

5.30 TOFACITINIB, Tablet (modified release) 11 mg, Xeljanz® XR, Pfizer Australia Pty Ltd

1 Purpose of Submission

- 1.1 The Category 4 submission requested to list a new form and strength of tofacitinib (tofacitinib tablet (modified release) 11 mg (Xeljanz® XR)) under the same circumstances as the current Pharmaceutical Benefits Scheme (PBS) listings for tofacitinib 5 mg tablets for the treatment of severe active rheumatoid arthritis (RA) and severe psoriatic arthritis (PsA).
- 1.2 Listing was requested on the basis of a cost-minimisation approach versus tofacitinib 5 mg tablets.

2 Background

- 2.1 Tofacitinib 5 mg tablets are currently listed on the PBS as:
 - a General Schedule Authority Required (Written) listing for severe active RA (initial treatment and first continuing treatment) and for severe PsA (initial treatment and continuing treatment).
 - a General Schedule Authority Required (STREAMLINED) listing for severe active RA (subsequent continuing treatment).
- 2.2 Tofacitinib 5 mg tablets are also listed on the PBS as:
 - a General Schedule Authority Required (Written) listing for moderate to severe ulcerative colitis (initial treatment), ankylosing spondylitis (initial treatment and continuing treatment), and severe active juvenile idiopathic arthritis (initial treatment).
 - a General Schedule Authority Required (Telephone/Online) listing for moderate to severe ulcerative colitis (continuing treatment).
 - a General Schedule Authority Required (STREAMLINED) listing for severe active juvenile idiopathic arthritis (continuing treatment).
- 2.3 The recommended dose for Xeljanz XR is 1 tablet once daily.

Registration status

- 2.4 Tofacitinib tablet (modified release) 11 mg was Therapeutic Goods Administration (TGA) registered on 5 January 2023 for the treatment of:

- moderate to severe active RA in adults who have had an inadequate response or are intolerant to methotrexate, to be used alone or in combination with conventional synthetic disease-modifying antirheumatic drugs (DMARDs), including methotrexate.
- active PsA in adult patients, who have had an inadequate response to a prior DMARD therapy, in combination with conventional synthetic DMARDs.

Previous PBAC consideration

- 2.5 Xeljanz XR has not been considered by the Pharmaceutical Benefits Advisory Committee (PBAC) previously.
- 2.6 At its March 2015 meeting, the PBAC recommended listing tofacitinib 5 mg tablets as an Authority Required listing for the treatment of severe active RA in patients meeting certain criteria on a cost-minimisation basis with adalimumab (paragraph 7.1, tofacitinib, Public Summary Document (PSD), March 2015 PBAC Meeting).
- 2.7 At its November 2018 meeting, the PBAC recommended listing tofacitinib 5 mg tablets as an Authority Required listing on a cost-minimisation basis with the least costly biological disease-modifying anti-rheumatic drug (bDMARD) for severe PsA (paragraph 7.1, tofacitinib, PSD, November 2018 PBAC Meeting).

3 Requested listing

- 3.1 The submission requested the following new listings:

Add new medicinal product pack as follows (as the requested listings for Xeljanz XR are under the same circumstances as the current listings for tofacitinib 5 mg tablets for severe active RA and severe PsA, the full restrictions have not been reproduced here):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB					
tofacitinib 11 mg modified release tablet, 28	NEW	1	28	3	Xeljanz XR
Restriction Summary 14482 / Treatment of Concept: 14498: Authority Required					
Concept ID (for internal Dept. use)	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)				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: Initial treatment - Initial 1 (new patient)				
Restriction Summary 14506 / Treatment of Concept: 14483: Authority Required					
	Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)				

