**National Institute for Health and Care Excellence**

**Single Technology Appraisal (STA)**

**Bimekizumab for treating moderate to severe chronic plaque psoriasis**

**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 | British Association of Dermatologists | *Would it be appropriate to refer this topic to NICE for appraisal?*<br>Yes | Comment noted. No action required. |
| | Leo Pharma | Yes it would be appropriate | Comment noted. No action required. |
| | Novartis | We consider the proposed appraisal appropriate. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Yes, it is entirely appropriate to appraise bimekizumab. | Comment noted. No action required. |
| | Pfizer Ltd. | It is appropriate to appraise bimekizuamb within its marketing authorisation for treating moderate to severe plaque psoriasis. | Comment noted. No action required. |
| | Psoriasis Association | *Would it be appropriate to refer this topic to NICE for appraisal?*<br>Yes | Comment noted. No action required. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | UCB Pharma Limited | UCB agree that an appraisal of bimekizumab is appropriate in order for NICE to be able to expedite timely access to an effective therapy. | Comment noted. No action required. |
| Wording | British Association of Dermatologists | *Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider?*<br>Yes | Comment noted. No action required. |
| | Leo Pharma | *Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider?*<br>Yes | Comment noted. No action required. |
| | Novartis | There is no clear definition of “moderate to severe plaque psoriasis”.<br>The evidence for clinical efficacy of bimekizumab comes from very similar 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. | Comment noted. NICE will appraise the technology within its marketing authorisation. |
| | Psoriasis and Psoriatic Arthritis Alliance | *Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider?*<br>Yes | Comment noted. No action required. |
| | Pfizer Ltd. | The wording is appropriate | Comment noted. No action required. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | Psoriasis Association | *Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider?*<br>Yes | Comment noted. No action required. |
| | UCB Pharma Limited | No changes are required to the wording of the remit. However, it should be noted that bimekizumab has been misspelt; UCB request that the spelling is corrected. | Comment noted. The wording of the remit has been corrected. |
| Timing Issues | British Association of Dermatologists | Should be assessed as soon as possible | Comment noted. The STA process timelines are designed to closely align with the regulatory timelines. |
| | Novartis | No comment. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | No particular urgency. | Comment noted. No action required. |
| | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | Psoriasis Association | It is our belief that this appraisal is needed, however the fact that Bimekizumab is yet to receive UK Marketing Authorisation would mean that this is not yet urgent. | Comment noted. The STA process timelines are designed to closely align with the regulatory timelines. |

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| | UCB Pharma Limited | Despite the availability of a number of treatment options for patients with moderate to severe psoriasis, there remains a clear unmet need for improved treatment options that can provide greater likelihood of patient response and higher levels of clearance of disease. Availability of NICE guidance as soon as possible following bimekizumab marketing authorisation, which is anticipated in [redacted], would therefore be valuable. | Comment noted. The STA process timelines are designed to closely align with the regulatory timelines. |
| Additional comments on the draft remit | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | UCB Pharma Limited | No additional comments. | Comment noted. No action required. |

**Comment 2: the draft scope**

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| Background information | British Association of Dermatologists | *Consider the accuracy and completeness of this information.*<br>Yes | Comment noted. No action required. |
| | Leo Pharma | Yes this information is accurate | Comment noted. No action required. |
| | Novartis | No comment | Comment noted. No action required. |
| | Psoriasis and | 'Trunk' and 'limbs' is not included as affected areas. In darker no Caucasian | Comment noted. The |

