

**11.02 IXEKIZUMAB,
Injection 80 mg in 1 mL single dose pre-filled pen,
Taltz[®],
Eli Lilly Australia Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 4 submission requested the PBAC to revise the maximum quantity (units) of its November 2021 recommendation to list ixekizumab (IXE) for the treatment of patients with non-radiographic ankylosing spondyloarthritis (nr-AxSpA) from 1 unit (pre-filled pen) to 2 units.

2 Background

- 2.1 IXE is listed on the PBS as an Authority Required (Written) listing for severe chronic plaque psoriasis, severe psoriatic arthritis, and ankylosing spondylitis.

Registration status

- 2.2 IXE was TGA-approved on 28 May 2021 for the treatment of adult patients with active nr-AxSpA with objective signs of inflammation as indicated by elevated CRP and/or MRI evidence, who have responded inadequately to, or are intolerant to, nonsteroidal anti-inflammatory drugs and was included in the Australian Register of Therapeutic Goods on 6 July 2021.

Previous PBAC consideration

- 2.3 IXE was first considered for this indication by the PBAC at its November 2021 meeting.
- 2.4 At its November 2021 meeting, the PBAC recommended the listing of IXE for the treatment of nr-AxSpA “based on, among other matters, its assessment that the cost-effectiveness of IXE would be acceptable if it were cost-minimised to the least costly biologic disease-modifying anti-rheumatic drug (bDMARD) for this indication” (paragraph 7.1, ixekizumab Public Summary Document [PSD], November 2021 PBAC Meeting).
- 2.5 The PBAC considered it reasonable to accept that IXE was non-inferior to secukinumab (SEC) and golimumab (GLM) in terms of comparative efficacy and safety, and that along with certolizumab pegol (CZP) to be reasonable comparators (paragraphs 7.2, 7.6 & 7.7, ixekizumab PSD, November 2021 PBAC Meeting). As such, the “PBAC recommended listing IXE under the same circumstances as that of the other bDMARDs for nr-AxSpA” (paragraph 7.3) and that “IXE be included within the current risk sharing arrangements (RSA) for GLM, CZP and SEC with no increase to the expenditure cap levels” (paragraph 7.9) as listing IXE was not expected to “result in any additional cost to the PBS” (paragraph 7.8, ixekizumab PSD, November 2021 PBAC Meeting).

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- 2.6 The PBAC noted that “IXE is currently listed as a pack containing 2 injections, equivalent to 2 months’ therapy per pack, which is inconsistent with the basis of most other bDMARD listings which typically provide for approximately a 1-month supply per pack (with some exceptions, such as some infusible therapies)” (paragraph 3.5, ixekizumab PSD, November 2021 PBAC Meeting). The PBAC considered it appropriate that IXE should be listed as per CZP, GLM and SEC with “one month of treatment per script dispensing” and that “it was appropriate to list IXE with a medicinal product pack containing 1 injection per containered product with a maximum quantity of one injection unit/pack plus 3 repeats for the initial restriction treatment and one injection plus 5 repeats for the continuing restriction treatment, which would provide ... one month of treatment per script dispensing without need for broken packs” (paragraph 7.4, ixekizumab PSD, November 2021 PBAC Meeting).
- 2.7 The PBAC has previously expressed a view (in July 2018 and again in 2021) that the sponsor should make a single injection pack available to align the treatment durations per pack of IXE with other bDMARD listings.
- 2.8 At the March 2023 PBAC meeting, upadacitinib (UPA) for nr-AxSpA was recommended by the PBAC. UPA was not yet listed on the PBS for this indication at the time of consideration of this submission.

3 Requested listing

- 3.1 The submission requested the same listing that was recommended by the PBAC in its previous consideration with the exception of the maximum quantity. For brevity, only this aspect of the requested listing has been presented. Additions have been marked in italics and deletions with strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty (packs)	Max. Qty. (units)	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer	
IXEKIZUMAB Initial treatment 1, 2 and 3 Injection 80 mg in 1 mL single use pre-filled pen, 2	1	2	1	\$3,258.28 – published DPMQ \$█ – effective DPMQ	Taltz	Eli Lilly Australia Pty Ltd.
IXEKIZUMAB Continuing treatment Injection 80 mg in 1 mL single use pre-filled pen, 2	1	2	2	\$3,258.28 - published DPMQ \$█ – effective DPMQ	Taltz	Eli Lilly Australia Pty Ltd.

