Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
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secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®)

SMC No. (1054/15)

Novartis Pharmaceuticals

08 May 2015

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

ADVICE: following a full submission

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

Indication under review: treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

SMC restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.

Secukinumab was superior to placebo and to a tumour necrosis factor (TNF) antagonist for improving symptoms of patients with moderate to severe plaque psoriasis.

This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of secukinumab. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.

Overleaf is the detailed advice on this product.

Chairman,
Scottish Medicines Consortium

Indication

Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Dosing Information

Two 150mg subcutaneous injections at weeks 0, 1, 2 and 3, then as a monthly maintenance dose starting at week 4.

Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with an initial partial response may subsequently improve with continued treatment beyond 16 weeks.

Secukinumab should be used under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.

Product availability date

4th March 2015

Summary of evidence on comparative efficacy

Secukinumab is the first in a new class of medicines that inhibit interleukin-17A (IL-17A). It is an IgG1 monoclonal antibody that binds to and neutralises IL-17A, which is a pro-inflammatory cytokine. By inhibiting the effects of IL-17A on various cell types including keratinocytes, it inhibits release of pro-inflammatory cytokines, chemokines and mediators of tissue damage, thereby reducing erythema, induration and desquamation in plaque psoriasis lesions. It is licensed for treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[1] The submitting company has requested that SMC considers secukinumab when positioned for use in patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments.

Four phase III studies (FIXTURE, ERASURE, FEATURE and JUNCTURE) recruited adults with moderate-to-severe plaque psoriasis diagnosed at least six months previously who had a psoriasis area and severity index (PASI) score of at least 12, a modified (2011) investigator's global assessment (IGA) score of at least 3 and involvement of at least 10% of their body surface area. Their psoriasis was poorly controlled with topical treatments, phototherapy, systemic therapy (including biologics) or a combination of these. Randomisation was stratified by body weight, <90kg versus ≥90kg, in all trials and also by geographical region in FIXTURE and ERASURE. Patients were equally assigned to placebo; secukinumab 150mg or 300mg (two 150mg) subcutaneous (SC) injections at weeks 0, 1, 2, 3, 4 and then every 4 weeks to week 48. In the FIXTURE study, patients could also be randomised to etanercept 50mg SC injection twice weekly for 12 weeks then once weekly to week 51. Patients in the placebo groups not achieving at least a 75% improvement in PASI score (PASI-75 response) at week 12 were re-randomised in a 1:1 ratio and treated from week 12 with secukinumab 150mg or 300mg SC injections in the

dose regimen detailed previously. The co-primary outcomes were proportions of patients achieving, at week12, a PASI 75 response and a modified (2011) IGA 0/1 response, which comprised an IGA score of 0 (clear) or 1 (almost clear) and a reduction of at least 2 points from baseline. These were assessed using a stratified Cochran-Mantel-Haenszel test in all randomised patients, with missing data input as non-response.[1-10]

Results are presented for the licensed dose of secukinumab 300mg. In all studies, co-primary endpoints (PASI 75 and modified (2011) IGA 0/1 at week 12) were achieved by significantly more patients in the secukinumab 300mg groups than in the placebo groups. In the FIXTURE study, co-primary endpoints were achieved by significantly more patients in the secukinumab 300mg group than in the etanercept group.[1-10]

Table: Psoriasis area and severity index (PASI) and Investigator's Global Assessment (IGA) outcomes at week 12 in FIXTURE, ERASURE, FEATURE and JUNCTURE studies

		Percentage (number) of patients achieving outcome				
	N	**PASI 75***	**IGA 0/1***	**PASI 50**	**PASI 90**	**PASI 100**
FIXTURE						
Secukinumab	323	77% (249)	63% (202)	92% (296)	54% (175)	24% (78)
Placebo	324	4.9% (16)	2.8% (9)	15% (49)	1.5% (5)	0
Etanercept	323	44% (142)	27% (88)	70% (226)	21% (67)	4.3% (14)
ERASURE						
Secukinumab	245	82% (200)	65% (160)	91% (222)	59% (145)	29% (70)
Placebo	246	4.5% (11)	2.4% (6)	8.9% (22)	1.2% (3)	0.8% (2)
FEATURE						
Secukinumab	58	76% (44)	69% (40)	88% (51)	60% (35)	43% (25)
Placebo	59	0	0	5.1% (3)	0	0
JUNCTURE						
Secukinumab	60	87% (52)	73% (44)	97% (58)	55% (33)	27% (16)
Placebo	61	3.3% (2)	0	8.2% (5)	0	0

