**National Institute for Health and Care Excellence**

**Multiple Technology Appraisal (MTA)**

**Certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs [ID579]**

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

**Comment 1: the draft remit**

| Section | Consultee/ Commentator | Comments | Action |
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| Appropriateness | | | |
| Certolizumab pegol | UCB Pharma | It is well understood that the use of TNFs improve the health of this population, there is no clinical uncertainty surrounding the use of certolizumab pegol in this population. There is no impact on service provision. Certolizumab Pegol has similar pricing to the other TNFs on the market and most of those are reviewed by NICE.<br>The SMC & AWMSG have already performed STAs and recommended certolizumab pegol in this population.<br>Based on the above, the timing of this STA relative to gaining our licence and the local access we have now gained, we do not feel an STA would add further value to the NHS in England. | Thank you for your comments. These comments will be taken into consideration by NICE and the Department of Health when deciding whether an appraisal is appropriate. |
| | Novartis Pharmaceuticals Ltd UK | Yes it is appropriate for this topic to be referred. | Thank you for your comments. No action required. |

| Section | Consultee/ Commentator | Comments | Action |
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| | Pfizer Ltd | Pfizer believe that it is appropriate to refer this topic to NICE for appraisal. | Thank you for your comments. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | It would be entirely appropriate to refer this treatment for appraisal. | Thank you for your comments. No action required. |
| | Psoriasis Association | Yes - there are patients for whom existing psoriatic arthritis treatments have not worked, or are not appropriate. Patients with this debilitating condition need access to all relevant therapies. | Thank you for your comments. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | It would be appropriate | Thank you for your comments. No action required. |
| | Psoriasis Association | Yes - there are patients for whom existing psoriatic arthritis treatments have not worked, or are not appropriate. This treatment offers targets a pathway no existing treatment does, and therefore offers a treatment alternative for those for whom all other treatments have failed, but also a new treatment technology that could benefit patients with active psoriatic arthritis. Patients with this debilitating condition need access to all relevant therapies. | Thank you for your comments. No action required. |
| | Royal College of Pathologists | Yes | Thank you for your comments. No action required. |
| | Pfizer Ltd | Pfizer believe that it is appropriate to refer this topic to NICE for appraisal. | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | Yes | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | Yes it is appropriate for referral. Psoriatic arthritis causes significant distress and psychological impact on a patient's life. Patients will welcome a choice of treatment for this condition. | Thank you for your comments. No action required. |
| Wording | | | |
| Certolizumab pegol | UCB Pharma | The draft remit is appropriate | Thank you for your comments. The remit has been updated in line with the marketing authorisation for Certolizumab pegol and the Committee for Medicinal Products for Human Use (CHMP) opinion for secukinumab. |
| | Novartis Pharmaceuticals Ltd UK | Yes | Thank you for your comments. No action required. |

| Section | Consultee/ Commentator | Comments | Action |
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| | Pfizer Ltd | The current description suggests that the patient population eligible to receive certolizumab pegol (CZP) are intolerant or contraindicated to all disease-modifying anti-rheumatic drugs (DMARDs). Pfizer note that the marketing authorisation for CZP states that:<br>*"Cimzia, in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Cimzia can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate."* [1]<br>Therefore, to reflect the marketing authorisation, Pfizer recommend that the text included here should clarify that CZP can be used in combination with methotrexate when DMARDs have been inadequately effective, or as monotherapy in patients in case of intolerance to methotrexate or when continued treatment is inappropriate. | Comments noted. Scoping workshop attendees agreed that this detail would be captured by the wording of the remit which specifies that the drug will be appraised "in accordance with its marketing authorisation" |
| | Psoriasis and Psoriatic Arthritis Alliance | The only issue is the marketing authorisation just says "inadequate" whereas the remit says "inadequately effective" is that the same? Does that make the remit more restrictive than the licence? | Thank you for your comments. The remit has been updated in line with the marketing authorisation for certolizumab pegol and the Committee for Medicinal Products for Human Use (CHMP) opinion for secukinumab |
| | Psoriasis | Yes | Thank you for your |

| Section | Consultee/ Commentator | Comments | Action |
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| | Association | | comments. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | It appears to match the use in research, but until final marketing authorisations is known, then it is unclear | Thank you for your comments. The remit has been updated in line with the marketing authorisation for certolizumab pegol and the Committee for Medicinal Products for Human Use (CHMP) opinion for secukinumab. |
| | Psoriasis Association | None | Thank you for your comments. No action required. |
| | Royal College of Pathologists | Yes | Thank you for your comments. The remit has been updated in line with the marketing authorisation for certolizumab pegol and the Committee for Medicinal Products for Human Use (CHMP) opinion for |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | secukinumab. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | Yes | Thank you for your comments. The remit has been updated in line with the marketing authorisation for certolizumab pegol and the Committee for Medicinal Products for Human Use (CHMP) opinion for secukinumab. |
| | Novartis Pharmaceuticals Ltd UK | The wording of the remit is appropriate. The licence wording is currently anticipated to be:<br>"Cosentyx, alone or in combination with methotrexate (MTX), is indicated for | Thank you for your comments. The remit has been updated in line with the marketing |

| Section | Consultee/ Commentator | Comments | Action |
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| | | the treatment of active psoriatic arthritis in adult patients when the response to previous disease modifying anti-rheumatic drug (DMARD) therapy has been inadequate." | authorisation for certolizumab pegol and the Committee for Medicinal Products for Human Use (CHMP) opinion for secukinumab. |
| Timing Issues | | | |
| Certolizumab pegol | UCB Pharma | It has now been 14 months since marketing authorisation and most access barriers due to lack of NICE review have been overcome. | Thank you for your comments. These comments will be taken into consideration by NICE and the Department of Health when deciding whether an appraisal is appropriate. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Psoriasis and | It is important for people with psoriatic arthritis to have options, when | Thank you for your |

