

**6.05 INFLIXIMAB,
Solution for injection 120 mg in 1 mL pre-filled pen,
Solution for injection 120 mg in 1 mL pre-filled
syringe,
Remsima® SC,
CELLTRION HEALTHCARE AUSTRALIA PTY LTD**

1 Purpose of Submission

1.1 The Category 3 submission requested an amendment to the restriction level of infliximab (IFX) 120 mg in 1 mL subcutaneous (SC) injection (Remsima® SC) from Authority Required (Written or Telephone/Online) (hereafter referred to as 'Authority Required') to Authority Required (STREAMLINED) (hereafter referred to as 'Streamlined') for the continuing treatment and balance of supply of the listings with the following indications:

- Ankylosing spondylitis (AS)
- Severe Crohn disease (CD)
- Severe chronic plaque psoriasis (CPP)
- Severe psoriatic arthritis (PsA)
- Severe active rheumatoid arthritis (RA)
- Complex refractory fistulising Crohn disease (RFCD)
- Moderate to severe ulcerative colitis (UC)

2 Background

2.1 Remsima SC is the only brand of SC IFX listed on the PBS. Two forms are listed: 120 mg pre-filled syringe (PFS) and 120 mg pre-filled pen (PFP). The initial and continuing treatment restrictions of SC IFX are Authority Required for each of the listed indications.

2.2 Unlike the 100 mg intravenous (IV) formulation, SC IFX is only recommended for adults and is not approved by the Therapeutic Goods Administration (TGA) for the treatment of CD, UC, or acute severe UC in children and adolescents aged 6-17 years. The safety and efficacy of Remsima® SC therapy in individuals under 18 years have not been established, with no available data.

2.3 The TGA Product Information (PI) states that treatment with IFX administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two IV IFX infusions, with the exception of the RA indication for

which it may be initiated with or without IV IFX loading doses. The recommended maintenance dose for SC IFX is 120 mg once every 2 weeks for all indications.

Registration status

- 2.4 SC IFX 120 mg PFP and PFS were TGA registered on 25 August 2021 for the currently PBS-listed indications as a new strength with an alternative route of administration to IV IFX (paragraph 2.1, infliximab SC, Public Summary Document (PSD), November 2020 PBAC meeting).
- 2.5 As per the PI, “Remsima® (IFX) is an approved biosimilar to the reference product Remicade® (IFX). Comparability in safety, efficacy, and quality between Remsima® and Remicade® has been established.” The PI was not specific about whether this applies to just the IV form or both forms of Remsima.

Previous PBAC consideration

- 2.6 At its November 2020 meeting, the PBAC first recommended listing SC IFX PFP and PFS for the treatment of severe active RA, moderate to severe UC, and severe refractory CD on a cost minimisation basis to IV IFX (paragraph 7.1, infliximab SC, PSD, November 2020 PBAC meeting). The PBAC considered that a SC formulation of IFX provides an additional patient-relevant option for maintenance therapy in RA, UC, and CD (paragraph 7.4). The PBAC considered that the restrictions of the SC form of IFX should not be based on the biosimilar preferred prescribing policy, as the assertion of biosimilarity for the purposes of PBS listing was not valid given the different routes of administration and evidence of different pharmacokinetic profiles (paragraph 7.6, infliximab SC, PSD, November 2020 PBAC meeting).
- 2.7 At the same meeting, the PBAC advised that the SC IFX restrictions should have an initial SC restriction that allows a transition from IV to SC at Week 6 through to assessment at Week 12, and a balance of supply listing to complete the treatment (initial and continuing) for each indication. The PBAC also considered a ‘continuing’ restriction would be required as ‘first continuing’ and ‘subsequent continuing’ restrictions would not be applicable (paragraph 7.8, infliximab SC, PSD, November 2020 PBAC meeting).
- 2.8 At its March 2022 meeting, the PBAC subsequently recommended the listing of SC IFX for the treatment of AS, severe CPP, severe active PsA, and complex RFCD on a cost minimisation basis to IV IFX, and advised that the claim of the non-inferior effectiveness and safety of SC IFX to IV IFX was likely to be reasonable based on the presented clinical studies and pharmacokinetic modelling study (paragraphs 6.1 and 6.5, infliximab SC, PSD, March 2022 PBAC meeting).
- 2.9 The PBAC has not reconsidered the authority level of SC IFX in the continuing treatment phase since first recommending it for listing.