PASI = psoriasis area and severity index; PASI 50, PASI 75, PASI 90 and PASI 100 correspond to reduction of 50%, 75%, 90% and 100%, respectively, in PASI score compared to baseline. IGA 0/1 = modified (2011) investigator's global assessment score of 0 or 1. N = number of patients. * = co-primary endpoint

In the FIXTURE and ERASURE studies, 84% (210/249) and 80% (161/200) of patients who achieved a PASI 75 response at week 12 maintained this at week 52 by continuing treatment with secukinumab 300mg. Corresponding figures for modified (2011) IGA 0/1 response were 80% (161/202) and 74% (119/160). In the FIXTURE study, these were significantly greater than proportions of week-12 responders maintaining PASI 75 and modified (2011) IGA 0/1 responses at week 52 with etanercept: 72% (103/142) and 57% (50/88), respectively.[2]

Pooled analyses of data to 52 weeks from the ERASURE, FIXTURE and SCULPTURE studies indicate that PASI 75 response rate at week 52 was 77% (605/784) and 55% (179/323) in the secukinumab 300mg and etanercept groups and modified (2011) IGA 0/1 response rates were 63% (495/784) and 37% (120/323), respectively. Response rates for these outcomes with secukinumab reached their plateau at week 16 and declined slightly thereafter.[3]

In the four pivotal studies, Dermatology Life Quality Index (DLQI) was significantly improved at week 12 with secukinumab 300mg compared to placebo, with mean decreases (improvements)

from baseline of -10.4 to -11.6 compared to -1.1 to -1.9 in the placebo groups and -7.9 in the etanercept group of the FIXTURE study.

In a double-blind phase III study (SCULPTURE) with the same inclusion criteria as the four pivotal studies described previously, 966 adults were randomised with stratification for body weight (<90kg or ≥90kg) and geographic region to secukinumab 300mg or 150mg SC at weeks 0, 1, 2, 3, 4 and 8. Those achieving a PASI 75 response at week 12 were re-randomised to their assigned dose of secukinumab every four weeks starting at week 12 (fixed-interval dosing group) or to receive placebo until they lost their PASI 75 response and at least 20% of their maximum PASI gain, then they received secukinumab weekly for 4 weeks then every 4 weeks until PASI 75 response was regained (start-of-relapse group). The study primarily assessed non-inferiority to the fixed-interval dosing group of the start-of-relapse group using a 15% margin for maintenance of PASI 75 at week 52 (in the fixed-interval group) and at week 40 or 52 (for start of relapse group who did not require and who did require retreatment at week 40, respectively). With secukinumab 300mg, PASI 75 response was maintained by 78% (169/216) and 68% (147/217) of patients in the respective groups. Non-inferiority of the start-of-relapse dosing to fixed-interval dosing was not demonstrated as the difference between the groups was -10% (lower bound of CI -19%) with secukinumab 300mg.[2,3,11]

Summary of evidence on comparative safety

For short-term safety, data to week 12 were pooled from the four pivotal studies (FIXTURE, ERASURE, FEATURE, JUNCTURE). These indicate small increases in rates of adverse events in the secukinumab 300mg, secukinumab 150mg and etanercept groups compared to placebo group: 56% (388/690), 60% (412/692) and 58% (186/323) versus 49% (340/694). However, rates of serious adverse events were similar across the groups: 2.0% (14/690), 2.0% (14/690), 0.9% (3/323) and 1.7% (12/694), respectively. The proportions of patients reporting infections or infestations in the secukinumab 300mg, secukinumab 150mg, etanercept and placebo groups was 28% (195/690), 29% (203/692), 26% (83/323) and 19% (134/694), respectively, and within the category, general disorders and administration site conditions occurred in 6.5% (45/690), 6.8% (47/692), 18% (58/323) and 5.9% (41/694), respectively. The most common adverse events were nasopharyngitis, headache, diarrhoea and pruritis.[2,3]

