**National Institute for Health and Care Excellence**

**Single Technology Appraisal (STA)**

**Risankizumab for treating moderate to severe plaque psoriasis**

**Response to consultee and commentator comments on the draft remit and draft scope (pre-invite)**

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

**Comment 1: the draft remit**

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| Appropriateness | AbbVie | AbbVie believes this is an appropriate topic to refer to NICE for appraisal. | Comment noted. No action required. |
| | British Association of Dermatologists | Yes | Comment noted. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | Yes, this is an appropriate topic for referral to NICE for appraisal | Comment noted. No action required. |
| | Leo Pharma | Yes it would be appropriate to refer this topic to NICE for appraisal. | Comment noted. No action required. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | Novartis Pharmaceuticals UK | We consider the proposed appraisal appropriate. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | It would be appropriate to appraise risankizumab. | Comment noted. No action required. |
| | Psoriasis Association | Yes | Comment noted. No action required. |
| Wording | AbbVie | Yes, it does. | Comment noted. No action required. |
| | British Association of Dermatologists | Yes | Comment noted. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | Yes,the wording is appropriate | Comment noted. No action required. |
| | Leo Pharma | Wording is appropriate | Comment noted. No action required. |
| | Novartis Pharmaceuticals UK | There is no clear definition of “moderate to severe plaque psoriasis”. Our understanding is that the Phase III studies of risankizumab in plaque psoriasis recruited patients with psoriasis area and-severity index (PASI) score of 12 or higher, static Physician's Global Assessment [sPGA] score of 3 | Comments noted. The scope is broad to ensure that NICE can appraise the technology |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | | or higher and involvement of 10% or more of the body-surface area (NCT02684357, NCT02684370 & NCT02694523). The population for whom evidence on risankizumab clinical efficacy is available is therefore closely aligned to the populations included in studies of secukinumab and other biologic agents. Whilst secukinumab and other biologic agents have marketing authorisation for treatment of moderate to severe plaque psoriasis, NICE recommendations for these products refer to severe disease. We therefore suggest that the appraisal should focus on patients with severe psoriasis. | within its marketing authorisation. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Yes, as long as it reflects final licensed indication and administered dose. | Comment noted. No action required. |
| | Psoriasis Association | Yes | Comment noted. No action required. |
| Timing Issues | AbbVie | Timing of this appraisal is appropriate. | Comment noted. No action required. |
| | British Association of Dermatologists | Should be assessed as soon as possible | Comment noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. No action required. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |
| | Leo Pharma | Physicians and patients do have alternative therapeutic options available hence this is not urgent but should be timely to enable NHS determine its place in the treatment pathway. | Comment noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. No action required. |
| | Novartis Pharmaceuticals UK | No comment. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | No particular urgency, as other similar class therapies are available. | Comment noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. No action required. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | Psoriasis Association | Not first in class so not immediately urgent | Comment noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. No action required. |
| Additional comments on the draft remit | AbbVie | No. | Comment noted. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | None | Comment noted. No action required. |

**Comment 2: the draft scope**

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| Background information | AbbVie | AbbVie considers the background information to be accurate and complete. | Comment noted. No action required. |
| | British Association of Dermatologists | No issue | Comment noted. No action required. |

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| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | NICE technology appraisal guidance TA521 published 13 June 2018, recommends guselkumab as a treatment options for adults with severe psoriasis (as defined by a total PASI score of 10 or more and a DLQI score of more than 10) whose disease has not responded to, or who are intolerant to or contraindicated to standard systemic therapies such as ciclosporin, methotrexate and PUVA. Please add this to the paragraph which details the current recommneded treatments alongside etanercept, adalimumab, ustekinumab, secukinumab, apremilast, ixekizumab, dimethyl fumarate and brodalumab. | Comment noted. The scope has been updated to reflect publication of TA521. |
| | Leo Pharma | No further comment | Comment noted. No action required. |
| | Novartis Pharmaceuticals UK | The final sentence is misleading since it suggests that biosimilar version of all biologic therapies are available. We recommend clarifying as follows: "Biosimilar products of some biological therapies are available for use in the NHS." | Comment noted. The scope has been amended. |
| | Psoriasis and Psoriatic Arthritis Alliance | Nail psoriasis could be added as that is included in the outcomes section, along with psoriatic arthritis as an associated condition. | Comments noted. The scope includes the outcome 'psoriasis symptoms on the face, scalp, **nails** and **joints**'. No action required. |
| The technology/ intervention | AbbVie | Yes. | Comment noted. No action required. |