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| | Psoriatic Arthritis Alliance | skin the appearance may not as obvious. | background of the scope has been updated to reflect this comment. |
| | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | UCB Pharma Limited | UCB would like to highlight the following:<br>• Plaque psoriasis is a chronic inflammatory systemic skin condition characterised by an accelerated rate of turnover of the keratinocytes within the epidermis (upper layer of the skin). This leads to an acanthotic (thick) epidermis with an overlying thick keratin layer manifested clinically with scaly plaques. These plaques can also be erythematous (red), itchy and burning because of the underlying inflammation. Plaque psoriasis may affect the scalp, elbows, knees and lower back and sometimes the face, nails and skin folds. Although it is a chronic, persistent, severe condition, its course may be unpredictable, with flare-ups and remissions.<br>• Symptoms of psoriasis, as described in the background information, have a significant impact on patients' quality of life and activities of daily life;[1] this therefore highlights the importance of measuring the impact of psoriasis, using the Dermatology Quality of Life Index (DLQI), for example. The DLQI is a validated tool that can be used to assess the impact of psoriasis on physical, psychological and social wellbeing.<br>• While topical treatments may reduce the severity of the flares, systemic treatments may reduce both the severity and the frequency of the flares and provide the potential for complete plaque clearance. Psoriasis has to be treated continually and on a long-term basis. Despite the importance of clear skin,[2] most of the patients with psoriasis are not aware that complete | Comment noted. The condition and any relative benefits of treatment will be considered in any future appraisal of this technology. |

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| | | skin clearance is achievable.<br>• There is a significant burden of treatment for patients with psoriasis, and as psoriasis is a lifelong condition, patient satisfaction and adherence to treatment are vital for successful disease management.[3]<br>• Lack of effectiveness has been identified as the most common reason for discontinuing a treatment, and patients frequently switch to alternative treatments in order to address this.[4, 5] | |
| The technology/ intervention | British Association of Dermatologists | *Is the description of the technology or technologies accurate?*<br>Yes | Comment noted. No action required. |
| | Novartis | No comment | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | *Is the description of the technology or technologies accurate?*<br>Yes | Comment noted. No action required. |
| | Pfizer Ltd. | No comment | Comment noted. No action required. |
| | UCB Pharma Limited | The description of the technology is not accurate: bimekizumab binds to and selectively neutralises IL-17A and IL-17F, rather than targeting the IL-17 receptor. UCB request that NICE use this terminology when referring to the mechanism of action for bimekizumab. | Comment noted. The technology section of the scope has been updated. |
| Population | British Association of Dermatologists | *Is the population defined appropriately?*<br>Yes | Comment noted. No action required. |

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| | Novartis | There is no clear definition of “moderate to severe plaque psoriasis”.<br>The evidence for clinical efficacy of bimekizumab comes from very similar 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. | Comment noted. NICE will appraise the technology [redacted] |
| | Psoriasis and Psoriatic Arthritis Alliance | *Is the population defined appropriately?*<br>Yes | Comment noted. No action required. |
| | Pfizer Ltd. | The definition of the population in appropriate. | Comment noted. No action required. |
| | UCB Pharma Limited | The population is defined appropriately.<br>Recommendations made in previous NICE technology appraisals regarding biologics for the treatment of plaque psoriasis,6-16 and hence the current positioning of biologics in the clinical pathway, relate to the subpopulation of adults with moderate to severe plaque psoriasis for whom non-biologic systemic treatment or phototherapy is inadequately effective, not tolerated of contraindicated.17 This group should therefore be considered separately – this aligns to the “previous use of phototherapy and systemic non-biological therapy” subgroup noted in the “Other considerations” section of the draft scope. | Comment noted. No action required. |
| Comparators | British Association of Dermatologists | The comparators mentioned are all established in clinical practice. However, 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. | Comment noted. The scope is intended to broad and inclusive; as such, PUVA remains in |

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| | | Thus, in any economic modelling, inclusion of ciclosporin may be problematic.<br><br>It is less appropriate 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 prior to phototherapy.<br><br>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) | scope. |
| | Leo Pharma | Yes, these are the standard treatments used in the NHS. Best alternative care would be the biosimilars and biologics. | Comment noted. No action required. |
| | Novartis | The description of the second population should state "AND" phototherapy, | Comment noted. The |

