

**5.11 ADALIMUMAB,
Injection 20 mg in 0.2 mL pre-filled syringe,
Injection 40 mg in 0.4 mL pre-filled syringe,
Injection 40 mg in 0.4 mL pre-filled pen,
Injection 80 mg in 0.8 mL pre-filled pen,
Amgevita HC,
Amgen Australia**

1 Purpose of Submission

- 1.1 The Category 4 submission sought to list a biosimilar brand of adalimumab (Amgevita HC®, the submission refers to these as high concentration formula Amgevita; hereafter referred to as Amgevita HC) in the forms and strengths of 20 mg in 0.2 mL, 40 mg in 0.4 mL, pre-filled syringe (PFS) and 40 mg in 0.4 mL, 80 mg in 0.8 mL pre-filled pen (PFP) and under the same circumstances as the currently PBS-listed reference biologic, Humira®.

2 Background

Registration status

- 2.1 The requested forms and strengths of Amgevita were registered on the Australian Register of Therapeutic Goods Administration (ARTG) on either 22 or 23 September 2025 and determined to be biosimilar to the reference brand Humira.

Previous PBAC consideration

- 2.2 This is the first PBAC submission for the requested forms and strengths of Amgevita.
- 2.3 The PBAC recommended 20 mg in 0.4 mL, 40 mg in 0.8 mL PFS and 40 mg in 0.8 mL PFP (low concentration formula Amgevita; hereafter referred to as Amgevita LC) at its July 2018 meeting and they are currently listed on the PBS.
- 2.4 Table 2 provides a summary of the forms and strengths requested in the submission against the current forms and strengths of adalimumab available in the different brands on the PBS.

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Table 1: Summary of the submission's request and the current brands of adalimumab available on the PBS

	Brands available	New form requested of AMGEVITA in the submission
High concentration formulation (100 mg/mL)		
Adalimumab 20 mg in 0.2 mL pre-filled syringe	Humira*	Yes
Adalimumab 40 mg in 0.4 mL pre-filled syringe	Humira, Hadlima, Yuflyma, Hyrimoz	Yes
Adalimumab 40 mg in 0.4 mL pre-filled pen	Humira, Hadlima, Yuflyma, Hyrimoz	Yes
Adalimumab 80 mg in 0.8 mL pre-filled pen	Humira, Hyrimoz	Yes
Adalimumab 80 mg in 0.8 mL pre-filled syringe	Humira, Hyrimoz	No
Low concentration formulation (50 mg/mL)		
Adalimumab 20 mg in 0.4 mL pre-filled syringe	Amgevita	No
Adalimumab 40 mg in 0.8 mL pre-filled pen	Amgevita, Hadlima, Hyrimoz, Abrilada	No
Adalimumab 40 mg in 0.8 mL pre-filled syringe	Amgevita, Hadlima, Hyrimoz, Abrilada	No

Table compiled during evaluation.

3 Requested listing

- 3.1 The submission requests listing Amgevita HC under the same circumstances as the PBS-listed reference biologic Humira.
- 3.2 The requested restrictions are complex due to the number of items and indications required for the listing. If recommended by the PBAC, the implementation of these listings may occur across separate stages. As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here. An example of the listing follows:

Name, restriction, manner of administration, form	Max. Qty (packs)	Max. Qty (units)	No. of repeats	PBS item code	Proprietary name and manufacturer
ADALIMUMAB adalimumab 40 mg/0.4 mL injection, pre-filled pen	1	2	2	12345R	Amgevita ® Amgen Australia
ADALIMUMAB adalimumab 40 mg/0.4 mL injection, pre-filled syringe	1	2	2	12338J	Amgevita ® Amgen Australia

The sponsor has requested the same number of item codes and indications as Humira. Maximum quantity packs and units and number of repeats will change to match the item code and indication. The example indication used is "Severe Crohn disease Treatment Phase: Initial treatment - Initial 1 (new patient)".