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Restriction Summary 14497 / Treatment of Concept: 14486: Authority Required	
	Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)
Restriction Summary 14490 / Treatment of Concept: 14488: Authority Required	
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB					
tofacitinib 11 mg modified release tablet, 28	NEW	1	28	5	Xeljanz XR
Restriction Summary 14484 / Treatment of Concept: 14493: Authority Required					
Concept ID (for internal Dept. use)	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)				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: First continuing treatment				
Restriction Summary 14481 / Treatment of Concept: 14507: Authority Required					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Treatment Phase: First continuing treatment - balance of supply				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB					
tofacitinib 11 mg modified release tablet, 28	NEW	1	28	5	Xeljanz XR
Restriction Summary 14480 / Treatment of Concept: 14499: Authority Required Streamlined					
Concept ID (for internal Dept. use)	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [14499]				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: Subsequent continuing treatment				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB					
tofacitinib 11 mg modified release tablet, 28	NEW	1	28	3	Xeljanz XR
Restriction Summary 11969 / Treatment of Concept: 11944: Authority Required					
Concept ID (for internal Dept. use)	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)				
	Indication: Severe psoriatic arthritis				
	Treatment Phase: Initial treatment - Initial 1 (new patient)				

Restriction Summary 11884 / Treatment of Concept: 11945: Authority Required	
	Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)
Restriction Summary 11955 / Treatment of Concept: 11956: Authority Required	
	Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)
Restriction Summary 11943 / Treatment of Concept: 9064: Authority Required	
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB					
tofacitinib 11 mg modified release tablet, 28	NEW	1	28	5	Xeljanz XR
Restriction Summary 11977 / Treatment of Concept: 11978: Authority Required					
Concept ID (for internal Dept. use)	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)				
	Indication: Severe psoriatic arthritis				
	Treatment Phase: Continuing treatment				
Restriction Summary 11885 / Treatment of Concept: 11886: Authority Required					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Treatment Phase: Continuing treatment - balance of supply				

- 3.2 The submission requested a maximum quantity and number of repeats for Xeljanz XR to align with the current PBS listings of tofacitinib 5 mg tablets for severe active RA and severe PsA and the different stages of treatment. A maximum quantity of 28 tablets for Xeljanz XR provides 4 weeks of treatment per dispensing at the recommended dose of 1 tablet daily, aligning with the current listings of tofacitinib 5 mg tablets, which has a maximum quantity of 56 tablets and recommended dose of 1 tablet twice daily.
- 3.3 The submission requested that Xeljanz XR be listed as an Authority Required (STREAMLINED) listing for the subsequent continuing treatment of severe active RA, consistent with the listing for tofacitinib 5 mg tablets.

4 Comparator

- 4.1 The submission did not nominate a comparator, however considered that, if recommended for listing, the new form of tofacitinib (11 mg modified release tablet) will substitute for the current listings of tofacitinib 5 mg tablets for severe active RA and severe PsA.

- 4.2 At its March 2015 consideration of tofacitinib 5 mg tablets for severe active RA, the PBAC considered the nominated main comparator of adalimumab to be acceptable (paragraph 7.2, tofacitinib, PSD, March 2015 PBAC Meeting).
- 4.3 At its November 2018 meeting, the PBAC accepted any of the currently PBS-listed bDMARDs for severe PsA could be an alternative therapy to tofacitinib (paragraph 7.1, tofacitinib, PSD, November 2018 PBAC Meeting). The PBAC noted that no evidence was presented to support a claim that tofacitinib provided a significant improvement in efficacy or reduction of toxicity (paragraph 7.5, tofacitinib, PSD, November 2018 PBAC Meeting). The PBAC considered the equi-effective doses of tofacitinib (at the recommended dose of 5 mg twice daily) and alternative bDMARDs could be derived from the Product Information and with reference to the previously recommended equi-effective doses collated in the PBS Therapeutic Relativity Sheets. (paragraph 7.2, tofacitinib, PSD, November 2018 PBAC Meeting).
- 4.4 Alternative bDMARDs listed on the PBS for severe active RA and severe PsA are summarised in Table 1. Upadacitinib for severe active RA and severe PsA and baricitinib for severe active RA are also once daily oral bDMARDs.