3 Requested listing

- 3.1 The submission requested changing the restriction level of the SC IFX:
- continuing treatment listings across all indications from Authority Required to Streamlined to align with other disease-modifying anti-rheumatic drugs (DMARDs) that have Streamlined restrictions, and
 - continuing treatment balance of supply listings for the CD, RA and UC indications from Authority Required to Streamlined. The AS, CPP, PsA, and RFCD indications were not included in this request because their listings do not restrict the balance of supply listing to a treatment phase.
- 3.2 Table 1 provides a summary of the authority levels of SC IFX and IV IFX and the requested changes.

Table 1: A summary of the current authority levels of SC IFX and IV IFX, and the requested authority changes

Indication	SC IFX 120 mg/mL PFP/PFS			IV IFX 100 mg vial	
	Treatment phase/PBS item codes	Current restriction level	Requested restriction level	Treatment phase/PBS item codes	Current restriction level
Severe active rheumatoid arthritis	Continuing or switching from IV (12554R, 12553Q)	Authority Required	Authority Required (STREAMLINED)	First and subsequent continuing ^a (13734W, 13700C, 11490R, 11483J)	Authority Required (STREAMLINED)
	Balance of supply for initial and continuing (12566J, 12555T)	Authority Required	Authority Required (STREAMLINED)	Initial, first continuing, balance of supply for first continuing ^c (5757B, 6397Q)	Authority Required
	Initial with concurrent IV authority application (12577Y, 12576X)	Authority Required	Not requested		
Severe Crohn disease	Continuing or switching from IV (12560C, 12586K)	Authority Required	Authority Required (STREAMLINED)	Subsequent continuing ^b (11396T, 11400B)	Authority Required (STREAMLINED)
	Balance of supply for initial and continuing (12567K, 12597B)	Authority Required	Authority Required (STREAMLINED)	Initial, first continuing, balance of supply for first continuing ^c (5754W, 9613Y)	Authority Required
	Initial with concurrent IV authority application (12551N, 12585J)	Authority Required	Not requested		
Moderate to severe ulcerative colitis	Continuing or switching from IV (12587L, 12552P)	Authority Required	Authority Required (STREAMLINED)	Continuing treatment ^b (11461F, 11796W)	Authority Required (STREAMLINED)
	Balance of supply for initial and continuing (12584H, 12550M)	Authority Required	Authority Required (STREAMLINED)	Initial, balance of supply ^c (10196P, 10184B)	Authority Required
	Initial with concurrent IV authority application (12575W, 12561D)	Authority Required	Not requested		
Ankylosing spondylitis	Continuing or switching from IV (13048R, 13069W)	Authority Required	Authority Required (STREAMLINED)	First and subsequent continuing ^b (11486M, 11488P)	Authority Required (STREAMLINED)
	Balance of supply (13075E, 13065P) Initial with concurrent IV authority application (13049T, 13057F)	Authority Required	Not requested	Initial, first continuing, balance of supply of first continuing ^c (5753T, 6448J)	Authority Required

Indication	SC IFX 120 mg/mL PFP/PFS			IV IFX 100 mg vial	
	Treatment phase/PBS item codes	Current restriction level	Requested restriction level	Treatment phase/PBS item codes	Current restriction level
Severe psoriatic arthritis	Continuing or switching from IV (13054C, 13047Q)	Authority Required	Authority Required (STREAMLINED)	Subsequent continuing ^b (11514B, 11515C)	Authority Required (STREAMLINED)
	Balance of supply (13056E, 13078H) Initial with concurrent IV authority application (13077G, 13066Q)	Authority Required	Not requested	Initial, first continuing, balance of supply of first continuing ^c (6496X, 5756Y)	Authority Required
Complex refractory fistulising Crohn disease	Continuing or switching from IV (13060J, 13073C)	Authority Required	Authority Required (STREAMLINED)	Subsequent continuing ^b (11423F, 11432Q)	Authority Required (STREAMLINED)
	Balance of supply (13061K, 13074D), Initial with concurrent IV authority application (13055D, 13072B)	Authority Required	Not requested	Initial, first continuing, balance of supply ^c (9654D, 9674E)	Authority Required
Severe chronic plaque psoriasis	Continuing or switching from IV (13076F, 13050W)	Authority Required	Authority Required (STREAMLINED)	Subsequent continuing ^b (11605T, 11595G)	Authority Required (STREAMLINED)
	Balance of supply (13070X, 13058G) Initial with concurrent IV authority application (13062L, 13067R)	Authority Required	Not requested	Initial, first continuing, balance of supply for initial and continuing ^c (5758C, 9617E)	Authority Required

