NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Technology Appraisal Review Proposal paper

Review of TA350; Secukinumab for treating moderate to severe plaque psoriasis

Original publication date:	22 July 2015
Review date	July 2018
Existing recommendations:	Optimised To see the complete existing recommendations and the original remit for TA350, see Appendix A.

1. Proposal

We propose that TA340 should be transferred to the 'static guidance list.'

2. Rationale

No new evidence is available that would require an update of this guidance. NICE Guideline CG153 'Psoriasis: assessment and management' cross-refers to this guidance.

3. Summary of new evidence and implications for review

TA350 included evidence comparing secukinumab to placebo and etanercept. Further clinical evidence from the secukinumab clinical trial programme published since the appraisal (see appendix C for further details) includes:

- 2 randomised clinical trials (RCTs) comparing secukinumab to ustekinumab
- 1 RCT comparing secukinumab to fumaric acid esters
- RCTs comparing secukinumab to placebo in patients with:
 - palmoplantar psoriasis
 - o nail psoriasis
 - scalp psoriasis
- an open-label non-comparator study of secukinumab use in the UK within the population recommended by TA350
- pooled safety data for secukinumab (up to 5 years)

subgroup analyses of individual trials and pooled trials

There is no direct head-to-head evidence comparing secukinumab to systemic biologic therapies other than etanercept and ustekinumab, although several network meta-analyses (NMAs) and indirect comparisons have been published. A Cochrane systematic review and meta-analysis concluded that while ranking the efficacy of biologic treatments was possible the evidence base for the NMA was limited to induction therapy and "not sufficiently relevant for a chronic disease." The review also noted that due to the scarcity of long-term evidence for safety outcomes "it will be necessary to evaluate non-randomised studies and postmarketing reports released from regulatory agencies" (Sbidian 2017). One potential source for such evidence in the UK setting is the British Association of Dermatologists Biologic Interventions Register (BADBIR), a UK observational study designed to assess the long-term safety of biological treatments for psoriasis.

The new evidence available supports the recommendations made in TA350.

Has there been any change to the price of the technology(ies) since the guidance was published?

No change to list price. The company has indicated that it plans to continue the Patient Access Scheme without any changes.

Are there any existing or proposed changes to the marketing authorisation that would affect the existing guidance?

No.

Were any uncertainties identified in the original guidance? Is there any new evidence that might address this?

Long-term safety and subgroup analyses

NICE clinical guideline 153 research recommendation 2.3 states the following research question:

"In people with psoriasis, does early intervention with systemic treatments improve the long-term prognosis of psoriasis severity, comorbidities (including psoriatic arthritis), or treatment-related adverse effects, and are there any clinical (for example demographic or phenotypic) or laboratory (for example genetic or immune) biomarkers that can be used to identify those most likely to benefit from this treatment approach?"

Committee also noted these uncertainties in TA350. Since publication of the guidance, efficacy and safety data for secukinumab has been published for a period of up to 5 years (Bissonnette 2017, Van De Kerkhof 2017). Several subgroup analysis have been published including comparisons with placebo,

etanercept and ustekinumab in patients with concomitant psoriatic arthritis (Gottlieb, Langley 2015, Gottlieb, Thaci 2015, Gottlieb 2016). This evidence does not impact the current recommendations because there is not sufficient long term evidence to determine whether secukinumab has greater benefit/risk compared to other systemic biological treatments or in any specific subgroup compared to the overall population in the clinical trials.

Subgroup analyses by prior therapy

Committee noted in TA350 that "it would have liked to have seen more analyses using patient-level data for people who have previously received either systemic non-biological or biological treatments, to help reduce any uncertainty about the extent to which prior treatment affects clinical effectiveness."

Subgroup analyses of patients by prior therapy have been published (Papp 2014, Foley 2015, Griffiths 2015). Results from these analyses indicate that secukinumab has superior efficacy to placebo and etanercept in patients exposed to previous biologic therapy. Results from the open-label non-comparator SIGNATURE trial, evaluated the safety and efficacy of secukinumab in a patient population which matched the eligible population in the recommendations of TA350 (Warren, 2017). The study showed that the benefit/risk profile of secukinumab was in line with that observed in clinical trials, supporting the current recommendation.

Use of registry data in analyses

Committee noted in TA350 that future appraisals would benefit from the use of registry data but acknowledged that the company did not have access to these data during the appraisal.