For the FIXTURE study over the entire study period to 52 weeks, rates of adverse events per 100-patient years' exposure in the secukinumab 150mg, secukinumab 300mg, placebo and etanercept groups were 236.4, 252.0, 329.7 and 243.4, and for serious adverse events were 6.0, 6.8, 8.3 and 7.0, respectively. Infections and infestation adverse event rates were 91.9, 105.4, 89.5 and 91.4 per 100-patient years' exposure, respectively.[4]

Summary of clinical effectiveness issues

Secukinumab is the first in a new class of medicines that inhibit interleukin-17A (IL-17A). However, it is the fifth biologic therapy marketed for treatment of moderate to severe plaque psoriasis in adults. Other biologic therapies include the tumour necrosis factor (TNF) antagonists, infliximab, etanercept, adalimumab and an antagonist of interleukin (IL)-12 and IL-23, ustekinumab. These can be used within NHS Scotland with some restrictions, which mainly relate to response to previous therapies. The submitting company has requested that SMC considers secukinumab when positioned for use in patients who have failed to respond to

standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these. In this context, the other biologic therapies are relevant comparators.

Co-primary outcomes in the pivotal studies were PASI 75 and modified (2011) IGA 0/1 response. PASI is a well recognised assessment of psoriasis symptom severity. The European Medicines Agency (EMA) review noted that modified (2011) IGA scale is more stringent than the physician global assessment (PGA) scale from which it was developed as it corresponds to a PASI 90 rather than a PASI 75 response, as evidenced by phase III efficacy results. The co-primary endpoints of PASI 75 and modified (2011) IGA 0/1 were considered to correspond to clinically highly relevant efficacy.[3] Secukinumab 300mg was superior to placebo for co-primary outcomes in four well conducted phase III studies and superior to etanercept in one of these studies.[1-10]

In the pivotal studies, approximately 50% to 60% of patients had previously received non-biologic systemic therapies[4,7,9] Subgroup analyses indicated that response rates were lower in those with greater body weight, although treatment effect remained significant versus placebo in all subgroups.[1-10] In practice, the likelihood of achieving a response may be influenced by a patient's bodyweight.

In the two large pivotal studies, FIXTURE and ERASURE, secukinumab was administered from a vial of powder for solution for injection; in the FEATURE study, it was administered from a pre-filled syringe; and in the JUNCTURE study, it was administered from a pre-filled auto-injector pen. The pre-filled syringe and auto-injector pen are marketed in the UK. There are no direct or indirect comparative analyses of secukinumab across the varying formulations. However, response rates with secukinumab across these studies appear similar.[1-10]

Bayesian network meta-analyses (NMA) compared secukinumab to adalimumab, etanercept, infliximab and ustekinumab in adults with moderate-to-severe chronic plaque psoriasis for PASI 50, PASI 75 and PASI 90 response rates. However, safety outcomes were not assessed. The base case included data from 30 studies. Results suggest that secukinumab 300mg is at least as effective as etanercept, ustekinumab, adalimumab and infliximab. There are some weaknesses which limit the validity of these results. These include heterogeneity across the studies in previous exposure to biologics, baseline PASI, duration of psoriasis and time-point for assessment of primary outcome. However, sensitivity and scenario analyses provide some reassurance with respect to these. There was also variation across the studies in the outcomes achieved in the placebo common control groups. In the main studies of ustekinumab, some patients may have been sub-optimally dosed and some may have received higher doses than they would be given in practice. The external validity of the NMA is compromised as some of the studies had populations that only partly reflected the patients in which secukinumab may be used in practice.

Clinical experts consulted by SMC considered that there is unmet need in this therapeutic area, namely for effective treatments with fewer side-effects and risks than existing treatment options. Some patients with moderate to severe plaque psoriasis do not respond or have lost responsiveness to currently available treatment options.

Clinical experts consulted by SMC considered that secukinumab is a therapeutic advancement due to its novel mechanism of action.

Clinical experts consulted by SMC considered that the place in therapy of secukinumab would be as an alternative treatment option for patients who have not responded to or have lost responsiveness to other therapies for psoriasis.

Other data were also assessed but remain commercially confidential.

