

7.07 SECUKINUMAB,

Solution for injection 300 mg in 2 mL pre-filled syringe,

Solution for injection 150 mg in 1 mL pre-filled syringe,

Solution for injection 150 mg in 1 mL pre-filled pen,

Solution for injection 300 mg in 2 mL pre-filled pen,

Cosentyx[®],

NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED

1 Purpose

- 1.1 The early re-entry re-submission sought to address the issues raised by the Pharmaceutical Benefits Advisory Committee (PBAC) at its previous consideration of secukinumab (SEC) for the treatment of moderate to severe hidradenitis suppurativa (HS) in July 2023. The re-submission presented a revised cost minimisation approach (CMA) and utilisation and financial estimates.
- 1.2 A summary of the key matters of concern raised by the PBAC to be addressed is presented in the table below.

Table 1: Summary of key matters to be addressed

| Matter of concern | Response | Addressed? |
|--|--|--|
| <p>The PBAC considered a re-submission should present a revised CMA, as the submission did not account for any use of the Q2W maintenance dosing schedule or response being measured at a later timepoint than for ADA (paragraphs 7.10; 7.12)</p> | <p>The re-submission presented a revised CMA assuming 20% use of a Q2W regimen in maintenance therapy. The assumption was based on a dermatologist survey as no data was available to inform likely Q2W use in practice. Updated ADA prices (based on the Humira brand AEMP of \$618.90) were used in the CMA (discussed in the July 2023 PSD)</p> | <p>Partially addressed. Q2W use is considered, but not timing of response assessment in the CMA.</p> |
| <p>The PBAC considered a re-submission should present revised financial estimates which account for the use of the Q2W regimen and more reliably estimate the extent of use in patients who have failed treatment with ADA (paragraph 7.12).</p> | <p>The re-submission presented revised utilisation and financial estimates using changed script equivalence in initial treatment (SEC 1.33:1.00 ADA) to account for the extra SEC dose with assessment in weeks 16-20 with SEC (compared to 12-16 for ADA), and an assumption that 20% of SEC use would be subsequent to ADA (i.e. failed treatment with ADA). Cost offsets for ADA were also changed, based on 1 April 2023 prices.</p> <p>The re-submission argued Q2W use has been adequately accounted for in the CMA and further argues the assumptions about script equivalence and use subsequent to ADA may be unrealistic in practice and presented additional sensitivity analyses on the financial estimates.</p> | <p>Yes; but some assumptions remain contested.</p> |

Source: Summarised by the Secretariat from the secukinumab July 2023 PSD and early re-entry re-submission.

Abbreviations: CMA = cost minimisation approach; Q2W = 2-weekly regimen; ADA = adalimumab; COM = commentary; SEC = secukinumab; PSD = Public Summary Document

- 1.3 In addition to the above, the PBAC previously considered that the claim that SEC was non-inferior to adalimumab (ADA) in terms of effectiveness was uncertain (paragraph 7.8, secukinumab Public Summary Document (PSD), July 2023), however the extent of uncertainty regarding this claim may be acceptable in the context of the high clinical need for additional therapies if there was additional certainty regarding the cost minimised price for SEC and the net PBS/RPBS cost (paragraph 7.1, secukinumab PSD July 2023).

2 Background

- 2.1 SEC was TGA registered on 15 September 2023 for the treatment of HS. The approved indication is:

COSENTYX is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic hidradenitis suppurativa therapy.

- 2.2 The PICO from the previous submission, updated to include the Q2W regimen of SEC is presented below.

Table 2: Key components of the clinical issue addressed by the submission

| Component | Description |
|----------------|--|
| Population | Patients with moderate to severe hidradenitis suppurativa |
| Intervention | Secukinumab (300 mg at week 0,1,2,3 and 4 followed by 300 mg every 4 weeks or every 2 weeks). |
| Comparator | Adalimumab (160 mg at day 1, 80 mg at day 15, followed by 40 mg every week/80 mg fortnightly from day 29). |
| Outcomes | Clinical response: proportion of patients meeting hidradenitis suppurativa response criteria (HiSCR50); change in safety and tolerability. |
| Clinical claim | In patients with moderate to severe hidradenitis suppurativa secukinumab is superior in terms of comparative effectiveness and inferior in terms of comparative safety compared with placebo. In patients with moderate to severe hidradenitis suppurativa secukinumab is non-inferior in terms of comparative effectiveness and equivalent in terms of comparative safety compared with adalimumab. |

Source: Reproduced from Table 1 of the SEC July 2023 PSD.

