

**6.13 INFLIXIMAB,
Solution for injection 120 mg in 1 mL pre-filled syringe,
Solution for injection 120 mg in 1 mL pre-filled pen
Remsima SC[®],
Celltrion Healthcare Australia Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 3 submission sought a General Schedule Authority Required listing for infliximab (IFX) administered via subcutaneous (SC) injection in the form of a 120 mg in 1 mL pre-filled syringe (PFS) and pre-filled autoinjector pen (PFP) for the treatment of ankylosing spondylitis (AS), severe chronic plaque psoriasis (CPP), severe active psoriatic arthritis (PsA), and complex refractory fistulising Crohn’s Disease (RFCD).

Table 1: Key components of the clinical issue addressed by the submission

Component	Description
Population	Adult patients with AS, severe CPP, severe PsA and complex RFCD.
Intervention	IFX SC
Comparator	IFX IV
Outcomes	All populations: Population (PK) modelling In RFCD (peri-anal CD): treatment persistence, serum IFX levels, adverse events In PsA: Clinical assessments (CRP, Patient/Physician pain VAS), SIAQ (self-injection questionnaire)
Clinical Claim	The population PK modelling presented demonstrates that the therapeutic target for SC is similar to that of IV, at the recommended doses, providing sufficient information, in the absence of clinical trial data, to support the non-inferior effectiveness of IFX SC in AS, severe PsA, severe CPP and complex RFCD. Therefore, the non-inferior doses approved for IFX SC by the TGA during maintenance are the appropriate non-inferior doses vs. IFX IV.
Economic Claim	IFX SC 120mg fortnightly is non-inferior to IFX IV 5mg/kg 8 weekly for severe PsA, severe CPP and complex RFCD, and 6 weekly for AS. The same price agreed for severe active RA, moderate to severe UC and severe CD is requested for the outstanding indications
Financials	Savings to government of \$[REDACTED] by year 6 is forecast.

AS ankylosing spondylitis; CD Crohn’s disease; CPP chronic plaque psoriasis; IFX infliximab; IV intravenous; PK pharmacokinetic; PsA psoriatic arthritis; RFCD refractory fistulising Crohn’s disease; SC subcutaneous;
Source: Table 1-3, pg 4 of submission

2 Background

Previous PBAC consideration

- 2.1 At its November 2020 meeting, the PBAC recommended the listing of IFX SC on a cost minimisation basis to IFX intravenous (IV). The PBAC considered non-inferiority of IFX SC to IFX IV was supported for the treatment of severe active rheumatoid arthritis

(RA), moderate to severe ulcerative colitis (UC) and severe refractory Crohn's disease (CD). The PBAC advised that the listing of IFX SC should be based on the equi-effective dose of IFX SC 120 mg Q2W and (i) IFX IV 3 mg/kg Q8W in RA; and (ii) IFX IV 5 mg/kg Q8W in UC and CD

- 2.2 However, the PBAC did not recommend the listing of IFX SC for AS, CPP, PsA and RFCD. The PBAC noted there were no clinical trials assessing the efficacy of IFX SC in patients with these conditions and did not consider extrapolation of clinical evidence from RA, UC and CD to AS, CPP, PsA, and RFCD was adequate to support PBS listings.

Registration status

- 2.3 IFX SC was registered on the Australian Register of Therapeutic Goods on 25 August 2021 for AS, CD, CPP, PsA, RA, RFCD and UC.

3 Requested listing

- 3.1 The submission requested listing of IFX SC under the same circumstances as IFX IV. The restrictions recommended by PBAC are presented in Section 7.

4 Comparator

- 4.1 The submission nominated IFX IV as the comparator.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC welcomed and noted the advice received from the Gastroenterological Society of Australia (GESA) stating the addition of infliximab SC to the PBS for patients with fistulising Crohn's Disease would provide more therapeutic options to patients and physicians, improve patients' quality of life, decrease the financial impact of two monthly infusions and provide better access and convenience with treatment. GESA also noted in the setting of the COVID-19 pandemic, or future outbreaks, the risk associated with attending a hospital or infusion centre for IV medication administration would also be reduced with the option for self-administration of IFX SC.