Summary of comparative health economic evidence

The company submitted a cost-minimisation analysis comparing secukinumab to etanercept, adalimumab, ustekinumab 45mg and 90mg and infliximab, for treatment in patients with moderate to severe plaque psoriasis who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments. A 5-year time horizon was used in the analysis to reflect the chronic nature of the condition and capture the variation in first year and subsequent year treatment costs. SMC clinical expert responses have indicated that the comparators are appropriate.

The clinical data used to support the economic analysis were taken from a Bayesian NMA as described above. The analysis consisted of 30 studies and included the results of the FIXTURE study, which compared secukinumab to etanercept. The results of this head to head study indicated that secukinumab was associated with significantly higher PASI 75 and modified (2011) IGA 0/1 responses versus etanercept 50mg. Based on the overall results of the NMA, secukinumab was considered to be at least as effective as etanercept, adalimumab, infliximab and ustekinumab for all PASI scores. It should be noted that the results of the economic analysis are dependent on the assumption of comparable efficacy between secukinumab and the comparators.

The costs included in the economics were drug costs only. A patient access scheme (PAS) is in place for ustekinumab 90mg and was included in the analysis as the relevant price for ustekinumab. All treatments except for etanercept were associated with loading doses in the first year and a reduced maintenance dose in subsequent years. Administration and monitoring costs were assumed to be the same across all subcutaneous treatments and were therefore excluded from the analysis. It should be noted that administration costs were included for infliximab as it is administered by intravenous infusion. An all cause discontinuation rate was applied across all treatments. In year 1, all treatments were assumed to be associated with an 11.7% discontinuation rate, which was derived from the FIXTURE and ERASURE studies. A 20% rate was applied from years 2-5 based on assumption.

The base case results were presented on a per patient basis and incorporate the probability of a single patient remaining on treatment. The results showed that secukinumab is expected to result in an incremental cost per patient over 5 years of between £19,494 and £23,083 depending on the comparator. Due to the administration costs associated with infliximab, secukinumab results in incremental savings per patient of £19,260 over 5 years.

A Patient Access Scheme (PAS) was submitted by the company and was assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHS Scotland.

Under the PAS, a simple discount was offered which reduced the cost of secukinumab. With the PAS, secukinumab became a cost-effective treatment option. It should be noted, however, that in year 1, secukinumab (with PAS) was more costly than some biologic treatments and less costly than others.

A simple sensitivity analysis was provided, which varied the rate of all cause discontinuation by +/-10% after the first year of treatment i.e. in years 2 to 5, and varied the time horizon by +/-2 years. When the time horizon was reduced to 3 years, secukinumab (with the PAS) resulted in savings versus most biologic treatments.

The analysis was generally well conducted though here was some uncertainty surrounding the time horizon used. However, based on SMC expert responses, 5 years was considered to be appropriate given the chronic nature of the condition. As secukinumab (with PAS) is cost saving versus all comparators at year 5, the economic case has been demonstrated.

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

Summary of patient and public involvement

The following information reflects the views of the specified Patient Groups.

- Submissions were received from The Psoriasis and Psoriatic Arthritis Alliance (PAPAA), Psoriasis Association and Skin Conditions Campaign Scotland (SCCS). All three are registered charities.

- The Psoriasis Association and SCCS have received pharmaceutical company funding in the past two years, with the Psoriasis Association receiving funding from the submitting company. PAPAA has not received any pharmaceutical company funding.

- Plaque psoriasis is a lifelong condition. The physical effects of inflamed, itchy or painful scaling and flaking skin and scalp, with cracked fingers, toes, palms and soles can cause difficulty with washing and dressing, standing and anything that involves working with hands. Owing to the highly visible nature of psoriasis, patients often avoid social situations and it can affect employability. The psychological effects combined with the physical discomfort impact on all aspects of their lives. Amongst long-term conditions moderate to severe plaque psoriasis produces some of the greatest reductions in quality of life indices.

- Current therapies have limitations. DMARDs and current biologic agents do not appear to benefit everyone or may stop working. Biologic agents are considered by patients to be the most effective of existing drugs.

- Secukinumab targets a different part of the immune system from other existing biological agents and offers hope to those patients who respond poorly to existing drugs.