Source: Submission main body, p5 of 2023 Submission.

4 Comparator

- 4.1 At its meeting in November 2021, the PBAC considered SEC and GLM as reasonable comparators to IXE in the treatment of nr-AxSpA. The PBAC also considered it reasonable to include CZP as a third comparator (paragraph 7.2, ixekizumab PSD, November 2021 PBAC Meeting).
- 4.2 This submission did not wish to re-examine the comparators accepted by the PBAC in November 2021.

5 Consideration of the evidence

Sponsor hearing

- 5.6 There was no hearing for this item.

Consumer comments

- 5.7 The PBAC noted that no consumer comments were received for this item.

Justification of Changes to Recommended Maximum Dispensing Quantity

- 5.8 Concerning the maximum quantity/amount that can be requested for a proposed medicine, the PBAC Guidelines state that “for a chronic-use therapy, [the submission must] demonstrate that the maximum quantity/amount is consistent with the likely use of the proposed medicine for one month of therapy between each dispensing by the pharmacist, and that the number of repeats (usually) permits six months of therapy between each prescription” (Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee, Version 5.0, September 2016). The guidelines state that deviations from this must be justified such as to “to minimise wastage or to facilitate intermittent therapy” and submissions also must “demonstrate that the requested maximum quantities/amounts and the requested numbers of any repeats are consistent with the TGA-approved dosage recommendations” (Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee, Version 5.0, September 2016). In this context, minimising wastage is in reference to medicine that has been dispensed but not used.
- 5.9 The submission presented several reasons to justify the listing of a 2-pen pack (or two month’s supply) as a deviation to supplying one month of therapy:
- The sponsor registered the 1-pen pack with the TGA with the intention that it be used for sampling, and not be marketed.
 - The sponsor conducted an internal analysis that presents “many complications associated with of the introduction of a 1-pen pack” including:
 - “International price referencing concerns”, which “presents a risk to continuity of supply as our organisation may apply pressure to withdraw, in order to

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mitigate a broader risk.” The sponsor says that this would impact patients who are prescribed IXE for other indications, such as chronic plaque psoriasis (CPP).

- Cold-chain costs for the higher volume of packaging required for two 1-pen packs versus one 2-pen pack.
 - That the cost to manufacture the 1-pen pack is relatively higher than the 2-pen pack i.e. the cost is not proportional for the smaller pack size.
 - Difficulty in forecasting and manufacturing stock to meet the requirements of a market with both 1-pen and 2-pen packs, leading to stock shortages. The sponsor argued that the shortage occurred in Germany for this reason.
 - Over-forecasting leading to expired stock (wastage).
 - The sponsor has not seen specific requests from clinicians and patients for a 1-pen pack since the 2-pen pack was listed in 2017 for other conditions.
 - Clinicians and patients are familiar with the dosing schedule for a 2-pen pack and that a 1-pen pack may cause confusion and incorrect dosing advice from clinicians and pharmacists.
- 5.10 It was noted that a sponsor’s intentions when registering a pack size with the TGA, international price referencing concerns, cold chain and manufacturing costs and issues with stock forecasting are the responsibility of the sponsor and are not matters for PBAC consideration. Furthermore, it was noted that expired warehouse stock is not the type of wastage that is referenced in the PBAC Guidelines.
- 5.11 The submission raised quality use of medicine concerns about confusion and incorrect dosing advice from clinicians and pharmacists if a 1-pen pack were to be introduced. This concern was not adequately justified in the submission as both the 2-pen pack and 1-pen pack is dosed as 1-pen per month (4 weeks). Clinicians, pharmacists and patients would be familiar with monthly dosing for IXE as well as GLM, SEC and CZP, noting that SEC and CZP have more complex dosing regimens for the initiation phase. The Pre-PBAC response stated that the confusion would exist for clinicians treating conditions other than nr-AxSpA with the currently listed 2-pen pack and could lead to miscommunication to patients. This response assumes that clinicians and pharmacists are not already familiar with differentiating the dosing regimens for different indications.
- 5.12 The PBAC did not recommend two-months dispensing for bDMARDs as part of the “Medicine List for Increased Dispensing Quantities” for the 60 day dispensing of PBS medicines budget measure policy where the PBAC considered the “clinical safety and suitability for inclusion” of the drugs listed in this recommendation. The sponsor raised in the Pre-PBAC response that IXE has been listed as a 2-pen pack “since February 2017 for three different indications without any concerns about the clinical safety”. As part of the consideration of SEC in July 2017 and July 2021, the PBAC in both instances recommended that the maximum quantity for IXE for the treatment of CPP be amended such that only 1 months’ supply is dispensed.