- 3.3 The PBS indications requested in the submission for Amgevita HC are:

- Severe Crohn disease
- Moderate to severe ulcerative colitis
- Severe active juvenile idiopathic arthritis
- Entesitis/spondylitis related juvenile idiopathic arthritis
- Complex refractory Fistulising Crohn disease

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- Severe active rheumatoid arthritis
 - Severe psoriatic arthritis
 - Ankylosing spondylitis
 - Severe chronic plaque psoriasis
 - Moderate to severe hidradenitis suppurativa
 - Vision-threatening non-infectious uveitis
- 3.4 The PBAC was asked to advise whether biosimilar uptake drivers, including the differential authority requirements for subsequent continuing treatment between the reference and biosimilar brands; and inclusion of an administrative note encouraging the use of biosimilar brands for treatment naïve patients, should apply to Amgevita HC PFS and PFP if they are recommended for listing.
- Prescribing of the biosimilar brand [Amgevita HC] 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 Medicines webpage (www.health.gov.au/health-topics/medicines)
- 3.5 Table 2 is a summary of the current brands, forms and strengths of adalimumab available on the PBS which are equivalent to each other for the purposes of substitution.

Table 2: Summary of the current brands, forms and strengths of adalimumab available on the PBS which are equivalent to each other for the purposes of substitution (i.e. 'a' flagged in the schedule)

Form	Brand Name	a-flagged (Y/N/if an exception applies)
'a' flagging for 20mg adalimumab syringe		
20 mg/0.2 mL injection, 2 x 0.2 mL syringes*	Humira	Y
20 mg/0.4 mL injection, 0.4 mL syringe*	Amgevita	Y
'a' flagging for 40mg adalimumab pen devices		
40 mg/0.4 mL injection, 2 x 0.4 mL pen devices ***	Hadlima	Y
	Humira	Y, except for with item codes 13214L ^b , 13215M ^c , 13221W ^d , 13223Y ^e , 13225C ^a , 13226D ^f , 13230H ^g , 13691N ^h , 13703F ^h , 13764K ⁱ & 14234E
	Hyrmoz	Y
	Yuflyma	Y
40 mg/0.8 mL injection, 2 x 0.8 mL pen devices***	Amgevita	Y
	Hadlima	Y
	Hyrmoz	Y
	Abrilada	Y
'a' flagging for 40mg adalimumab syringes		
40 mg/0.4 mL injection, 2 x 0.4 mL syringes**	Hadlima	Y
	Humira	Y, except for with item codes 13208E ^f , 13209F ^e , 13216N ^b , 13217P ^c , 13219R ^a ,

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		13220T ^g , 13704G ^h , 13732R ^h , 13763J ^f & 14629Y ⁱ
	Hyrimoz	Y
	Yuflyma	Y
40 mg/0.8 mL injection, 2 x 0.8 mL syringes**	Amgevita	Y
	Hadlima	Y
	Hyrimoz	Y
'a' flagging for 80mg adalimumab pen device		
80 mg/0.8 mL injection, 0.8 mL pen device	Humira	Y, except for with item code 14587R ^d
	Hyrimoz	Y
	Yuflyma	Y
'a' flagging for 80mg adalimumab syringes		
80 mg/0.8 mL injection, 0.8 mL syringe	Humira	Y, except for with item code 14622N ^d
	Yuflyma	Y

Table compiled during evaluation.

a Indicated for severe Crohn disease.

b Indicated for severe psoriatic arthritis.

c Indicated for severe chronic plaque psoriasis.

d Indicated for moderate to severe hidradenitis suppurativa.

e Indicated for severe active juvenile idiopathic arthritis.

f Indicated for ankylosing spondylitis.

g Indicated for complex refractory Fistulising Crohn disease.

h Indicated for severe active rheumatoid arthritis.

i Indicated for vision threatening non-infectious uveitis

* 20 mg in 0.2 mL PFS of the different brands of adalimumab should be treated as equivalent to the 20 mg in 0.4 mL PFS of the different brands of adalimumab for the purposes of substitution (i.e. 'a' flagged in the schedule)

**40 mg in 0.4 mL PFS of the different brands of adalimumab should be treated as equivalent to the 40 mg in 0.8 mL PFS of the different brands of adalimumab for the purposes of substitution (i.e. 'a' flagged in the schedule).

