

**5.14 ADALIMUMAB,  
Injection 80mg in 0.8mL single use pre-filled syringe,  
Injection 80mg in 0.8mL single use pre-filled pen,  
Humira®,  
AbbVie Pty Ltd**

**1 Purpose of Application**

1.1 The minor submission requested an Authority Required listing of an additional strength of adalimumab, injection 80 mg in 0.8 mL single use pre-filled syringe/pen, for treatment of moderate to severe hidradenitis suppurativa (HS), under the same conditions as the current adalimumab 40 mg listings. The new form was requested to allow for fortnightly maintenance dosing.

**2 Requested listing**

2.1 In this minor submission, the Sponsor requested the following new listings of adalimumab 80 mg to allow for maintenance dosing following the induction treatment phase.

2.2 Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out with strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty	Nº of Rpts	Dispensed Price for Max. Qty (Published)	Proprietary Name and Manufacturer
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL syringe	2	2	\$ [REDACTED]	Humira® AbbVie
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL pen device	2	2	\$ [REDACTED]	

<b>Category / Program:</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Moderate to severe
<b>Condition:</b>	hidradenitis suppurativa
<b>PBS Indication:</b>	Moderate to severe hidradenitis suppurativa
<b>Treatment phase:</b>	Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input checked="" type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
<b>Treatment criteria:</b>	Must be treated by a dermatologist.

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<b>Clinical criteria:</b>	Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recommencement of treatment restriction to complete a maximum of 16 weeks treatment.
<b>Prescriber Instructions:</b>	A maximum of 12 weeks of treatment will be authorised under this restriction.
<b>Administrative Advice:</b>	Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty (Published)	Proprietary Name and Manufacturer
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL syringe	2	25	\$ [REDACTED]	Humira® AbbVie
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL pen device	2	25	\$ [REDACTED]	

<b>Category / Program:</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Moderate to severe
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<b>PBS Indication:</b>	Moderate to severe hidradenitis suppurativa
<b>Treatment phase:</b>	Continuing treatment
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
<b>Treatment criteria:</b>	Must be treated by a dermatologist
<b>Clinical criteria:</b>	Patient must have previously received PBS-subsidised treatment with this drug for this condition AND Patient must have demonstrated a response to treatment with this drug for this condition

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<p><b>Prescriber Instructions:</b></p>	<p>A response to treatment is defined as:</p> <p>Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.</p> <p>For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.</p> <p>The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.</p> <p>Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.</p> <p>A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> <li>(a) a completed authority prescription form; and</li> <li>(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result.</li> </ul>
<p><b>Administrative Advice:</b></p>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services          Complex Drugs          Reply Paid 9826          HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised.          No increase in the maximum number of repeats may be authorised.          Special Pricing Arrangements apply.</p>


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

### **3 Background**

#### ***Registration status***

- 3.1 Adalimumab was registered on the ARTG on 26 July 2016 for the treatment of active moderate to severe HS in adult patients with an inadequate response to conventional systemic HS therapy.
- 3.2 The current TGA approved Product Information states that the recommended adalimumab dose regimen for adult patients with HS is 160 mg initially at Day 1, followed by 80 mg two weeks later at Day 15. Two weeks later (Day 29) continue with a dose of 40 mg every week or 80 mg fortnightly.
- 3.3 The adalimumab 80 mg fortnightly dosing regimen was approved by the TGA on 17 June 2019 based on a population pharmacokinetic/pharmacodynamics analysis.

#### ***Previous PBAC consideration***

- 3.4 The PBAC deferred making a recommendation on adalimumab 40 mg for the treatment of patients with moderate to severe HS at its November 2016 meeting. Subsequent to the November 2016 meeting, the sponsor provided the PBAC with a revised price offer, a revised incremental cost effectiveness ratio (ICER), revised financial estimates and a proposed Risk Sharing Arrangement (RSA) with yearly subsidisation caps. The PBAC recommended the listing of adalimumab 40 mg for HS at a meeting held on 16 December 2016. (Addendum, adalimumab Public Summary Document, Nov 2016)
- 3.5 Adalimumab is currently listed on the general schedule of the PBS as an Authority Required listing for treatment of HS with a Special Pricing Arrangement and an RSA in the form of a subsidisation cap, with rebates for any expenditure over the cap.  

- 3.6 The PBAC recommended at its July 2018 meeting to list adalimumab 80 mg for two induction doses (2 x 80 mg given on day 1, 1 x 80 mg give on day 15) for the treatment of moderate to severe HS. At that time, only adalimumab 40 mg was listed in the Product Information for maintenance therapy. This recommendation is yet to be implemented.

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

### **4 Comparator**

- 4.1 The PBAC considered that the nominated comparator of adalimumab 40 mg weekly 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 that no consumer comments were received for this item.

### **Clinical claim**

5.3 The submission claimed adalimumab 80 mg fortnightly maintenance dosing in HS is equivalent to 40 mg weekly maintenance dosing with respect to efficacy and safety.