Clinical trials

- 5.3 The submission presented clinical studies in perianal CD (to support use in RFCD) and PsA and an expert report on population pharmacokinetic (PK) modelling to support non-inferiority of IFX SC to IFX IV in AS, CPP, PsA, and RFCD (Table 2). As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Table 2: Studies presented in the submission

Study ID	Protocol/Publication Title
Clinical studies	
Smith 2021	Smith PJ, Story D, et al. (2021). Efficacy of subcutaneous infliximab in perianal Crohn's disease. UEGW. Virtual.
Baraliakos 2021 ¹	Baraliakos X, Tsiami S, et al. (2021). Real-world evidence for subcutaneous infliximab (CT-P13 SC) treatment in patients with psoriatic arthritis during the coronavirus disease (COVID-19) pandemic: a case series. Department of Rheumatology, N. C. H., Royal Wolverhampton NHS Trust.
Non-clinical studies	
Lange and Kinnear 2021	Evaluation of the strength of evidence to support of the use of Remsima SC across all TGA-approved indications.

Source: sponsor's submission, p 35

1. Full publication available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8777045/pdf/CCR3-10-e05205.pdf>

Comparative effectiveness

- 5.4 The submission presented a single centre, observational, retrospective study of patients with perianal CD (pCD) who were maintained on IFX IV and switched to IFX SC (Smith 2021, available as an abstract only). The success of IFX SC treatment was defined by clinical success at 6 months assessed by the physician's judgment without additional medical or surgical treatment for pCD. Of 18 patients that initiated treatment with IFX SC, treatment persistence at 6 months was 89% (16 patients). Treatment switch was associated with an increase in IFX levels and there were no safety issues or adverse events of note. Two patients had a recurrence of symptoms after switching and required further antibiotic treatment and examination under anaesthesia. These 2 patients switched back to IFX IV after a median 2.25 months.
- 5.5 The submission presented a case series of 10 PsA patients receiving IFX SC treatment at 2 centres in Germany (n=3) and the UK (n=7) (Baraliakos 2022). Two patients initiated on IFX SC following 2 doses of IFX IV and 8 patients had been on IFX IV for varying amounts of time prior to IFX SC initiation. After a median follow up of 5.5 months, 7 patients remained on IFX SC treatment and 3 patients had switched back to IFX IV. There were no new or unexpected safety findings.
- 5.6 The submission provided an expert report that evaluated the expected clinical outcomes based on population pharmacokinetics for IFX IV and SC. In the absence of randomised, controlled clinical trial data, a population pharmacokinetic approach was undertaken to evaluate the strength of evidence to support the use of IFX SC across all TGA-approved indications. Representative *in silico* patient populations were constructed for each indication based on previously reported data and predicted concentration-time profiles at steady-state were compared for IFX IV and SC dosing.
- 5.7 The expert report concluded that the comparative pharmacokinetics of the formulations indicated SC administration is associated with a flatter concentration-time profile, with lower maximum concentrations and higher trough concentrations, when compared to IV dosing. The report states that given the trough concentration has been associated with clinical efficacy of IFX in a range of inflammatory diseases,

dosing of IFX via the SC route is expected to result in a high probability of target attainment in the context of previously proposed therapeutic targets. For SC administration, target attainment is predicted in 100% of patients across all indications when considering a target of 1 mg/L; this compares to values of 57 – 88% for IV administration of IFX.

- 5.8 The pre-PBAC response included additional clinical studies to support use in CD and perianal disease (the study focused on maintaining fistula closure in RFCD), UC, PsA and AS in a total of N=185 patients, with key outcomes showing:
- Maintenance of clinical remission 6 months after switch from IV (Argüelles-Arias 2021).
 - Improvement or maintenance in inflammatory markers 6 months after switch from IV (Smith 2021a, Argüelles-Arias 2021).
 - Increases in serum IFX concentrations reported with SC at 3 and 6 months vs. baseline (Argüelles-Arias 2021, Smith 2021a, Smith 2021b).
 - Persistence to SC therapy reported to be unrelated to patient weight in AS (Vijayan 2022).
 - AEs were generally infrequent, mild and did not lead to discontinuation, including mainly injection site reactions (Argüelles-Arias 2021, McGorran 2022, Vijayan 2022, Smith 2021a, Smith 2021b).