3 Requested listing

3.1 The PBAC previously considered the PBS listings of SEC for HS should be under the same conditions as the current listings for ADA, with the exception that it may be reasonable to allow response to SEC to be assessed at 16-20 weeks (rather than 12-16 weeks for ADA), with required quantities and repeats for initial treatment. This was accepted in the re-submission. For brevity reasons, an abridged listing is presented below.

| MEDICINAL PRODUCT | Dispensed Price for Max. Qty* | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|--|-------------------------------|----------------|----------------|-------------|--------------------------------------|
| Initial treatment 1, 2 and balance of supply | | | | | |
| Secukinumab, 150 mg/mL injection, 2 x1 mL pen devices/syringe | \$4,267.29 | 4 | 8 | 0 | Cosentyx Novartis Pharmaceuticals |
| Secukinumab, 150 mg/mL injection, 2 x1 mL pen devices/syringes | \$1,142.52 | 1 | 2 | 3 | |
| Secukinumab, 300 mg/2mL injection, 2 mL pen device/syringe | \$4,267.29 | 4 | 1 | 0 | |
| Secukinumab, 300 mg/2mL injection, 2 mL pen device/syringe | \$1,142.52 | 1 | 1 | 3 | |
| Continuing treatment (continuing and grandfather) | | | | | |
| Secukinumab, 150 mg/mL injection, 2 x1 mL pen devices/syringes | \$1,142.52 | 1 | 2 | 5 | Cosentyx Novartis Pharmaceuticals |
| Secukinumab, 300 mg/2mL injection, 2 mL pen device/syringes | \$1,142.52 | 1 | 1 | 5 | |

Source: Table 1.6, p35 of the submission.

*The submission stated that should the PBAC recommend secukinumab for listing, the sponsor will work with the Department on the published and effective prices. All prices presented in the submission were calculated using the published price of adalimumab. Following the submission, the price of adalimumab reduced on 1 April 2023. Further discussion is presented in the economic analysis section.

| |
|--|
| Category / Program: General Schedule (Code GE) |
| Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives |
| Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload) |
| Administrative Advice: Subcutaneous injection |
| Severity: Moderate to severe |
| Condition: Hidradenitis suppurativa |

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|---|
| Treatment Phase: Initial treatment 1, new patient |
| Clinical criteria: |
| Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, |
| AND |
| Clinical criteria: |
| Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR |
| Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR |
| Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, |
| AND |
| The treatment must be limited to a maximum duration of 20 weeks. |
| Treatment criteria: |
| Must be treated by a dermatologist |
| Population criteria: |
| Adult patients |
| Prescribing Instructions: Assessment of disease severity must be no more than 1 month old at the time of application. An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 16 weeks of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 20 of treatment under Initial treatment 1 – New patient or Initial treatment 2 – Recommencement of treatment – balance of supply |

Source: Reproduced from Section 3 of the SEC July 2023 PSD, with *minor amendments to facilitate assessment of response at weeks 16-20*

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|--|
| Category / Program: General Schedule (Code GE) |
| Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives |
| Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload) |
| Administrative Advice: Subcutaneous injection |
| Severity: Moderate to severe |
| Condition: Hidradenitis suppurativa |
| Treatment Phase: Continuing treatment |
| Clinical criteria: |
| Patient must have previously received PBS-subsidised treatment with this drug for this condition, |
| AND |
| Clinical criteria: |
| Patient must have demonstrated a response to treatment with this drug for this condition. |
| Prescribing Instructions: For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. |

Source: Reproduced from Section 3 of the SEC July 2023 PSD

- 3.2 Two-weekly treatment with SEC may be achieved by the prescriber requesting an increased maximum quantity of units at time of authority application and/or through the balance of supply restrictions. It is noted the dosing regimen in the approved Product Information does not specify any restrictions around the timing of using a Q2W regimen.
- 3.3 If recommended for listing, changes to the existing listings for ADA for HS (which will also apply to the listing of SEC) will be required to facilitate the entry of a second biologic disease modifying anti-rheumatic drug (bDMARD) to the market.