***40 mg in 0.4 mL PFP of the different brands of adalimumab should be treated as equivalent to the 40 mg in 0.8 mL PFP of the different brands of adalimumab for the purposes of substitution (i.e. 'a' flagged in the schedule).

4 Comparator

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

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer inputs

- 5.2 The PBAC noted and welcomed the input from Australasian Society of Clinical Immunology and Allergy (ASCIA) and individuals (2), via the Office of Health Technology Assessment Consultation Hub. The inputs described a range of benefits associated with new strengths and forms of Amgevita including improving quality of life and financial burden to patients. The ASCIA provided input supporting the listing of new strengths and forms of Amgevita. Their inputs highlighted improvement access to effective therapeutic options for patients with active rheumatoid arthritis and other

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autoimmune conditions and reduce financial burden to patients and the healthcare system.

Clinical trials

- 5.3 The submission presented the following clinical study (Table 3) to support the claim that Amgevita HC is similar to Amgevita LC and Humira in terms of pharmacokinetics, efficacy and safety. The TGA Delegate found that the results of the clinical study showed that the Amgevita HC and Amgevita LC were similar in terms of both efficacy and safety. The TGA Delegate considered the new 80 mg strength of is a useful addition to the product range, providing an alternative to two 40 mg injections.

Table 3: Studies and associated reports presented in the submission

Trial ID	Protocol title/publication title	Publication citation
20200286	A Randomized, Single-blind, Single-dose, 2-arm, Parallel-group Study to Determine the Pharmacokinetic Comparability of ABP 501 40 mg/0.4 mL (ABP 501-HCF) and ABP 501 40 mg/0.8 mL (ABP 501-LCF) in Healthy Adult Subjects Objective: To demonstrate PK comparability between Amgevita HC and Amgevita LC in terms of: C_{max} and AUC in healthy adult subjects and to determine the safety, tolerability, and immunogenicity of Amgevita HC in healthy adult subjects compared with Amgevita LC	Clinical Study Report Report date: 26 August 2022

Source: Submission document -Attachment 04 CSR-20200286 Amgevita HC.

Clinical claim

- 5.4 The submission claimed that Amgevita HC is non-inferior in terms of comparative efficacy and safety to Humira. The approved product information states Amgevita HC is biosimilar to Humira.

Economic analysis

- 5.5 The submission requested listing of Amgevita HC on a cost-minimisation basis to Humira. The submission requested the same AEMP for Amgevita HC as Humira for the equivalent form and strength. The equi-effective dose is 1 mg of Amgevita HC = 1 mg Humira.

Estimated PBS usage and financial implications

- 5.6 The submission used the PBS services volumes from calendar year 2024 and an assumed flat annual growth rate of 2% for each presentation, with █% uptake of each Amgevita HC presentation to estimate the PBS usage and financial implications.
- 5.7 The submission estimated a nil net financial impact to the PBS/RPBS over a period of six years (Table). The evaluation considers the nil cost the PBS/RPBS will be based on the following criteria:
- No change to size of patient population (no change in market size).

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- No change to the current treatment algorithm (no change in annual packs consumed).
- No change to the price per unit of existing medications (no change in total cost).
- No change to the service delivery arrangements (no flow-on change to Services Australia).
- No change to the utilisation of testing or medical imaging (no flow-on change to Medical Benefits Schedule).