Table 1: PBS-listed bDMARDs for severe active rheumatoid arthritis and severe psoriatic arthritis as of February 2024

Severe active rheumatoid arthritis	Severe psoriatic arthritis
Adalimumab	Adalimumab
Abatacept	Certolizumab pegol
Baricitinib	Etanercept
Certolizumab pegol	Golimumab
Etanercept	Guselkumab
Golimumab	Infliximab
Infliximab	Ixekizumab
Rituximab	Secukinumab
Tocilizumab	Upadacitinib 15 mg
Upadacitinib 15 mg	Ustekinumab

bDMARD = biological disease-modifying anti-rheumatic drug, PBS = Pharmaceutical Benefits Scheme

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from CreakyJoints Australia on behalf of itself and its parent organisation Global Healthy Living Foundation Australia via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with Xeljanz XR, including easier and less time-consuming administration with oral tablets compared to medicines requiring subcutaneous injection or infusion. The comments stated that many patients do not like using needles, and self-injectable medicines required training and practice to use properly. Tofacitinib did not have these administration requirements, making it an appealing

option which could also improve treatment adherence. The comments stated that tofacitinib 5 mg tablets have been shown to be effective for severe forms of RA and PsA, and that the once daily modified release formulation may have less variation in drug concentration levels and therefore symptoms throughout the day compared to the twice daily formulation. The comments also stated environmental benefits from fewer tablets of Xeljanz XR required compared to tofacitinib 5 mg tablets, leading to a reduction in the amount of packaging required, storage space and wastage.

Clinical trials

- 5.3 The submission cited one real-world study comparing tofacitinib XR 11 mg once daily with tofacitinib 5 mg twice daily for RA, which found that after 12 months there was improved adherence and at least comparable efficacy with tofacitinib 11 mg compared with tofacitinib 5 mg (Cohen et al., 2021a). The submission also cited studies comparing the pharmacokinetics of tofacitinib XR 11 mg with tofacitinib 5 mg (Lamba et al., 2016; Lamba et al., 2017).
- 5.4 The submission provided the following clinical trials to show the safety and effectiveness of tofacitinib XR 11 mg:
- a Phase 3 randomised controlled trial in Japan comparing tofacitinib XR 11 mg once daily with tofacitinib 5 mg twice daily with stable methotrexate. After 12 weeks, non-inferiority of tofacitinib XR 11 mg once daily to tofacitinib 5 mg twice daily was not met, however clinically meaningful improvements were seen in both groups and the safety profile was similar between the two formulations (Tanaka et al., 2019).
 - the ORAL Shift open label trial, which found after 24 weeks of treatment with tofacitinib XR 11 mg once daily plus methotrexate for moderate-to-severe RA there were improvements in disease activity measures, functional outcomes and patient-reported outcomes. The authors concluded that the safety profile was generally consistent with the historic safety profile of tofacitinib (Cohen et al., 2021b).

Table 2: Trials presented in the submission

Trial ID	Publication title	Publication citation
	Lamba M et al. Extended-release once-daily formulation of tofacitinib: evaluation of pharmacokinetics compared with immediate-release tofacitinib and impact of food.	J Clin Pharmacol 2016; 56(11): 1362-1371.
	Lamba M et al. Model-informed development and registration of a once-daily regimen of extended-release tofacitinib.	Clin Pharmacol Ther 2017; 101(6):745-753.
NCT02281552	Tanaka Y et al. Modified- versus immediate-release tofacitinib in Japanese rheumatoid arthritis patients: a randomized, phase III, non-inferiority study.	Rheumatology (Oxford) 2019; 58(1): 70-79.
NCT04018001 NCT04267380	Cohen SB et al. (2021a) Real-world evidence to contextualize clinical trial results and inform regulatory decisions: tofacitinib modified-release once-daily vs immediate-release twice-daily for rheumatoid arthritis.	Adv Ther 2021; 38(1): 226-248.
NCT02831855	Cohen SB et al. (2021b) Efficacy and safety of tofacitinib modified-release 11 mg once daily plus methotrexate in adult patients with rheumatoid arthritis: 24-week open-label phase results from a phase 3b/4 methotrexate withdrawal non-inferiority study (ORAL Shift).	RMD Open 2021; 7(2):e001673.

Source: pp3-6 of the submission

5.5 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

5.6 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of Xeljanz XR compared with tofacitinib 5 mg tablets. The PBAC considered that the claim of non-inferior comparative effectiveness and non-inferior comparative safety was reasonable.