| Section | Consultee/ Commentator | Comments | Action |
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| | Psoriatic Arthritis Alliance | treatments fail, but as there are similar class established therapies available, an appraisal for this agent is less urgent. | comments. No action required. |
| | Psoriasis Association | This treatment is already approved for use in people with psoriatic arthritis in Scotland by the Scottish Medicines Consortium. | Thank you for your comments. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | For those where the current therapies have failed then any additional option for treating psoriatic arthritis is urgent. Currently the agent does not have marketing authorisation for psoriatic arthritis, so only more urgent once available for use within the NHS. | Thank you for your comments. No action required. |
| | Psoriasis Association | This treatment offers a new approach to the management of psoriatic arthtritis - a serious condition causing erosion of the joints - with timely access to the appropriate treatments, debilitation can be contained. | Thank you for your comments. No action required. |
| | Royal College of Pathologists | As soon as possible | Thank you for your comments. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | required. |
| | British Association of Dermatologists | None | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | The STA process is appropriate in order for timely guidance to be issued for this area of unmet need and to give patients access to this therapy. | Thank you for your comments. No action required. |
| Additional comments on the draft remit | | | |
| Certolizumab pegol | Pfizer Ltd | References<br>[1]. Certolizumab pegol summary of product characteristics, European Medicines Agency. Accessed: 30/01/2015. Link: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf | Thank you for your comments. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for comment. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comments. No action required. |
| | Psoriasis Association | None | Thank you for your comments. No action |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | required. |
| | Royal College of Pathologists | None | Thank you for your comments. No action required. |
| | Pfizer Ltd | None | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | None | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | None | Thank you for your comments. No action required. |

**Comment 2: the draft scope**

| Section | Consultee/ Commentator | Comments | Action |
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| Background information | | | |
| Certolizumab pegol | UCB Pharma | On the whole the background information seems accurate. We do feel that the explicit importance of the impact of chronic pain and fatigue on patients needs to be highlighted. In addition the more common signs, symptoms and functional impact of common co-morbidities such as enthesitis and dactylitis need to be explicitly mentioned. Iritis and uveitis occur in up to 20% patients and can cause blindness. Patients are also more prone to inflammatory bowel disease. | Thank you for your comments. The background section is intended to provide a brief overview of the disease and its associated management. |
| | Novartis Pharmaceuticals Ltd UK | Dactylitis and enthesitis should be included as symptoms and the impact of co-morbidities related to psoriatic arthritis (premature cardiovascular disease, infectious complications, malignancy risk and osteoporosis) should be mentioned. | Thank you for your comments. The background section is intended to provide a brief overview of the disease and its associated management. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | The psychological impact of psoriasis is well known, but many people with psoriatic arthritis also report low mood and feeling depressed.<br>It should be noted this group of patients is of working age and also potentially have, or are trying to start a family. | Thank you for your comments. The background section is intended to provide a brief overview of the |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | disease and its associated management. |
| | Psoriasis Association | Ciclosporin is not routinely used as a DMARD for psoriatic arthritis - its use is greater in psoriasis | Thank you for your comments. Azathioprine and ciclosporin have been removed as examples of disease modifying anti-rheumatic drugs (DMARDs) from the background section. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | The psychological impact of psoriasis is well known, but many people with psoriatic arthritis also report low mood and feeling depressed.<br>It should be noted this group of patients is of working age and also potentially have, or are trying to start a family | Thank you for your comments. The background section is intended to provide a brief overview of the disease and its associated management. |
| | Psoriasis Association | Ciclosporin is not routinely used as a DMARD for psoriatic arthritis - its use is greater in psoriasis | Thank you for your comments. Following the scoping workshop, azathioprine and |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | ciclosporin have been removed as examples of disease modifying anti-rheumatic drugs (DMARDs) from the background section. |
| | Royal College of Pathologists | Satisfactory | Thank you for your comments. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | Fine | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | Dactylitis and enthesitis should be included as symptoms and the impact of co-morbidities related to psoriatic arthritis (premature cardiovascular disease, infectious complications, malignancy risk and osteoporosis) should be mentioned. | Thank you for your comments. The background section is intended to provide a brief overview of the |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | disease and its associated management. |
| The technology/ intervention | | | |
| Certolizumab pegol | UCB Pharma | Query that this should only include the name of the technology as opposed to the indication. Suggest the removal of MTX in this section.<br>Please note the symbol ® should appear next to the technology brand name :<br>Cimzia ® | Thank you for your comments. The technology section is intended to briefly describe the technology and the indication being considered for appraisal. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Appears to be | Thank you for your comments. No action required. |
| Secukinumab | Psoriasis and Psoriatic | Appears to be | Thank you for your comments. No action |

| Section | Consultee/ Commentator | Comments | Action |
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| | Arthritis Alliance | | required. |
| | Psoriasis Association | None | Thank you for your comments. No action required. |
| | Royal College of Pathologists | Further details including side effect profile of the technology should be included | Thank you for your comments. The technology section is intended to briefly describe the technology and the indication being considered for appraisal. The side effect profile of the technology will be considered by the Appraisal Committee based on the evidence available. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |

| Section | Consultee/ Commentator | Comments | Action |
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| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | Yes | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | Secukinumab does have a brand name "Cosentyx". The marketing authorisation is specific to the subcutaneous administration and will not include intravenous infusion. | Thank you for your comment. The technology section has been updated. |
| Population | | | |
| Certolizumab pegol | UCB Pharma | Query whether the population be defined only for those who have failed/intolerant/contra-indicated at least 2 DMARDs. This is the population that current NICE & BSR/BHPR guidance on biologics applies to.<br>The population should further be defined as per existing NICE biologic guidance in terms of swollen / painful joint count etc. | Thank you for your comments. Scoping workshop attendees agreed that the population should be kept broad as the marketing authorisation for certolizumab pegol does not specify the number of prior DMARDs or the number of painful or swollen joints. |