For more detail on PBAC’s view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

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

Economic analysis

- 4.3 At its July 2023 meeting, the PBAC considered, based on the CMA presented in that submission, that treatment with SEC was likely to be more costly than treatment with ADA as the submission did not account for any use of the Q2W maintenance dosing schedule or response being measured at a later timepoint than for ADA (paragraph 7.10). The re-submission noted there is no clinical trial data or real world evidence to inform the likely use of the Q2W and Q4W regimens in practice and collected inputs from a sponsor advisory board, with survey responses from five dermatologists.
- 4.4 Based on the survey results, the revised CMA in the re-submission included an assumption that 20% of patients would receive a Q2W maintenance regimen of SEC and presented a weighted CMA on that basis.
- 4.5 Cost minimised prices for the SEC Q2W and Q4W regimens are presented in the table below (based on the published Humira brand of ADA price at 1 April 2023).

Table 3: Cost minimisation of secukinumab (Q2W and Q4W) and adalimumab

| | Adalimumab | Secukinumab q4w | Secukinumab q2w |
|------------------------------------|------------|-----------------|-----------------|
| Administrations over two years | 53 | 29 | 54 |
| Dose duration | 2 years | 2 years | 2 years |
| AEMP per dose | \$618.90 | \$1,131.09 | \$607.44 |
| Total cost over two years (@ AEMP) | \$32,802 | \$32,802 | \$32,802 |

Abbreviations: AEMP= Agreed ex-manufacturer price; PBS= Pharmaceutical Benefits Scheme; q4w= every 4 weeks; q2w= every 2 weeks.

Source: Table 2 of the re-submission

4.6 Results of the SEC CMA, applying weightings of 80% use of the Q4W regimen and 20% use of the Q2W regimen are presented in the table below.

Table 4: Results of the weighted cost minimisation approach for secukinumab

| Dosing regimen | Price per 300mg | Weighting |
|-----------------------|-----------------|-----------|
| Q4W | \$1,131.09 | 80% |
| Q2W | \$607.44 | 20% |
| Weighted average AEMP | \$1,026.36 | |
| Price to pharmacy | \$1,080.50 | |
| DPMQ | \$1,142.52 | |

Abbreviations: AEMP= Agreed ex-manufacturer price; DPMQ= dispensed price for maximum quantity; q4w= every 4 weeks; q2w= every 2 weeks.

Source: Table 3 of the re-submission

4.7 The revised CMA did not consider the potential cost implications of an additional dose in the induction phase, which may lead to an incremental cost because patients who otherwise would have discontinued treatment with ADA would receive an extra dose of SEC before being assessed to have not adequately responded to treatment. The re-submission stated approximately 90% of patients treated with ADA appeared to enter continuing treatment; substantially higher than the pooled ADA response rate from the clinical trials of 50.3% (Table 8, July 2023 SEC PSD). Therefore, in practice it may be reasonable to assume a high proportion of patients would receive continuing therapy and to not account for this in the CMA. The evaluation noted this was accounted for in the financial estimates in the initial phase by assuming a 1:1.33 script equivalence.

Utilisation and financial estimates

4.8 Revised utilisation and financial estimates were presented in the resubmission, which included the following changes based on the July 2023 PBAC PSD:

- The current list prices of the Humira brand of ADA (varies depending on dose and quantities) and weighted SEC price as calculated in the economic analysis section (DPMQ \$1,142.52);
- No further adjustment for Q2W use, as the assumption of 20% use of the Q2W regimen was included in the CMA and the total number of scripts would not change (just the quantities of SEC dispensed per script);
- Script equivalence in initial treatment through the Balance of Supply (BoS) arrangements was changed from 1:1 to 1.33:1, to account for additional dosing as part of the longer initial treatment period with SEC (similar to sensitivity analyses in Table 14 of the July 2023 PSD); and
- Estimated 'ADA failure' use (i.e. use of SEC in the ADA failure subgroup) of 20% of the total ADA forecasts.

