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SMC2592

secukinumab 150 mg or 300 mg solution for injection in pre-filled pen or pre-filled syringe (Cosentyx®)

Novartis Pharmaceuticals UK Ltd

12 January 2024

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a full submission

secukinumab (Cosentyx®) is accepted for restricted use within NHSScotland.

Indication under review: for the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy.

SMC restriction: for use in adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.

In two phase III studies in patients with moderate to severe HS, the proportion of patients who achieved a clinical response (defined as at least a 50% decrease in abscess and inflammatory nodule [AN] count with no increase in the number of abscesses and/or in the number of draining fistulae) was significantly increased with secukinumab (every two weeks) compared with placebo.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Secukinumab is a recombinant, human immunoglobulin G1/κ (IgG1/κ) monoclonal antibody that binds and neutralises interleukin (IL)-17A. The inhibition of IL-17A reduces the release of pro-inflammatory cytokines, chemokines and mediators of tissue damage, and limits IL-17A-mediated contributions to inflammatory diseases such as hidradenitis suppurativa (HS).[1-5] The recommended dose of secukinumab in adults is 300 mg by subcutaneous (SC) injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Depending on the clinical response, the maintenance dose can be increased to 300mg every 2 weeks.[1-4]

1.2. Disease background

HS also known as 'acne inversa' or 'Verneuil's disease' is a chronic, inflammatory skin disease that usually presents with recurrent, deep-seated and painful lesions that can progress to become chronic with purulent discharge, scarring and sinus formation; these mainly occur in areas like the armpits, groin and anogenital regions. HS has a highly negative impact on quality of life and devastating psychological effects, with an impact greater than for many other dermatologic diseases. The extent and severity of HS are often determined using the Hurley staging system; the focus of the company's submission is moderate (Hurley stage 2) to severe (Hurley stage 3) HS.[5-7] Onset of HS is typically after puberty and affects women two to five times more commonly than men. The 1-year prevalence is rare with estimates of around 1%.[8, 9] People with HS have an unmet medical need because of diagnostic delays and limited range of effective therapies.[10-12]

1.3. Company proposed position

The company has requested that SMC considers secukinumab when positioned for use in adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.

1.4. Treatment pathway and relevant comparators

Symptoms of HS are managed in a stepwise approach dependent on disease severity. In mild to moderate settings, HS is initially treated with topical antiseptics and antibiotics, switching to systemic antibiotics if there is continued progression. Upon failure of systemic antibiotics other conventional therapies are trialled including retinoid therapy, dapsone, ciclosporin and metformin.[13] In the case that all conventional therapies are exhausted, then adalimumab is the only other licensed option for moderate to severe HS in NHS Scotland (SMC1143/16).

For the proposed positioning, the submitting company consider best supportive care (defined as biologics, topical antibiotics, oral antibiotics, dapsone, retinoids, ciclosporin and anti-androgens) to be the only relevant comparator within NHS Scotland. Clinical experts contacted by SMC noted that infliximab (off-label) is sometimes used as a treatment option in this population.[13]

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence to support the efficacy and safety of secukinumab for the treatment of patients with moderate to severe HS comes from SUNSHINE and SUNRISE studies. Details are summarised in Table 2.1.

Table 2.1. Overview of relevant studies

Criteria	SUNSHINE and SUNRISE[5, 14]
Study design	Multicentre, randomised, double-blind, parallel-group, phase III studies.
Eligible patients	• ≥18 years of age. • Diagnosis of HS ≥1 year prior to baseline. • Patients with moderate to severe HS defined as a total of at least five inflammatory lesions (that is abscesses and/or inflammatory nodules) that affect at least two distinct anatomic areas. • Patient's agreement to daily use of topical over-the-counter antiseptics on the areas affected by HS lesions while on study treatment.
Treatments and randomisation	Patients were randomised equally (1:1:1) to receive (from weeks 0 to 16): • Secukinumab 300 mg subcutaneously every two weeks or • secukinumab 300 mg subcutaneously every four weeks or • matching placebo Randomisation was stratified according to geographical region (Europe, Asia-Pacific, Middle East and Africa, Latin America, the Caribbean and Canada, USA, and Japan), concomitant antibiotic use (yes vs no), and body weight (<90kg or ≥90kg). At week 16, patients who were randomised to placebo were reassigned to receive secukinumab 300 mg at weeks 16, 17, 18, 19 and 20, followed by either 300 mg every two weeks or 300 mg every four weeks.
Primary outcome	The proportion of patients with HS HiSCR (defined as at least a 50% decrease in AN count with no increase in the number of abscesses and/or in the number of draining fistulae) at week 16.
Key Secondary outcomes	• Percentage change from baseline in AN count at week 16. • Proportion of patients with HS flares
Statistical analysis	A hierarchical statistical testing strategy was applied where all primary and secondary endpoints were tested in the following pre-specified order within each individual study, including: • Secukinumab every 2 weeks (HiSCR50 response) • Secukinumab every 4 weeks (HiSCR50 response) • Secukinumab every 2 weeks (percentage change from baseline in AN count) • Secukinumab every 4 weeks (percentage change from baseline in AN count) • Secukinumab every 2 weeks (proportion of patients with flare count) • Secukinumab every 4 weeks (proportion of patients with flare count) Secondary outcomes were controlled for multiplicity.