Table 4: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts	1 ¹	1 ¹	2 ²	2 ²	2 ²	2 ²
Estimated financial implications						
New PBS listing	\$ ³	\$ ³	\$ ³	\$ ³	\$ ³	\$ ³
Changed PBS listing	-\$ ⁴	-\$ ⁴	-\$ ⁴	-\$ ⁴	-\$ ⁴	-\$ ⁴
Net cost to PBS	\$0	\$0	\$0	\$0	\$0	\$0
New RPBS listing	\$ ⁵	\$ ⁵	\$ ⁵	\$ ⁵	\$ ⁵	\$ ⁵
Changed RPBS listing	-\$ ⁴	-\$ ⁴	-\$ ⁴	-\$ ⁴	-\$ ⁴	-\$ ⁴
Net cost to RPBS	\$0	\$0	\$0	\$0	\$0	\$0
Net financial implications						
Net cost to PBS/RPBS	\$0	\$0	\$0	\$0	\$0	\$0

Source: Submission's financial model spreadsheet. Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges:

¹ 20,000 to < 30,000

² 30,000 to < 40,000

³ \$10 million to < \$20 million

⁴ net cost saving

⁵ \$0 to < \$10 million

6 PBAC Outcome

6.1 The PBAC recommended the Authority Required listing of adalimumab (Amgevita HC) in the forms and strengths of 20 mg in 0.2 mL, 40 mg in 0.4 mL, pre-filled syringe (PFS) and 40 mg in 0.4 mL, 80 mg in 0.8 mL pre-filled pen (PFP under the same circumstances as the currently PBS-listed reference biologic, Humira® for the following indications:

- Severe Crohn disease
- Moderate to severe ulcerative colitis
- Severe active juvenile idiopathic arthritis
- Enthesitis/spondylitis related juvenile idiopathic arthritis
- Complex refractory Fistulising Crohn disease
- Severe active rheumatoid arthritis
- Severe psoriatic arthritis
- Ankylosing spondylitis

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- Severe chronic plaque psoriasis
 - Moderate to severe hidradenitis suppurativa
 - Vision-threatening non-infectious uveitis
- 6.2 The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Amgevita HC strengths of 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP would be acceptable if they were cost-minimised to Humira.
- 6.3 The PBAC advised the equi-effective doses to be 1 mg of Amgevita HC = 1 mg of Humira.
- 6.4 The PBAC accepted the claim of biosimilarity for Amgevita HC 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP compared to Humira. The PBAC noted the clinical evidence presented aligned with the evidence presented to the TGA to inform its outcome of bioequivalence.
- 6.5 The PBAC advised that biosimilar uptake drivers, including the differential authority requirements for subsequent continuing treatment between the reference and biosimilar brands and inclusion of an administrative note encouraging the use of biosimilar brands for treatment naïve patients, should apply to Amgevita HC 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP.
- 6.6 The PBAC advised that, under Section 101(4AACD) of the National Health Act 1953 (the Act), in the Schedule of Pharmaceutical Benefits, Amgevita HC 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP should be treated as equivalent, respectively, to Humira 20 mg in 0.2 mL PFS and 40 mg in 0.4 mL PFS 40 mg in 0.4 mL PFP, 80 mg in 0.8 mL PFP for the purposes of substitution (i.e. 'a'-flagged in the Schedule).
- 6.7 The PBAC also advised that, under Section 101(4AACD) of the Act, in the Schedule of Pharmaceutical Benefits, Amgevita HC 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP should be considered equivalent for the purposes of substitution, respectively, with any adalimumab 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP, consistent with its previous considerations of adalimumab.
- 6.8 The PBAC also advised that, Amgevita HC 40 mg/0.4 PFS and PFP should also be considered equivalent for the purposes of substitution, with any adalimumab 40mg/0.8mL PFS and PFP respectively and Amgevita HC 20 mg/0.2mL PFS and PFP equivalent with any adalimumab 20 mg/0.4 mL PFS and PFP.
- 6.9 The PBAC considered that the listing of Amgevita HC 20 mg in 0.2 mL PFS and 40 mg in 0.4 mL PFS 40 mg in 0.4 mL PFP, 80 mg in 0.8 mL PFP, is expected to be cost-neutral to Government given that Amgevita HC will likely substitute for the reference biologic Humira and therefore not increase overall market utilisation.