4.9 The resubmission revised base case financials estimated a net cost to the PBS of \$0 to < \$10 million in Year 6 of listing, with a total net cost to the PBS of

\$20 million to < \$30 million over the first 6 years of listing (up from a net cost of \$0 to < \$10 million in the original submission); see table below.

Table 6: Estimated use and financial implications (revised base case)

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 |
|--|------------------|------------------|------------------|------------------|------------------|------------------|
| Estimated extent of use | | | | | | |
| ADA scripts: projected, without SEC available | 1 ¹ | 1 ¹ | 1 ¹ | 6 ⁶ | 6 ⁶ | 6 ⁶ |
| SEC substitution | 10% | 16% | 22% | 28% | 34% | 40% |
| ADA scripts: projected reduction, with SEC available | - 2 ² | - 2 ² | - 2 ² | - 5 ⁵ | - 5 ⁵ | - 1 ¹ |
| Total number of SEC scripts dispensed ^a | 2 ² | 5 ⁵ | 5 ⁵ | 5 ⁵ | 1 ¹ | 1 ¹ |
| Estimated financial implications | | | | | | |
| Cost to PBS/RPBS for proposed listing | 3 ³ | 3 ³ | 3 ³ | 7 ⁷ | 7 ⁷ | 7 ⁷ |
| Reduction in cost for affected medicines | 4 ⁴ | 4 ⁴ | 4 ⁴ | 4 ⁴ | 4 ⁴ | 4 ⁴ |
| Net cost to PBS/RPBS | 3 ³ | 3 ³ | 3 ³ | 3 ³ | 3 ³ | 3 ³ |
| Previous submission | | | | | | |
| SEC scripts total | 2 ² | 2 ² | 2 ² | 5 ⁵ | 5 ⁵ | 1 ¹ |
| Net cost to PBS/RPBS | 3 ³ | 3 ³ | 3 ³ | 3 ³ | 3 ³ | 3 ³ |

^a Assuming 1:1 script substitution for initial and continuing scripts, 1:1.33 for BoS scripts. Plus an additional 20% of net ADA scripts to account for treatment failures per patient per year as estimated by the (re)submission.

Abbreviations: BoS = balance of supply

Source: Table 4 of the resubmission; cells D24-I24, sheet 3c, cells D24-I24, sheet 4b

The redacted values correspond to the following ranges:

¹ 10,000 to < 20,000

² 500 to < 5,000

³ \$0 to < \$10 million

⁴ net cost saving

⁵ 5,000 to < 10,000

⁶ 10,000 to < 20,000

⁷ \$10 million to < \$20 million

4.10 However, the re-submission argued a number of inputs to the revised base case utilisation and financial estimates, as requested by the PBAC in July 2023, may not be realistic. These arguments included:

- For the proposed script equivalence of 1.33:1 for the BoS initial period (to account for the longer initial treatment period for SEC), the re-submission argued this would likely be an overestimation against SEC, as the duration of the initiation phase would, in practice, offset some ADA maintenance use, noting that in the maintenance phase, a script equivalence of 1:1 is applied.
- For the assumed 'ADA failure' rate of 20%, the re-submission argued that while the suggested approach in the sensitivity analyses in the previous PBAC PSD may offer a pragmatic method in the face of no epidemiological or market data to reliably model the size of this patient subgroup, that the response rate on the PBS appears to be higher, with ~90% entering the continuation phase. Furthermore, the re-submission also noted current ADA restrictions allow patients who achieve an adequate response during maintenance therapy to stop and re-commence treatment as necessary, meaning utilisation data suggestive of treatment failure

may not actually represent such an outcome. As a third argument against accepting an ADA failure rate of 20%, the re-submission also noted such an assumption would imply a very high uptake of SEC amongst this subgroup of patients.

- 4.11 Sensitivity analyses on the utilisation and financial estimates, removing the changes in the revised base case (i.e. without the initial/continuing script equivalence adjustment and no consideration for ADA failure) are presented below.