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| | British Association of Dermatologists | Yes | Comment noted. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |
| | Leo Pharma | Description of technology is correct | Comment noted. No action required. |
| | Novartis Pharmaceuticals UK | No comment. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Appears to match description in trial data. | Comment noted. No action required. |
| Population | AbbVie | Yes. | Comment noted. No action required. |
| | British Association of Dermatologists | The population is appropriate; no sub-population requires separate consideration | Comment noted. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |

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| | Leo Pharma | Population is appropriate | Comment noted. No action required. |
| | Novartis Pharmaceuticals UK | There is no clear definition of “moderate to severe plaque psoriasis”. Our understanding is that the Phase III studies of risankizumab in plaque psoriasis recruited patients with psoriasis area and-severity index (PASI) score of 12 or higher, static Physician's Global Assessment [sPGA] score of 3 or higher and involvement of 10% or more of the body-surface area (NCT02684357, NCT02684370 & NCT02694523). The population for whom evidence on risankizumab clinical efficacy is available is therefore closely aligned to the populations included in studies of secukinumab and other biologic agents. Whilst secukinumab and other biologic agents have marketing authorisation for treatment of moderate to severe plaque psoriasis, NICE recommendations for these products refer to severe disease. We therefore suggest that the appraisal should focus on patients with severe psoriasis. | Comments noted. The scope is broad to ensure that NICE can appraise the technology within its marketing authorisation. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Maybe say adult population >18 years as per trial. | Comment noted. No action required. |
| Comparators | AbbVie | AbbVie suggests potentially narrowing scope of comparators to the most recently appraised **IL-23** inhibitor treatment **guselkumab**, given guselkumab represents the relevant class of drugs with similar mechanism of action to risankizumab. | Comments noted. The scope includes all the relevant comparators that NICE considers standard routine practice in the NHS where possible. The company can justify any cost-effectiveness analysis that does not fulfil this reference case |

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| | | | requirement. No action required. |
| | British Association of Dermatologists | As indicated in NICE guideline CG153, ciclosporin should only be used for a maximum of 1 year. Therefore, it is only ever a relatively 'short-term' option. Psoriasis is a long-term condition and no treatments are 'curative' so far. Thus, in any economic modelling, inclusion of ciclosporin is problematic.<br><br>It is appropriate not to include PUVA (i.e. phototherapy with psoralen); whilst effective, it is no longer used routinely in people with psoriasis due to its propensity to cause skin cancer, particularly when followed by immunosuppression. In NICE guideline CG153 certain groups are specified as 'DO NOT USE" populations; when considering PUVA this should only be when other options – including biologic therapies – have been offered and can't be used or are inappropriate.<br><br>Established clinical practice is very much in line with CG153, i.e. topicals for limited psoriasis only (not in the population being considered). Phototherapy (specifically UVB), and then systemic (non-biologic) therapy, particularly methotrexate. Where psoriatic arthritis is present, methotrexate may be used before phototherapy. Acitretin is not considered cost-effective for patients who meet NICE criteria for biologic therapy and has limited utility due to poor tolerability and teratogenicity (a risk that persists for 3 years following treatment cessation). Methotrexate is often contraindicated or is poorly tolerated due to abnormal LFTs.<br><br>The population of patients with moderate disease (i.e. PASI<10) may still have significant disease with major impact (DLQI>10) and treatment options for this group are profoundly limited if methotrexate is ineffective or not tolerated, and ciclosporin cannot be used long-term. Treatments used include acitretin, fumaric acid esters/dimethyl fumarate, apremilast, biologic drugs (but only if funded under IFR route). | Comments noted. NICE clinical guideline 153 makes recommendations on phototherapy and psoralen in certain circumstances. In a single technology appraisal, the company and clinical experts can give their views and make their case on whether PUVA is used in clinical practice in their evidence submissions. The company can justify any cost-effectiveness analysis that does not fulfil this reference case requirement.<br><br>NICE will appraise the technology within its marketing authorisation. The scope allows for consideration of subgroups (for example severity of psoriasis) where evidence allows.<br><br>No action required. |