Clinical claim

- 5.9 The submission claimed that, for the treatment of AS, CPP, PsA and RFCD, IFX SC is non-inferior to IFX IV in terms of efficacy and safety.
- 5.10 The PBAC noted the clinical claim was based on a small number of observational studies and a pharmacokinetic study but considered that, overall, the claim of non-inferior comparative effectiveness was reasonable.
- 5.11 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

Economic analysis

- 5.12 As a Category 3 submission, the economic analysis has not been independently evaluated.
- 5.13 The submission presented a cost-minimisation approach (CMA) of IFX SC compared with IFX IV. The equi-effective doses were estimated as IFX SC 120 mg Q2W and IFX IV 5 mg/kg Q8W for CPP, PsA and RFCD and Q6W in AS. The submission calculated an ex-manufacturer price (EMP) of \$1 per injection. The CMA is summarised in the tables below. The methodology applied was consistent with that used for RA, UC and CD.

Table 3: Cost of IFX IV over 24 months (based on AEMP per 100 mg vial = \$320.71)

Indication	AS	CPP	PsA	RFCD
Dose	5 mg/ kg Q6W	5 mg/ kg Q8W	5 mg/ kg Q8W	5 mg/ kg Q8W
Number of doses over 24 months	17.3	13	13	13
Average number of vials per dose ¹				
% Public hospital use				
Total drug cost (net of patient copayment) (\$)				
Total admin cost (\$)				
Total cost (\$)				
% use				
Weighted total cost (\$)				

AS ankylosing spondylitis; CPP chronic plaque psoriasis; PsA psoriatic arthritis; RFCD refractory fistulising Crohn's disease

1. Based on an analysis of Prospecion data (summary table only, provided as Attachment 4 to the submission) based on data from November 2019 to October 2020

Table 4: Cost calculation for IFX SC

IFX SC cost over 24 months	\$ [REDACTED]
Accounting for 10% of injections requiring GP assistance ¹	-\$ [REDACTED]
Cost over 24 months	\$ [REDACTED]
Cost per 4 weeks (i.e., 2 injections)	\$ [REDACTED]
Add back patient copayment	+\$32.52
DPMQ	\$ [REDACTED]
EMP per 2 injections	\$ [REDACTED]
EMP per injection	\$ [REDACTED]

DPMQ dispensed price for maximum quantity; EMP ex-manufacturer price; IFX infliximab; SC subcutaneous

1. Based on 10% of patients requiring a GP visit (MBS item 116)

5.14 Despite the CMA supporting a price of \$ [REDACTED] per injection, the submission proposed the same price for AS, CPP, PsA and RFCD as agreed for the currently listed PBS indications of RA, UC and CD (\$).

Drug cost/patient/2-years: \$ [REDACTED]

5.15 Assuming a DPMQ of \$ [REDACTED] and 26 scripts over two years of treatment with IFX SC, the cost per patient is \$ [REDACTED]. Using the same assumptions as presented in Table 3, the cost per patient for IFX IV (including administration) ranged from \$ [REDACTED] (for RFCD) to \$ [REDACTED] (for AS)¹.

¹ Using Cost-Min worksheet in Infliximab SC – Section 3 – Cost minimisation – March 2022.xls with copayment (row 20) set to \$0, for comparison to the cost per patient for IFX SC.

Estimated PBS utilisation and financial implications

5.16 The submission used a market share approach to estimate the number of patients switching to IFX SC from IFX IV.

Table 5: Data sources and parameter values applied in the utilisation and financial estimates

Data	Value and Source							Comment
	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	
IFX market growth	[REDACTED]							Consistent with assumptions previously accepted for IFX SC.
Market uptake of IFX SC		Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Consistent with assumptions previously accepted for IFX SC.
	Init.*	[REDACTED]						
	Cont.	[REDACTED]						
	*Initial market uptake limited to [REDACTED] %							
Script equivalence	1.81							The submission noted a lower script equivalence than the previous submission (2.0) was accounted for by the increased frequency of AS dosing with IFX IV (Q6W rather than Q8W).
Weighted average number of vials per infusion	4.632							Based on proportion of use and number of vials for each indication as outlined in Table 4.

AS ankylosing spondylitis; IFX infliximab; IV intravenous; SC subcutaneous;

5.17 The estimated extent of use is presented in the table below. The submission estimated that 5,000 to < 10,000 patients would be supplied IFX SC over the first six years of listing (440 in Year 1 to 1,637 in Year 6). The submission estimated a net save to the PBS of \$0 to < \$10 million in Year 6 of listing, with a total net save to the PBS of \$0 to < \$10 million over the first 6 years of listing.