5.7 Tofacitinib XR 11 mg once daily did not meet all the TGA criteria to demonstrate bioequivalence to tofacitinib 5 mg twice daily. The TGA Delegate’s Overview concluded that the application provided evidence to support a conclusion that the efficacy and safety of tofacitinib XR 11 mg once daily and tofacitinib 5 mg twice daily was similar when used for RA and PsA (Delegate’s Overview).

5.8 The submission claimed that as a modified release tablet that is taken once daily, Xeljanz XR offers a reduced pill burden compared to tofacitinib 5 mg tablets which is taken twice daily, leading to improved adherence.

Economic analysis

5.9 The submission presented a cost-minimisation analysis of tofacitinib XR 11 mg tablets compared with tofacitinib 5 mg tablets. The equi-effective doses were estimated as tofacitinib XR 11 mg one tablet daily and tofacitinib 5 mg one tablet twice a day. It was assumed there would be no differences in treatment duration and monitoring requirements between the two forms of tofacitinib.

Table 3: Cost-minimisation analysis

	Tofacitinib XR 11 mg	Tofacitinib IR 5 mg
Severe rheumatoid arthritis		
AEMP per prescription*	\$	\$
Treatment days per prescription	28 (28 tablets / 1 tablet per day)	28 (56 tablets / 2 tablets per day)
Cost of treatment per 28 days	\$	\$
Difference in cost of treatment	\$0.00	
Severe psoriatic arthritis		
AEMP per prescription*	\$	\$
Treatment days per prescription	28 (28 tablets / 1 tablet per day)	28 (56 tablets / 2 tablets per day)
Cost of treatment per 28 days	\$	\$
Difference in cost of treatment	\$0.00	

Source: Table 5 of the submission

*Based on the effective AEMP of tofacitinib 5 mg tablets as of February 2024

AEMP = approved ex-manufacturer price, IR = immediate release, XR = modified release

- 5.10 The submission noted a Special Pricing Arrangement (SPA) applies to the listing of tofacitinib 5 mg tablets and requested this also apply to the requested listing for tofacitinib XR 11 mg tablets.
- 5.11 As a Category 4 submission, the economic analysis has not been independently evaluated.

Drug cost/patient/year: \$ [redacted] for RA and \$ [redacted] for PsA

- 5.12 The estimated drug cost/patient per year would be \$ [redacted] for RA and \$ [redacted] for PsA, based on an effective dispensed price for maximum quantity (DPMQ) of \$ [redacted] for RA and \$ [redacted] for PsA and 13 prescriptions per year.

Estimated PBS usage and financial implications

- 5.13 The requested published approved ex-manufacturer price (AEMP) for tofacitinib XR 11 mg, 28 tablets, was equivalent to the published AEMP for tofacitinib 5 mg, 56 tablets, listed in the PBS in February 2024.
- 5.14 Table 4 presents the estimated extent of use, cost to the PBS/RPBS and the net financial implications to the PBS/RPBS of tofacitinib XR 11 mg tablets. The financial impact to Services Australia will be determined by that agency as part of the post-PBAC process.
- 5.15 The submission adopted a market share approach to estimate the utilisation and financial impact of listing the new form of tofacitinib. The submission assumed that tofacitinib XR 11 mg tablets is expected to substitute for tofacitinib 5 mg tablets on a four-week to four-week basis at the same price.
- 5.16 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of tofacitinib XR 11 mg tablets is \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).

Table 4: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use of tofacitinib XR 11 mg						
Number of scripts dispensed for RA	¹	¹	¹	¹	¹	¹
Number of scripts dispensed for PsA	²	²	²	²	²	²
Total number of scripts dispensed	¹	¹	¹	¹	¹	¹
Estimated financial implications of tofacitinib XR 11 mg						
Cost to PBS/RPBS less co-payment	³	³	³	³	³	³
Estimated financial implications of tofacitinib 5 mg						
Cost to PBS/RPBS less co-payment	³	³	³	³	³	³
Net financial implications						
Net cost to PBS/RPBS	⁴	⁴	⁴	⁴	⁴	⁴