Table 7: Sensitivity analyses on the financial estimates

| Year | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 |
|---|--------|--------|--------|--------|--------|--------|
| Net costs to the PBS / RPBS combined, revised base case (1.33:1 script equivalence & 20% “adalimumab failure”) | | | | | | |
| New listing | 1 | 1 | 1 | 3 | 3 | 3 |
| Changed listing | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost | 1 | 1 | 1 | 1 | 1 | 1 |
| Net costs to the PBS / RPBS combined, 1:1 script equivalence only | | | | | | |
| New listing | 1 | 1 | 1 | 3 | 3 | 3 |
| Changed listing | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost | 1 | 1 | 1 | 1 | 1 | 1 |
| Net costs to the PBS / RPBS combined, 1:1 script equivalence & no consideration for “adalimumab failure” | | | | | | |
| New listing | 1 | 1 | 1 | 1 | 3 | 3 |
| Changed listing | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost | 1 | 2 | 2 | 2 | 2 | 2 |

Source: Table 7 of the re-submission.

Abbreviations: PBS = pharmaceutical benefits scheme; RPBS = repatriation pharmaceutical benefits scheme

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

³ \$10 million to < \$20 million

- 4.12 The sensitivity analyses show the financial estimates are most sensitive to assumptions around the proportion of use in the ADA failure population. At the revised cost minimised price of SEC (accounting for 20% Q2W use), and removing the script equivalence adjustment for the longer initial treatment period and with no consideration for use in adalimumab failure patients (consistent with the original submission base case) resulted in a net save to the PBS/RPBS of approximately \$0 to < \$10 million over 6 years. However, an assumption of no post-adalimumab failure use may be unrealistic. The pre-PBAC response acknowledged that some of the use of SEC would arise from patients who have previously failed/were intolerant to adalimumab but reiterated the arguments made in the re-submission that an assumption of 20% use in this population was overestimated (see paragraph 4.10).

For more detail on PBAC’s view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended the Authority Required listing of secukinumab (SEC) for the treatment of moderate to severe hidradenitis suppurativa (HS). The PBAC's recommendation was based on, among other matters, its assessment the cost-effectiveness of SEC would be acceptable if it were cost minimised to adalimumab (ADA) (noting it was the only biologic disease modifying anti-rheumatic drug (bDMARD) currently PBS listed for HS).
- 5.2 The PBAC considered the equi-effective doses were:
- SEC 300 mg (which could be in the form of 2 x 150 mg doses or 1 x 300 mg doses) given at weeks 0, 1, 2, 3, 4, 8, 12 and 16 (initial phase), followed by SEC 300 mg given either once every two weeks or once every four weeks; and
 - ADA 160 mg at day 1, followed by 80 mg at day 15, with by 80 mg once every two weeks or 40 mg weekly thereafter.
- 5.3 The PBAC considered that the resubmission had adequately addressed the substantive outstanding issues identified at the July 2023 meeting via amendments to the cost minimisation approach (CMA) to account for the use of a fortnightly (Q2W) regimen and updated utilisation and financial estimates accounting for a longer induction phase with SEC (compared to ADA) and some use in a post-ADA (i.e. 'ADA failure') population (further detail in Table 1).
- 5.4 The PBAC reaffirmed its view expressed in July 2023 that there was a high clinical need for additional pharmacological treatment options for HS, as ADA is currently the only therapy subsidised for moderate to severe HS after other options (such as antibiotics) have been found to be ineffective or not tolerated. The Committee also recalled there was strong consumer support for additional treatment options for HS expressed in its July 2023 consideration (paragraph 7.3, secukinumab PSD July 2023).
- 5.5 The PBAC reaffirmed it considered the listing of SEC for HS should be under the same conditions as the current listings for ADA, except for the duration of initial treatment, and advised it was reasonable to allow response to SEC to be assessed at 16-20 weeks (compared to 12-16 weeks for ADA), with appropriate quantities and repeats for initial treatment. The PBAC noted the existing restrictions for ADA for HS will need to be re-designed to facilitate the entry of a second biologic disease modifying anti-rheumatic drug (bDMARD), including provisions for treatment cycles, a treatment break of 5 years after a lack of response or loss of response to both ADA and SEC, and an initial 3 restriction for re-initiation after the prescribed treatment break period, consistent with other bDMARD listings for other indications. The PBAC also recalled, however, that in its consideration of ozanimod in November 2022 that it would be timely to review the design of treatment cycle requirements for biologics broadly given the range of available treatments with different mechanisms of action since these requirements were originally devised (paragraph 7.12, ozanimod PSD, November 2022; paragraph 7.3, upadacitinib PSD, November 2022).