Source: Compiled by the Secretariat during evaluation

^a Only the biosimilar brands of IV IFX are Streamlined in the first continuing treatment phase of RA, all brands are Streamlined in the subsequent continuing treatment phase.

^b Only applicable to the biosimilar brands of IV IFX; Inflectra and Renflexis.

^c All brands (reference and biosimilars) of IV IFX are included.

- 3.3 As outlined in Table 1, only the biosimilar brands of IV IFX are Streamlined listings in the continuing (first or subsequent) treatment phases of IV IFX with the exception of the subsequent treatment phase of RA where the reference brand (Remicade) is a Streamlined listing.
- 3.4 As the submission did not provide the suggested wording changes associated with lowering the authority level, the Secretariat proposed changes to the Prescribing Instructions for the continuing treatment of SC IFX in line with the current concept codes of the Streamlined authority for IV IFX. No other changes to the treatment and clinical criteria across all indications were proposed.
- 3.5 An abridged version of the requested listings is presented below. Suggested additions and deletions to the submission’s request are in italics and strikethrough respectively.

Severe active rheumatoid arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12554R	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12553Q	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	Prescribing Instructions: An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a 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 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: <i>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</i>				
	Prescribing Instructions: Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.				
	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 application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.				
	Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.				

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	<p>Prescribing Instructions: If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>
	<p>Prescribing Instructions: If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>
	<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>
	<p>Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>
	<p>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. 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 7004</p>

Severe active rheumatoid arthritis – balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12566J	1	1	0	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12555T	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 PBS Authorities system)				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form				
	Clinical criteria:				
	The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; or				
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment – subcutaneous form				
	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. Monday to Friday).				

Severe Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12560C	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12586K	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe Crohn disease				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	Prescribing Instructions: Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application – Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment.				
	Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response conducted up to 12 weeks of therapy and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.				
	Prescribing Instructions: The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.				
	Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.				
	Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.				
	Prescribing Instructions: A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.				

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	<p>Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>
	<p>Prescribing Instructions: If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>
	<p>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 7004</p>

Severe Crohn disease – balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12567K	2	2	0	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12597B	2	2	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 PBS Authorities system)				
	Indication: Severe Crohn disease				
	Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form				
	Clinical criteria:				
	Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); or				
	Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment				
	AND				
	Clinical criteria:				
	The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; or				
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment – subcutaneous form				
	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. Monday to Friday).				

Moderate to severe ulcerative colitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12587L	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12552P	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Indication: Moderate to severe ulcerative colitis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	Prescribing Instructions: Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.				
	Prescribing Instructions: Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.				
	Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.				
	Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.				
	Prescribing Instructions: The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.				
	Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.				
	Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.				
	Prescribing Instructions: A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.				

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	<p>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).</p>
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Moderate to severe ulcerative colitis – balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12584H	2	2	0	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12550M	2	2	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 PBS Authorities system)				
	Indication: Moderate to severe ulcerative colitis				
	Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form				
	Clinical criteria:				
	Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); or				
	Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment				
	AND				
	Clinical criteria:				
	The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; or				
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment – subcutaneous form				
	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. Monday to Friday).				