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| | | 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. | description of the second population has been updated. The description of the population in which infliximab is a relevant comparator has also been updated.<br><br>The scope is intended to be broad and inclusive. As such, best supportive care remains in scope. |
| | Psoriasis and Psoriatic Arthritis Alliance | *Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as 'best alternative care'?*<br><br>Yes | Comment noted. No action required. |
| | Pfizer Ltd. | The list of comparators is correct. | Comment noted. No action required. |
| | Psoriasis Association | Yes - these are the standard treatments currently used in the NHS.<br><br>It would be difficult to describe any as "best alternative care" owing to the individual needs of patients (co-morbidities, suitability and tolerability of the treatments) | Comment noted. No action required. |
| | UCB Pharma Limited | Dimethyl fumarate and apremilast should not be included as comparators as, although they appear at the same position as biologics in the NICE clinical pathway, they are not considered to be alternatives to biologics in clinical | Comment noted. The scope is intended to be broad and inclusive. As |

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| | | practice. The NICE FADs for apremilast (TA419) and dimethyl fumarate (TA475) state that, in general, these treatments would not displace a biological therapy in the treatment pathway.[18, 19] Furthermore, recent NICE technology appraisal submissions for biologics in plaque psoriasis have also excluded apremilast and dimethyl fumarate as comparators (TA521, TA574, TA575. TA596).[20-23]<br><br>Infliximab should not be included as a comparator as it is restricted to use in patients with very severe psoriasis (PASI ≥20, DLQI >18) and is therefore not used in the same population as other biologics.<br><br>UCB believe that etanercept should not be included as a comparator in this appraisal. The most recent (2020) BAD guidelines state to "Consider etanercept for use in people where a TNF antagonist is indicated and other available biologic agents have failed or cannot be used, or where a short half-life is important".[24] Furthermore, market research indicates that the combined market share for both the branded etanercept originator (Enbrel®, 0.3%) and etanercept biosimilars (3.8%) is very small (4.8%; data from May 2020).[25]<br><br>Etanercept and infliximab are appropriate to consider in the network meta-analysis to ensure assessment of relative effectiveness is based on a comprehensive network, but UCB consider they should not represent relevant modelled comparators for the decision problem.<br><br>Finally, UCB would like to highlight that the term used to group brodalumab, ixekizumab and secukinumab ('IL-17 inhibitors or receptor inhibitors') is not accurate: secukinumab and ixekizumab are IL-17A inhibitors. Due to its distinct mechanism of action, brodalumab binds to IL-17 receptor, preventing IL-17 activation of downstream signalling and as a consequence also inhibits other IL-17 family members including IL-17C and IL-17E (also known as IL-25). UCB would therefore request that brodalumab is considered in a separate category to the IL-17A inhibitors. | such, etanercept, dimethyl fumarate and apremilast remain in scope. The description of the population in which infliximab is a relevant comparator has been updated. The description of the IL-17 inhibitors or receptor inhibitors has been updated. |

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| Outcomes | British Association of Dermatologists | The outcome measures are appropriate; further clarification could be made on some of the outcomes listed in the draft scope:<br>• Psoriasis symptoms affceting difficult-to-treat sites e.g. palms, soles and flexures<br>• Injection site reactions<br>• Mood | Comment noted. The detail included in the outcomes section is not intended to be exhaustive and the outcomes included are considered to be broad enough to capture important aspects to patients and carers. Scope unchanged. |
| | Leo Pharma | *Will these outcome measures capture the most important health related benefits (and harms) of the technology?*<br>Yes | Comment noted. No action required. |
| | Novartis | In general the outcomes specified are appropriate.<br>We note that consideration of bimekizumab's benefits in treating psoriasis symptoms including itch on the face, scalp, nails and joints, and other difficult-to-treat areas such as the hand, feet and genitals 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). | Comment noted. The detail included in the outcomes section is not intended to be exhaustive. Outcomes are chosen on the basis that they are 'important to patients and/or their carers' not the availability of evidence Scope unchanged. |
| | Psoriasis and | The psoriasis symptoms list is very specific and appears to miss 'trunk' and | Comment noted. Other |