| Section | Consultee/ Commentator | Comments | Action |
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| | Novartis Pharmaceuticals Ltd UK | Patients who are anti-TNFα inadequate responders should be considered as a subgroup. | Thank you for your comments. Scoping workshop attendees agreed that this group is part of the main population of the scope. |
| | Pfizer Ltd | Please see comment on the draft remit above. | Thank you for your comments. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | It would be useful for patients who have both psoriatic arthritis and psoriasis to have "added" benefit, if outcomes in both conditions were considered, when prescribing or stopping, as a composite score, whereas in isolation they might be considered inadequate. | Thank you for your comments. Scoping workshop attendees agreed the outcomes specified in the scope should focus on those related to psoriatic arthritis. |
| | Psoriasis Association | Yes | Thank you for your comments. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | It would be useful for patients who have both psoriatic arthritis and psoriasis to have "added" benefit, if outcomes in both conditions were considered, when prescribing or stopping, as a composite score, whereas in isolation they might be considered inadequate. | Thank you for your comments. Scoping workshop attendees agreed the outcomes specified in the scope should focus on those |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | related to psoriatic arthritis. |
| | Psoriasis Association | Involvement of nail psoriasis amongst those with psoriatic arthritis is high and of great concern to patients. | Thank you for your comments. Scoping workshop attendees considered that the current wording of the population does not exclude patients with nail psoriasis, therefore they agreed that wording of the population as specified in the scope should focus on psoriatic arthritis only. |
| | Royal College of Pathologists | Yes | Thank you for your comments. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British | None | Thank you for your |

| Section | Consultee/ Commentator | Comments | Action |
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| | Association of Dermatologists | | comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | The population should be defined as 'active psoriatic arthritis in adult patients when the response to previous disease modifying anti-rheumatic drug (DMARD) therapy has been inadequate.' Sub-groups that should be considered within this population are:<br>• Patients who are anti-TNFα inadequate responders<br>• Patients with concomitant moderate to severe plaque psoriasis where the recommended dose is 300 mg by subcutaneous injection | Thank you for your comments. The population has been amended in line with the marketing authorisation for certolizumab pegol and the Committee for Medicinal Products for Human Use (CHMP) opinion for secukinumab. |
| Comparators | | | |
| Certolizumab pegol | UCB Pharma | • For people who have only received 1 prior non-biological disease modifying anti-rheumatic drug (DMARD), as per the comment above this population is not in line with NICE current pathways or BSR guidance. We request a more explicit rationale to understand why NICE are interested in this population. | Thank you for your comments. Scoping workshop attendees agreed that in clinical practice, people would receive at least 2 DMARDs before receiving biological treatment. Scoping workshop attendees accepted that the scope should remain broad and inclusive so that it |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | reflects the wording of the marketing authorisation. Therefore this population has been retained in the scope. No action required. |
| | | • For people whose disease has inadequately responded to at least 2 DMARDs or for whom DMARDs cannot be tolerated or are contraindicated, we believe that ustekinumab is not routinely used in clinical practice, is currently not recommended by NICE, and is therefore not an appropriate comparator. | For people who have received at least 2 DMARDs, ustekinumab has been removed as a comparator in line with the NICE technology appraisal guidance 340. In addition, attendees agreed that apremilast, which has a licence for psoriatic arthritis, and secukinumab which is currently being considered for appraisal, should also |

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| | | • For people in whom DMARDs and biological therapies (including etanercept, adalimumab, infliximab and golimumab) are not tolerated or contraindicated: we believe that ustekinumab is not routinely used in clinical practice, is currently not recommended by NICE and is therefore not an appropriate comparator.<br>• In line with the 2012 BSR/BHPR guidelines, we understand standard of care (pathway before biologics) to be conventional DMARDs.<br>• We note that biosimilars are listed as comparators in the appraisal. However, recent NICE biosimilar guidance (6th January 2015) indicated that biosimilars would not be included as comparators in Single Technology Appraisals. The following statement is quoted from the NICE news website: 'These products will usually be considered in the context of a Multiple Technology Appraisal in parallel with their reference products in the indication under consideration.<br>In other circumstances, where it is considered a review of the evidence for similar biological medicinal product is necessary, NICE will consider producing an 'Evidence summary new medicine'. because they will not be established in UK clinical practice by the time the guidance is published.<br>As such, biosimilars should not be included as comparators in this proposed STA. | be included.<br>Ustekinumab has been included as a comparator in line with the NICE technology appraisal guidance 340. .<br>Thank you for your comments. No action required.<br>Scoping workshop attendees noted that biosimilar versions of infliximab have been licensed for psoriatic arthritis. The Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting |

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| | | | guidance, to relevant licensed biosimilar products which subsequently appear on the market. The economic analysis section of the scope notes that the availability and cost of biosimilars should be taken into consideration. |
| | AbbVie Ltd | It is unclear why only this anti-TNF is being considered for use after failure of only one DMARD. The previous guidance recommends anti-TNF therapy after at least two DMARDs and use after one DMARD was not considered. There are limited data to show the efficacy of conventional DMARDs in psoriatic arthritis but if a decision is made to expand the recommendation to use certolizumab after one DMARD it would be important for this to apply to all anti-TNF therapies. As the guidance for the existing anti-TNF therapies is on the static list this may necessitate a guidance executive review of the recommendations for all anti-TNFs with existing guidance. | Thank you for your comments. Scoping workshop attendees agreed that in clinical practice, people would receive at least 2 DMARDs before receiving biological treatment. Scoping workshop attendees accepted that the scope should remain broad and inclusive so that it reflects the wording of |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | the marketing authorisation Therefore this population has been retained in the scope. No action required. |
| | Merck Sharp and Dohme | MSD notes that previous NICE guidance (TA199, TA220) and the NICE commissioning algorithm for biolgic drugs for the treatment of psoriatic arthritis recommend TNF inhibitors only in patients who have not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is not clear on what basis certolizumab pegol should be considered in patients who have only received one prior non-biologic DMARD given that the marketing authorisation for certolizumab pegol is aligned to that of other biologics licensed for psoriatic arthritis.<br>It is not clear why certolizumab pegol would be considered as an option for use in people for whom DMARDs and biological therapies (including etanercept, adalimumab, infliximab, and golimumab) are not tolerated or contraindicated given that certolizuamb pegol has the same mechanism of action as these other biologics (TNF inhibitor). | Thank you for your comments. Scoping workshop attendees agreed that in clinical practice, people would receive at least 2 DMARDs before receiving biological treatment. Scoping workshop attendees accepted that the scope should remain broad and inclusive so that it reflects the wording of the marketing authorisation. Therefore this population has been retained. No action required. |
| | Novartis Pharmaceuticals | Comparators are appropriate. | Thank you for your comments. No action |