- 5.13 Listing IXE with two months' supply per dispensing (and by implication, only one patient co-payment per 2 months) could be perceived as an unfair advantage to IXE compared to other bDMARDs listed for the same indication. Requests from the sponsor of SEC to increase the listed maximum quantity of SEC to 2 months' supply were not recommended by the PBAC at both its July 2017 and July 2021 PBAC meetings (paragraphs 5.1 - 5.2, Secukinumab PSD July 2017 PBAC meeting, and paragraphs 5.1 - 5.2, Secukinumab PSD July 2021 PBAC meeting). In the July 2021 consideration of secukinumab, "the submission claimed that the different maximum quantity between secukinumab and ixekizumab may incentivise prescribers and patients to choose ixekizumab over secukinumab" (paragraphs 5.3, Secukinumab PSD July 2021 PBAC meeting). In its Pre-PBAC response the sponsor raised that in paragraph 5.3 from the Secukinumab PSD of the July 2021 PBAC meeting, the PBAC "considered that choice of treatment would be largely driven by individual patient characteristics related to clinical suitability to a particular drug and clinician familiarity with the drug." While this is true, it does not negate the perception amongst sponsors that an unfair advantage could arise when the PBAC Guidelines are not applied to medicines of the same class and for the same indication, especially where a patient's individual characteristics may make them clinically suitable to use either drug.
- 5.14 In its November 2021 consideration, "The PBAC considered that, because IXE would be the fourth bDMARD for nr-AxSpA, there was no urgent clinical need for an additional bDMARD to be listed for this indication" (paragraph 7.4, ixekizumab PSD, November 2021 PBAC Meeting). It was noted that if UPA lists on the PBS for this indication, IXE would be the fifth bDMARD for nr-AxSpA.

Clinical evidence

- 5.15 This submission did not present any new clinical data, nor did it seek to review the clinical claim.
- 5.16 At its November 2021 meeting, the PBAC considered the claim that IXE had non-inferior efficacy and safety compared to GLM and SEC was reasonable.

Economic analysis

- 5.17 As a Category 4 submission, the economic analysis has not been independently evaluated.
- 5.18 The PBAC had previously accepted that it would be reasonable to list IXE for this indication based on a cost-minimisation analysis compared with the "least costly alternative bDMARD over 2 years" (paragraph 7.8 IXE PSD, November 2021 PBAC Meeting).
- 5.19 In November 2021 (paragraph 7.1 IXE PSD, November 2021 PBAC Meeting), the PBAC advised the equi-effective doses were:
- IXE 80 mg once every four weeks;
 - GLM 50 mg once every four weeks;