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| | Psoriatic Arthritis Alliance | 'limbs'. 'Itch on the face" is a strange phrase, I would have thought itch anywhere would be more appropriate, unless there is a reason why that outcome in this therapy is particularly important for that domain. | areas of itch have been included as examples. The wording has been updated for clarity. |
| | Pfizer Ltd. | The list of outcomes is in line with previous NICE scopes for psoriasis. | Comment noted. No action required. |
| | Psoriasis Association | Outcome measures relating to "itch" should not be restricted to "the face".<br>Response rate and duration of response are important. | Comment noted. Other areas of itch have been included as examples. The wording has been updated for clarity. |
| | UCB Pharma Limited | UCB would request that NICE revise the outcome 'itch on the face' to consider two separate concepts: itch, which is a patient reported outcome, and psoriasis of the face, a location of psoriasis. UCB propose that this outcome be reworded to:<br>• "Patient reported outcomes, such as itch and pain;<br>• "Symptoms in specific locations such as face, scalp, nails, palms, soles and genitals."<br>UCB also request that depth and speed of response are included in the list of important outcome measures.<br>Sufficient data will not be available from psoriasis trials to support mortality endpoints relating to treatment. However, background mortality can be considered in the cost-effectiveness model. No prior psoriasis appraisals have modelled mortality as treatment dependent. | Comment noted. The outcomes section is not intended to be exhaustive and the outcomes included are considered to be broad enough to capture important aspects to patients and carers.<br>Outcomes are chosen on the basis that they are 'important to patients and/or their carers' not the availability of evidence. Scope unchanged. |

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| Economic analysis | British Association of Dermatologists | Cost comparison is generally appropriate (see above re: ciclosporin) | Comment noted. A cost comparison case can be made if a health technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication. No changes to the scope are required. |
| | Novartis | No comment. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | *Comments on aspects such as the appropriate time horizon.*<br>Yes | Comment noted. No action required. |
| | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | UCB Pharma Limited | The time horizon should be sufficient to capture all relevant differences in costs and outcomes and to reflect the chronic nature of psoriasis. | Comment noted. No action required. |
| Equality and | British Association of | Please note, the erythema component of psoriasis (captured as part of the PASI) may be underestimated in darker skins. Thus, PASI may not be | Comment noted. The committee will consider |

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| Diversity | Dermatologists | representative in such skin tones. Additionally, inflammatory skin disorders such as psoriasis may have an increased impact on some people with darker skin tones due to their ethnicity – this is due to the inflammation potentially leading to longer-term effects on skin pigmentation following resolution of the inflammation.<br>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 is also known to capture anxiety and depression poorly across all groups (two parameters that are commonly negatively influenced by psoriasis). | whether any future recommendations they make has a disproportionate affect on people with certain characteristics and whether any reasonable adjustments can be made to account for this. |
| | Novartis | No comment. | Comment noted. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | None | Comment noted. No action required. |
| | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | UCB Pharma Limited | No comment. | Comment noted. No action required. |
| Other considerations | British Association of Dermatologists | The other considerations are appropriate. | Comment noted. No action required. |
| | Novartis | See comments above on remit wording and population in relation to the lack of clear definitions for moderate and severe psoriasis. | Comment noted. See responses on remit |

