg in 0.4 mL pre-filled syringe (PFS), 40 mg in 0.8 mL PFS and 40 mg in 0.8 mL pre-filled pen (PFP) for the same indications as the PBS-listed reference biologic Humira.

**2 Background**

***Registration status***

- 2.1 Abrilada was TGA approved on 8 February 2021 and was determined to be a biosimilar to the reference brand Humira. Abrilada has the same TGA indications as Humira.

*For more detail on PBAC's view, see section 6 PBAC outcome.*

**3 Requested listing**

- 3.1 The proposed Authority Required listings are for all indications for which the reference brand Humira is currently PBS listed:
- Severe Crohn disease
  - Moderate to severe ulcerative colitis
  - Severe active juvenile idiopathic arthritis
  - Complex refractory fistulising Crohn disease
  - Severe active rheumatoid arthritis
  - Severe psoriatic arthritis
  - Ankylosing spondylitis
  - Severe chronic plaque psoriasis
  - Moderate to severe hidradenitis suppurativa.

- 3.2 The applicant requested biosimilar uptake drivers to apply to the listing of Abrilada in terms of the level of authority applied, consistent with the current PBS listings for adalimumab biosimilar brands. This was appropriate and updated by the Secretariat below for clarity. If biosimilar uptake drivers are recommended for this listing, the “Biosimilar prescribing policy” administrative note encouraging the use of biosimilar brands for treatment naïve patients would also need to be updated for all adalimumab biosimilar brands to include Abrilada to the list.
- Authority Required (Written/digital submission) listing of Abrilada for initial treatment restrictions, first and subsequent continuing treatment restrictions.
  - A separate Authority Required (Streamlined) listing of Abrilada for subsequent continuing treatment restriction.
- 3.3 The submission requested Abrilada PFS and PFP to be ‘a’-flagged against Humira of the same strength and form. The PBAC previously advised that, under Section 101(4AACD) of the *National Health Act 1953 (the Act)*, in the Schedule of Pharmaceutical Benefits, the same form and strength for the brands Hadlima, Amgevita, Hyrimoz, Idacio and Humira should be treated as equivalent (‘a’ flagged) to each other for the purpose of substitution.
- 3.4 The requested restrictions are complex due to the number of items and indications required for the listing. If recommended by the PBAC, implementation of these listings may occur across separate stages. As the applicant requested no changes to the restrictions compared to Humira, the restrictions have not been reproduced.

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

## **4 Comparator**

- 4.1 The submission nominated the reference brand of adalimumab, Humira, as the main comparator. This was appropriate.

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

## **5 Consideration of the evidence**

### ***Sponsor hearing***

- 5.1 There was no hearing for this item as it was a minor submission.

### ***Consumer comments***

- 5.2 The PBAC noted and welcomed the input from an organisation (1) via the Consumer Comments facility on the PBS website. The National Paediatric Medicines Forum (NPMF) supported the listing of the adalimumab biosimilar brand and noted its importance in the national paediatric population, particularly in the paediatric setting for inflammatory bowel disorders where adalimumab is highly utilised.

### **Clinical trials**

5.3 The submission presented the following clinical study report.

**Table 1. Studies presented in the submission**

<b>Trial ID</b>	<b>Protocol/Publication Title</b>	<b>Publication Citation</b>
B5381002	A Phase 3 Randomized, Double-Blind Study Assessing the Efficacy and Safety of PF-06410293 and Adalimumab in Combination With Methotrexate in Subjects With Moderately to Severely Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Methotrexate	Clinical Study Report Report Dates: 26 May 2018; 26 July 2018

Source: Table 2-1, p10 of the submission

5.4 The submission also cited three other trials including Trial ID B5381001, B5381005 and B5381007 (p10-11 of the submission). However, the clinical study reports were not provided.

5.5 The clinical trials presented in the submission formed part of the TGA submission to register Abrilada as a biosimilar to Humira. The TGA Delegate Overview noted that the data presented in TGA submission demonstrated that Abrilada is highly similar to the Australian reference product, Humira, with comparable pharmacokinetics, efficacy, safety, and immunogenicity.