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- SEC: 150 mg at Week 0, 1, 2, 3 and 4, then SEC 150 mg every 4 weeks; or SEC 150 mg every 4 weeks, at a 70:30 weighting for loading dose versus no loading dose (as outlined in paragraph 7.7 of the SEC November 2020 PSD); and
 - CZP: 400 mg at Week 0, 2, 4, then 200 mg every 2 weeks; or CZP 400 mg every 4 weeks.
- 5.20 In March 2023 (paragraph 7.2 UPA PSD, March 2023 PBAC Meeting), the PBAC added the equi-effective dose for UPA:
- UPA 15 mg once daily.
- 5.21 The submission requested a special pricing arrangement (SPA) for the nr-AxSpA therapeutic indication of IXE as it did in November 2021. At the time the Department provided the relevant comparator information to the sponsor following the November 2021 recommendation of IXE, the sponsor presented an effective ex-manufacturer price for the 2-pen pack consistent with that of the least costly bDMARD for this indication.
- 5.22 The submission presented a comparison (shown in Table 1) between the 1-pen pack and 2-pen pack of IXE using an effective ex-manufacturer price (EMP) of \$| for the 2-pen pack and \$| (half of the 2-pen pack EMP) for the 1-pen pack.
- 5.23 Noting that the requested EMP per dose (a single 80 mg pen) is the same between the 1-pen pack and 2-pen pack, the submission claimed that a 1-pen pack will have a larger expenditure per pen for the Commonwealth due to supply chain mark-ups.

Table 1: Comparison of the Commonwealth Expenditure per pen with a 2-pen pack listing vs a 1-pen pack listing

	EMP (effective)	Wholesale markup	AHI Fee	Preparation fee	Total supply chain mark-ups	Patient Co-pay ^a	Expenditure per pen
1 pack		\$	\$	\$7.82	\$	\$24.57	\$
2 pack		\$	\$	\$7.82	\$	\$24.57	\$

Source: Table 2, p9 of the submission; Pharmaceutical Benefits: Fees, Patient Contributions and Safety Net Threshold, <https://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee>, visited 19/05/2023

^a Derived by sponsor from the financial utilisation model. Current co-payment = \$30.00.

- 5.24 The submission requested a published EMP of \$3,097.00 for the 2-pen pack.
- 5.25 The submission claimed a cost-saving to the Commonwealth of \$20.60 per pen with the 2-pen pack.
- 5.26 It was noted that supply chain mark ups are not a matter for the PBAC.

Drug cost/patient/year: \$21,178.82

- 5.27 The estimated drug cost/patient/year would be \$21,178.82, based on 6.5 scripts/year for the 2-pen pack at a published DMPQ of \$3,258.28.
- 5.28 The total estimate remains the same, assuming the published DPMQ for the 1-pen pack is \$1,629.14 (\$3,258.28), with 13 scripts per year. Using the DMPQ calculated in the financial workbook provided with the submission (\$1,689.91), the cost would be \$21,968.83 per year.

Estimated PBS usage and financial implications

- 5.29 As a Category 4 submission, the financial implications have not been independently evaluated.
- 5.30 The submission presented financial estimates and implications comparing a 1-pen pack to a 2-pen pack being listed on the PBS, to support the request for a revised maximum quantity. The 2-pen pack provides a minor cost saving; however, it is to be noted that the effective price does not necessarily reflect what the Government would agree to for a 1-pen pack.
- 5.31 The financial estimates were derived using an epidemiological approach that was calculated by the Department in August 2022 as part of the pricing negotiations that took place after the PBAC recommendation in November 2021. The estimates considered by the PBAC in November 2021 were based on a market share approach.
- 5.32 The submission presented two estimates for the cost to the PBS/RPBS, one for listing the 1-pen pack and one for the 2-pen pack, using an effective EMP of \$| (1-pen pack) and \$| (2-pen pack). The submission assumed that 2 scripts of the 1-pen pack equal one script of 2-pen pack. No broken pack fees or wastage factors were included in the financial estimates.
- 5.33 Table 2 presents the estimated extent of use, cost of the 1-pen pack of IXE to the PBS/RPBS, and the net financial implications to the PBS/RPBS. Table 3 presents the estimated extent of use, cost of the 2-pen pack of IXE to the PBS/RPBS, and the net financial implications to the PBS/RPBS.

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Table 2: Estimated use and financial implications for 1-pen pack

	Year 1 (2023)	Year 2 (2024)	Year 3 (2025)	Year 4 (2026)	Year 5 (2027)	Year 6 (2028)
Estimated extent of use						
Number of scripts dispensed ^a	¹	²	²	²	³	³
Estimated financial implications of IXE 1-pen pack						
Cost to PBS/RPBS less co-payment (\$)	⁴	⁴	⁴	⁴	⁴	⁴
Estimated financial implications of Comparators						
Cost to PBS/RPBS less co-payment (\$)	⁵	⁵	⁵	⁵	⁵	⁵
Net financial implications						
Net cost to PBS/RPBS (\$)	⁵	⁵	⁵	⁵	⁵	⁵

^a Assuming 13 per patient per year as estimated by the submission.