The British Association of Dermatologists Biologic Interventions Register (BADBIR) is a UK observational study designed to assess the long-term safety of biological treatments for psoriasis. In addition to safety, analysis of data from this registry may also provide insights into other areas, for example the optimum sequencing of biological therapies and cost-effectiveness analyses. The study began in 2007 and recruitment of patients treated with secukinumab began in 2016, therefore it is unlikely that there will be sufficient data to address uncertainties in the original guidance at this time.

Are there any related pieces of NICE guidance relevant to this appraisal? If so, what implications might this have for the existing guidance?

See Appendix C for a list of related NICE guidance.

Additional comments

The <u>appendix to NICE clinical guideline CG153</u> contains information to facilitate discussion of risks and benefits of treatments of people with psoriasis. The table of "Systemic, biologic therapies (short-term)" does not currently include secukinumab. This was because NICE is not able to keep this table continuously up to date and during the review the approach of NICE towards decision aids was under review. Therefore, it was considered that any amendments to the decision aids should be examined at a later date.

The search strategy from the original Assessment Report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from October 2014 to May 2018 were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section above. See Appendix C for further details of ongoing and unpublished studies.

4. Equality issues

When using the DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate.

GE paper sign off: Helen Knight, 23/08/2018

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Appendix A – Information from existing guidance

5. Original remit

To appraise the clinical and cost effectiveness of secukinumab within its licensed indication for moderate to severe plaque psoriasis in people for whom other systemic therapies have been inadequately effective, not tolerated or contraindicated.

6. Current guidance

- 1.1 Secukinumab is recommended, within its marketing authorisation, as an option for treating adults with plaque psoriasis only when:
 - the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
 - the disease has failed to respond to standard systemic therapies, for example, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or these treatments are contraindicated or the person cannot tolerate them
 - the company provides secukinumab with the discount agreed in the patient access scheme.
- 1.2 Secukinumab treatment should be stopped in people whose psoriasis has not responded adequately at 12 weeks. Further treatment cycles are not recommended in these people. An adequate response is defined as either:
 - a 75% reduction in the PASI score from when treatment started (PASI 75) or
 - a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.
- 1.3 People whose treatment with secukinumab is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.
- 1.4 When using the DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate.

7. Cost information from original guidance

The undiscounted price for 2 × 150 mg prefilled pen or syringe is £1218.78 (excluding VAT, 'Monthly Index of Medical Specialities' [MIMS] May 2015). The

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Appendix A

company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of secukinumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.

Appendix B – Explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	Consequence	Selected - 'Yes/No'
A review of the guidance should be planned into the appraisal work programme. The review will be conducted through the Technology Appraisals process.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred to a specific date or trial.	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review.	No
	This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	

Options	Consequence	Selected - 'Yes/No'
The guidance should be updated in an on-going clinical guideline ¹ .	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn.	No
	Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes
The guidance should be withdrawn	The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS. The guidance will be stood down and any funding direction associated with a positive recommendation will not be preserved.	No

¹ Information on the criteria for NICE allowing a technology appraisal in an ongoing clinical guideline can be found in section 6.20 of the <u>guide to the processes of technology appraisal</u>.

Appendix C – other relevant information

1. Relevant Institute work

Published

Psoriasis: The assessment and management of psoriasis (2012, updated 2017) NICE guideline CG153

Psoriasis (2013) NICE quality standard 40

Psoriasis (2013 updated 2018) NICE pathway

Adalimumab for the treatment of adults with psoriasis (2008) NICE technology appraisal guidance 146

Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (2017) NICE technology appraisal guidance 455

Apremilast for treating moderate to severe plaque psoriasis (2016) NICE technology appraisal guidance 419

Brodalumab for treating moderate to severe plaque psoriasis (2018) NICE technology appraisal guidance 511

Dimethyl fumarate for treating moderate to severe plaque psoriasis (2017) NICE technology appraisal guidance 475

Etanercept and efalizumab for the treatment of adults with psoriasis (2006) NICE technology appraisal guidance 103

Guselkumab for treating moderate to severe psoriasis (2018) NICE technology appraisal guidance 521

Infliximab for the treatment of psoriasis (2008) NICE technology appraisal guidance 134

Ixekizumab for treating moderate to severe plaque psoriasis (2017) NICE technology appraisal guidance 442

Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009) NICE technology appraisal guidance 180

Grenz rays therapy for inflammatory skin conditions (2007) NICE interventional procedure guidance 236

In progress

Certolizumab pegol for treating moderate to severe plaque psoriasis [ID1232] NICE technology appraisal guidance. Publication expected April 2019.