5.6 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

### **Clinical claim**

5.7 The submission claimed that Abrilada was biosimilar to Humira.

### **Pricing consideration**

5.8 The submission requested listing Abrilada on a cost-minimisation basis to Humira at a 1:1 unit equivalence for Abrilada to Humira. The submission considers Abrilada is expected to substitute directly with the 20 mg PFS and 40 mg PFS and 40 mg PFP of Humira. The submission presented no economic or financial analysis. It is expected that the listing of Abrilada will not have a financial impact.

*For more detail on PBAC's view, see section 6 PBAC outcome.*

## 6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required listing of adalimumab (Abrilada) in the form of 20 mg in 0.4 mL PFS, 40 mg in 0.8 mL PFS and 40 mg in 0.8 mL PFP as a biosimilar brand of Humira on the General Schedule (Section 85) and Section 100 (Highly Specialised Drug Program). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Abrilada PFP and PFS would be acceptable if it were cost-minimised to Humira for the following indications:
- Severe Crohn disease
  - Moderate to severe ulcerative colitis
  - Severe active juvenile idiopathic arthritis
  - Complex refractory fistulising Crohn disease
  - Severe active rheumatoid arthritis
  - Severe psoriatic arthritis
  - Ankylosing spondylitis
  - Severe chronic plaque psoriasis
  - Moderate to severe hidradenitis suppurativa.
- 6.2 The PBAC advised the equi-effective doses to be a 1:1 unit equivalence for Abrilada to Humira and all other biosimilar brands and formulations of adalimumab.
- 6.3 The PBAC considered that the claim of biosimilarity for Abrilada compared to Humira was reasonably supported by the data. The TGA Delegate noted that Abrilada is similar to the Australian reference product Humira with comparable pharmacokinetics, efficacy, safety, and immunogenicity.
- 6.4 The PBAC considered that the biosimilar uptake drivers should be applied to Abrilada consistent with the current PBS listings for adalimumab biosimilar brands, including:
- Authority Required (Written/digital submission) listing of Abrilada for initial treatment restrictions, first and subsequent continuing treatment restrictions.
  - A separate Authority Required (Streamlined) listing of Abrilada for subsequent continuing treatment restriction.
  - The application of the 'Biosimilar prescribing policy' administrative note encouraging the use of biosimilar brands for treatment naïve patients (this note will need to be updated for the other biosimilar brands of adalimumab to include Abrilada in the list):

*Prescribing of the biosimilar brand, ABRILADA, is encouraged for treatment naïve*

patients.

*Encouraging biosimilar prescribing for treatment naïve 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](http://www.health.gov.au/biosimilars))*

- 6.5 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, in the Schedule of Pharmaceutical Benefits, Abrilada, Amgevita, Hadlima, Hyrimoz, Humira and Idacio PFS should be treated as equivalent to each other; and Abrilada, Amgevita, Hadlima, Hyrimoz, Humira and Idacio, PFP should be treated as equivalent to each other for the purpose of substitution (i.e. 'a' flagged in Schedule with a NOTE stating PBS of one form and PBS of another form are equivalent for the purpose of substitution).
- 6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Abrilada is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Humira, or 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 2009* for Pricing Pathway A were not met.
- 6.7 The PBAC noted that this submission is not eligible for Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## 7 Recommended listing

7.1 Add new adalimumab brand (Abrilada) with schedule equivalence ('a' flag) for the same indications as Humira as noted in Section 3.

7.2 Amend existing/recommended listing as follows:

- Authority Required (Written/digital submission) listing of Abrilada for initial treatment restrictions, first and subsequent continuing treatment restrictions.
- A separate Authority Required (Streamlined) listing of Abrilada for subsequent continuing treatment restriction.
- The application of the 'Biosimilar prescribing policy' administrative note encouraging the use of biosimilar brands for treatment naïve patients (this note will need to be updated for the other biosimilar brands of adalimumab to include Abrilada in the list):

*Prescribing of the biosimilar brand, ABRILADA, is encouraged for treatment naïve patients.*

*Encouraging biosimilar prescribing for treatment naïve 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](http://www.health.gov.au/biosimilars))*

***This restriction 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.