

5.12 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

Amgevita[®], Amgen Australia

1 Purpose of Application

- 1.1 The minor submission sought an Authority Required listing for a new biosimilar brand of adalimumab (Amgevita[®]).

2 Requested listing

- 2.1 The submission requested listing Amgevita for all indications for which the reference brand Humira is currently PBS listed:

- Severe active rheumatoid arthritis
- Severe psoriatic arthritis
- Ankylosing spondylitis
- Severe chronic plaque psoriasis
- Juvenile Idiopathic Arthritis
- Severe Crohn disease
- Refractory fistulising Crohn disease
- Moderate to severe ulcerative colitis
- Moderate to severe hidradenitis suppurativa

- 2.2 The sponsor has requested listing on the General PBS schedule (Section 85) for all indications except paediatric juvenile idiopathic arthritis, for which it has requested a Section 100 Highly Specialised Drug listing in line with the reference brand, Humira.

- 2.3 In accordance with the Government's biosimilar uptake measures, the sponsor proposed:

- splitting the continuation criteria for Amgevita and Humira to allow for a less stringent prescription authority level to be applied to subsequent continuing scripts for Amgevita. 'First continuing' scripts will remain as written authority for Humira and Amgevita, and 'subsequent continuing' scripts will be written authority for Humira and Streamlined authority for Amgevita. Initial 1 scripts (new patients) and Initial 2 scripts (recommencement or switch) will remain as written authorities for both brands; and
- the application of an Administrative Note encouraging the use of biosimilar brands for treatment naïve patients.

- 2.4 The presentations and pack sizes for Amgevita correspond with those listed on the PBS for Humira as of July 2018. The PBAC noted that, at its July 2018 meeting, it was considering the following new strengths and forms of Humira: 20 mg/0.2 mL pre-filled syringe and 80 mg/0.8 mL pre-filled syringe and cartridge.
- 2.5 Amgevita is TGA approved for the same indications as the reference brand, Humira. The sponsor sought PBS listing for the same indications and restrictions as Humira, and noted that although both brands are TGA-approved for use in uveitis, given that Humira is not currently PBS-listed for this indication, PBS listing for Amgevita for uveitis is not being sought.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Background

- 3.1 The Amgevita brand of adalimumab was TGA approved on 18 October 2017.
- 3.2 At its meeting on 4 August 2017, the ACM advised at that, overall, bioequivalence criteria for Amgevita were met (ACM meeting minutes, 4 August 2017).
- 3.3 The PBAC has not previously considered a submission for this brand of adalimumab.
- 3.4 At its July 2018 meeting, the PBAC also considered another adalimumab biosimilar brand, Hadlima® for severe active rheumatoid arthritis, with Humira as the reference product.

Brand equivalence and substitution at the pharmacist level ('a' flagging)

- 3.5 The Schedule of Pharmaceutical Benefits provide the following definition of brand equivalence:

Extract from the Explanatory Notes to the PBS Schedule¹

BRAND EQUIVALENCE

'a' located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Therapeutic Goods Administration. It would thus be expected that these brands may be interchanged without differences in clinical effect.

- 3.6 Many medicines are available on the PBS in different brands. The Schedule of Pharmaceutical Benefits indicates where different brands are considered equivalent for the purposes of substitution at the point of dispensing by using 'a' flags.

¹ Symbols used in the Schedule - <http://www.pbs.gov.au/info/healthpro/explanatory-notes/section2/section-2-symbols>

- 3.7 The ability for prescribers and pharmacists to substitute generic or biosimilar brands for originator brands is an important part of encouraging use of generics and biosimilars in the marketplace and adds to the sustainability of the PBS.
- 3.8 For any individual prescription, a prescriber may choose to not permit brand substitution by indicating ‘substitution not permitted’ on the prescription. Likewise, when substitution is permitted, a patient may nominate which ‘a’ flagged brand they wish to receive from the pharmacist, except when State or Territory Law prohibits substitution (e.g. for Schedule 8 drugs of dependence). The substitution process allows for patient and prescriber choice and is not automatic.
- 3.9 The *National Health Act 1953* (“The Act”) makes it an offence for a pharmacist to supply a pharmaceutical benefit other than the benefit directed to be supplied in a prescription except when, amongst other criteria, the Schedule issued by the Department of Health states that the specified benefit and the substitute benefit are equivalent.
- 3.10 At its March 2018 meeting, the PBAC advised that the following revised considerations will be used to make a recommendation on brand equivalence (‘a’ flagged) of biosimilars with the reference brand;
- The Therapeutic Goods Administration has determined that the product is a biosimilar of the reference medicine as evidenced by ARTG registration documentation;
 - Availability of supportive data relating to the effects of switching between the reference product and the biosimilar product/s; and
 - Practical considerations relating to substitution by the pharmacist at the point of dispensing. This includes strength of formulation, number of units per pack and maximum quantities between the brands, which may make substitution at the pharmacy level difficult from a practical perspective.
- 3.11 The PBAC considered that where a biosimilar product could not be recommended to be brand equivalent (‘a’ flagged) at the time of PBS listing, data should be collected to support this consideration at a later point.
- 3.12 If the PBAC provides advice on brand equivalence (‘a’ flagging), the decision to apply brand equivalence to listings in the Schedule is made by the Minister for Health (or Delegate).