AN = abscess and inflammatory nodule; HiSCR = hidradenitis suppurativa clinical response; HS= hidradenitis suppurativa.

For the primary outcome (HiSCR50 response), treatment with secukinumab 300 mg every 2 weeks resulted in a statistically significant improvement compared with placebo at week 16 (both studies); treatment with secukinumab 300 mg every 4 weeks also resulted in a statistically significant improvements compared with placebo at week 16 (SUNRISE only). See table 2.2 for detailed results.

Table 2.2 Primary and selected secondary outcomes from SUNSHINE and SUNRISE studies at week 16.[5, 14]

	SUNSHINE			SUNRISE		
	Secukinumab 300mg every 2 weeks (n=181)	**Secukinumab 300mg every 4 weeks (n=180)**	**Placebo (n=180)**	**Secukinumab 300mg every 2 weeks (n=180)**	**Secukinumab 300mg every 4 weeks (n=180)**	**Placebo (n=183)**
Primary outcome: HiSCR50 response						
HiSCR50 response	45%	42%	34%	42%	46%	31%
OR versus placebo (95% CI)	1.8 (1.1 to 2.7)	1.5 (1.0 to 2.3)	-	1.6 (1.1 to 2.6)	1.9 (1.2 to 3.0)	-
One-sided p-value	0.0070[a]	NSS	-	0.0149[a]	0.0022[a]	-
Secondary outcome: change from baseline in AN count						
Mean	-47%	-42%	-24%	-39%	-46%	-22%
LS mean difference (95% CI)	-23% (-34 to -12)	-19% (-29 to -8)	-	-16% (-29 to -4)	-23% (-35 to -11)	-
One-sided p-value	<0.0001[a]	NSS	-	0.0051[a]	0.0001[a]	-
Secondary outcome: proportion of patients with HS flares						
Response	15%	23%	29%	20%	16%	27%
OR versus placebo (95% CI)	0.4 (0.3 to 0.7)	0.7 (0.4, 1.2)	-	0.7 (0.4, 1.1)	0.5 (0.3, 0.8)	-
One-sided p-value	0.0010[a]	NSS	-	NSS	0.0049[a]	-

[a] Statistically significant based on the pre-defined testing hierarchy.

Abbreviations: AN: abscess and inflammatory nodule count; CI: confidence interval; HiSCR: Hidradenitis Suppurativa clinical response; HS: Hidradenitis Suppurativa; LS: least squares; NSS = not statistically significant; OR: odds ratio.

2.2. Evidence to support the positioning proposed by the submitting company

The submitting company has positioned secukinumab for use in adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment; however, only about 23% of patients recruited to each study had received previous systemic biologic treatment, mostly with adalimumab. Subgroup analysis of the primary outcome was statistically significant only in patients without previous exposure to biologics. Additionally, in terms of severity of the disease, both secukinumab doses were significantly better than placebo in the subgroup of patients with Hurley stage II (moderate) disease, but no significant differences in treatment effect was observed in patients with Hurley stage III (severe) disease. Evidence from both studies support the use of secukinumab in patients who are contraindicated or unsuitable to use adalimumab; however, evidence to support the use of secukinumab in patients who failed previous treatment with adalimumab is less certain.