| Section | Consultee/ Commentator | Comments | Action |
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| | Ltd UK | | required. |
| | Pfizer Ltd | Previous NICE guidance on the use of biologics for adults with active and progressive psoriatic arthritis recommended that biologics be used when the following criteria were met:<br>*"The person has peripheral arthritis with three or more tender joints and three or more swollen joints, and*<br>*The psoriatic arthritis has not responded to adequate trials of at least two standard disease-modifying antirheumatic drugs (DMARDs), administered either individually or in combination." [2,3]*<br>Given that the license granted for CZP is similar to other licensed biologics for psoriatic arthritis [4-8], Pfizer suggest that the scope be amended to remove people who have only received one prior non-biological DMARD to ensure consistency with previous evaluations. | Thank you for your comments. Scoping workshop attendees agreed that in clinical practice, people would receive at least 2 DMARDs before receiving biological treatment. Scoping workshop attendees accepted that the scope should remain broad and inclusive so that it reflects the wording of the marketing authorisation. Therefore this population has been retained in the scope. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Yes | Thank you for your comments. No action required. |
| | Psoriasis Association | Yes | Thank you for your comments. No action |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | Yes | Thank you for your comments. No action required. |
| | Psoriasis Association | Yes - however Ciclosporin is not routinely used as a DMARD for psoriatic arthritis - its use is greater in psoriasis. | Thank you for your comments. Ciclosporin has been removed from the background section. No action required for the comparators. |
| | Royal College of Pathologists | Yes | Thank you for your comments. No action required. |
| | Pfizer Ltd | Previous NICE guidance on the use of biologics for adults with active and progressive psoriatic arthritis recommended that biologics be used when the following criteria were met:<br>"The person has peripheral arthritis with three or more tender joints and three or more swollen joints, and<br>The psoriatic arthritis has not responded to adequate trials of at least two standard disease-modifying antirheumatic drugs (DMARDs), administered either individually or in combination." [1,2]<br>Pfizer suggest that the scope be amended to remove people who have only received one prior non-biological DMARD to ensure consistency with previous evaluations. | Thank you for your comments. Scoping workshop attendees agreed that in clinical practice, people would receive at least 2 DMARDs before receiving biological treatment. Scoping workshop attendees accepted that the scope should remain broad and inclusive so that it |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | reflects the wording of the marketing authorisation. Therefore this population has been retained in the scope. No action required. |
| | Merck Sharp and Dohme | MSD notes that previous NICE guidance (TA199, TA220) and the NICE commissioning algorithm for biolgic drugs for the treatment of psoriatic arthritis recommend TNF inhibitors only in patients who have not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is not clear on what basis secukinumab should be considered in patients who have only received one prior non-biologic DMARD. | Thank you for your comments. Scoping workshop attendees agreed that in clinical practice, people would receive at least 2 DMARDs before receiving biological treatment. Scoping workshop attendees accepted that the scope should remain broad and inclusive so that it reflects the wording of the marketing authorisation. Therefore this population has been retained in the scope. No action required. |

| Section | Consultee/ Commentator | Comments | Action |
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| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | Yes | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | The standard treatments secukinumab should be compared to are the biological therapies (including etanercept, adalimumab, infliximab, golimumab and ustekinumab [subject to ongoing NICE appraisal]). These treatments can be described as 'best alternative care' and represent clinical practice as stipulated in previous NICE technology appraisals for psoriatic arthritis (TA 313, TA 199 and TA 220). The non-biological DMARDs should not be considered as comparators because these treatments are used earlier in the treatment pathway and the anticipated licence is in patients with an inadequate response to DMARDs.<br><br>Best supportive care should be listed as a comparator as patients who are contraindicated or intolerant to existing biologic therapy will likely be assigned best supportive care, in the absence of any biologic therapeutic alternative. | Thank you for your comments. Scoping workshop attendees agreed that in clinical practice, people would receive at least 2 DMARDs before receiving biological treatment. However, the NICE team agreed that people who have had only 1 prior DMARD would be included within the marketing authorisation for secukinumab, therefore this population was relevant and should be retained to keep the scope broad and inclusive at this stage. |

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| Outcomes | | | |
| Certolizumab pegol | UCB Pharma | It is important to separate out 'Pain', 'Fatigue' and explicitly note common co-morbidities & measures such as Enthesitis, dactyilitis, PASI75. | Thank you for your comments. The outcomes section has been updated, including the addition of "periarticular disease [for example tendonitis, enthesitis, and dactylitis]". Scoping workshop attendees agreed that the outcomes should be focused on psoriatic arthritis.<br><br>Scoping workshop attendees agreed that pain and fatigue were important outcomes and agreed that they were covered by the existing, broader outcomes. No action required. |
| | Novartis Pharmaceuticals | Peripheral symptoms (including enthesitis, peripheral arthritis and dactylitis) should also be included. The other outcomes listed in the draft scope are | Thank you for your comments. The |