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: lxezumab_Mar23_UCM_1pack.xlsx

The redacted values correspond to the following ranges:

¹ <500

² 500 to < 5,000

³ 5,000 to < 10,000

⁴ \$0 to < \$10 million

⁵ net cost saving

Table 3: Estimated use and financial implications for 2-pen pack

	Year 1 (2023)	Year 2 (2024)	Year 3 (2025)	Year 4 (2026)	Year 5 (2027)	Year 6 (2028)
Estimated extent of use						
Number of scripts dispensed ^a	¹	²	²	²	²	²
Estimated financial implications of IXE 2-pen pack						
Cost to PBS/RPBS less co-payment (\$)	³	³	³	³	³	³
Estimated financial implications of Comparators						
Cost to PBS/RPBS less co-payment (\$)	⁴	⁴	⁴	⁴	⁴	⁴
Net financial implications						
Net cost to PBS/RPBS (\$)	⁴	⁴	⁴	⁴	⁴	⁴

^a Assuming 6.5 per patient per year as estimated by the submission.

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: lxezumab_Mar23_UCM_2pack.xlsx

The redacted values correspond to the following ranges:

¹ <500

² 500 to < 5,000

³ \$0 to < \$10 million

⁴ net cost saving

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Table 4: Estimated use and financial implications comparison of 1-pen pack and 2-pen pack

	Year 1 (2023)	Year 2 (2024)	Year 3 (2025)	Year 4 (2026)	Year 5 (2027)	Year 6 (2028)
Estimated financial implications of IXE 1-pen pack						
Cost to PBS/RPBS less co-payment (\$)	¶ ¹	¶ ¹	¶ ¹	¶ ¹	¶ ¹	¶ ¹
Estimated financial implications of IXE 2-pen pack						
Cost to PBS/RPBS less co-payment (\$)	¶ ¹	¶ ¹	¶ ¹	¶ ¹	¶ ¹	¶ ¹
Net financial implications of listing 1-pen pack						
Net cost to PBS/RPBS (\$)	¶ ¹	¶ ¹	¶ ¹	¶ ¹	¶ ¹	¶ ¹

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: lxekezumab_nrAxSpA_Cat4_Mar2023.docx p8

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

- 5.34 The submission estimated that 500 to < 5,000 patients would be supplied IXE over the first six years of listing (< 500 in Year 1 to 500 to < 5,000 in Year 6). The submission assumed that an increasing proportion of eligible patients are going to initiate IXE from 3% (i.e. < 500 patients) in Year 1 to 20% (i.e. < 500 patients) in year 6. These patients were assumed to have a 100% persistence rate after commencing treatment.
- 5.35 The submission claimed that the cost of the IXE 1-pen pack to the PBS/RPBS is expected to be \$20 million to < \$30 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).
- 5.36 The submission stated that the estimated net financial impact to the PBS/RPBS of listing the IXE 1-pen pack is a \$0 to < \$10 million save over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).
- 5.37 The submission claimed that the cost of the IXE 2-pen pack to the PBS/RPBS is expected to be \$20 million to < \$30 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).
- 5.38 The submission stated that the estimated net financial impact to the PBS/RPBS of listing the IXE 2-pen pack is \$0 to < \$10 million save over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).
- 5.39 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of the IXE 1-pen pack over the IXE 2-pen pack is \$0 to < \$10 million over the first six years of listing (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).
- 5.40 In November 2021, the PBAC considered that “if listed under the parameters of its recommended listing on a cost minimisation basis with the least costly alternative bDMARD for nr-AxSpA, [...] the listing of IXE should not result in any additional cost to the PBS.” (paragraph 7.8, IXE PSD, November 2021 PBAC meeting).
- 5.41 In the November 2021 estimates, and current estimates, the comparator costs are not based on the effective EMPs for CZP, GLM and SEC, but the published EMPs. “The net financial implications for the PBS/ RPBS when estimated using the indication-specific

effective prices for all medicines are likely to be marginal. The PBAC noted these costs were based on the published price of the comparator. The net cost to the PBS will reduce once the effective price of the comparator is applied.” (paragraph 6.43 IXE PSD, November 2021 PBAC Meeting).