Tildrakizumab for treating moderate to severe plaque psoriasis [ID1060] NICE technology appraisal guidance. Publication expected April 2019.

Suspended/terminated

Briakinumab for the treatment of moderate to severe chronic plaque psoriasis [ID65] NICE technology appraisal guidance. Publication date to be confirmed. Company has withdrawn its application for a centralised marketing authorisation (November 2008)

2. Details of new products

Drug (company)	Details (phase of development, expected launch date)
Calcipotriol (Polichem)	Phase III Clinical Trials
	UK launch
Halobetasol, Jemdel (Ortho Dermatologics)	Phase III Clinical Trials
	UK launch
	US FDA acceptable February 2018
IDP-118 Tazarotene with ulobetasol (Valeant)	Phase III Clinical Trials
	UK launch
Pefcalcitol (Maruho)	UK launch was expected in 2017
Piclidenoson (Can-Fite BioPharma)	Phase III Clinical Trials
	UK launch
Risankizumab (AbbVie)	Phase III Clinical Trials
	UK launch
Tofacitinib, Xeljanz (Pfizer)	
Voclosporin (Aurinia Pharmaceuticals)	Unknown

3. Details of changes to the indications of the technology

Indication and price considered in original appraisal	Proposed indication (for this appraisal) and current price
Secukinumab has a marketing authorisation for 'the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy'.	No change Source: current SPC (August 2017) No change - £1218.78 Source: BNF (April 2018)
The undiscounted price for 2 × 150 mg prefilled pen or syringe is £1218.78 (excluding VAT, 'Monthly Index of Medical Specialities' [MIMS] May 2015).	

4. Registered and unpublished trials

Completed trials listed as ongoing in the Company submission for TA350.

Trial name and registration number	Details
A 52-week, Multicenter, Randomized, Double-blind Study of Subcutaneous	Phase: 3
Secukinumab to Demonstrate Efficacy as Assessed by Psoriasis Area and	Status: completed
Severity Index at 16 Weeks of	Start date: February 2014
Treatment Compared to Ustekinumab and to Assess Long-term Safety,	Completion date: June 2016
Tolerability and Efficacy in Subjects With Moderate to Severe Plaque	Participants: 676
Psoriasis	Results: available <u>here</u>
CLEAR	
NCT02074982	

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Trial name and registration number	Details
A Randomized, Double-blind, Placebo-	Phase: 3
controlled, Multicenter Study to Demonstrate the Efficacy at 16 Weeks	Status: completed
of Secukinumab 150 and 300 mg s.c. and to Assess Safety, Tolerability and	Start date: June 2013
Long-term Efficacy up to 132 Weeks in Subjects With Moderate to Severe	Completion date: June 2016
Palmoplantar Psoriasis	Participants: 205
GESTURE	Results: available <u>here</u>
NCT01806597	
A Randomized, Double-blind, Placebo-	Phase: 3
controlled, Parallel-group, Multicenter Study to Demonstrate the Efficacy of	Status: completed
Subcutaneous Secukinumab [300 mg] as Assessed by the Psoriasis Scalp	Start date: September 2014
Severity Index (PSSI) at 12 Weeks of Treatment, Compared to Placebo, and	Completion date: December 2015
to Assess Safety and Tolerability up to 24 Weeks in Adult Subjects With	Participants: 102
Moderate to Severe Scalp Psoriasis	Results: available <u>here</u>
SCALP	
NCT02267135	
Secukinumab In Patients With Moderate	Phase: 3
to Severe Active, Chronic Plaque Psoriasis Who Have Failed on TNFα	Status: completed
antaGoNists: A Clinical Trial EvalUating Treatment REsults	Start date: October 2013
SIGNATURE	Completion date: July 2016
NCT01961609	Participants: 230
	Results: registry results not yet available, see here