Biosimilar uptake measures

- 3.13 The biosimilar uptake measures were agreed as part of the strategic agreements that the Government reached with Medicines Australia, the Generic and Biosimilar Medicines Association and the Pharmacy Guild of Australia as part of the 2017 Budget process.

- 3.14 The PBAC will advise whether implementation of the uptake drivers is likely to raise any clinical or other concerns about appropriate use on the PBS. The PBAC may, on a case-by-case basis, provide advice relating to:
- encouraging the prescribing of a biosimilar brand for treatment naïve patients; and
 - applying a lower level of authority to biosimilar brand(s) than exists for the reference brand of biological medicines.
- 3.15 After PBAC advice is received, a decision will be made about applying the drivers for the relevant medicine. The policy provides for lower authority requirements only for biosimilar brands, but there will be no increase in authority requirements to prescribe reference brands.
- 3.16 The PBAC has previously stated it had no concerns about encouraging prescribing of a biosimilar brand rather than the reference biological agent brand for treatment naïve patients, including through notes in the Schedule and prescribing software changes. (Etanercept (Brenzys) Public Summary Document, August 2017 PBAC Meeting).

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

- 4.2 The PBAC noted and welcomed the input from individuals (1) via the Consumer Comments facility on the PBS website.

Clinical trials

- 4.3 The minor submission presented the following clinical trials to support the efficacy, safety and immunogenicity of Amgevita compared to Humira.