2.3. Health-related quality of life outcomes

Health Related Quality of Life (HRQoL) was assessed using two questionnaires: the Dermatology Life Quality Index (DLQI) (response defined as decrease of five points or more from baseline) and

the EuroQol five-dimensional (EQ-5D) visual analogue scale (VAS). These instruments were used at screening, then weeks 2, 4, 12, 16, 28, and 52 (end of treatment period 2). Both the secukinumab 300 mg every 2 weeks and 300mg every 4 weeks groups had higher DLQI responder rates than placebo in SUNSHINE and SUNRISE at the end of treatment period 1 (16 weeks). This effect remained stable up to week 52. In addition, improvements in DLQI occurred once patients were reassigned from the placebo group to the secukinumab group (weeks 16 onwards).

Similar increases from both treatment regimens were found in EQ-5D VAS score from screening to week 16 compared to placebo. When the placebo group was switched to treatment with secukinumab there was an increase in score up to week 52.[14]

2.4. Supportive studies

Patients that completed the entire 52-week study period in SUNSHINE and SUNRISE were allowed to continue secukinumab treatment in a planned four-year multicentre, double-blind, phase III, randomised extension study (CAIN457M2301E1, NCT04179175). CAIN457M2301E1 study has a primary endpoint planned for August 2023.[15]

3. Summary of Safety Evidence

The overall safety profile of secukinumab at both doses (300 mg every 2 weeks and 300 mg every 4 weeks) for patients with moderate to severe HS was deemed to be consistent with the known safety profile of this medicine for other indications; this conclusion applied to both the short-term (up to 16 weeks) and long-term (up to 52 weeks) safety data.[5]

In SUNSHINE and SUNRISE, there were no numerically or clinically meaningful differences in adverse event (AE) frequency reported between the two secukinumab groups (300 mg every 2 weeks and 300 mg every 4 weeks) compared with placebo; the majority of AEs were non-serious, mild to moderate in severity, and did not require discontinuation of secukinumab.[5, 14]

In SUNSHINE and SUNRISE (during the entire 52-week period) respectively, the incidence of serious AEs in any of the secukinumab 300 mg every 2 weeks groups (n=266 and n=261) were 6.8% and 8.4%; and in any of the secukinumab 300 mg every 4 weeks (n=267 and n=266) groups were 7.1% and 8.6%. The only serious AEs that occurred in between 1% and 2% of patients in either any treatment group was an exacerbation of HS and sweat gland infection.[14]

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- In SUNSHINE and SUNRISE, secukinumab 300mg every 2 weeks resulted in a statistically significant improvement in HiSCR50 response at week 16, compared with placebo. Secukinumab 300 mg every 4 weeks also improved HiSCR50 response at week 16, compared with placebo, in both studies, however this was only statistically significant in SUNRISE.
- Results from subgroup analyses were consistent with the primary analysis; improvements in HiSCR50 were seen in biologic-naïve and biologic-exposed patients and regardless of previous or concomitant antibiotic treatment.[5, 14]

- In both studies, the onset of action of secukinumab occurred as early as week 2, the efficacy progressively increased to week 16 and was maintained up to week 52.[5, 14]
- No new safety signals were identified in this group of patients compared to the established safety profile in other indications. The proportion of patients suffering from a serious AE was low.
- Compared with placebo, secukinumab treatment (in both dosing groups) resulted in greater improvements in HRQoL (measured by DLQI response) in both studies at week 16; the effect also lasted up to week 52.[5, 14]

4.2. Key uncertainties

- In both studies, the efficacy of secukinumab over placebo was only assessed up to 16 weeks. After week 16, all patients were treated with secukinumab and there is no comparative efficacy data. Data for weeks 16 to 52 are presented as observed with no control group. There was no data beyond week 52, which raises uncertainty given HS is a chronic, recurrent condition.
- Both studies excluded patients with very severe HS (those with a total fistula count ≥20 at baseline); the mean total baseline fistulae count at baseline was 4.8 in both studies. Additionally, both secukinumab doses (300 mg every 2 weeks and 300 mg every 4 weeks) were significantly better than placebo in the subgroup of patients with Hurley stage II disease, but no significant differences in treatment effect were observed in patients with stage III disease. This raises uncertainty about the effectiveness of secukinumab in those with a more severe form of HS.
- There is uncertainty whether there is a dose-response effect of secukinumab for treating HS given that there were conflicting results for the two regimens (300 mg every 2 weeks and 300 mg every 4 weeks) in two identically designed studies.[5] Therefore, it is recommended that patients are not initially commenced on 300 mg every 2 weeks but can be escalated to this dose if they have an insufficient response.[1-4]
- Pooled subgroup analyses for the primary outcome were generally consistent across all subgroups, numerically favouring both secukinumab dosing regimens over placebo. However, results were only statistically significant for patients with no prior exposure to biologics.