- 5.6 The PBAC reaffirmed its view expressed in July 2023 that the nominated comparator of ADA was reasonable.
- 5.7 The PBAC recalled in July 2023 it had previously considered the available clinical evidence for SEC in HS indicated it was likely superior to placebo, but that the effect appeared to be relatively modest; and further, based on the indirect treatment comparisons (ITCs) presented, that the clinical claim that SEC was of non-inferior comparative effectiveness to ADA was uncertain, as whilst the ITCs suggested SEC may be inferior to ADA, exchangeability issues and higher placebo response rates in the SEC trials complicated interpretation of the evidence (paragraphs 7.7 and 7.8, secukinumab PSD July 2023). The Committee also reaffirmed its view that the available evidence supported a claim that SEC is of non-inferior comparative safety to ADA. Overall, the PBAC reaffirmed its view that listing SEC on a cost minimisation basis with ADA may be acceptable, in the context of the high clinical need and changes made in the early re-entry submission (see paragraph 5.3).
- 5.8 The PBAC considered the revised CMA presented in the re-submission, accounting for the assumption of 20% use of the Q2W regimen, was generally consistent with the standard two-year approach for bDMARDs and was reliable for decision-making. The Committee noted the early re-entry submission did not account for the potential cost implications of a longer initial treatment period for SEC (and subsequently not progressing to continuing therapy) compared to ADA, however considered it was acceptable to not account for this in the context of high continuation rates in practice of ADA for HS, which suggested most patients will continue with treatment past the initial phase (see paragraph 4.7).
- 5.9 The PBAC noted the revised base case utilisation and financial estimates incorporated the changes requested by the Committee in its July 2023 consideration of SEC and considered the base case estimates to be reasonable. However, the PBAC noted the re-submission highlighted the projected cost to the PBS was largely driven by assumptions about the level of SEC use that is subsequent to ADA (i.e. the 'ADA failure' population) where the listing of SEC represents an additional line of therapy for these patients. In this context, the PBAC considered that given the high rate of ADA continuation in practice (see paragraph 4.7), the extent of use in an 'ADA failure' population that resulted in an incremental cost was uncertain in practice. Furthermore, the PBAC also considered that a small incremental cost to the PBS was reasonable given that SEC provided an additional treatment option for patients for a condition with a high clinical need.
- 5.10 The PBAC advised, under Section 101 (4AACD) of the National Health Act, that the SEC 300 mg pre-filled pen and pre-filled syringe; and SEC 150 mg pre-filled pen and pre-filled syringe (but not the 150 mg and 300 mg forms of SEC) should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule with a NOTE stating PBS of one form and PBS of another form are equivalent for the purposes of substitution).

- 5.11 The PBAC advised that SEC is not suitable for prescribing by nurse practitioners for HS, as the recommended listing is restricted to specialist medical practitioners.
- 5.12 The PBAC noted the flow-on restriction changes:
- Addition of treatment cycle rules and an initial 3 restriction for ADA listings to facilitate the entry of a second bDMARD for HS and associated rules for treatment breaks.
 - The PBAC noted some further restriction work may be required to facilitate these changes, making the restriction complex.
- 5.13 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because SEC is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over ADA, 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.
- 5.14 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Add new indication to secukinumab as follows:

| Name, Restriction, Manner of administration and form | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Proprietary Name and Manufacturer | |
|--|-------------------|----------------|----------------|-------------|--|--|
| SECUKINUMAB | | | | | | |
| | Initial treatment | | | | | |
| 150 mg/mL injection, 2 ×1 mL syringe | New | 4 | 8 | 0 | Cosentyx® Novartis Pharmaceutical S | |
| 150 mg/mL injection, 2 ×1 mL syringe | New | 1 | 2 | 3 | | |
| 150 mg/mL injection, 2 ×1 mL pen devices | New | 4 | 8 | 0 | | |
| 150 mg/mL injection, 2 ×1 mL pen devices | New | 1 | 2 | 3 | | |
| 300 mg/mL injection, 2 mL syringe | New | 4 | 4 | 0 | | |
| 300 mg/mL injection, 2 mL syringe | New | 1 | 1 | 3 | | |
| 300 mg/mL injection, 2 mL pen | New | 4 | 4 | 0 | | |
| 300 mg/mL injection, 2 mL pen devices | New | 1 | 1 | 3 | | |
| | Balance of Supply | | | | | |