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| | | | wording and population. |
| | Psoriasis and Psoriatic Arthritis Alliance | None | Comment noted. No action required. |
| | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | UCB Pharma Limited | The draft scope captures potential subgroups of relevance. These subgroups will be addressed where the evidence allows and where the subgroup corresponds to a clinically relevant use of the technology in NHS clinical practice.<br>The cost-effectiveness analysis will be in line with the population and comparators identified, and will aim to address the cost-effectiveness of bimekizumab in the identified relevant populations. | Comment noted. No action required. |
| Innovation | British Association of Dermatologists | Bimekizumab will be a competitor drug for secukinumab and ixekizumab so must demonstrate an individual characteristic to define its setting in a therapeutic pathway.<br>Bimekizumab benefits are likely to be similar to those already established in the anti-IL17 group. | Comment noted. No action required. |
| | Leo Pharma | No as there are already 13 biological molecules available and approved for the management of psoriasis. These include 3 that work on the IL-17 pathway. | Comment noted. No action required. |
| | Novartis | Since NICE has already approved multiple therapies for plaque psoriasis, including other IL-17 inhibitors (brodalumab, ixekizumab and secukinumab), we do not consider bimekizumab will constitute a “step-change” in | Comment noted. No action required. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | | management of the condition. | |
| | Psoriasis and Psoriatic Arthritis Alliance | No | Comment noted. No action required. |
| | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | Psoriasis Association | Yes – we consider it to be innovative in that it targets IL17A and IL17F. But it will unlikely result in a step-change in the management of the condition. | Comment noted. |
| | UCB Pharma Limited | UCB considers that bimekizumab is an innovative technology:<br>• Bimekizumab's mechanism of action differs to other currently approved IL-17 inhibitors for moderate to severe psoriasis. While secukinumab and ixekizumab inhibit IL-17A, bimekizumab selectively inhibits both IL-17A and IL-17F. Although IL-17F is less potent than IL-17A, it is more abundant in psoriasis skin lesions and can drive inflammation independently of IL-17A. Bimekizumab also differs to brodalumab in that it selectively targets only IL-17A and IL-17F, whereas brodalumab targets the IL-17 receptor and as a consequence also inhibits other IL-17 family members (IL-17C and IL-17E, also known as IL-25).<br>Through selective inhibition of IL-17F in addition to IL-17A, treatment with bimekizumab is expected to result in an unprecedented depth of response (as demonstrated by rates of total [PASI 100] and near-total skin clearance [PASI 90]), and a greater rapidity of response and durability of response.26-29 Bimekizumab is therefore anticipated to provide a step-change in the management of psoriasis.<br>UCB considers that the use of bimekizumab will result in a number of important health-related benefits that will not be fully reflected in the QALY | Comment noted. The extent to which the technology may or may not be innovative will be considered in any appraisal of the technology. |

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| | | calculation.<br>• Firstly, the rapidity of BKZ response will not be fully captured within the cost-effectiveness model, due to limitations of the available comparative evidence at earlier timepoints (such as Week 4).<br>• Secondly, the durability of BKZ response will not be fully captured within the cost-effectiveness model, due to limitations of the available comparative evidence at later timepoints (such as Week 52).<br>• Thirdly, the EQ-5D may not fully differentiate between quality of life of patients at the highest levels of PASI response,30 meaning that health state utility values included in the cost-effectiveness model may not fully capture the benefits of complete skin clearance.<br>• Finally, use of the PASI measure to define response and as the basis of health state utilities within the model means that the benefits of bimekizumab associated with treatment of 'difficult to treat' areas will not be fully included in the QALY calculation.<br>UCB will provide comprehensive clinical data from four Phase 3 clinical trials of bimekizumab versus both placebo and three active comparators from three different classes; in particular, data relating to PASI response (including complete clearance), speed of response, durability of response and impact of treatment on difficult to treat areas (scalp and nail psoriasis) will be presented. | |
| Questions for consultation | Novartis | Have all relevant comparators for bimekizumab been included in the scope?<br>Novartis: See comments above on "Comparators".<br>Which treatments are considered to be established clinical practice in the NHS for moderate to severe plaque psoriasis?<br>Novartis: We consider the treatment pathway outlined in the Background | Comments noted. See responses in 'Comparators', 'Outcomes' and 'Innovation'. No further action required. |

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| | | Information section to be accurate.<br><br>Are the outcomes listed appropriate?<br><br>Novartis: See comments above on “Outcomes”.<br><br>Are the subgroups suggested in ‘other considerations appropriate? Are there any other subgroups of people in whom bimekizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?<br><br>Novartis: Nothing further to add beyond the comment that moderate and severe psoriasis are poorly defined.<br><br>In clinical practice, would treatment decisions be influenced by severity of disease (for example, are people with moderate disease treated in the same way as those with severe disease)?<br><br>Novartis: There is no clear definition of “moderate to severe plaque psoriasis”. Whilst secukinumab and other biologic agents have a marketing authorisation for treatment of moderate to severe plaque psoriasis, NICE recommendations for these products refer to severe disease.<br><br>Healthcare professionals (HCPs) follow NICE advice and the British Association of Dermatologists (BAD) guidelines, and could choose any of the following 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); etanercept, adalimumab, ustekinumab, secukinumab, apremilast, ixekizumab, dimethyl fumarate, brodalumab, guselkumab, certolizumab pegol, tildrakizumab and risankizumab. For patients with very severe disease (PASI score of 20 or more and DLQI of more than 18), HCPs can use Infliximab as per NICE TA134.<br><br>How widespread is the use of biosimilar products in clinical practice? | |