4.3. Clinical expert input

Clinical experts consulted by SMC considered secukinumab to be a therapeutic advancement and would fulfil an unmet need in this therapeutic area where patients only have limited, off-label treatment options following adalimumab treatment.

4.4. Service implications

Clinical experts consulted by SMC indicated that there would be no major service implications since this treatment is already used for other indications. For this indication and proposed positioning, one biologic (adalimumab) would be switched to another.

5. Summary of Patient and Carer Involvement

No patient group submission was received.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

The submitting company provided an economic case, as described in Table 6.1.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-utility analysis
Time horizon	Lifetime
Population	Adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.
Comparators	Best supportive care (BSC).
Model description	A 5-state Markov model was implemented. Health states were based on HiSCR scores and included high responders (HiSCR≥75), responders (HiSCR 50-74), partial responders (HiSCR 25-49) and non-responders (HiSCR<25). All patients enter the model in the induction phase receiving either secukinumab every 4 weeks or BSC. The induction phase lasts for 16 weeks with response being assessed every 4 weeks. Secukinumab non-responders at week 16 were modelled to up-titrate to bi-weekly dosing for a further 12 weeks. At the end of the up-titration phase (week 28), treatment responders were modelled to continue to receive secukinumab bi-weekly and these patients could transition between HiSCR categories and a stopping rule was applied for patients who failed to respond to secukinumab every 2 weeks at Week 28. Patients on BSC could not transition between HiSCR health states beyond 16 weeks. The cycle length was 4-weeks, and the model adopts an NHSScotland and social care perspective.
Clinical data	The key effectiveness data for secukinumab were based on pooled data from the SUNSHINE and SUNRISE studies. To model up-titration, the company used transition probabilities based on week 16 to week 28 efficacy data for everyone on the secukinumab bi-weekly regimen in the two trials. Effectiveness data for BSC up to 16 weeks were based on pooled data from the two studies. Loss of response for patients on BSC was modelled at an annual rate of 9.61%
Extrapolation	In the maintenance phase, average per cycle transition probabilities for secukinumab-treated patients were derived from the week 16 to 52 data from the SUNSHINE and SUNRISE studies for each dosing regimen. Transitions between response categories for BSC treatment responders were not modelled in the maintenance phase. However, transitions from any response categories to the not responding health state were informed based on risk of loss of response estimates from the PIONEER 2 study (adalimumab vs placebo). In the absence of data, it was assumed that the maintenance phase data for week 16 to 52 would continue to be applied in week 52+ for all treatments.

Quality of life	Utility values were based on pooled EQ-5D-3L data from SUNSHINE and SUNRISE. Treatment-specific utility values were applied to the different response health states. Utility values were age-adjusted. No adverse event disutilities were included in the base case.
Costs and resource use	The economic analysis included costs associated with medicine acquisition, administration, components of BSC, and health-state related surgical and non-surgical procedures.
PAS	A Patient Access Scheme (PAS) was submitted by the company and assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHSScotland. Under the PAS, a discount was offered on the list price.

Abbreviations: BSC: best supportive care; HiSCR: Hidradenitis Suppurativa clinical response; HS: Hidradenitis Suppurativa.

6.2. Results

The base case analysis presented by the submitting company indicated that secukinumab was dominant compared to BSC, meaning it was estimated as resulting in lower costs and better health outcomes for patients. Secukinumab dominated BSC.

Table 6.2 Base case cost utility analysis (CUA) results (PAS Price)

Technologies	ICER (£/QALY)
Secukinumab vs BSC	Dominant (-£4,077) *

Abbreviations: BSC, best supportive care; ICER, incremental cost-effectiveness ratio; QALY: quality adjusted life year.
* Secukinumab was dominant compared to BSC, meaning it was estimated as resulting in lower costs and better health outcomes for patients.

6.3. Sensitivity analyses

In deterministic one-way sensitivity analysis, the parameters with the greatest impact on ICER were the resource use frequencies and costs of surgical and non-surgical hospitalisations. A range of scenario analyses were performed and are presented in Table 6.3.