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| | Celgene | Best Supportive Care should only be included as a comparator post biologic or when biologics are contraindicated or not tolerated, i.e. it is not a relevant comparator for severe psoriasis patients who are eligible for biologics. | Comments noted. Best supportive care has been retained because it is the only treatment option for people unable to take any of the available alternative therapies. No action required. |
| | Eli Lilly and Company | Tildrakizumab and certolizumab pegol are currently undergoing a NICE appraisal, therefore these may also be relevant comparators. | Comment noted. The comparators have been updated to include tildrakizumab and certolizumab pegol, 'subject to ongoing NICE appraisal'. |
| | Janssen | Please note that the technology appraisal for guselkumab is now complete. (TA521 published on 13 June 2018). https://www.nice.org.uk/guidance/ta521 | Comment noted. The scope has been updated to reflect publication of TA521. |
| | Leo Pharma | The standard treatments in the NHS have been included.<br>Brodalumab is an IL-17RA (receptor antagonist) which is a different mode of action from secukinumab and ixekizumab which are IL-17A.(antagonists)<br>Best alterntive care would be the newer generation biologics (IL-17A;IL-17RA;IL-23 classes) that have demonstrated ability to deliver higher levels of PASI90 and PASI 100 and are more likely to be alternatives where risankizumab will be positioned on local pathways . | Comments noted. The comparators has been updated to reflect the difference between brodalumab and IL-17 inhibitors. The scope is kept broad to ensure that NICE can appraise the technology within its marketing authorisation |

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| | | | and its likely position in NHS clinical practice. |
| | Novartis Pharmaceuticals UK | We suggest that consistent terminology should be used for the non-biologic systemic therapies. The first bullet has "systemic non-biological" whilst the second has "conventional systemic non-biological". For consistency with CG153, we recommend "systemic non-biological".<br><br>The description of the second population should state "AND" phototherapy, not "OR" phototherapy i.e. it should be corrected to "If systemic non-biological treatment and phototherapy are inadequately effective, not tolerated or contraindicated:"<br><br>Infliximab is included as a comparator for the population with inadequate response to non-biologic systemics. However, it is only recommended by NICE for patients with PASI or 20 or more and DLQI of 18 or more (as described in the Background Information), so is only a relevant comparator for a subgroup of this population.<br><br>We query the relevance of best supportive care as a comparator given the number of therapies that have now been recommended as options by NICE for patients with plaque psoriasis. | Comments noted. The second bullet uses the term 'conventional systemic non-biological' therapy to differentiate between ciclosporin/methotrexate/ acitretin and apremilast/dimethyl fumarate.<br><br>"Or" is appropriately used because not everyone may be eligible to have systemic non-biological therapy and phototherapy.<br><br>Infliximab has been included to ensure that NICE can appraise the technology within its marketing authorisation and its position in NHS clinical practice.<br><br>Best supportive care has been retained because it is the only treatment option for people unable to take any of the |