6 PBAC Outcome

- 6.1 The PBAC did not recommend revising its November 2021 recommendation to list IXE for the treatment of patients with nr-AxSpA to increase the maximum quantity (units) from one to two. The PBAC’s decision to not recommend was based on, among other matters, consistent and fair application of the PBAC Guidelines that drugs listed on the General Schedule are to have a maximum quantity per prescription that provides supply sufficient for one months’ treatment.
- 6.2 The PBAC noted that the standing recommendation not implemented from November 2021 will be due for review in November 2023.
- 6.3 The PBAC considered that listing IXE with two months’ supply per dispensing (and by implication, one patient co-payment per 2 months) would be perceived as an unfair advantage to IXE compared to other bDMARDs listed for the same indication . While the PBAC recalled its consideration that the “choice of treatment would be largely driven by individual patient characteristics related to clinical suitability to a particular drug and clinician familiarity with the drug ” (paragraph 5.3, Secukinumab PSD July 2021 PBAC meeting), it noted a perception of inequity could arise if the PBAC Guidelines are not applied equally to medicines of the same class and for the same indication (see 5.15).
- 6.4 The PBAC considered that, because IXE would be the fourth or fifth bDMARD listed for the treatment of nr-AxSpA, there was no urgent clinical need for an additional bDMARD to be listed for this indication.
- 6.5 The PBAC noted that the sponsor’s intentions when registering a pack size with the TGA, international price referencing concerns, cold chain and manufacturing costs, and issues with stock forecasting are not matters for PBAC consideration.
- 6.6 The PBAC did not expect the quality use of medicine concerns raised to be realised in practice, as clinicians, pharmacists and patients would be familiar with managing the different dosing regimens for different bDMARDs and indications (see 5.12).
- 6.7 The PBAC did not find the justification that IXE has been listed as a 2-pen pack “since February 2017 for three different indications without any concerns about the clinical safety” (Pre-PBAC response) to be sufficient. As part of the consideration of SEC in July 2017 and July 2021, the PBAC in both instances recommended that the maximum quantity for IXE for the treatment of CPP be amended such that only 1 months’ supply is dispensed. The PBAC recalled that at its November 2021 meeting, it had “recommended listing IXE under the same circumstances as that of the other

bDMARDs for nr-AxSpA” (paragraph 7.3 ixekizumab PSD, November 2021 PBAC Meeting) and maintained this position.

- 6.8 The PBAC recalled that it had not recommended bDMARDs as suitable for inclusion on the “Medicine List for Increased Dispensing Quantities” (PBAC December Intracycle meeting 2022) for the 60 day dispensing of PBS medicines policy and maintained this position.
- 6.9 The PBAC noted that the clinical need, clinical comparators, the clinical place for IXE in the treatment of nr-AxSpA, comparative clinical benefits and harms, and appropriateness of equi-effective doses and interchangeability advice were not considered as part of this submission. The PBAC recalled that it had made recommendations regarding the appropriateness of these claims and listing conditions at its November 2021 meeting and thus its view remained unchanged.
- 6.10 The PBAC considered that listing a 2-pen pack over the 1-pen pack has the potential to provide a small cost saving to the PBS and patients, as presented in the economic analysis and utilisation estimates, noting that these analyses have not been independently evaluated. However, the PBAC considered that this was not a reasonable justification to recommend a maximum quantity outside that recommended in the PBAC Guidelines and the November 2021 PBAC Meeting for IXE, and inconsistent with other bDMARDs listed for this indication.
- 6.11 The PBAC noted the sponsor’s concerns regarding the supply and costs involved with supplying a 1-pen pack and that the sponsor may not be able to secure 1-pen pack supply on an ongoing basis.
- 6.12 The PBAC noted that this submission is not eligible for an Independent Review because it was a request to modify a previous PBAC recommendation.

Outcome:

Not recommended

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.