Table 6.3 Results of scenario analyses (PAS Price)

	Scenario	ICER (£/QALY)*
	Base case	***-£4,077***
1	Assume per cycle TPs	-£4,154
2	Assume no up-titration of non-responders	-£3,465
3	Assume 24 week BSC TPs from TA392	-£2,473
4	Assume no treatment dependent utilities	-£6,116
5	Assume TA392 utilities	-£3,435
6	Include AE-related QALY decrements & costs	-£4,092
7	Assume no BSC costs	-£951
8	Assume only biologic-experienced population & utilities	-£3,023
9	Scenario's 2 + 7 + 8 combined	£1,923
10	Scenario's 2 + 3 + 7 + 8 combined	£3,449

Abbreviations: AE, adverse events; BSC, best supportive care; ICER, incremental cost-effectiveness ratio; QALY: quality adjusted life year; TP, transition probability
* Secukinumab was dominant compared to BSC in all scenarios, meaning it was estimated as resulting in lower costs and better health outcomes for patients.

6.4. Key strengths

An appropriately structured model which captures the key features of HS and the clinical pathway of care. The use of a granular model, given the dichotomous primary end point (HiSCR50 response) in the SUNSHINE and SUNRISE trials, allows for assessing a greater range of response.

6.5. Key uncertainties

There were some limitations with the analysis which include the following:

- The SUNSHINE and SUNRISE studies were not designed to assess up-titration of secukinumab in non-responders. The use of effectiveness data for all patients in the studies on the bi-weekly dosing schedule, to determine transition probabilities for secukinumab non-responders being up-titrated, is a source of bias and could potentially overestimate effectiveness of secukinumab in this subgroup. Furthermore, there is no clear dose-response relationship for secukinumab from the two studies to support the clinical utility of up-titration in patients not responding to secukinumab within the first 16 weeks. It is also not known whether some patients with an initial partial response to secukinumab may subsequently improve with continued treatment beyond 16 weeks.
- There was no stopping rule in place for patients who had a response at week 16 or week 28; entering the maintenance phase implied treatment with secukinumab indefinitely, even if patients stop responding in the long term. It was also assumed that secukinumab all-cause discontinuation rates did not vary with HiSCR response category or dosing regimen.
- The model may not have adequately captured the response to BSC. This is because the study protocol prohibited treatment with antibiotics and other components of BSC costed for in the economic model. This implies that the costs of BSC treatments used in UK practice are included in the model but the treatment benefits are not. However, a scenario in which BSC costs were excluded still showed secukinumab to be dominant. There is also some uncertainty about the transition probabilities for patients on BSC. Due to absence of data beyond 16 weeks, the company used data from the placebo arm of the PIONEER2 study for adalimumab to model transitions to the not responding state for patients on BSC. Differences in baseline characteristics of patients in SUNSHINE and SUNRISE studies vs PIONEER2 might influence the transferability of results.
- SUNSHINE and SUNRISE only provide for 16 weeks of comparative effectiveness data for secukinumab vs placebo. The follow-up duration of the two studies was also short. Hence, there is some uncertainty regarding the extrapolation of lifetime outcomes associated with secukinumab.

7. Conclusion

After considering all the available evidence, the Committee was able to accept secukinumab for use in NHS Scotland.

8. Guidelines and Protocols

In 2018, the British Association of Dermatologists (BAD) published guidelines: British Association of Dermatologists guidelines for the management of hidradenitis suppurativa (acne inversa) 2018.[13]

9. Additional Information

9.1. Product availability date

20 June 2023

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year (£)
Secukinumab (Cosentyx®)	**300 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks.*** **Each 300 mg dose can be given as one 300 mg injection or two 150 mg injections.**	**First year: 19,500 to 29,250*** **Subsequent years: 14,625 to 29,250***

**The first assessment of clinical response is assumed to occur after 16 weeks (4 months) as per the SUNSHINE and SUNRISE studies, meaning any increase in maintenance dose would occur at this point. Costs from BNF online on 25 October 2023. Costs calculated using the full cost of vials/ampoules assuming wastage. Costs do not take any patient access schemes into consideration.*

10. Company Estimate of Eligible Population and Estimated Budget Impact

The submitting company estimated there would be 8 patients estimated to receive treatment in year 1 rising to 49 patients in year 5.

SMC is unable to publish the with PAS budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget with the PAS.