Ankylosing spondylitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13048R	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13069W	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Ankylosing spondylitis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	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 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 used to assess all future responses to treatment.				
	Prescribing Instructions: The assessment of response to treatment must be documented in the patient's medical records <i>and must be no more than 4 weeks old at the time of the authority application.</i>				
	Prescribing Instructions: All measurements provided must be no more than 1 month old at the time of application.				
	Prescribing Instructions: <i>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</i>				
	Prescribing Instructions: <i>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</i>				
	Administrative Advice: <i>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. Monday to Friday).</i>				

Severe psoriatic arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13054C	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13047Q	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe psoriatic arthritis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	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.				
	Prescribing Instructions: <i>The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.</i>				
	Prescribing Instructions: <i>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</i>				
	Prescribing Instructions: <i>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</i>				

<p>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. 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 7004</p>
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Complex refractory fistulising Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13060J	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13073C	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Indication: Complex refractory Fistulising Crohn disease					
Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form					
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.					
Prescribing Instructions: The measurement of response to the prior course of therapy must be documented in the patient's medical notes.					
Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.					

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<p>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. 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 7004</p>
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Severe chronic plaque psoriasis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13076F	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13050W	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form					
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. State the qualifying PASI score in the authority application. 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. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; 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. State the qualifying numerical percentage figure in the authority application for each affected area. All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline.					

	<p>Prescribing Instructions: <i>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</i></p>
	<p>Prescribing Instructions: <i>Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.</i></p>
	<p>Prescribing Instructions: <i>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</i></p>
	<p>Prescribing Instructions: <i>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</i></p>
	<p>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. 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 7004</p>

3.6 The balance of supply in PBS restrictions allows prescribers to request additional quantities of a medicine to ensure patients have enough supply to complete their treatment. Changing the restriction level for the continuing treatment phase of the CD, RA and UC indications to Streamlined permits prescribers to write subsequent prescriptions to complete the treatment course without requiring prior authority approval. As an initial treatment prescription is typically authorised once only, if the quantity prescribed is insufficient for the initial treatment period, a balance of supply listing is required. Should all continuing treatment phase listings of SC IFX be changed to Streamlined, a balance of supply for continuing treatment is no longer necessary. Introducing a Streamlined balance of supply listing is unprecedented and may not be appropriate as it would create inconsistencies with the current administration of balance of supply restrictions, which are all Authority Required. The PBAC advised that the balance of supply for initial treatment listings should remain Authority Required and references to providing a balance in the continuing treatment phase be removed.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted and welcomed the input from the Australasian Society of Clinical Immunology and Allergy (ASCIA) and the Australasian College of Dermatologists (ACD) via the Consumer Comments facility on the PBS website. Both ASCIA and the ACD emphasised the importance of the early and effective treatment of autoimmune conditions. ASCIA specifically advocated for the streamlining SC IFX to facilitate early treatment ensuring better long-term clinical outcomes and quality of life, while the ACD supported streamlining to ease the administrative burden and ensure timely and appropriate access to treatment for patients. The PBAC noted that this advice was supportive of the submission's request.

Justification for request

- 4.3 The submission claimed that SC IFX should be considered biosimilar to IV IFX and that biosimilar uptake drivers should be applied. At its November 2020 and March 2022 considerations of SC IFX, the PBAC determined that SC IFX restrictions should not be based on the biosimilar policy due to the different route of administration and pharmacokinetic profile compared to IV IFX, however, considered the IV and SC formulations therapeutically equivalent and non-inferior in comparative effectiveness and safety across the requested indications.
- 4.4 The submission stated that the primary purpose of the Streamlined authority process is to reduce the administrative burden on prescribers in relation to chronic, stable long-term conditions (SCAC 2007¹), and it is not solely intended as a biosimilar uptake driver. Therefore, the submission asserted that a Streamlined restriction can apply to biologics, regardless of the biosimilar driver initiative, and that the application of the policy does not preclude the PBAC from recommending a change in the authority level of a product that is not the reference product.
- 4.5 The submission claimed that the current disparity in authority requirements between the IV and SC IFX formulations appears to impede equitable access to the SC formulation, where authority levels could be tailored to specific clinical scenarios. At its November 2020 consideration, the PBAC considered that the authority level of SC IFX in the subsequent continuing treatment (or 'continuing treatment' in UC) phase should be based on consistency with other SC agents and/or similar indications (paragraph 3.4, infliximab SC, PSD, November 2020 PBAC meeting). At its March 2023 meeting, the PBAC recommended the Section 100 (Highly Specialised Drugs Program) Streamlined listing of natalizumab 150 mg in 1 mL PFS for SC injection under the same circumstances as the PBS-listed natalizumab 300 mg in 15 mL vial for IV infusion (paragraph 6.1, natalizumab PSD, March 2023 PBAC meeting). Abatacept also has

¹ Inquiry into National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007, Senate Community Affairs Committee (SCAC) at https://www.aph.gov.au/~media/wopapub/senate/committee/clac_ctte/completed_inquiries/2004_07/nathpbs_07/submissions/sub04_pdf.ashx

Streamlined listings of both the IV and the SC forms for the subsequent continuing treatment of severe active rheumatoid arthritis.