Table 1. Trials and associated reports presented in the submission

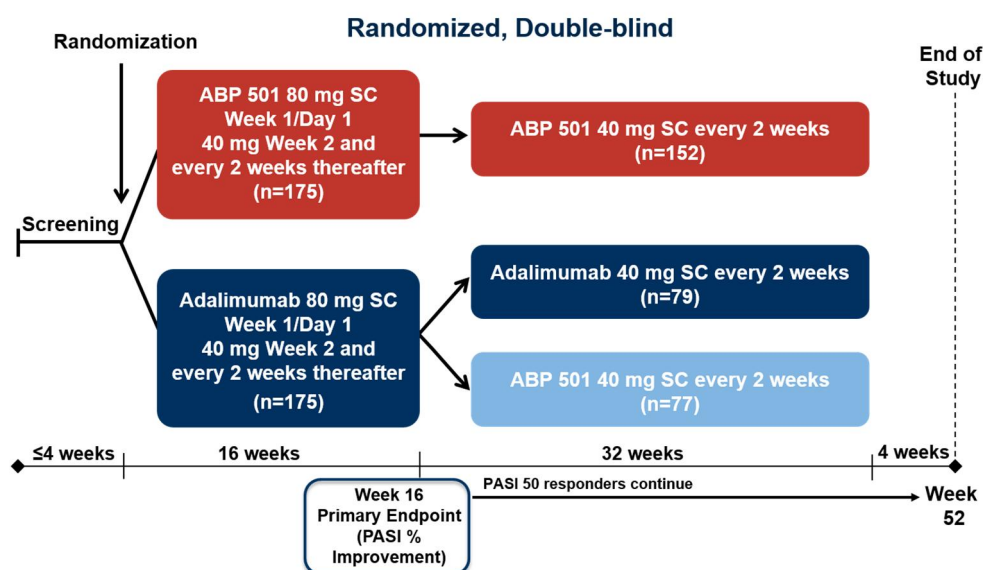
Trial ID (Full Study No.)	Protocol title/publication title	Publication citation
Direct randomised trials		
Study 262 (20120262) RA	A randomized, double-blind, phase 3 study of ABP 501 efficacy and safety compared to adalimumab in subjects with moderate to severe rheumatoid arthritis.	Clinical Study Report ³ Report date: 21 May 2015 ..
	<u>Main publication</u> Cohen S, Genovese MC, Choy E, et al. Efficacy and safety of the biosimilar ABP 501 compared with adalimumab in patients with moderate to severe rheumatoid arthritis: a randomised, double-blind, phase III equivalence study Cohen S, Pablos JL, Zhang N, et al. ABP 501 Long-Term Safety/Efficacy: Interim Results from an Open-Label Extension Study [abstract]. Available at: http://acrabstracts.org/abstract/ABP-501-long-term-safetyefficacy-interim-results-from-an-open-label-extension-study/	Ann Rheum Dis. 2017a;76:1679-1687 ⁴
Study 263 (20120263) PsO	A phase 3, multicenter, randomised, double-blind study evaluating the efficacy and safety if ABP 501 compared with adalimumab in subjects with moderate to severe plaque psoriasis.	Clinical Study Report Report date: 22 July 2015 ⁵
	<u>Main publication</u> Papp K, Bachelez H, Costanzo A, et al. Clinical similarity of biosimilar ABP 501 to adalimumab in the treatment of patients with moderate to severe plaque psoriasis: A randomized, double-blind, multicenter, phase III study.	J Am Acad Dermatol 2017;76:1093-1026 ⁶ .
	Papp K, Bachelez H, Costanzo A, et al. Clinical similarity of the biosimilar ABP 501 compared with adalimumab after single transition: long-term results from a randomized controlled, double-blind, 52-week, phase III trial in patients with moderate-to-severe plaque psoriasis.	Br J Dermatol 2017;177:1562-747.
Supporting studies		
Study 258 (20130258) Open-label extension, RA	An open-label single-arm extension study to evaluate the long-term safety and efficacy of ABP 501 in subjects with moderate to severe rheumatoid arthritis	Clinical Study Report Report date: 5 October 2016 ¹²
	<u>Main Publication</u> Cohen S, Pablos JL, Wang H, et al. ABP 501 biosimilar to adalimumab: Final safety, immunogenicity, and efficacy results from an open-label extension study.	Poster presented at: European League Against Rheumatism Congress; Madrid, Spain; June 14-17, 2017b ¹³
Study 217 (Study 20110217) PK Study	A Randomized, Single-Blind, Single-Dose, 3-Arm, Parallel-Group Study to Determine the Pharmacokinetic Equivalence of ABP 501 and Adalimumab (Humira®) in Healthy Adult Subjects <u>Main publication</u> Kaur P, Chow V, Zhang N, et al. A randomised, single-blind, single-dose, three-arm, parallel-group study in healthy subjects to demonstrate pharmacokinetic equivalence of ABP 501 and adalimumab.	Clinical Study Report Report date: 18 April 2013 ¹⁰ Ann Rheum Dis. 2017; 76:526-533 ¹¹ .

Source: Table 2-1 of the submission.

Benefits & harms

- 4.4 The submission’s clinical claim was that Amgevita is non-inferior to Humira in terms of effectiveness, and has a comparable safety profile to Humira.
- 4.5 The sponsor provided a copy of the draft Australian Public Assessment Report for Amgevita which provided the following information on the clinical trials.
- 4.6 In Study 262, patients with rheumatoid arthritis received either Amgevita or Humira for up to 30 weeks. The primary efficacy endpoint was the risk ratio of at least 20% improvement in a core set of measures assessing rheumatoid arthritis symptoms at Week 24. Results were within the pre-defined limits for equivalence.
- 4.7 In Study 263, patients with severe chronic plaque psoriasis were randomised to receive either Amgevita or adalimumab. At week 16, patients with 50% or more improvement in Psoriasis Area and Severity Index (PASI) score from baseline were eligible to continue in the study: those initially receiving Amgevita continued treatment and patients receiving adalimumab were re-randomised to either continue adalimumab or switch to Amgevita (see Figure 1). The treatment effect was maintained in all treatment groups and the results were within the pre-defined limits for equivalence.
- 4.8 The safety data from the two equivalence studies did not show clinically significant differences in any of the safety outcomes assessed.
- 4.9 Overall, the TGA Delegate found that the two clinical equivalence studies convincingly demonstrated clinical equivalence for subjects with rheumatoid arthritis and plaque psoriasis.