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| | | | available alternative therapies.<br>No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Phototherapy with or without psoralen suggests UVA, whereas narrowband UVB is more commonly used now, so perhaps qualify that.<br>Infliximab is in use for severe group PASI >20<br>Best supportive care needs to be clearly defined in the appraisal, given where this drug is going to be positioned following inadequate response of other therapies. | Comments noted. The scope has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation and its likely position in NHS clinical practice. Some people may still have PUVA. No action required. |
| Outcomes | AbbVie | AbbVie suggests replacing 'remission' with 'complete skin clearance' as term 'remission' is not widely used for plaque psoriasis. | Comment noted. Remission is not included in the scope. No action required. |
| | British Association of Dermatologists | Additional outcomes that should be considered includes:<br>1. Other high-impact and difficult-to-treat sites:<br>□ Palms<br>□ Soles<br>□ Flexures<br>□ Genitals<br>2. Injection site reactions<br>3. Mood | Comment noted. The scope has been updated to include examples of difficult-to-treat areas. Injection site reactions and mood are captured in 'adverse effects of treatment'. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |

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| | Janssen | No comment | Comment noted. No action required. |
| | Leo Pharma | Outcome measures considered are appropriate for the technology appraisal.<br>Severity as measured by PASI should also be looked at against a higher threshold of gain i.e PASI90 and clearance PASI 100 as being where the newer agents should be seen as improving care, not just adding to the range of availability and reaching PASI75. | Comments noted. No action required. |
| | Novartis Pharmaceuticals UK | In general the outcomes specified are appropriate.<br>However, since joint symptoms are a comorbidity indicating presence of another condition, and are neither primary nor secondary outcomes in the risankizumab psoriasis trials (NCT02684357, NCT02684370 & NCT02694523), we do not consider joint symptoms relevant to an economic assessment in psoriasis.<br>We note that consideration of risankizumab's benefits in treating psoriasis symptoms on the face, scalp and nails would require studies adequately powered to detect statistically significant differences between interventions on these outcomes.<br>Given the short-term nature of most clinical studies in psoriasis, we consider it unlikely that adequate data to support mortality endpoints will be available.<br>Duration of response is not an endpoint of psoriasis trials. Therefore we consider it may be more appropriate to measure outcomes at specific timepoints (e.g. 52 weeks). | Comments noted. The scope has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation and its likely position in NHS clinical practice. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Joints is a little vague, given psoriatic arthritis also affects connective tissue too. So perhaps look at the tools that measure symptoms that may be more reflective of psoriatic arthritis specific symptoms. | Comments noted. Although related, psoriatic arthritis is outside the remit of this appraisal. No action required. |

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| | Psoriasis Association | Psoriasis symptoms should include itch - an under-treated / reported aspect of psoriasis that causes great distress to patients | Comment noted. Itch has been included as an example of psoriasis symptoms. |
| Economic analysis | AbbVie | AbbVie considers risankizumab may be suitable for Fast Track Appraisal (FTA) and as a result cost comparison may be an appropriate option. | Comments noted. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |
| | Leo Pharma | The time horizon is appropriate | Comment noted. No action required. |
| | Novartis Pharmaceuticals UK | No comment. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Psoriasis is a relapsing/remitting life-long disease that often starts in teenage years and can last well into old age, so long-term benefit and adverse events needs to be included within the lifetime case. | Comment noted. No action required. |
| Equality and Diversity | AbbVie | No comment. | Comment noted. No action required. |
| | British Association of Dermatologists | Please note, the erythema component of psoriasis (captured as part of the PASI) may be underestimated in darker skins. Thus PASI may not be representative in brown and black skin. | Comments noted. In line with other technology appraisals in psoriasis, these equality issues will be considered by the committee during the |

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| | | The DLQI may not adequately capture impact in older people (question about work, studying, sport) or those who are not in a relationship (question about sexual activity). It also is known to capture anxiety and depression poorly across all groups (two parameters that are commonly negatively influenced by psoriasis) | appraisal. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |
| | Leo Pharma | The time horizon is appropriate | Comment noted. No action required. |
| | Novartis Pharmaceuticals UK | No comment. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | None that we are aware. | Comment noted. No action required. |
| Other considerations | AbbVie | No comment. | Comment noted. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |

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| | Novartis Pharmaceuticals UK | See comments above on remit wording and population in relation to the lack of clear definitions for moderate and severe psoriasis. | Comments noted. The scope is broad to ensure that NICE can appraise the technology within its marketing authorisation. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Many other drugs in this class are also used for psoriatic arthritis, which may influence prescribing, if a patient has both conditions.<br><br>There are trials being conducted in psoriatic arthritis, any potential benefit this drug has for that group could be useful. | Comments noted. Although related, psoriatic arthritis is outside the remit of this appraisal. No action required. |
| Innovation | AbbVie | AbbVie considers risankizumab will provide an effective and well tolerated choice for HCPs and their patients. The dosing schedule is convenient compared to comparators (every 12 weeks vs 8 weeks for guselkumab for example). | Comments noted. The company will have an opportunity to provide evidence on the innovative nature of its product in its submission Innovation will be considered by the appraisal committee when formulating its recommendations.. No action required. |
| | British Association of Dermatologists | The p19 inhibitors are considered to be a 'step change' in terms of mechanism of action, specificity, effectiveness (particularly clearance which is very important to patients) and prolonged action. | Comments noted. The appraisal committee will discuss the potentially innovative nature of this technology. No action required. |

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| | | Indirect comparison of phase III studies suggest that risankizumab may be marginally better than guselkumab (PASI 90/100 rates) | |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |
| | Leo Pharma | With the newer generation biologics on the market i.e IL-17A(secukinumab and ixekizumab);IL-17RA (brodalumab) and considering risankizumab will be the second IL-23 inhibitor to market, with an identical mechanism of action to guselkumab, we do not consider risankizumab to be innovative or a step-change in the management of psoriasis treatment. | Comments noted. The appraisal committee will discuss the potentially innovative nature of this technology. No action required. |
| | Novartis Pharmaceuticals UK | Since NICE has already approved multiple therapies for plaque psoriasis, including another IL-23 inhibitor (guselkumab), we do not consider risankizumab will constitute a “step-change” in management of the condition. | Comments noted. The appraisal committee will discuss the potentially innovative nature of this technology. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Not particularly, given that there are other similar targetted therapies now. | Comments noted. The appraisal committee will discuss the potentially innovative nature of this technology. No action required. |
| | Psoriasis Association | No | Comment noted. No action required. |

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| Questions for consultation | AbbVie | **Q:** Have all relevant comparators for risankizumab been included in the scope? Should the comparators be limited to only IL-23 inhibitors?<br>**A:** AbbVie suggests potentially narrowing scope of comparators to the most recently appraised **IL-23** inhibitor treatment **guselkumab**.<br><br>**Q:** Would it be appropriate to use the cost comparison methodology for this topic?<br>**A:** Yes. | Comments noted. The scope includes all the relevant comparators that NICE considers standard routine practice in the NHS where possible. The company can justify any cost-effectiveness analysis that does not fulfil the reference case requirement. No action required. |
| | Eli Lilly and Company | No comment | Comment noted. No action required. |
| | Janssen | No comment | Comment noted. No action required. |
| | Leo Pharma | If using the the cost comparison methodology in the appraisal for this topic - the newer agents highlighted in sections above would be the most suitable comparators. | Comments noted. No action required. |
| | Novartis Pharmaceuticals UK | Have all relevant comparators for risankizumab been included in the scope? Should the comparators be limited to only IL-23 inhibitors?<br>Novartis: See comments above on “Comparators”. We do not consider that the comparators should be limited to only IL-23 inhibitors.<br>Which treatments are considered to be established clinical practice in the NHS for chronic plaque psoriasis?<br>Novartis: We consider the treatment pathway outlined in the Background Information section to be accurate. | Comments noted.<br>The scope is broad to ensure that NICE can appraise the technology within its marketing authorisation.<br>Best supportive care has been retained because it is the only treatment |