5.18 The submission presented a sensitivity analysis that increased IFX SC market share (increased to [REDACTED] % for initial scripts and [REDACTED] % for continuing scripts) which resulted in higher savings.

Table 6: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of patients treated	1	5	5	5	5	5
Number of scripts dispensed ^a	2	2	6	6	6	7
Estimated financial implications of IFX SC						
Cost to PBS/RPBS less co-payment (\$)	3	3	3	8	8	8
Estimated financial implications of IFX IV for the PBS/RPBS						
Cost to PBS/RPBS less co-payment (\$)	3	6	6	8	8	8
Estimated financial implications of IFX IV for the health budget						
Net change in MBS 14245 (\$)	-4	-4	-4	-4	-4	-4
Net financial implications						
Net cost to PBS/RPBS (\$)	-4	-4	-4	-4	-4	-4
Net cost to health budget (\$)	-4	-4	-4	-4	-4	-\$4

^a Assuming 13 scripts per patient per year as estimated by the submission. Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: 4-10 p86 of the submission.

The redacted values correspond to the following ranges:

¹ < 500

² 5,000 to < 10,000

³ \$0 to < \$10 million

⁴ net cost saving

⁵ 500 to < 5,000

⁶ 10,000 to < 20,000

⁷ 20,000 to < 30,000

⁸ \$10 million to < \$20 million

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of infliximab (IFX) subcutaneous (SC) for the treatment of ankylosing spondylitis (AS), severe chronic plaque psoriasis (CPP), severe active psoriatic arthritis (PsA), and complex refractory fistulising Crohn's Disease (RFCD) on a cost minimisation basis to IFX intravenous (IV).
- 6.2 The PBAC advised the listing of IFX SC should be based on the equi-effective dose of IFX SC 120 mg Q2W to IFX IV 5 mg/kg Q8W for CPP, PsA and RFCD and Q6W in AS. The PBAC noted that based on the submission offer to accept the same price in AS, CPP, PsA and RFCD as agreed for the currently listed PBS indications of RA, UC and CD (\$332.80), there would be cost savings for the additional PBS listings of IFX SC.
- 6.3 The PBAC noted the additional PBS listings would align to the current TGA approved indications for IFX SC.
- 6.4 The PBAC noted correspondence received from the Gastroenterological Society of Australia in relation to this submission.
- 6.5 The PBAC noted the submission was based on supportive observational studies and a

PK modelling study to establish non-inferiority of IFX SC to IFX IV. The PBAC accepted the submission’s claim of the non-inferior effectiveness and safety of IFX SC was likely to be reasonable based on the presented clinical studies and pharmacokinetic modelling study.

- 6.6 The PBAC considered the assumptions for the financial estimates to be reasonable and noted there would be a total net savings to the PBS of \$0 to < \$10 million over the first 6 years of listing.
- 6.7 The PBAC considered the Safety Net early supply rule should continue to apply to IFX SC.
- 6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because IFX SC is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over IFX IV, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.9 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 A new indication for IFX SC

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL syringe	NEW	2	2	2	Remsima SC
infliximab 120 mg/mL injection, 1 mL pen device	NEW	2	2	2	Remsima SC
Restriction Summary / Treatment of Concept:					
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (In-writing only via post/HPOS upload)					
Episodicity: Treatment where a concurrent PBS authority application for the IV formulation is being made for any of					
Severity: [blank]					
Condition: the PBS-listed indications					
Indication: Treatment where a concurrent PBS authority application for the intra-venously (IV) administered formulation is being made for any of the PBS-listed indications					
Treatment Phase: [blank]					

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	Treatment criteria:
	Must be treated by the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine;
	AND
	Treatment criteria:
	Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved
	Prescribing Instructions: This authority application must be made in writing. The PBS administrator will confirm that: (i) there is a concurrent authority application for the intra-venous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.
	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
	Administrative Advice: Advise a patient attending a NSW/ACT public hospital outpatient clinic that the sub-cutaneous formulation prescription must be dispensed at a non-hospital pharmacy (i.e. at a community pharmacy).
	Administrative Advice: Where there is already an approved authority prescription for the IV formulation, an authority application for this benefit can be made under one of: (1) The 'Balance of Supply' listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a 'Continuing treatment' listing. (2) A 'Continuing treatment' (First Continuing/Subsequent Continuing) listing – apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL syringe	NEW	1	1	0	Remsima SC
infliximab 120 mg/mL injection, 1 mL pen device	NEW	1	1	0	Remsima SC