Trial name and registration number	Details
A Randomized, Double-blind, Placebo- controlled, Multicenter, Study to Demonstrate the Efficacy at 16 Weeks of Secukinumab 150 and 300 mg s.c. and to Assess Safety, Tolerability and Long-term Efficacy up to 132 Weeks in Subjects With Moderate to Severe Nail Psoriasis TRANSFIGURE NCT01807520	Phase: 3 Status: completed Start date: June 2013 Completion date: January 2017 Participants: 198 Results: available here
A 52-week, Multicenter, Randomized, Double-blind, Placebo-controlled Study of Subcutaneous Secukinumab to Demonstrate Efficacy as Assessed by Palmoplantar Pustulosis Psoriasis Area and Severity Index (ppPASI) at 16 Weeks of Treatment, Compared to Placebo, and to Assess Long-term Safety, Tolerability, and Efficacy in Subjects With Moderate to Severe Chronic Palmoplantar Pustular Psoriasis 2PRECISE NCT02008890	Phase: 3 Status: completed Start date: December 2013 Completion date: May 2017 Participants: 239 Results: not yet available
A Randomized, Double-blind, Double Dummy, Multicenter Study to Assess the Safety, Tolerability and Long-term Efficacy of Intravenous (10mg/kg) and Subcutaneous (300mg) Secukinumab in Subjects With Moderate to Severe Chronic Plaque-type Psoriasis Who Are Partial Responders to Secukinumab STATURE NCT01412944	Phase: 3 Status: completed Start date: December 2011 Completion date: April 2013 Participants: 43 Results: available here

Trial name and registration number	Details
A Randomized, Double-blind,	Phase: 3
Multicenter Study of Subcutaneous Secukinumab, Assessing Psoriasis	Status: completed
Area and Severity Index (PASI) Response and Maintenance of	Start date: August 2011
Response in Subjects With Moderate to Severe Chronic Plaque-type Psoriasis	Completion date: May 2013
on Either a Fixed Dose Regimen or on a Retreatment at Start of Relapse	Participants: 967
Regimen	Results: available <u>here</u>
SCULPTURE	
NCT01406938	
Extension Study of Secukinumab	Phase: 3
Prefilled Syringes in Subjects With Moderate to Severe Chronic Plaque-	Status: completed
type Psoriasis Completing Preceding Secukinumab Phase III Studies	Start date: August 2008
SCULPTURE EXTENSION	Completion date: May 2017
NCT01640951	Participants: 675
	Results: registry results not yet available, see here
Multicenter, Double-blind, Randomized	Phase: 3
Withdrawal Extension Study of Subcutaneous Secukinumab in Prefilled	Status: completed
Syringes to Demonstrate Long-term Efficacy, Safety, and Tolerability up to 4	Start date: August 2004
Years in Subjects With Moderate to Severe Chronic Plaque-type Psoriasis	Completion date: June 2017
Completing Preceding Psoriasis Phase III Studies With Secukinumab	Participants: 1150
ERASURE AND FIXTURE EXTENSION	Results not yet available
CAIN457A2302E1	
NCT01544595	

Other trials not previously considered in TA350.

Trial name and registration number	Details
A Randomized, Controlled, Multicenter, Open-label Study With Blinded	Phase: 3
Assessment of the Efficacy of	Status: completed
Subcutaneous Secukinumab Compared to Fumaderm in Adults With Moderate	Start date: April 2015
to Severe Plaque Psoriasis	Completion date: June 2016
PRIME NCT02474082	Participants: 202
NC102474062	Results: available <u>here</u>
A Randomized, Double-blind, Placebo- controlled, Multicenter, Exploratory	Phase: 3
Evaluation of Surrogate Markers of Cardiovascular Risk in Patients With	Status: completed
Active Chronic Plaque-type Psoriasis	Start date: April 2014
Treated for up to 52 Weeks With Subcutaneous (s.c.) Secukinumab (300	Completion date: April 2016
mg or 150 mg) CARIMA	Participants: 151
NCT02559622	Results: available <u>here</u>
Long Term Clear Skin Maintenance Treatment Optimization in Patients With	Phase: 3
Moderate to Severe Chronic Plaque Psoriasis: A Randomized, Multicenter,	Status: completed
Open-label With Blinded-assessment, Comparative, 52 Week Study to	Start date: January 2015
Evaluate the Efficacy, Safety and Tolerability of Secukinumab 300 mg s.c.	Completion date: May 2017 Participants: 1580
OPTIMISE	Results: registry results not yet available, see
NCT02409667	here