| Section | Consultee/ Commentator | Comments | Action |
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| | Ltd UK | adequate. | outcomes section has been updated, including the addition of "periarticular disease [for example tendonitis, enthesitis, and dactylitis]". |
| | Pfizer Ltd | No comment | Thank you for comment. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | Reductions in pain and fatigue would be of interest to patients. | Thank you for your comments. The outcomes section has been updated. Scoping workshop attendees agreed that pain and fatigue were important outcomes and agreed that they were covered by the existing, broader outcomes. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | Reductions in pain and fatigue would be of interest to patients | Thank you for your comments. The outcomes section has been updated to include "periarticular disease |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | [for example tendonitis, enthesitis, and dactylitis]". Scoping workshop attendees agreed that pain and fatigue were important outcomes however would be covered by the existing, broader outcomes. |
| | Psoriasis Association | Yes - however nail involvement should perhaps be considered in its own right owing to the prevalence of it amongst people with psoriatic arthritis, and the debilitating effect it can have (rather than grouped under "other complications of psoriatic arthritis"). | Thank you for your comments. The outcomes section has been updated to include "periarticular disease [for example tendonitis, enthesitis, and dactylitis]". Scoping workshop attendees agreed that nail involvement was related to psoriasis rather than psoriatic arthritis so it was suggested this outcome be removed. |
| | Royal College of Pathologists | Yes | Thank you for your comments. No action |

| Section | Consultee/ Commentator | Comments | Action |
|---|---|---|---|
| | | | required. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | Yes | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | Peripheral symptoms (including enthesitis, peripheral arthritis and dactylitis) should also be included. The other outcomes listed in the draft scope are adequate:<br>• Disease activity (American College of Rheumatology response criteria (ACR 20 response, ACR 50 response, change in disease activity score DAS28-CRP)<br>• functional capacity as measured by physical function (HAQ-DI)<br>• disease progression (joint/bone structural preservation (X-ray)) | Thank you for your comments. The outcomes section has been updated to include "periarticular disease [for example tendonitis, enthesitis, and dactylitis]". |

| Section | Consultee/ Commentator | Comments | Action |
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| | | • other complications of psoriatic arthritis (skin assessment for psoriasis signs (PASI scores)<br>• health-related quality of life SF36-PCS; HAQ-DI; ACR50 response | |
| Economic analysis | | | |
| Certolizumab pegol | UCB Pharma | Standard | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comment. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comments. No action required. |
| | Psoriasis Association | None | Thank you for your comments. No action required. |
| | Royal College of | No specific time length for assesment has been provided. | Thank you for your |

| Section | Consultee/ Commentator | Comments | Action |
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| | Pathologists | | comments. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British Association of Dermatologists | None | Thank you for your comments. No action required. |
| Equality and Diversity | | | |
| Certolizumab pegol | UCB Pharma | No Comments | Thank you for your comment. No action required. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |

| Section | Consultee/ Commentator | Comments | Action |
|---|---|---|---|
| | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comment. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comments. No action required. |
| | Psoriasis Association | None | Thank you for your comments. No action required. |
| | Royal College of Pathologists | None | Thank you for your comments. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comments. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comments. No action required. |
| | AbbVie | None | Thank you for your comments. No action required. |
| | British | Fine | Thank you for your |

| Section | Consultee/ Commentator | Comments | Action |
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| | Association of Dermatologists | | comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comments. No action required. |
| Other considerations | | | |
| Certolizumab pegol | UCB Pharma | Please clarify the sub group populations and how they explicitly differ to the comparator section | Thank you for your comments. The subgroup section has been updated as follows:<br><br>The subgroup "previous treatment (including previous treatment with DMARDs and TNF-α inhibitors)" has been removed as scoping workshop attendees agreed this was part of the main population. The subgroup "reason for treatment failure (for example due to lack of efficacy or adverse events)" has been amended to read |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | "reason for treatment failure (for example due to lack of efficacy, intolerance, or adverse events)" |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comment. No action required. |
| | Psoriasis Association | Nail involvement as a distinct issue amongst people with psoriatic arthritis. | Thank you for your comments. The outcomes section has been updated, including the addition of "periarticular disease [for example tendonitis, enthesitis, and dactylitis]". Scoping workshop attendees agreed that nail involvement was related |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | to psoriasis rather than psoriatic arthritis so it was suggested this outcome be removed. |
| | Royal College of Pathologists | List of side effect of this treatment should be included | Thank you for your comments. The outcome 'adverse effects of treatment' is included in the scope. The specific adverse effects of the technology will be considered by the Appraisal Committee based on the evidence available. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comment. No action required. |
| | AbbVie | None | Thank you for your comment. No action |

| Section | Consultee/ Commentator | Comments | Action |
|---|---|---|---|
| | | | required. |
| | British Association of Dermatologists | None | Thank you for your comment. No action required. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| Innovation | | | |
| Certolizumab pegol | UCB Pharma | Clinical data is in line with other TNFs. | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | No | Thank you for your comment. No action required. |
| | Psoriasis | I do not believe that this is a step-change, but will offer an alternative treatment option within the somewhat limited pool available for people with | Thank you for your comments. The |

| Section | Consultee/ Commentator | Comments | Action |
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| | Association | psoriatic arthritis. | innovative aspects of certolizumab pegol will be considered by the Appraisal Committee. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | Although the target of secukinumab is different to similar class agents, which may be considered innovative, the method of delivery is not, and patients would not necessarily see it as a step change in their treatment. | Thank you for your comments. The innovative aspects of secukinumab will be considered by the Appraisal Committee. |
| | Psoriasis Association | Yes - this is a step-change in that it offers a new treatment target not currently available for people with psoriatic arthritis. The current NICE approved biologics for psoriatic arthritis are all tumour necrosis factor alpha inhibitors, therefore this treatment increases the options available to patients and clinicians with active psoriatic arthritis. | Thank you for your comments. The innovative aspects of secukinumab will be considered by the Appraisal. |
| | Royal College of Pathologists | Yes | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comment. No action |