*Other data were also assessed but remain confidential.**

References

1. Novartis Pharmaceuticals UK Ltd. Secukinumab 150 mg solution for injection in pre-filled pen (Cosentyx®) Summary of product characteristics. Electronics Medicines Compendium www.medicines.org.uk. Last updated: 08 Aug 2023.
2. Novartis Pharmaceuticals UK Ltd. Secukinumab 150 mg solution for injection in pre-filled syringe (Cosentyx®) Summary of product characteristics. Electronics Medicines Compendium www.medicines.org.uk. Last updated: 08 Aug 2023.
3. Novartis Pharmaceuticals UK Ltd. Secukinumab 300 mg solution for injection in pre-filled pen (Cosentyx®) Summary of product characteristics. Electronics Medicines Compendium https://www.medicines.org.uk/. Last updated: 08 Aug 2023.
4. Novartis Pharmaceuticals UK Ltd. Secukinumab 300 mg solution for injection in pre-filled syringe (Cosentyx®) Summary of product characteristics. Electronics Medicines Compendium https://www.medicines.org.uk/. Last updated: 08 Aug 2023.
5. The European Medicines Agency (EMA) European Public Assessment Report. Secukinumab (Cosentyx®). EMEA/H/C/003729/II/0090. Published 26 April 2023. Available at: www.ema.europa.eu [Accessed 09 November 2023].
6. Dufour DN, Emtestam L, Jemec GB. Hidradenitis suppurativa: a common and burdensome, yet under-recognised, inflammatory skin disease. Postgrad Med J. 2014 Apr; 90(1062):216-221; quiz 220. doi: 10.1136/postgradmedj-2013-131994.
7. Zouboulis CC, Tsatsou F. Chapter 85. Disorders of the Apocrine Sweat Glands. In: Goldsmith LA, Katz SI, Gilchrest BA, Paller AS, Leffell DJ, Wolff K, editors. Fitzpatrick's Dermatology in General Medicine, 8e. New York, NY: The McGraw-Hill Companies; 2012.
8. Jemec GB, Heidenheim M, Nielsen NH. The prevalence of hidradenitis suppurativa and its potential precursor lesions. J Am Acad Dermatol. 1996;35(2 Pt 1):191-4.
9. Revuz JE, Canoui-Poitrine F, Wolkenstein P, Viallette C, Gabison G, Pouget F*, et al.* Prevalence and factors associated with hidradenitis suppurativa: results from two case-control studies. J Am Acad Dermatol. 2008;59(4):596-601.
10. Condamina M, Penso L, Tran VT, Hotz C, Guillem P, Villani AP*, et al.* Baseline Characteristics of a National French E-Cohort of Hidradenitis Suppurativa in ComPaRe and Comparison with Other Large Hidradenitis Suppurativa Cohorts. Dermatology. 2021;237(5):748-58.
11. Garg A, Neuren E, Cha D, Kirby JS, Ingram JR, Jemec GBE*, et al.* Evaluating patients' unmet needs in hidradenitis suppurativa: Results from the Global Survey Of Impact and Healthcare Needs (VOICE) Project. J Am Acad Dermatol. 2020;82(2):366-76. Epub 2019/07/07.
12. Saunte DM, Boer J, Stratigos A, Szepietowski JC, Hamzavi I, Kim KH*, et al.* Diagnostic delay in hidradenitis suppurativa is a global problem. Br J Dermatol. 2015;173(6):1546-9. Epub 2015/07/23.
13. Ingram JR, Collier F, Brown D, Burton T, Burton J, Chin MF*, et al.* British Association of Dermatologists guidelines for the management of hidradenitis suppurativa (acne inversa) 2018. British Journal of Dermatology. 2019;180(5):1009-17.
14. Kimball AB, Jemec GBE, Alavi A, Reguiai Z, Gottlieb AB, Bechara FG*, et al.* Secukinumab in moderate-to-severe hidradenitis suppurativa (SUNSHINE and SUNRISE): week 16 and week 52 results of two identical, multicentre, randomised, placebo-controlled, double-blind phase 3 trials. The Lancet. 2023.
15. ClinicalTrials.gov. Extension Study to Assess Effects of Non-interrupted Versus Interrupted and Long Term Treatment of Two Dose Regimes of Secukinumab in Subjects With Hidradenitis Suppurativa. [cited; Available from: https://clinicaltrials.gov/ct2/show/NCT04179175.

This assessment is based on data submitted by the applicant company up to and including **21 December 2023.**

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.