Source: Tab 3c Xeljanz XR (tofacitinib) – UCM – RA and PsA of the submission

PBS = Pharmaceutical Benefits Scheme, PsA = psoriatic arthritis, RA = rheumatoid arthritis, RPBS = Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges

¹ 10,000 to < 20,000

² 500 to < 5,000

³ \$10 million to < \$20 million

⁴ \$0 to < \$10 million

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of a new form and strength of tofacitinib (tofacitinib tablet (modified release) 11 mg (Xeljanz[®] XR)) under the same circumstances as the current Pharmaceutical Benefits Scheme (PBS) listings for tofacitinib 5 mg tablets for the treatment of severe active rheumatoid arthritis (RA) and severe psoriatic arthritis (PsA).
- 6.2 The PBAC, considering Xeljanz XR as an appropriate comparator, acknowledged that a proportion of patients who would use Xeljanz XR would either switch from the currently PBS-listed tofacitinib 5 mg tablets or commence treatment with Xeljanz XR instead of choosing tofacitinib 5 mg tablets. However, the PBAC noted there are also other relevant comparators for the treatment of severe active RA and severe PsA, recalling that it previously recommended tofacitinib 5 mg tablets for the treatment of severe active RA on a cost-minimisation basis with adalimumab at its March 2015 meeting, and on a cost-minimisation basis with the least costly bDMARD for severe PsA at its November 2018 meeting.
- 6.3 The PBAC noted that it could only recommend listing Xeljanz XR at a higher price than the alternative therapy or therapies if it is satisfied that Xeljanz XR provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies. The alternative therapies in this case include tofacitinib 5 mg tablets and all bDMARDs listed in Table 1.
- 6.4 The PBAC considered the submission did not provide evidence to demonstrate that

Xeljanz XR provides, for some patients, a significant improvement in efficacy or reduction in toxicity compared to any of the currently listed bDMARDs for severe active RA and severe PsA. The PBAC considered that tofacitinib 5 mg tablets and other currently listed bDMARDs for severe active RA and severe PsA could be considered alternative therapies for the purposes of Section 101(3B) of the *National Health Act 1953*.

- 6.5 The PBAC therefore recommended listing Xeljanz XR on a cost-minimisation basis with the least costly PBS-listed bDMARD for severe active RA and severe PsA, respectively.
- 6.6 The PBAC advised that the cost-minimisation approach should be based on the equi-effective doses of Xeljanz XR 11 mg (1 tablet once daily), tofacitinib 5 mg (1 tablet twice daily), and with the doses of alternative bDMARDs derived from the relevant Product Information documents. The PBAC considered a standard cost minimisation approach with costs over two years was appropriate, consistent with the previous approach for bDMARDs.
- 6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Xeljanz XR is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed bDMARDs or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Add new item:

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB						
tofacitinib 11 mg modified release tablet, 28		NEW	1	28	3	Xeljanz XR
Concept ID (for internal Dept. use)	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)						
Prescribing rule level	Administrative Advice: PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS					
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
	Administrative Advice: No increase in the maximum number of repeats may be authorised.					
	Administrative Advice: Special Pricing Arrangements apply.					
Restriction Summary 14482 / Treatment of Concept: 14498: Authority Required						

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	Indication: Severe active rheumatoid arthritis
	Treatment Phase: Initial treatment - Initial 1 (new patient)
	Treatment criteria:
	Must be treated by a rheumatologist; or
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis
	Clinical criteria:
	Patient must not have received PBS-subsidised treatment with a biological medicine for this condition
	AND
	Clinical criteria:
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or
	Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application
	AND
	Clinical criteria:
	Patient must not receive more than 16 weeks of treatment under this restriction
	Population criteria:
	Patient must be at least 18 years of age
	Prescribing Instructions: If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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	<p>Prescribing Instructions: The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (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: The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p>
	<p>Prescribing Instructions: If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</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 assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of 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: 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>Administrative Advice: The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.</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 7001</p>
Restriction Summary 14506 / Treatment of Concept: 14483: Authority Required	
	Indication: Severe active rheumatoid arthritis
	Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)
	Treatment criteria:
	Must be treated by a rheumatologist; or
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis
	Clinical criteria:
	Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
	Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication
	AND
	Clinical criteria:
	Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times
	AND
	Clinical criteria:
	Patient must not receive more than 16 weeks of treatment under this restriction.
	Population criteria:
	Patient must be at least 18 years of age.
	<p>Prescribing Instructions: Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p>
	<p>Prescribing Instructions: Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p>