Additional information: guidelines and protocols

In October 2010 the Scottish Intercollegiate Guidelines Network (SIGN) published guidance 121: Diagnosis and management of psoriasis and psoriatic arthritis in adults. This recommends that patients with severe psoriasis who fail to respond to, or have a contraindication to, or are intolerant of phototherapy and systemic therapies including ciclosporin and methotrexate, should be offered biologic therapy unless they have contraindications or are at increased risk of hazards from these therapies. Good practice points note that the use of biologic treatments should conform to BAD guidelines. The comparative long term safety of systemic and biologic treatments for severe psoriasis is currently being investigated in a five-year treatment register, the British Association of Dermatologists Biologic Interventions Register (BADBIR) (www.badbir.org). Patients on biologic therapies should be offered the opportunity to join the long term safety register BADBIR.[12]

In July 2006 the National Institute for Health and Care Excellence (NICE) published the following in relation to the multiple technology assessment number 103; etanercept and efalizumab for the treatment of adults with psoriasis: Etanercept should be offered as an option for treating adults with severe plaque psoriasis when other treatments haven't worked (for example, drugs given by injection or orally, that is, by mouth), or these other treatments cause a reaction which means that the person shouldn't continue taking them, or the person has another condition or uses another medicine that means they should not take these other treatments. If the person's psoriasis has not shown a measured response to etanercept after 12 weeks, the treatment should be stopped.

Efalizumab: The European Medicines Agency (EMEA), the European Union (EU) body which is responsible for monitoring the safety of medicines, has withdrawn the marketing authorisation for MerckSerono's psoriasis drug efalizumab (Raptiva). The EMEA's Committee for Medicinal Products for Human Use has reviewed possible links between the drug and a rare but deadly brain infection and said the benefits of efalizumab no longer outweigh its risks, because of safety concerns, notably the occurrence of progressive multifocal leukoencephalopathy. As a result the 'British national formulary' has been updated to say that efalizumab should not be prescribed for patients who are not already taking it. Treatment for patients who are taking efalizumab should be reviewed. Therefore, NICE has withdrawn its guidance on the use of efalizumab for the treatment of adults with psoriasis. Guidance on the use of etanercept for the treatment of adults with psoriasis remains the same and in force.[13]

On 26 July 2006 NHS HIS issued the following a statement in relation to NICE MTA 103: The European Medicines Agency (EMEA), the European Union (EU) body which is responsible for monitoring the safety of medicines, has recommended that marketing authorisation be suspended for Serono's psoriasis drug efalizumab (raptiva). The EMEA's Committee for Medicinal Products for Human Use (CHMP) said the benefits of efalizumab no longer outweigh its risks, because of safety concerns. As a result of the EMEA's decision, NICE has temporarily withdrawn its guidance on the use of efalizumab for the treatment of adults with psoriasis. Guidance on the use of etanercept for the treatment of adults with psoriasis remains the same and in force. NICE will continue to review the status of its guidance in light of any further changes to efalizumab's marketing authorisation. While the NICE guidance on efalizumab is withdrawn, the NHS QIS advice statement will apply to etanercept only.

This NICE appraisal has been considered by NHS Quality Improvement Scotland through its revised procedure of processing of NICE appraisals. NHSScotland should note that:
1. NHS Quality Improvement Scotland advises that the NICE appraisal (etanercept only) is as valid for Scotland as for England and Wales.
2. Section 6.2 of the NICE guidance recommends support for the UK wide registry for biological treatments in psoriasis (BADBIR) which is due to become active January 2007.
3. NHSScotland should take account of the NICE appraisal and this NHS Quality Improvement Scotland email in its planning, funding and provision of services to ensure that recommended drugs or treatments are made available to meet clinical need.
4. NHS Quality Improvement Scotland advice represents the evidence-based view of NHS Quality Improvement Scotland.
5. This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer.
6. No other publications on the NICE appraisal will be issued by NHS Quality Improvement Scotland.[14]

In November 2009 the British Association of Dermatologists published clinical guidelines on the use of biologic interventions for psoriasis.[15] These are currently being updated.