4.6 The submission stated that reducing the authority level for the continuing treatment of SC IFX has a low clinical risk due to:

- confirmed patient suitability,
- established response,
- demonstrated tolerability, and
- regular monitoring.

4.7 The submission further stated that the use of SC IFX is safeguarded by the current restrictions which include:

- treatment initiation and supervision by qualified physicians,
- an appropriate authority level for the initial restriction,
- mandatory regular follow-up, and
- clear patient selection criteria.

Estimated PBS usage and financial implications

4.8 The submission estimated that the requested change to the SC IFX restriction authority level would have no financial impact to the PBS/RPBS (see Table 2) as no change in market uptake was anticipated, noting that the financial impact to Services Australia would be determined by that agency as part of the post-PBAC process.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed ^a	¹	²	²	²	²	²
Net financial implications						
Net cost to PBS/RPBS ^a	\$0	\$0	\$0	\$0	\$0	\$0

^a The financial impact was calculated based on the AEMPs of Remsima® SC Drug A, with the pre-filled pen at \$252.4 and the pre-filled syringe at \$332.8, respectively.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; AEMP = Approved ex-manufacturer price

Source: Financial Estimates workbook

The redacted values correspond to the following ranges:

¹ 30,000 to < 40,000

² 40,000 to < 50,000

Quality use of medicines

4.9 If listed, the sponsor is expected to provide training and resources to prescribers, including specialist physicians, on the current treatment guidelines and the recommended PBS eligibility criteria of the respective indications of Remsima SC to support appropriate prescribing. Prescribers are required to prescribe in accordance

with PBS restriction criteria and maintain evidence of compliance and patient eligibility on patient records.

5 PBAC Outcome

- 5.1 The PBAC recommended changing the authority level of SC IFX from Authority Required to Streamlined for the continuing treatment listings of all the listed indications (AS, severe CD, severe CPP, severe PsA, severe active RA, complex RFCD, and moderate to severe UC). In recommending this, the PBAC considered it appropriate to amend the Prescribing Instructions of the continuing treatment restrictions to be consistent with a Streamlined authority level.
- 5.2 At its November 2020 meeting the PBAC considered that the restrictions of the SC form of IFX should not be based on the biosimilar preferred prescribing policy, despite Remsima not being the innovator brand of IFX, as the assertion of biosimilarity for the purposes of PBS listing was not valid given the different routes of administration and evidence of different pharmacokinetic profiles. The PBAC considered that the authority level of SC IFX in the subsequent continuing treatment (or ‘continuing treatment’ in UC) phase should be based on consistency with other SC agents and/or similar indications. The PBAC noted its March 2023 recommendation of a new SC PFS form of natalizumab and noted that abatacept has Streamlined listings of both the IV and the SC forms for the subsequent continuing treatment of severe active rheumatoid arthritis. Given the precedent of listing SC forms of listed IV medicines for the treatment of similar indications to IFX at a Streamlined authority level, the PBAC considered that there was no clinical reason to have SC IFX listed at a higher authority level than the IV listings for the same indication and equivalent treatment phase.
- 5.3 The PBAC also recommended the removal of reference to continuing treatment from the SC IFX balance of supply restrictions and to retain its authority level. The PBAC noted that changing the restriction level of a continuing treatment restriction to Streamlined permits prescribers to write subsequent prescriptions to complete a treatment course without requiring prior authority approval. The PBAC therefore did not consider it appropriate to have a Streamlined balance of supply restriction as it would create inconsistencies with the current administration of balance of supply restrictions, which are all Authority Required, and advised that reference to continuing treatment be removed from the SC IFX balance of supply restrictions.
- 5.4 The PBAC agreed that no change in market uptake was anticipated and that there would be no financial implications to the PBS from lowering the restriction authority level to Streamlined.
- 5.5 The PBAC noted that this submission is not eligible for an Independent Review.