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- 6.10 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Amgevita HC 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 2022 for Pricing Pathway A were not met.
- 6.11 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 Add adalimumab biosimilar brand Amgevita HC, in the forms and strengths of 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP, with schedule equivalence ('a' flag) for the same indications as Humira 20 mg in 0.2 mL, 40 mg in 0.4 mL, PFS and 40 mg in 0.4 mL, 80 mg in 0.8 mL PFP as noted in Section 6.
- 7.2 Amend existing/recommended listing as follows:
- Create new item codes for 20 mg/0.2 mL injection, 0.2 mL syringe for all indications that Humira is currently listed for, applying the biosimilar policies and 'a' flagging to the current 20 mg forms.
 - Add Amgevita HC to all indications that Humira is currently listed for the 40 mg/0.4 mL PFs/PFP and 80 mg/0.8 mL PFP.

Moderate to Severe Ulcerative Colitis**Initial treatment/Initial Balance of Supply:**

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>3</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	12371D	1	2	3	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12350B	2	2	3	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12347W	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12412G	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12382Q	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12359L	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12374G	3	3	0	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First Continuing treatment/Continuing Balance of Supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	12337H	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12357J	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12358K	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12391E	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

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Subsequent Continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	14996G	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12351C	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13211H	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13213K	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Severe Crohn disease

Initial treatment (paediatric patients):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>3</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	12407B	1	2	3	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12332C	2	2	3	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12432H	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12373F	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12455M	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12338J	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12426B	3	3	0	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Balance of supply for paediatric patient:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>0</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	12423W	1	2	0	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12354F	2	2	3	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12411F	1	2	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12379M	1	2	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First Continuing treatment of Crohn disease in a paediatric patient:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	12424X	1	2	5	Humira

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adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12440R	2	2	5	Amgevita
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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12341M	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12413H	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Subsequent Continuing treatment of Crohn disease in a paediatric patient:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	14995F	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12436M	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13224B	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13218Q	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Initial treatment/Balance of Supply (adult patients):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12433J	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12345R	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12453K	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12451H	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12419P	3	3	0	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First Continuing/Subsequent Continuing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12389C	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12410E	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Subsequent Continuing (adult patients):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13225C	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

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adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13219R	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
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Complex refractory fistulising Crohn disease:**Initial treatment/Balance of Supply:**

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12340L	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12381P	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12397L	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12380N	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12360M	3	3	0	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First continuing treatment/Subsequent continuing treatment/Balance of supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12446C	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12405X	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
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Subsequent continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13230H	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13220T	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

Severe active juvenile idiopathic arthritis

Initial treatment/Balance of Supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>0</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	12406Y (HB) 12443X (HS)	1	2	0	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12435L (HB) 12439Q (HS)	2	2	0	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12428D	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12444Y (HB) 12335F (HS)	1	2	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12364R	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12431G (HB) 12396K (HS)	1	2	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Continuing treatment

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	13293P (HB) 13292N (HS)	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	12417M (HB) 12349Y (HS)	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13212J (HB) 13229G (HS)	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13228F (HB) 13210G (HS)	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Transitioning from non-PBS to PBS-subsidised treatment – Grandfather arrangements

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	15156Q (HB) 15173N (HS)	1	2	5	Humira

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adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	15143B (HB) 15202D (HS)	2	2	5	Amgevita
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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	15138R (HB) 15142Y (HS)	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	15177T (HB) 15178W (HS)	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First Continuing treatment, Balance of Supply, Subsequent Continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12425Y	1	2	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12399N	1	2	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Subsequent Continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13223Y	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13209F	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

Enthesitis/spondylitis related juvenile idiopathic arthritis:

Initial treatment/Balance of Supply:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>0</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	15148G	1	2	3	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	15155P	2	2	3	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	15146E	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	15201C	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Continuing treatment