| Section | Consultee/ Commentator | Comments | Action |
|---|---|---|---|
| | | | required. |
| | AbbVie | None | Thank you for your comment. No action required. |
| | British Association of Dermatologists | Yes.<br><br>Limited studies published but do suggest benefit. | Thank you for your comment. No action required. |
| | Novartis Pharmaceuticals Ltd UK | Psoriatic arthritis has a mean age of diagnosis in the range of 40-46 year. As such, there will be health-related indirect benefits of treatment (such as work productivity) that will not be included in the QALY calculation. | Thank you for your comments. The innovative aspects of secukinumab will be considered by the Appraisal Committee |
| Questions for consultation | | | |
| Certolizumab pegol | UCB Pharma | Yes - all relevant comparators considered in established clinical practice for certolizumab pegol been included in the scope (in line with previous comments in this response)<br><br>We understand best supportive care to be the use of conventional DMARDs as per the BSR/BHPR guidance. | Thank you for your comments. No action required.<br><br>Thank you for your comment. Scoping workshop attendees agreed that best supportive care may |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | consist of the use of disease modifying anti-rheumatic drugs, or the use of non-steroidal anti-inflammatory drugs for pain relief, however best supportive care was not defined in current psoriatic arthritis guidelines |
| | | We consider that Cimzia ® would be used in line with other TNFs | Thank you for your comment. |
| | | Re: subgroups suggested in 'other considerations we are unclear on these definitions.<br>No - there are no other subgroups of people in whom certolizumab pegol is expected to be more clinically effective and cost effective or other groups that should be examined separately? | Thank you for your comment. The subgroup section has been updated as follows:<br>The subgroup "previous treatment (including previous treatment with DMARDs and TNF-α inhibitors)" has been removed as scoping workshop attendees agreed this was part of |

| Section | Consultee/ Commentator | Comments | Action |
|---|---|---|---|
| | | | the main population. The subgroup "reason for treatment failure (for example due to lack of efficacy or adverse events)" has been amended to read "reason for treatment failure (for example due to lack of efficacy, intolerance, or adverse events)" |
| | | No – as per previous comments - biosimilars are not expected to be established clinical practice for treating psoriatic arthritis within the next 12 months | The Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on the market. The economic analysis section of the scope notes that the |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | availability and cost of biosimilars should be taken into consideration. |
| | AbbVie Ltd | Regarding the pathway for treatment of psoriasis question, it should be noted that certolizumab is not licensed for the treatment of chronic plaque psoriasis.<br><br>As biosimilars are not yet commercially available it is difficult to project whether their use will be established clinical practice within 12 months. | Thank you for your comment. No action required.<br><br>Thank you for your comment. The Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on the market. The economic analysis section of the scope notes that the availability and cost of biosimilars should be taken into consideration. |

| Section | Consultee/ Commentator | Comments | Action |
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| | Merck Sharp and Dohme | Biosimilar infliximab has a marketing authorisation for psoriatic arthritis and will be marketed in the UK from the 25th February 2015. | Thank you for your comments. The Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on the market. The economic analysis section of the scope notes that the availability and cost of biosimilars should be taken into consideration. |
| | Novartis Pharmaceuticals Ltd UK | Have all relevant comparators for secukinumab been included in the scope?<br>Apremilast could be added as a comparator as it has a UK licence for PsA although it would not be considered routine clinical practice in the UK. | Thank you for your comments. Apremilast has a marketing authorisation for psoriatic arthritis and is subject to an on-going NICE appraisal. |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | Attendees noted that apremilast was not routinely used in current clinical practice but acknowledged if apremilast is recommended by NICE, its use in clinical practice would increase and may become established practice by the time of an appraisal. Apremilast has been added as a comparator subject to ongoing NICE appraisal. |
| | | Which treatments are considered to be established clinical practice in the NHS for psoriatic arthritis?<br>Specialist Share Data from NHiS indicates that in September 2014 the biologics patient shares were as follows (this is CIC information below):<br>• Adalimumab- [redacted]%<br>• Etanercept - [redacted]%<br>• Golimumab – [redacted]%<br>• Infliximab- [redacted]% | Thank you for your comments. No action required. |

| Section | Consultee/ Commentator | Comments | Action |
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| | | How should best supportive care be defined?<br>For patients intolerant to DMARDs and biologics best supportive care is not defined in current psoriatic arthritis guidelines. | Thank you for your comment. Scoping workshop attendees agreed that best supportive care may consist of the use of disease modifying anti-rheumatic drugs, or the use of non-steroidal anti-inflammatory drugs for pain relief, however best supportive care was not defined in current psoriatic arthritis guidelines |
| | | Are there any subgroups of people in whom secukinumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?<br>Subgroups relating to TNF-alpha inhibitor incomplete responders (TNF-IR) versus TNF-alpha inhibitor naive patients should be considered. | Thank you for your comment. The subgroup section has been updated as follows:<br>The subgroup "previous treatment (including previous treatment with DMARDs and TNF-α |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | inhibitors)" has been removed as scoping workshop attendees agreed this was part of the main population. The subgroup "reason for treatment failure (for example due to lack of efficacy or adverse events)" has been amended to read "reason for treatment failure (for example due to lack of efficacy, intolerance, or adverse events)" |
| | | Where do you consider certolizumab pegol will fit into the existing NICE pathway, psoriasis?<br>Pending the outcome of this appraisal we would envisage that certolizumab pegol will fit within the "psoriatic arthritis" section of the psoriasis NICE pathway. | Thank you for your comment. No action required. |
| | | Are biosimiliars expected to be established clinical practice for treating | Thank you for your comment. The |

| Section | Consultee/ Commentator | Comments | Action |
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| | | psoriatic arthritis within the next 12 months?<br>Biosimiliars are not established treatments in the UK and are not expected to be routine clinical practice within the next 12 months. | Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on the market. The economic analysis section of the scope notes that the availability and cost of biosimilars should be taken into consideration. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Psoriasis and Psoriatic Arthritis Alliance | 1.Etanercept and adalimumab (from calls to our information line) appear to be the most commonly offered biologic agents for psoriatic arthritis, but this probably reflects the length of time they have been available.<br>2.Best supportive care, unfortunately for some people we speak to, is nothing, apart from basic NSAIDs such as ibruprofen for pain relief. Although | Thank you for your comments. No action required.<br>Thank you for your comment. Scoping |