Figure 1. Trial design for Study 263



Source: Submission, Figure 2-2

Estimated PBS usage & financial implications

- 4.10 The minor submission estimated that the savings to the PBS/RPBS if Amgevita is listed would be \$30 - \$60 million per year (Year 1-6), without accounting for any price disclosure cuts, and that this would increase to more than \$100 million by Year 6 if price disclosure cuts are realised.
- 4.11 In formulating the estimated savings, the sponsor made the following assumptions:
- A 7% annual growth rate for adalimumab services (based on the average annual historical growth rate for Humira from 2014-2017);
 - An uptake rate of adalimumab biosimilars of 10% to 30%, increasing over the 6 year period; and
 - The removal of existing SPA rebates for Humira once Amgevita is PBS listed. The sponsor estimated the rebate to be 28%, based on the revealed rebate when Enbrel (etanercept) moved from F1 to F2.

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of adalimumab (Amgevita) as a biosimilar of adalimumab (Humira) for all of the indications for which Humira is PBS-listed.
- 5.2 The PBAC noted that the ACM was satisfied that the bioequivalence criteria for Amgevita were met.
- 5.3 The PBAC noted that the TGA Delegate was satisfied that the two clinical equivalence studies presented in the submission convincingly demonstrated clinical equivalence for subjects with rheumatoid arthritis and plaque psoriasis, and that the safety data from the trials did not show clinically significant differences in any of the safety outcomes assessed.
- 5.4 The PBAC agreed that the following biosimilar uptake drivers should be applied to adalimumab consistent with previous recommendations regarding the application of the drivers to other biosimilar biological medicines listed for the same indications. These are as follows:
- Retain the initial 1 and 2 restrictions as Authority Required (written) benefits; and
 - split the continuation criteria into 'first continuing' and 'subsequent continuing', to allow for the subsequent continuing restriction for the biosimilar to be Streamlined authority while subsequent continuing restriction for the reference biological medicine will remain as a written authority; and
 - the application of an Administrative Note encouraging the use of biosimilar brands for treatment naïve patients.

- 5.5 The PBAC noted that the Advisory Committee on Medicines (ACM), in its consideration of Amgevita, stated that a quality use of medicine issue was ‘the potential difference in injection device in the context of switching between biosimilar medicines’. The PBAC recalled that it had encountered this issue in its consideration of the etanercept biosimilar, Brenzys, and stated in that case that differences in auto injector presentations were ‘likely to be minor and can be managed through the regular patient education and counselling on the use of the devices that is provided to patients by prescribers and pharmacists.’ (etanercept public summary document, July 2016). The PBAC considered that, as with Brenzys, the differences between Amgevita and Humira are likely to be minor and manageable.
- 5.6 The PBAC noted that another adalimumab biosimilar brand, Hadlima® for severe active rheumatoid arthritis, was also considered at its July 2018 PBAC meeting, with Humira as the reference product. The PBAC considered that it would be appropriate for all three brands of adalimumab (Humira, Amgevita and Hadlima) to be ‘a’ flagged to each other.
- 5.7 The PBAC advised that, under Section 101(4AACD) of the *National Health Act, 1953*, in the Schedule of Pharmaceutical Benefits, Amgevita, Hadlima and Humira pre-filled syringes should be treated as equivalent to each other and Amgevita, Hadlima and Humira cartridges should be treated as equivalent to each other.
- 5.8 The PBAC reiterated its previous advice that adalimumab should not be exempt from the Early Supply Rule.
- 5.9 The PBAC reiterated its previous advice that adalimumab is not suitable for prescribing by nurse practitioners.
- 5.10 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

The full restriction for the hidradenitis suppurativa indication is shown below. The restrictions for all other indications will be based upon the etanercept and infliximab biosimilar restrictions, which will incorporate the same biosimilar uptake drivers as the Amgevita restriction.

Add new item:

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Initial 1

Name, Restriction, Manner of administration and form	Max. Qty Packs	Max Qty Units	No. of Rpts	Proprietary Name and Manufacturer	
ADALIMUMAB adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pre-filled pens	1	1	0	AMGEVITA	AN
Category/Program	Authority Required				
Severity:	Moderate to severe				
Condition:	Moderate to severe hidradenitis suppurativa				
PBS Indication:	Moderate to severe hidradenitis suppurativa				
Treatment phase:	Initial treatment 1 - New patient				
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined				
Clinical criteria:	<p>Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3,</p> <p>AND</p> <p>Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition;</p> <p>OR</p> <p>Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition,</p> <p>AND</p> <p>The treatment must be limited to a maximum duration of 16 weeks.</p>				
Population criteria:					
Treatment criteria:	Must be treated by a dermatologist				
Prescriber Instructions	<p>Assessment of disease severity must be no more than 1 month old at the time of application. An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.</p> <p>At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:</p> <p>(i) the Hurley stage grading; and</p> <p>(ii) the AN count; and</p> <p>(iii) the name of the antibiotic/s received for two separate courses each of three months; or</p>				