Restriction Summary / Treatment of Concept:

	Category / Program: GENERAL – General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online via HPOS)

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	Episodicity: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription for any of
	Severity: [blank]
	Condition: the PBS-listed indications
	Indication: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription for any of the PBS-listed indications
	Treatment Phase: [blank]
	Treatment criteria:
	Must be treated by the same specialist prescriber type/s as that appearing on the most recent PBS authority approval for this drug/biological medicine
	AND
	Treatment criteria:
	Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR
	Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions
	Prescribing Instructions: Where there is a current, approved PBS-prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
	Administrative Advice: Advise a patient attending a NSW/ACT public hospital outpatient clinic that the sub-cutaneous formulation prescription must be dispensed at a non-hospital pharmacy (i.e. at a community pharmacy).

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL syringe	NEW	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL pen device	NEW	2	2	5	Remsima SC
Restriction Summary / ToC: : Authority Required					
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (In-writing only via post/HPOS upload)					
COMMON TO ALL Restriction Summaries					
Administrative Advice:					

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	<p>Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
	<p>Administrative Advice: Advise a patient attending a NSW/ACT public hospital outpatient clinic that the sub-cutaneous formulation prescription must be dispensed at a non-hospital pharmacy (i.e. at a community pharmacy).</p>
	<p>Indication: Ankylosing spondylitis</p>
	<p>Treatment Phase: Continuing treatment</p>
	<p>Clinical criteria:</p>
	<p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must not receive more than 24 weeks of treatment under this restriction</p>
	<p>AND</p>
	<p>Population criteria:</p>
	<p>Patient must be aged 18 years or older</p>
	<p>AND</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a rheumatologist; or</p>
	<p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis</p>
	<p>Prescribing Instructions: The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>
	<p>Prescribing Instructions: An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.</p>
	<p>Prescribing Instructions: All measurements provided must be no more than 1 month old at the time of application.</p>

	Administrative Advice [specific to this restriction summary]: TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLYITIS -----
Restriction Summary / ToC::	
	Indication: Severe psoriatic arthritis
	Treatment Phase: Continuing treatment
	Treatment criteria: Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis
	Clinical criteria: Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition
	AND
	Clinical criteria: The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy
	AND
	Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction
	AND
	Population criteria: Patient must be aged 18 years or older
	Prescribing Instructions: The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
	Prescribing Instructions: An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
	Prescribing Instructions: The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.
	Administrative Advice [specific to this restriction summary]: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS -----

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Restriction Summary / ToC:	
	Indication: Severe chronic plaque psoriasis
	Treatment Phase: Continuing treatment (whole body, or, face/hand/foot)
	Clinical criteria:
	Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition
	AND
	Clinical criteria:
	The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy
	AND
	Clinical criteria:
	The treatment must be as systemic monotherapy (other than methotrexate)
	AND
	Clinical criteria:
	Patient must not receive more than 24 weeks of treatment under this restriction
	AND
	Population criteria:
	Patient must be aged 18 years or older
	AND
	Treatment criteria:
	Must be treated by a dermatologist
	Prescribing Instructions: The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
	Prescribing Instructions: Where the condition is affecting the whole body, an adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by at least 75%, or, is sustained at this level, when compared with the baseline value for this treatment cycle. Where the condition is affecting the face/hand/foot, an adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or, sustained at this level, as compared to the baseline values; or (ii) a reduction by at least 75% in the skin area affected, or, sustained at this level, as compared to the baseline value for this treatment cycle.

Restriction Summary / ToC:	
	Indication: Complex refractory Fistulising Crohn disease
	Treatment Phase: Continuing treatment
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:

	Patient must have demonstrated an adequate response to treatment with this drug
	AND
	Treatment criteria:
	Must be treated by a gastroenterologist (code 87); or
	Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
	Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]
	Prescribing Instructions: The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
	Prescribing Instructions: An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.
	Prescribing Instructions: The most recent fistula assessment must be no more than 1 month old at the time of application.
	Administrative Advice: TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

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.