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|--|---|---|---|---|--|--|
| 150 mg/mL injection, 2 x1 mL syringe | New | 1 | 2 | 3 | | |
| 150 mg/mL injection, 2 x1 mL pen devices | New | 1 | 2 | 3 | | |
| 300 mg/mL injection, 2 mL syringe | New | 1 | 1 | 3 | | |
| 300 mg/mL injection, 2 mL pen devices | New | 1 | 1 | 3 | | |
| | Continuing treatment and Grandfather arrangements | | | | | |
| 150 mg/mL injection, 2 x1 mL syringe | New | 1 | 2 | 5 | | |
| 150 mg/mL injection, 2 x1 mL pen devices | New | 1 | 2 | 5 | | |
| 300 mg/mL injection, 2 mL syringe | New | 1 | 1 | 5 | | |
| 300 mg/mL injection, 2 mL pen devices | New | 1 | 1 | 5 | | |

Restriction Summary: / Treatment of Concept:

| |
|---|
| Category / Program: GENERAL – General Schedule (Code GE) |
| Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| Restriction Level / Method: <input checked="" type="checkbox"/> Authority Required – In Writing |
| Administrative Advice: Increased maximum quantities for the single pack listing of secukinumab up to 2 packs may only be authorised for patients requiring maintenance dosing once every two weeks (Q2W regimen). |
| Administrative Advice: No increase in the maximum number of repeats may be authorised. |
| Administrative Advice: Special pricing arrangements apply. |
| Severity: Moderate to severe |
| Condition: Hidradenitis suppurativa |
| Indication: Moderate to severe hidradenitis suppurativa |
| Treatment Phase: Initial treatment - Initial 1 (new patient) |
| Clinical criteria: Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3 |
| AND |
| Clinical criteria: Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; or |
| Clinical criteria: Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; or |
| Clinical criteria: Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition |
| AND |
| Clinical criteria: |

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| | Patient must not have received PBS-subsidised treatment with a biological medicine for this condition |
| | AND |
| | Clinical criteria: |
| | Patient must not receive more than 16 weeks of treatment under this restriction |
| | AND |
| | Treatment criteria: |
| | Must be treated by a dermatologist |
| | Prescribing Instructions: Assessment of disease severity must be no more than 4 weeks old at the time of application. |
| | Prescribing Instructions: An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. |
| | Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. |
| | Prescribing Instructions: The authority application must be made in writing and must include; (1) a two completed authority prescription forms; 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) which includes; (i) the Hurley stage grading; and, (ii) the AN count; and, (iii) the name of the antibiotic/s received for two separate courses each of three months; or, (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. |
| | Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats. |
| | Administrative Advice: 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. |
| | 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 |
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| | Indication: Moderate to severe hidradenitis suppurativa |

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| | Treatment Phase: Initial treatment - Initial 2 (<i>Change or re-commencement of treatment after a break in biological medicine of less than 5 years</i>) |
| | Clinical criteria: |
| | Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle |
| | AND |
| | Clinical criteria: |
| | Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle |
| | AND |
| | Clinical criteria: |
| | 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 |
| | AND |
| | Treatment criteria: |
| | Must be treated by a dermatologist |
| | Prescribing Instructions: Assessment of disease severity must be no more than 4 weeks old at the time of application. |
| | Prescribing Instructions: A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. |
| | 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 16 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: The authority application must be made in writing and must include:; (1) two completed authority prescription forms; 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) which includes:; (i) the Hurley stage grading; and, (ii) the AN count. |
| | Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: |

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| | One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats. |
| | Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. |
| | 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. |
| | 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 |
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| | Indication: Moderate to severe hidradenitis suppurativa |
| | Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 5 years) |
| | Clinical criteria: |
| | Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3 |
| | AND |
| | 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 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition |
| | AND |
| | Clinical criteria: |
| | Patient must not receive more than 16 weeks of treatment under this restriction |
| | AND |
| | Treatment criteria: |
| | Must be treated by a dermatologist |
| | Prescribing Instructions: Assessment of disease severity must be no more than 4 weeks old at the time of application. |
| | Prescribing Instructions: A response to treatment is defined as:., Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. |
| | Prescribing Instructions: To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 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: |