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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: An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p>
	<p>Prescribing Instructions: To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</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: 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: 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: A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</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 7001</p>
Restriction Summary 14497 / Treatment of Concept: 14486: Authority Required	
	Indication: Severe active rheumatoid arthritis
	Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)
	Treatment criteria:
	Must be treated by a rheumatologist; or
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition.
	AND
	Clinical criteria:
	Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition,
	AND
	Clinical criteria:
	Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition,
	AND
	Clinical criteria:
	Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times,
	AND
	Clinical criteria:
	The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
	The condition must have a C-reactive protein (CRP) level greater than 15 mg per L,
	AND
	Clinical criteria:
	The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints,
	AND
	Clinical criteria:
	Patient must not receive more than 16 weeks of treatment under this restriction.
	Population criteria:
	Patient must be at least 18 years of age

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	<p>Prescribing Instructions: Major joints are defined as (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: All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p>
	<p>Prescribing Instructions: If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</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: To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</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: 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>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 7001</p>
<p>Restriction Summary 14490 / Treatment of Concept: 14488: Authority Required</p>	
	<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)</p>
	<p>Indication: Severe active rheumatoid arthritis</p>

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	Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply
	Treatment criteria:
	Must be treated by a rheumatologist; or
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis
	Clinical criteria:
	Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or
	Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; or
	Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment
	AND
	Clinical criteria:
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions
	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).

MEDICINAL PRODUCT		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
medicinal product pack						
TOFACITINIB						
tofacitinib 11 mg modified release tablet, 28		NEW	1	28	5	Xeljanz XR
Prescribing rule level		Administrative Advice: PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS				
		Administrative Advice: No increase in the maximum quantity or number of units may be authorised.				
		Administrative Advice: No increase in the maximum number of repeats may be authorised.				
		Administrative Advice: Special Pricing Arrangements apply.				
Restriction Summary 14484 / Treatment of Concept: 14493: Authority Required						
Concept ID (for internal Dept. use)	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)						
Indication: Severe active rheumatoid arthritis						
Treatment Phase: First continuing treatment						
Treatment criteria:						
Must be treated by a rheumatologist; or						
Must be treated by a clinical immunologist with expertise in the management of rheumatoid 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:						
Patient must have demonstrated an adequate response to treatment with this drug,						
AND						

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	Clinical criteria:
	Patient must not receive more than 24 weeks of treatment under this restriction.
	Population criteria:
	Patient must be at least 18 years of age.
	<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: 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: 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>

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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 7001</p>
Restriction Summary 14481 / Treatment of Concept: 14507: Authority Required	
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Indication: Severe active rheumatoid arthritis
	Treatment Phase: First continuing treatment - balance of supply
	Treatment criteria:
	Must be treated by a rheumatologist; or
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
	Clinical criteria:
	Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment,
	AND
	Clinical criteria:
	The treatment must provide no more than the balance of up to 24 weeks treatment.
	<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. Monday to Friday).</p>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB					
tofacitinib 11 mg modified release tablet, 28	NEW	1	28	5	Xeljanz XR
Restriction Summary 14480 / Treatment of Concept: 14499: Authority Required Streamlined					
Concept ID (for internal Dept. use)	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [14499]				
Prescribing rule level	Administrative Advice: PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS				
	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).				
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Administrative Advice: Special Pricing Arrangements apply.				
	Indication: Severe active rheumatoid arthritis				
	Treatment Phase: Subsequent continuing treatment				
	Treatment criteria:				