| Section | Consultee/ Commentator | Comments | Action |
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| | | generally there will be a mix of non-biologic interventions, based on previous successes and failures, patient preference and their adverse event profiles. | workshop attendees agreed that best supportive care may consist of the use of disease modifying anti-rheumatic drugs, or the use of non-steroidal anti-inflammatory drugs for pain relief, however best supportive care was not defined in current psoriatic arthritis guidelines |
| | | 3.Sub-groups. Those with severe psoriasis as an added outcome benefit. | Thank you for your comment. The subgroup section has been updated as follows:<br>The subgroup "previous treatment (including previous treatment with DMARDs and TNF-α inhibitors)" has been removed as scoping workshop attendees agreed this was part of the main population. The subgroup |

| Section | Consultee/ Commentator | Comments | Action |
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| | | 4. Pathway. As choice in same place as other biologic agents.<br><br>5.It would be remiss to not consider the role of biosimilars, given the cost to the NHS of the current agents, although for patients it will be important to know that the biosimilars perform in exactly the same way when replacing the original formulation, therefore head-to-head trial data would be useful. Otherwise, straight substitution might provide lower acquisition cost, but not equal lower cost-effectiveness in respect of benefit and outcomes. | The subgroup "reason for treatment failure (for example due to lack of efficacy or adverse events)" has been amended to read "reason for treatment failure (for example due to lack of efficacy, intolerance, or adverse events)"<br><br>Thank you for your comment.<br><br>Thank you for your comments. The Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on |

| Section | Consultee/ Commentator | Comments | Action |
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| | | | the market. The economic analysis section of the scope notes that the availability and cost of biosimilars should be taken into consideration. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | 1.Etanercept and adalimumab (from calls to our information line) appear to be the most commonly offered biologic agents for psoriatic arthritis, but this probably reflects the length of time they have been available.<br>2. Best supportive care, unfortunately for some people we speak to, is nothing, apart from basic NSAIDs such as ibruprofen for pain relief. Although generally there will be a mix of non-biologic interventions, based on previous successes and failures, patient preference and their adverse event profiles.<br>3. Sub-groups. Those with severe psoriasis as an added outcome benefit.<br>4. Pathway. As a choice in same place as other biologic agents, but given it has a different target, it would be useful for patients if there could some type of test to establish effectiveness before prescribing, therefore avoiding try and fail prescribing.<br>5. It would be remiss to not consider the role of biosimilars, given the cost to the NHS of the current agents, although for patients it will be important to know that the biosimilars perform in exactly the same way when replacing the original formulation, therefore head-to-head trial data would be useful. Otherwise, straight substitution might provide lower acquisition cost, but not | Thank you for your comment. No action required.<br>The Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on the market. The economic analysis section of the scope notes that the |

| Section | Consultee/ Commentator | Comments | Action |
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| | | equal lower cost-effectiveness in respect of benefit and outcomes. For secukinumab, there may not be a biosimilar to directly compare, so that might be problematic. | availability and cost of biosimilars should be taken into consideration. |
| | Psoriasis Association | None | Thank you for your comment. No action required. |
| | Royal College of Pathologists | No further comments | Thank you for your comment. No action required. |
| | Pfizer Ltd | No comment | Thank you for your comment. No action required. |
| | Merck Sharp and Dohme | Biosimilar infliximab has a marketing authorisation for psoriatic arthritis and will be marketed in the UK from the 25th February 2015. | Thank you for your comment. The Department of Health has confirmed that a technology appraisal remit referred to NICE enables NICE to decide to apply the same remit, and the resulting guidance, to relevant licensed biosimilar products which subsequently appear on |

| Section | Consultee/ Commentator | Comments | Action |
|---|---|---|---|
| | | | the market. The economic analysis section of the scope notes that the availability and cost of biosimilars should be taken into consideration |
| | AbbVie | As at time of writing no biosimilars are commercially available for this indication, it is difficult to project whether these will represent standard clinical practice within the next 12 months. | Thank you for your comment. The economic analysis section of the scope notes that the availability and cost of biosimilars should be taken into consideration. |
| | British Association of Dermatologists | None | Thank you for your comment. No action required. |
| | Novartis Pharmaceuticals Ltd UK | Have all relevant comparators for secukinumab been included in the scope?<br>Apremilast and certolizumab pegol could be added as comparators as both have UK licences for PsA although neither could be considered routine clinical practice in the UK.<br><br>Which treatments are considered to be established clinical practice in the NHS for psoriatic arthritis? | Thank you for your comment. Apremilast has been added as a comparator for people would receive at least 2 DMARDs before receiving biological treatment and for |

| Section | Consultee/ Commentator | Comments | Action |
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| | | Specialist Share Data from NHiS indicates that in September 2014 the biologics patient shares were as follows:<br>• Adalimumab- [redacted]%<br>• Etanercept - [redacted]%<br>• Golimumab - [redacted]%<br>• Infliximab - [redacted]%<br><br>How should best supportive care be defined?<br>For patients intolerant to DMARDs and biologics best supportive care is not defined in current psoriatic arthritis guidelines.<br><br>Are there any subgroups of people in whom secukinumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?<br>Subgroups relating to TNF-alpha inhibitor incomplete responders (TNF-IR) versus TNF-alpha inhibitor naive patients will be analysed as patients stratified using this criteria in the FUTURE 1(CAIN457F2306) and FUTURE 2 (CAIN457F2312) trials.<br>FUTURE 1: 70.8% TNF naïve and 29.2% TNF-IR.<br>FUTURE 2: 65% TNF naïve and 35% TNF-IR<br><br>Where do you consider secukinumab will fit into the existing NICE pathway, psoriasis?<br>Pending the outcome of this appraisal we would envisage that secukinumab will fit within the "psoriatic arthritis" section of the psoriasis NICE pathway. | people whose disease has not adequately responded to both DMARDs and biological therapies (including etanercept, adalimumab, infliximab and golimumab), subject ongoing NICE appraisal. The scope also notes that the interventions (certolizumab pegol and secukinumab) will be compared with each other. |