Outcome:

Recommended

6 Recommended listing

6.1 Amend existing listings as follows:

Ankylosing spondylitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13048R	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13069W	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Ankylosing spondylitis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	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 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 used to assess all future responses to treatment.				
	Prescribing Instructions: The assessment of response to treatment must be documented in the patient's medical records <i>and must be no more than 4 weeks old at the time of the authority application.</i>				
	Prescribing Instructions: All measurements provided must be no more than 1 month old at the time of application.				
	Prescribing Instructions: <i>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</i>				
	Prescribing Instructions: <i>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</i>				
	Administrative Advice: <i>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. Monday to Friday).</i>				

Severe Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12560C	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12586K	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe Crohn disease				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	Prescribing Instructions: Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application – Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment.				
	Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response conducted up to 12 weeks of therapy and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.				
	Prescribing Instructions: The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.				
	Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.				
	Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.				
	Prescribing Instructions: A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.				

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	<p>Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>
	<p>Prescribing Instructions: If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>
	<p>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 7004</p>

Severe Crohn disease – balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12567K	2	2	0	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12597B	2	2	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 PBS Authorities system)				
	Indication: Severe Crohn disease				
	Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form				
	Clinical criteria:				
	Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); or				
	Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment				
	AND				
	Clinical criteria:				
	The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; or				
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment – subcutaneous form				
	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. Monday to Friday).				

Severe chronic plaque psoriasis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13076F	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13050W	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe chronic plaque psoriasis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	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. State the qualifying PASI score in the authority application. 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. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; 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. State the qualifying numerical percentage figure in the authority application for each affected area. All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline.				
	Prescribing Instructions: The measurement of response to the prior course of therapy must be documented in the patient's medical notes.				
	Prescribing Instructions: Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.				
	Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.				

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	<p>Prescribing Instructions: A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>
	<p>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. 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 7004</p>

Severe psoriatic arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13054C	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13047Q	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe psoriatic arthritis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	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).				

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	<p>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.</p>
	<p>Prescribing Instructions: <i>The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.</i></p>
	<p>Prescribing Instructions: <i>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</i></p>
	<p>Prescribing Instructions: <i>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</i></p>
	<p>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. 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 7004</p>

Severe active rheumatoid arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12554R	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12553Q	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				

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	<p>Prescribing Instructions: An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a 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 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).</p>
	<p>Prescribing Instructions: <i>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</i></p>
	<p>Prescribing Instructions: Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</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 application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p>
	<p>Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>
	<p>Prescribing Instructions: <i>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</i></p>
	<p>Prescribing Instructions: If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>
	<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>
	<p>Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>

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	<p>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. 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 7004</p>
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Severe active rheumatoid arthritis – balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12566J	1	1	0	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12555T	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 PBS Authorities system)				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form				
	Clinical criteria:				
	The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; or				
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form				
	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. Monday to Friday).				

Complex refractory fistulising Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	13060J	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	13073C	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Complex refractory Fistulising Crohn disease				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	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.				
	Prescribing Instructions: The measurement of response to the prior course of therapy must be documented in the patient's medical notes.				
	Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.				
	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. 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 7004				

Moderate to severe ulcerative colitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12587L	2	2	5	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12552P	2	2	5	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 (Streamlined) <input type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Indication: Moderate to severe ulcerative colitis				
	Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form				
	Prescribing Instructions: Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.				
	Prescribing Instructions: Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.				
	Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.				
	Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.				
	Prescribing Instructions: The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.				
	Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.				
	Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.				
	Prescribing Instructions: A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.				

	<p>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).</p>
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Moderate to severe ulcerative colitis – balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 120 mg/mL injection, 1 mL pen device	12584H	2	2	0	Remsima SC
infliximab 120 mg/mL injection, 1 mL syringe	12550M	2	2	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 PBS Authorities system)					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form					
Clinical criteria:					
Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); or					
Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment					
AND					
Clinical criteria:					
The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; or					
The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment – subcutaneous form					
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. Monday to Friday).					

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 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.

8 Sponsor's Comment

The sponsor had no comment.