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| | | How should best supportive care be defined?<br>Novartis: As noted above in the "Comparators" section we are unsure whether best supprotive care remains a relevant comparator given the number of therapies that have now been recommended as options by NICE for patients with plaque psoriasis.<br>Are the outcomes listed appropriate?<br>Novartis: See comments above on "Outcomes".<br>Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom risankizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?<br>Novartis: Nothing further to add beyond comment that moderate and severe psoriasis are poorly defined.<br>Where do you consider risankizumab will fit into the existing NICE pathway, Psoriasis?<br>Novartis: We would expect risankizumab to be positioned alongside the other biologics recommended by NICE for treating severe psoriasis.<br>NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims.<br>Novartis: No comment.<br>Do you consider risankizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?<br>Novartis: See comments above on "Innovation"<br>Do you consider that the use of risankizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? | option for people unable to take any of the available alternative therapies.<br>The addendum to NICE guide to the methods of technology appraisal is appropriately referenced.<br>No action required. |

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| | | Novartis: No comment.<br>To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.<br>Novartis: No comment.<br>NICE has published an addendum to its guide to the methods of technology appraisal (available at https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost-comparison.pdf), which states the methods to be used where a cost comparison case is made.<br>Novartis: The April 2018 process guide, rather than the addendum, can now be referenced.<br>Would it be appropriate to use the cost comparison methodology for this topic?<br>Novartis: No comment.<br>Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?<br>Novartis: No comment.<br>Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?<br>Novartis: No comment.<br>Is there any substantial new evidence for the comparator technologies that has not been considered? Are there any important ongoing trials reporting in the next year?<br>Novartis: In the period since TA350, further phase III / IV randomised evidence on the licensed dose of secukinumab in plaque psoriasis has been published. This includes:<br>• The CLEAR and CLARITY studies provide evidence for the superior efficacy of secukinumab 300 mg compared to ustekinumab. | |

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| | | • Extension studies of the trials on which TA350 was based, provide evidence for the long-term safety and efficacy of secukinumab over up to 5 years.<br>• SIGNATURE provides UK specific evidence demonstrating the efficacy of secukinumab 300 mg in patients with severe psoriasis who have failed TNF $\alpha$ inhibitors.<br>• 3 studies have demonstrated efficacy in in different manifestations of plaque psoriasis. GESTURE and TRANSFIGURE demonstrate the efficacy of secukinumab in palmoplantar and nail psoriasis, respectively. The SCALP study demonstrates efficacy in patients with moderate to severe scalp psoriasis with or without moderate to severe plaque psoriasis. | |
| | Psoriasis and Psoriatic Arthritis Alliance | Should the comparators be limited to only IL-23 inhibitors?<br>No, it would be useful to see how this compares to other agents, as this could aid both patient and physcian by avoiding inefective therapies<br><br>Subgroups - Given psoriasis is a life long condition, consideration should be given to those who have cycled through all current therapies and then had treatment failure. It appears to be discriminatory for an individual who has been prescribed drugs in the past to be excluded from accessing new therapies because of accidents of timing and longevity of disease. | Comments noted. The scope has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation and its likely position in NHS clinical practice.<br>The scope includes "where the evidence allows, the following subgroups will be considered:<br>• previous use of phototherapy and systemic non-biological therapy |

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| | | | • previous use of biological therapy".<br>No action required. |
| Additional comments on the draft scope | AbbVie | No further comments. | Comment noted. No action required. |
| | Eli Lilly and Company | Prior biologic therapy use is listed as a subgroup for consideration. Where possible, this subgroup should be differentiated by reason for discontinuation, e.g. inadequate response, secondary loss of response, intolerance or discontinuation due to any other reason.<br><br>A stopping rule of 16 weeks should be considered for risankizumab in line with the stopping rule for other IL-23 treatments recommended by NICE, i.e. ustekinumab (TA180) and guselkumab (TA521). | Comments noted. No action required. |
| | Janssen | The section under the 'Related NICE recommendations' and 'Appraisals in Development', should be updated to reflect the completion of the appraisal for guselkumab (technology appriasal guidance [TA521], published on 13 June 2018). https://www.nice.org.uk/guidance/ta521. | Comment noted. The scope has been updated to reflect publication of TA521. |
| | Novartis Pharmaceuticals UK | None. | Comment noted. No action required. |

**The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope**

Department of Health and Social Care