Additional information: comparators

Within the licensed indication, comparators would be other systemic therapies for psoriasis, e.g. ciclosporin, methotrexate, etanercept, infliximab, adalimumab and ustekinumab. The submitting company has requested that SMC consider secukinumab when positioned for use in patients who are unsuitable for standard systemic therapies (including ciclosporin, methotrexate and phototherapy). In this context, the comparators are biologic therapies, i.e. etanercept, infliximab, adalimumab and ustekinumab.

Cost of relevant comparators

Drug	Dose Regimen	Cost per year (£)
Secukinumab	**300mg SC at weeks 0, 1, 2, 3, and 4 and then monthly**	**First year: 19,500 Subsequent years: 14,625**
Infliximab[#]	5 mg/kg IV at weeks 0, 2 and 6 weeks, then every 8 weeks	First year: 12,088 – 13,424 Subsequent years: 9,066 – 10,071
Etanercept	25mg SC twice weekly; or 50mg SC weekly*	9,295
Ustekinumab	45mg (or 90mg[**]) SC at weeks 0 and 4 then every 12 weeks	First year: 12,882 Subsequent years: 8,588
Adalimumab	80mg SC, then 40 mg alternate weeks***	First year: 9,860 Subsequent years: 9,156

Doses are for general comparison and do not imply therapeutic equivalence. Costs for adalimumab and etanercept are from eVadis on 3 March 2015 and costs for ustekinumab and infliximab from MIMs March 2015. Costs for secukinumab from MIMs June 2015. Costs based on a bodyweight of 70kg. * If necessary, etanercept 50mg SC twice weekly may be given for 12 weeks then 25mg twice weekly or 50mg weekly. ** ustekinumab 90mg given if bodyweight >100kg. *** costs are based on one year of

treatment but this will be shorter if there is no response. # Costs for infliximab reflect the range of list prices for the reference product and biosimilar products. SC = subcutaneous. IV = intravenous

Additional information: budget impact

The estimated number of patients assumed to be eligible for treatment is 2,305 in year 1, rising to 2,342 in year 5. The company assumed the market share to be 2.1% in year 1, rising to 9.9% in year 5.

Without PAS
The gross impact on the medicines budget was estimated to be £946k in year 1 and £3m in year 5. As other drugs were assumed to be displaced, the net medicines budget impact was estimated to be £395k in year 1 and £1m in year 5.

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

References

The undernoted references were supplied with the submission. Those shaded in grey are additional to those supplied with the submission.

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3. European Medicines Agency. European public assessment report for Cosentyx
4. Langley RG, Elewski BE, Lebwohl M et al. Secukinumab in plaque psoriasis – results of two phase 3 trials. N Engl J Med 2014; 371: 326-38
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6. Novartis. Clinical study report for ERASURE
7. Blauvelt A, Prinz JC, Gottlieb AB et al. Secukinumab administration by pre-filled syringe: efficacy, safety and usability results from a randomized controlled trial in psoriasis (FEATURE). British Journal of Dermatologists 2014: 172; 484-93
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9. Paul C, Lacour J-P, Tedremets L et al. Efficacy, safety and usability of secukinumab administration by autoinjector/pen in psoriasis: a randomised controlled trial (JUNCTURE). Journal of European Academy of Dermatology and Venereology 2014, early online publication on 22 September, DOI: 10.1111/jdv.12751
10. Novartis. Clinical study report for JUNCTURE
11. Novartis. Clinical study report for SCULPTURE
12. Scottish Intercollegiate Guidelines Network (SIGN). Guideline number 121: Diagnosis and management of psoriasis and psoriatic arthritis in adults, October 2010.
13. National Institute for Health and Care Excellence (NICE). Multiple technology assessment number 103; etanercept and efalizumab for the treatment of adults with psoriasis, July 2006
14. NHS Healthcare Improvement Scotland (NHS HIS). Statement in relation to NICE MTA 103, 26 July 2006.
15. British Association of Dermatologists. Clinical guidelines on the use of biologic interventions for psoriasis, November 2009.

This assessment is based on data submitted by the applicant company up to and including 17 April 2015.

**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:*
http://www.scottishmedicines.org.uk/About_SMC/Policy_Statements/Policy_Statements

Drug 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 drug 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 NHS Scotland 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 NHS Scotland 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.