| Section | Consultee/ Commentator | Comments | Action |
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| | | Are biosimiliars expected to be established clinical practice for treating psoriatic arthritis within the next 12 months?<br>Biosimiliars are not established treatments in the UK and are not expected to be routine clinical practice within the next 12 months. | |
| Additional comments on the draft scope | | | |
| Certolizumab pegol | UCB Pharma | Consider the inclusion of BSR guidance to be included as national clinical policy | Thank you for your comments. No action required. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |
| | Pfizer Ltd | References<br>[2]. TA199. Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis. Accessed: 30/01/2015. Link: http://www.nice.org.uk/search?q=ta199<br>[3]. TA220. Golimumab for the treatment of psoriatic arthritis. Accessed: 30/01/2015. Link: http://www.nice.org.uk/guidance/TA220<br>[4]. Etanercept Summary of Product Characteristics, European Medicines Agency. Accessed: 30/01/2015. Link: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000262/WC500027361.pdf<br>[5]. Infliximab Summary of Product Characteristics, European Medicines Agency. Accessed: 30/01/2015. Link: | Thank you for your comments. No action required. |

| Section | Consultee/ Commentator | Comments | Action |
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| | | http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000240/WC500050888.pdf<br><br>[6]. Adalimumab Summary of Product Characteristics, European Medicines Agency. Accessed: 30/01/2015. Link: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000481/WC500050870.pdf<br><br>[7]. Golimumab Summary of Product Characteristics, European Medicines Agency. Accessed: 30/01/2015. Link: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000992/WC500052368.pdf<br><br>[8]. Ustekinumab Summary of Product Characteristics, European Medicines Agency. Accessed: 30/01/2015. Link: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000958/WC500058513.pdf | |
| | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comment. No action required. |
| | Psoriasis Association | "Best supportive care" currently involves regression to a previously failed DMARD and pain management. Certolizumab Pegol would fit alongside the approved biologics for psoriatic arthritis in the existing NICE pathway. | Thank you for your comment. Scoping workshop attendees agreed that best supportive care may consist of the use of disease modifying anti-rheumatic drugs, or the use of non-steroidal anti-inflammatory drugs |

| Section | Consultee/ Commentator | Comments | Action |
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| | | A full MTA on the biologics for psoriatic arthritis would be useful but currently difficult to achieve owing to the drugs in the pipeline. Therefore an STA is more appropriate. | for pain relief, however best supportive care was not defined in current psoriatic arthritis guidelines<br>Thank you for your comment. Scoping workshop attendees agreed that a multiple technology appraisal would be useful. This appraisal has been referred as an MTA. |
| Secukinumab | Psoriasis and Psoriatic Arthritis Alliance | None | Thank you for your comment. No action required. |
| | Psoriasis Association | "Best supportive care" currently involves regression to a previously failed DMARD and pain management. Secukinumab would offer another treatment options alongside the currently approved biologics for psoriatic arthritis in the existing NICE pathway.<br>A full MTA on the biologics for psoriatic arthritis would be useful but currently difficult to achieve owing to the drugs in the pipeline. Therefore an STA is more appropriate. | Thank you for your comment. Scoping workshop attendees agreed that a multiple technology appraisal would be useful. This appraisal has been referred as an MTA. |

| Section | Consultee/ Commentator | Comments | Action |
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| | Royal College of Pathologists | None | Thank you for your comment. No action required. |
| | Pfizer Ltd | None | Thank you for your comment. No action required. |
| | Merck Sharp and Dohme | None | Thank you for your comment. No action required. |
| | AbbVie | No comments to add other than to note that the scope should be set in line with previous appraisals of biologics for the treatment of psoriatic arthritis. | Thank you for your comment. No action required. |
| | British Association of Dermatologists | None | Thank you for your comment. No action required. |
| | Novartis Pharmaceuticals Ltd UK | No comment | Thank you for your comment. No action required. |

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

British Association of Dermatologists
Department of Health

Royal College of Nursing

**Response to consultee and commentator comments on the provisional matrix of consultees and commentators (pre-referral)**

| | | | | | |
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| **Version of matrix of consultees and commentators reviewed:**<br>Provisional matrix of consultees and commentators sent for consultation | | | | | |
| **Summary of comments, action taken, and justification of action:** | | | | | |
| | Proposal: | Proposal made by: | | Action taken:<br><br>Removed/Added/Not included/Noted | Justification: |
| 1. | Afiya Trust | NICE Secretariat | | Removed | This organisation is no longer engaging with NICE.<br><br>The Afiya Trust has been removed from the matrix of consultees and commentators. |

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| 2. | Black Health Agency | NICE Secretariat | | Removed | This organisation has confirmed that they no longer wish to participate in appraisals of this indication.<br>The Black Health Agency has been removed from the matrix of consultees and commentators. |
| 3. | Equalities National Council | NICE Secretariat | | Removed | This organisation has confirmed that they no longer wish to participate in appraisals of this indication.<br>The Equalities National Council has been removed from the matrix of consultees and commentators. |
| 4. | Muslim Health Network | NICE Secretariat | | Removed | This organisation has disbanded. The Muslim Health Network has been removed from the matrix of consultees and commentators. |

| | | | | | |
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| 5. | Action Against Allergy | NICE Secretariat | | Removed | This organisation's interests are not closely related to the appraisal topic and as per our inclusion criteria. Action Against Allergy have been removed from the matrix of consultees and commentators. |
| 6. | Allergy UK | NICE Secretariat | | Removed | This organisation's interests are not closely related to the appraisal topic and as per our inclusion criteria. Allergy UK has been removed from the matrix of consultees and commentators. |