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	<p>(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics</p> <p>(v) a signed patient acknowledgement.</p>
Administrative instructions	<p>Note Biosimilar prescribing policy Prescribing of the biosimilar brands AMGEVITA and HADLIMA are encouraged for treatment naive patients. 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).</p> <p>Note 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). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>Note No increase in the maximum quantity or number of units may be authorised.</p> <p>Note No increase in the maximum number of repeats may be authorised.</p>

Initial 2

Name, Restriction, Manner of administration and form	Max. Qty Packs	Max Qty Units	No. of Rpts	Proprietary Name and Manufacturer	
ADALIMUMAB adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pre-filled pens	1	1	0	AMGEVITA	AN
Category/Program	Authority Required				
Severity:	Moderate to severe				
Condition:	Moderate to severe hidradenitis suppurativa				
PBS Indication:	Moderate to severe hidradenitis suppurativa				
Treatment phase:	Initial treatment 2 - Recommencement of treatment				
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined				

Clinical criteria:	<p>Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, AND The treatment must be limited to a maximum duration of 16 weeks. Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, AND Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, AND The treatment must be limited to a maximum duration of 16 weeks.</p>
Population criteria:	
Treatment criteria:	Must be treated by a dermatologist
Prescriber Instructions	<p>Assessment of disease severity must be no more than 1 month old at the time of application. 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. An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply 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: (i) the Hurley stage grading; and (ii) the AN count.</p>
Administrative instructions	<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). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs</p>

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Reply Paid 9826 HOBART TAS 7001 Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised.
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Initial 1 or 2 – Balance of supply

Name, Restriction, Manner of administration and form	Max. Qty Packs	Max Qty Units	No. of Rpts	Proprietary Name and Manufacturer	
adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges	1	1	2	AMGEVITA	AN
Category/Program	Authority Required				
Severity:	Moderate to severe				
Condition:	Moderate to severe hidradenitis suppurativa				
PBS Indication:	Moderate to severe hidradenitis suppurativa				
Treatment phase:	Treatment Phase: Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment – balance of supply				
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined				
Clinical criteria:	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.				
Population criteria:					
Treatment criteria:	Must be treated by a dermatologist				
Prescriber Instructions	A maximum of 12 weeks of treatment will be authorised under this restriction.				
Administrative instructions	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). Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised.				

First continuing

Name, Restriction, Manner of administration and form	Max. Qty Packs	Max Qty Units	No. of Rpts	Proprietary Name and Manufacturer	
ADALIMUMAB adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL pre-filled pens	1	1	5	AMGEVITA	AN
Category/Program	Authority Required				
Severity:	Moderate to severe				

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Condition:	Moderate to severe hidradenitis suppurativa
PBS Indication:	Moderate to severe hidradenitis suppurativa
Treatment phase:	First continuing treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	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.
Population criteria:	
Treatment criteria:	Must be treated by a dermatologist
Prescriber Instructions	<p>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.</p> <p>For the first application for <i>first</i> 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 <i>the first</i> 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 <i>under this restriction</i>. per continuing treatment.</p> <p>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.</p>
Administrative advice	<p>Note</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). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au</p> <p>Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>

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	<p>Note No increase in the maximum quantity or number of units may be authorised.</p> <p>Note No increase in the maximum number of repeats may be authorised.</p>
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Subsequent continuing

Name, Restriction, Manner of administration and form	Max. Qty Packs	Max Qty Units	No. of Rpts	Proprietary Name and Manufacturer	
ADALIMUMAB adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL pens	1	1	5	AMGEVITA	AN
Category/Program	Authority Required				
Severity:	Moderate to severe				
Condition:	Moderate to severe hidradenitis suppurativa				
PBS Indication:	Moderate to severe hidradenitis suppurativa				
Treatment phase:	Subsequent continuing treatment				
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined				
Clinical criteria:	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.				
Population criteria:					
Treatment criteria:	Must be treated by a dermatologist				
Prescriber Instructions	<p>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.</p> <p>For subsequent continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made every 24 weeks.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p>				
Administrative instructions	No increase in the maximum quantity or number of units may be authorised.				

7 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.

8 Sponsor's Comment

The sponsor had no comment.