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	15149H	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	15180Y	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	15153M	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	15189K	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Transitioning from non-PBS to PBS-subsidised treatment – Grandfather arrangements

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
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ADALIMUMAB					
adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe	NEW	2	2	5	Amgevita HC
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	15190L	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	15172M	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	15159W	1	2	5	Hadlima Humira Hyrimoz Yuflyma Amgevita HC
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	15170K	1	2	5	Hadlima Humira Hyrimoz Yuflyma Amgevita HC

Severe active rheumatoid arthritis:**Initial treatment/Balance of Supply:**

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12429E	1	2	3	Hadlima Humira Hyrimoz Yuflyma Amgevita HC
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12400P	1	2	3	Hadlima Humira Hyrimoz Yuflyma Amgevita HC

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13691N	1	2	3	Hadlima Hyrimoz Yuflyma Amgevita HC
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13704G	1	2	3	Hadlima Hyrimoz Yuflyma Amgevita HC

First continuing treatment/balance of supply:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12390D	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12430F	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13703F	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13732R	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

Subsequent continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13227E	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13222X	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Ankylosing spondylitis:

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Initial treatment/Balance of Supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12376J	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12442W	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13764K	1	2	3	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13763J	1	2	3	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

First continuing treatment/Subsequent continuing treatment/balance of supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12363Q	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12361N	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13226D	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13208E	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
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Severe chronic plaque psoriasis:**Initial treatment/Balance of Supply:**

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>4</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	14976F	1	2	4	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	14975E	2	2	4	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	15031D	1	2	4	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12421R	1	2	4	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12342N	1	2	4	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	15010B	1	2	4	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					

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adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12447D	1	1	0	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
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First continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	14997H	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	14998J	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	14973C	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	15009Y	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First continuing treatment/Subsequent continuing treatment/Balance of Supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12377K	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12422T	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Subsequent continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	15039M	1	2	5	Humira

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adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	15005R	2	2	5	Amgevita
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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	15038L	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	15007W	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13215M	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13217P	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

Severe psoriatic arthritis:**Initial treatment/Balance of Supply:**

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12362P	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12378L	1	2	3	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First continuing treatment/Subsequent continuing treatment/balance of supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12375H	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	12398M	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Subsequent continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13214L	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	13216N	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

Moderate to severe hidradenitis suppurativa:**Initial treatment:**

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12454L	3	6	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12450G	3	3	0	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Balance of supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					

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adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12383R	2	4	2	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12449F	2	2	2	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

First continuing treatment/Subsequent continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	12414J	2	4	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12448E	2	2	5	Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Subsequent continuing treatment:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	13221W	2	4	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	14587R	2	2	5	Hyrimoz Yuflyma <i>Amgevita HC</i>

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Vision threatening non-infectious uveitis:**Initial treatment/Recommencement of treatment:**

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>6</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	14244Q	1	2	6	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	14748F	2	2	6	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	14272E	1	2	6	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	14628X	1	2	6	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Balance of supply:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>0</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	14245R	1	2	0	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	14749G	2	2	0	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	14242N	1	2	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	14586Q	1	2	0	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

Continuing treatment:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.2 mL injection, 2 x 0.2 mL syringes	14275H	1	2	5	Humira
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	14747E	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/ 0.2 mL injection, 0.2 mL syringe</i>	<i>NEW</i>	<i>2</i>	<i>2</i>	<i>5</i>	<i>Amgevita HC</i>
adalimumab 20 mg/ 0.4 mL, 0.4 mL syringe	14772L	2	2	5	Amgevita

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	14221L	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	14591Y	1	2	5	Hadlima Humira Hyrimoz Yuflyma <i>Amgevita HC</i>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL pen devices	14234E	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>
adalimumab 40 mg/ 0.4 mL injection, 2 x 0.4 mL syringes	14629Y	1	2	5	Hadlima Hyrimoz Yuflyma <i>Amgevita HC</i>

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

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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.