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	Must be treated by a rheumatologist; or
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
	Clinical criteria:
	Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or
	Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine,
	AND
	Clinical criteria:
	Patient must have demonstrated an adequate response to treatment with this drug,
	AND
	Clinical criteria:
	Patient must not receive more than 24 weeks of treatment under this restriction.
	Population criteria:
	Patient must be at least 18 years of age.
	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: 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.
	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: 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.
	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.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
TOFACITINIB					
tofacitinib 11 mg modified release tablet, 28	NEW	1	28	3	Xeljanz XR
Restriction Summary 11969 / Treatment of Concept: 11944: Authority Required					
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					

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Concept ID (for internal Dept. use)	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
Prescribing rule level	Administrative Advice: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Indication: Severe psoriatic arthritis
	Treatment Phase: Initial treatment - Initial 1 (new patient)
	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 not have received PBS-subsidised treatment with a biological medicine for this condition,
	AND
	Clinical criteria:
	Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,
	AND
	Clinical criteria:
	Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
	Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,
	AND
	Clinical criteria:
	Patient must not receive more than 16 weeks of treatment under this restriction.
	Population criteria:
	Patient must be aged 18 years or older.
	Prescribing Instructions: Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
	Prescribing Instructions: Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.
	Prescribing Instructions: The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (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). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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	<p>Prescribing Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) 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 assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of 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: 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.</p>
	<p>Administrative Advice: The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.</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 7001</p>
Restriction Summary 11884 / Treatment of Concept: 11945: Authority Required	
	<p>Indication: Severe psoriatic arthritis</p>
	<p>Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)</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 psoriatic arthritis.</p>
	<p>Clinical criteria:</p>
	<p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle,</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle,</p>
	<p>AND</p>
	<p>Clinical criteria:</p>

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	Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle,
	AND
	Clinical criteria:
	Patient must not receive more than 16 weeks of treatment under this restriction.
	Population criteria:
	Patient must be aged 18 years or older.
	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 authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) 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 a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.
	Prescribing Instructions: To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.
	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: 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</p>
Restriction Summary 11955 / Treatment of Concept: 11956: Authority Required	
	Indication: Severe psoriatic arthritis
	Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)
	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 previously received PBS-subsidised treatment with a biological medicine for this condition,
	AND
	Clinical criteria:
	Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition,
	AND
	Clinical criteria:
	The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
	The condition must have a C-reactive protein (CRP) level greater than 15 mg per L,
	AND
	Clinical criteria:
	The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints,
	AND
	Clinical criteria:
	Patient must not receive more than 16 weeks of treatment under this restriction.
	Population criteria:
	Patient must be aged 18 years or older.
	Prescribing Instructions: Major joints are defined as (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: All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

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	<p>Prescribing Instructions: If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p>
	<p>Prescribing Instructions: Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will 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 demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p>
	<p>Prescribing Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) 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 a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p>
	<p>Prescribing Instructions: To demonstrate a response to treatment the application 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 biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</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: 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.</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 7001</p>
Restriction Summary 11943 / Treatment of Concept: 9064: Authority Required	
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Indication: Severe psoriatic arthritis

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	Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply
	Clinical criteria:
	Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or
	Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or
	Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment,
	AND
	Clinical criteria:
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.
	Treatment criteria:
	Must be treated by a rheumatologist; or
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
	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).

MEDICINAL PRODUCT		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
medicinal product pack						
TOFACITINIB						
tofacitinib 11 mg modified release tablet, 28		NEW	1	28	5	Xeljanz XR
Restriction Summary 11977 / Treatment of Concept: 11978: Authority Required						
Concept ID (for internal Dept. use)	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)						
Prescribing rule level	Administrative Advice: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS					
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
	Administrative Advice: No increase in the maximum number of repeats may be authorised.					
	Administrative Advice: Special Pricing Arrangements apply.					
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:						
Patient must have demonstrated an adequate response to treatment with this drug,						
AND						

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	Clinical criteria:
	Patient must not receive more than 24 weeks of treatment under this restriction.
	Population criteria:
	Patient must be aged 18 years or older.
	<p>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).</p>
	<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: The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) 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: 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.</p>
	<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. 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</p>
Restriction Summary 11885 / Treatment of Concept: 11886: Authority Required	
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Indication: Severe psoriatic arthritis
	Treatment Phase: Continuing treatment - balance of supply
	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 insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment,
	AND
	Clinical criteria:
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above 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>

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

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.