Trial name and registration number	Details
A 52-week (Plus Extension Until	Phase: 3
Commercialization), Single-arm Study to Evaluate Psoriasis Severity and Its	Status: completed
Psychosocial Impact Using the Simplified Psoriasis Index (SPI) at 16	Start date: May 2015
Weeks, as Well as Long-term Safety, Tolerability and Efficacy of	Completion date: February 2017
Secukinumab Administered Subcutaneously in Participants	Participants: 120
Suffering From Moderate to Severe Psoriasis	Results: registry results not yet available, see here
IPSI-PSO	
NCT02595970	
A 24-week, Multicenter, proSpective	Phase: 3
stUdy to Evaluate the PASI 90 Clinical Response Rate and the Safety PRofile	Status: completed
of sEcukinuMab 300 mg in Cw6- negativE and Cw6-positive Patients	Start date: April 2015
With Moderate to Severe Chronic Plaque-type Psoriasis	Completion date: June 2017
SUPREME	Participants: 434
NCT02394561	Results: registry results not yet available
A Randomized, Double-blind,	Phase: 3
Multicenter Study to Assess the Efficacy and Safety of 16 Weeks Secukinumab Dosage Interval Shortening in Comparison to Continued Standard	Status: completed
	Start date: May 21015
Treatment (4-weekly 300 mg s.c.) in Patients With Moderate-severe Plaque	Completion date: September 2016
Type Psoriasis Who Achieved Less Than Almost Clear Skin After 16 Weeks	Participants: 772
Under the Standard Dose of Secukinumab	Results: registry results not yet available, see here
GAIN	
NCT02474069	

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Trial name and registration number	Details
A Multicenter, Randomized, Double- blind, Placebo-controlled, 52-weeks	Phase: 3
Study to Demonstrate the Efficacy,	Status: active, not recruiting
Safety and Tolerability of Subcutaneous Secukinumab Injections With 2 mL Pre-	Start date: December 2016
filled Syringes (300 mg) in Adult Subjects With Moderate to Severe	Expected completion date: August 2018
Plaque Psoriasis	Participants: 210
ALLURE	Results
NCT02748863	
A 52-week, Randomized, Double-blind	Phase: 3
Study of Secukinumab (300 mg) Compared to Ustekinumab in Subjects	Status: active, not recruiting
With Moderate to Severe Plaque Psoriasis	Start date: June 2016
CLARITY	Expected completion date: August 2018
NCT02826603	Participants: 1109
A Randomized, Double-blind,	Phase: 3
Multicenter Study Assessing Short (16 Weeks) and Long-term Efficacy (up to 1	Status: not yet recruiting
Year), Safety, and Tolerability of Sub- cutaneous Secukinumab in Subjects of	Start date: June 2018
Body Weight 90 kg or Higher With Moderate to Severe Chronic Plaque-	Completion date: March 2021
type Psoriasis	Participants: 330
CAIN457A2324	
NCT03504852	

Trial name and registration number	Details
A Randomized, Double-blind, Placebo Controlled, Multicenter Study of Subcutaneous Secukinumab, to Demonstrate Efficacy After Twelve Weeks of Treatment and to Assess Safety, Tolerability and Long-term Efficacy up to One Year in Subjects With Moderate to Severe Chronic Plaque-type Psoriasis With or Without Psoriatic Arthritis Comorbidity CAIN457A2318 NCT03066609	Phase: 3 Status: active, not recruiting Start date: February 2017 Expected completion date: October 2018 Participants: 544

5. Relevant services covered by NHS England specialised commissioning

NHS England (2013) 2013/14 NHS standard contract for specialised dermatology services (all ages)

NHS England (2017) Manual for prescribed specialised services 2017/18 Chapter 61 – highly specialist dermatology services (adults and children)

6. Additional information

British Association of Dermatologists (2015) British Association of Dermatologists and British Photodermatology Group guidelines for the safe and effective use of psoralen–ultraviolet A therapy 2015

British Association of Dermatologists (2017) British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017

Clinical Knowledge Summaries (2017) Psoriasis

European Dermatology Forum (EDF), European Academy of Dermatology and Venereology (EADV) International Psoriasis Council (2017) European S3-Guideline on the systemic treatment of psoriasis vulgaris – Update Apremilast and Secukinumab – EDF in cooperation with EADV and IPC

Appendix D - References

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Sbidian E, Chaimani A, Garcia-Doval I, et al. (2017) Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. The Cochrane database of systematic reviews, 12: CD011535.

Van De Kerkhof P, Reich K, Leonardi C, et al. (2017) Secukinumab pooled and long-term safety: Analysis of 19 psoriasis clinical trials. British Journal of Dermatology, 177(5): e259-e260.

Warren RB, Barker J, Burden D, et al. (2017) Efficacy and safety of secukinumab in patients who have failed antitumour necrosis factor-a treatment from the U.K. and Republic of Ireland: results of the SIGNATURE study. British Journal of Dermatology, 177(5): e245.