### **Drug cost/patient/year: \$ [REDACTED]**

5.4 The proposed AEMP for adalimumab 80 mg PFS/pen, pack of 1, is half the AEMP for a pack of four adalimumab 40 mg PFS/pens. Published and effective prices are outlined in Table 1.

**Table 1: Published and Effective prices for adalimumab 40 mg/0.8 mL and 80 mg/0.8 mL injections for treatment of HS**

Drug and form	Max qty	AEMP	
		Published	Effective
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL syringe	2	\$ [REDACTED]	\$ [REDACTED]
ADALIMUMAB 40 mg/0.8 mL injection, 4 x 0.8mL pen devices	1	\$2303.75	\$ [REDACTED]
ADALIMUMAB 40 mg/0.8 mL injection, 6 x 0.8mL pen devices	1	\$3455.62	\$ [REDACTED]

\* The submission stated that a difference in the pack size and maximum quantity results in a slightly lower DPMQ for the 80mg presentation (published DPMQ \$2432.25) than the 40 mg presentation (published DPMQ \$2,455.87). The Secretariat noted the reason for the difference in the DPMQ in the submission was unclear.

### **Estimated PBS usage & financial implications**

5.5 The minor submission estimated there to be no additional financial impact. No change in PBS usage is expected as adalimumab 80 mg fortnightly would substitute for adalimumab 40 mg weekly and the drug cost of both strengths would be the same on a per mg basis.

5.6 As a minor submission, the financial estimates have not been independently evaluated.

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

## 6 PBAC Outcome

6.1 The PBAC recommended the listing of adalimumab in the form of 80 mg/0.8 mL single-use pre-filled syringe/pen for the treatment of moderate to severe HS, at the same cost per milligram as the 40 mg/0.8mL form.

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- 6.2 The PBAC recommended that the restriction should align with the current listing for adalimumab 40 mg/0.8 mL for treatment of HS. The PBAC also advised that maximum quantities and number of repeats should align with the listings for adalimumab 40 mg/0.8mL to permit a maximum quantity of two pens/PFS (one month's supply) with two repeats for the balance of supply, and five repeats for maintenance therapy.
- 6.3 The PBAC recalled it had previously recommended listing adalimumab 80 mg for treatment induction for HS at its July 2018 meeting.
- 6.4 The PBAC considered that the nominated comparator of adalimumab 40 mg weekly was appropriate.
- 6.5 The PBAC noted that the claims regarding equivalence of adalimumab 80 mg fortnightly dosing and 40 mg weekly dosing were based on a population pharmacokinetic/pharmacodynamics analysis rather than clinical trial data.
- 6.6 The PBAC noted that the new form of adalimumab is expected to replace equivalent utilisation of the 40 mg/0.8 mL form and therefore considered that the market is not expected to grow. The PBAC considered the listing was likely to be cost neutral to Government.
- 6.7 The PBAC noted that the proposed ex-manufacturer price for two adalimumab 80 mg/0.8 mL PFS/pens is equivalent to the AEMP for a pack of four adalimumab 40 mg/0.8 mL PFS/pens. The PBAC advised that the new form of adalimumab should be included under the existing risk sharing arrangement for HS.
- 6.8 The PBAC recommended the removal of 'Initial Treatment 3 – Grandfathered patient' for adalimumab 40 mg/0.8 mL (PBS item 11137E) as it has been more than 12 months following listing of adalimumab for moderate to severe HS.
- 6.9 The PBAC noted its previous advice that adalimumab should not be treated as interchangeable on an individual basis with any other drugs for treatment of HS.
- 6.10 The PBAC advised that, because adalimumab 80 mg/0.8 mL is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over adalimumab 40 mg/0.8 mL, 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 2009* for Pricing Pathway A were not met.
- 6.11 The PBAC recommended that the new form of adalimumab should not be exempt from the Early Supply Rule should for the treatment of moderate to severe HS.
- 6.12 The PBAC advised that adalimumab is not suitable for prescribing by nurse practitioners.
- 6.13 The PBAC noted that this submission is not eligible for an Independent Review as it has received a positive recommendation.

**Outcome:**

Recommended

## 7 Recommended listing

### 7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL syringe	2	2	Humira®	AbbVie
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL pen device	2	2		

<b>Category / Program:</b>	GENERAL – General Schedule (Code GE)
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<b>Condition:</b>	hidradenitis suppurativa
<b>PBS Indication:</b>	Moderate to severe hidradenitis suppurativa
<b>Treatment phase:</b>	Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input checked="" type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
<b>Treatment criteria:</b>	Must be treated by a dermatologist.
<b>Clinical criteria:</b>	Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recommencement of treatment restriction to complete a maximum of 16 weeks treatment.
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7.2 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL syringe	2	5	Humira®
ADALIMUMAB 80 mg/0.8 mL injection, 0.8 mL pen device	2	5	

<b>Category / Program:</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
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<b>Prescriber Instructions:</b>	A response to treatment is defined as:  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.  The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.  Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.  A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.  The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

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<b>Administrative Advice:</b>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.</p>
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7.3 Amend existing listing 11137E (adalimumab 40mg/0.8mL) as follows:

Remove the grandfather restriction

*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.