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| | | Novartis: No comment.<br><br>Where do you consider bimekizumab will fit into the existing NICE pathway, Psoriasis?<br><br>Novartis: We would expect bimekizumab to be positioned alongside the other biologics recommended by NICE for treating severe psoriasis.<br><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. In particular, please tell us if the proposed remit and scope:<br><br>• could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which bimekizumab will be licensed;<br><br>• could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;<br><br>• could have any adverse impact on people with a particular disability or disabilities.<br><br>Novartis: No comment.<br><br>Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.<br><br>Novartis: No comment.<br><br>Do you consider bimekizumab 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 | |

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| | | management of the condition)?<br><br>Novartis: See comments above on “Innovation.”<br><br>Do you consider that the use of bimekizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.<br><br>Novartis: No comment.<br><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><br>Novartis: No comment.<br><br>NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute’s Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).<br><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><br>• Would it be appropriate to use the cost comparison methodology for this topic?<br><br>Novartis: No comment.<br><br>• Is the new technology likely to be similar in its clinical efficacy and | |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | | 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 technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?<br>Novartis: BADBIR analysis of drug survival for adalimumab, secukinumab and ustekinumab - Yiu ZZ et al. Br J Dermatol 2020 Aug;183(2):294-302. doi: 10.1111/bjd.18981. Epub 2020 Mar 30 | |
| | Psoriasis and Psoriatic Arthritis Alliance | Pathway position – same as other similar class agents. | Comment noted. No action required. |
| | Pfizer Ltd. | No comment. | Comment noted. No action required. |
| | UCB Pharma Limited | *Have all relevant comparators for bimekizumab been included in the scope?*<br>• All relevant comparators have been included in the scope; however, as above, UCB consider that apremilast, dimethyl fumarate, infliximab and etanercept are not relevant comparators to bimekizumab.<br>*Are the subgroups suggested in 'other considerations appropriate?*<br>• Yes.<br>*Where do you consider bimekizumab will fit into the existing NICE pathway,* | Comments noted. See responses in 'Comparators' and 'Innovation'. No further changes required. |

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| | | *Psoriasis?*<br>• UCB anticipates that bimekizumab will be positioned in line with other biologics reimbursed for treating moderate to severe plaque psoriasis.<br>*Do you consider bimekizumab 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>• Yes, please refer to our above response to this question.<br>*Do you consider that the use of bimekizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?*<br>• The QALY calculation may not fully capture the health-related quality of life benefits of bimekizumab; please refer to our above response to this question.<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>• No barriers to the adoption of bimekizumab are anticipated.<br>*Would it be appropriate to use the cost comparison methodology for this topic?*<br>• [redacted].<br>*Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?*<br>• Bimekizumab is anticipated to exhibit improvement versus placebo, | |

| Section | Consultee/ Commentator | Comments [sic] | Action |
|---|---|---|---|
| | | adalimumab, ustekinumab and secukinumab.<br>• Bimekizumab is anticipated to be similar in terms of resource use compared to its comparators.<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>• The PASI outcome measure has been used in the four bimekizumab Phase 3 trials, has defined the model structure in all prior psoriasis appraisals that have performed a cost-effectiveness evaluation, and continues to be clinically relevant.[31] | |
| Additional comments on the draft scope | British Association of Dermatologists | • In clinical practice treatment decisions are regularly influenced by severity of disease<br>• Biosimilars are now in widespread use<br>• Head-to-head trials amongst biologics in the same class will be of increasing value to differentiate treatment choices; in the meantime, various network meta-analysis ad guideline publications will help guide treatment choice | Comment noted. No action required. |
| | Pfizer Ltd. | No additional comments. | Comment noted. No action required. |
| | UCB Pharma Limited | No comments. | Comment noted. No action required. |

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

AbbVie

Amgen