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| | 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: The authority application must be made in writing and must include: (1) two completed authority prescription forms; 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) which includes: (i) the Hurley stage grading; and, (ii) the AN count. |
| | Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. Prescribing the 150 mg presentation: One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Prescribing the 300 mg presentation: One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats. |
| | Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. |
| | 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 |

Restriction Summary: / Treatment of Concept:

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| | Category / Program: GENERAL – General Schedule (Code GE) |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input checked="" type="checkbox"/> Authority Required – Telephone/Electronic <input type="checkbox"/> Authority Required - Streamlined |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. |
| | Administrative Advice: Special pricing arrangements apply. |
| | 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). |
| | Severity: Moderate to severe |
| | Condition: Hidradenitis suppurativa |
| | Indication: Moderate to severe hidradenitis suppurativa |

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| | Treatment Phase: Initial 1 (new patient), 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. |
| | AND |
| | Treatment criteria: |
| | Must be treated by a dermatologist |

Restriction Summary: / Treatment of Concept:

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| | Category / Program: GENERAL – General Schedule (Code GE) |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Authority Required - Streamlined |
| | Administrative Advice: Increased maximum quantities for the single pack listing of secukinumab up to 2 packs may only be authorised for patients requiring maintenance dosing once every two weeks (Q2W regimen). |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. |
| | Administrative Advice: Special pricing arrangements apply. |
| | Indication: Moderate to severe hidradenitis suppurativa |
| | Treatment Phase: Continuing treatment |
| | Clinical criteria: |
| | Patient must have previously received PBS-subsidised treatment with this drug for this condition |
| | AND |
| | Clinical criteria: |
| | Patient must have demonstrated a response to treatment with this drug for this condition |
| | AND |
| | Treatment criteria: |
| | Must be treated by a dermatologist |
| | Prescribing Instructions: A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. |

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| | <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: A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.</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) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.</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> |

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| | <p>Category / Program: GENERAL – General Schedule (Code GE)</p> |
| | <p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p> |
| | <p>Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Authority Required - Streamlined</p> |
| | <p>Administrative Advice: Increased maximum quantities for the single pack listing of secukinumab up to 2 packs may only be authorised for patients requiring maintenance dosing once every two weeks (Q2W regimen).</p> |
| | <p>Administrative Advice: No increase in the maximum number of repeats may be authorised.</p> |
| | <p>Administrative Advice: Special pricing arrangements apply.</p> |
| | <p>Indication: Moderate to severe hidradenitis suppurativa</p> |
| | <p>Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> |
| | <p>Clinical criteria: Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to [listing date],</p> |
| | <p>AND</p> |
| | <p>Clinical criteria: Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition</p> |

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| | AND |
| | Clinical criteria: |
| | Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer, |
| | AND |
| | Clinical criteria: |
| | Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR |
| | Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR |
| | Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition. |
| | AND |
| | Clinical criteria: |
| | Patient must not receive more than 24 weeks of treatment under this restriction |
| | AND |
| | Treatment criteria: |
| | Must be treated by a dermatologist |
| | Prescribing Instructions: A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. |
| | Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. |
| | Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. |
| | Prescribing Instructions: Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated |
| | Prescribing Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics |

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| | (v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment |
| | Prescribing Instructions: A patient may only qualify for PBS-subsidised treatment under this restriction once only. |
| | Prescribing Instructions: For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. |
| | 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 |

Overarching Administrative Note:

TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to [LISTING DATE] is considered to start their first cycle as of [LISTING DATE].

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to [LISTING DATE] and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised

treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

- 6.2 Flow on overarching administrative advice, initial 3 and amendments to initial 1/2 to adalimumab for moderate to severe hidradenitis suppurativa (Initial PBS item codes: 12454L, 12383R, 12356H, 12385W, 12450G, 12449F, 12524E, 12395J; Continuing PBS item codes: 12414J, 13221W, 12330Y, 12369B, 12448E, 12408C).

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

7 Context for Decision

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

8 Sponsor's Comment

The sponsor had no comment.